

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

FORM 10-Q

(Mark One)

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 from ____ to ____

Commission File Number 001-33351

NEUROMETRIX, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

04-3308180

(I.R.S. Employer Identification No.)

1000 Winter Street, Waltham, Massachusetts

(Address of principal executive offices)

02451

(Zip Code)

(781) 890-9989

(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 exchange on which registered
Common Stock, \$0.0001 par value per share	NURO	The Nasdaq Stock Market LLC
Preferred Stock Purchase Rights	NUROW	
Warrants to Purchase Common Stock		

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 and post 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 definition 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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 9,781,755 shares of common stock, par value \$0.0001 per share, were outstanding as of July 12, 2019.

In addition, there were 454,781 warrants to purchase shares of the issuer's common stock listed under NUROW on the Nasdaq stock exchange outstanding as of July 12, 2019.

NeuroMetrix, Inc.
Form 10-Q
Quarterly Period Ended June 30, 2019

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

**NeuroMetrix, Inc.
Balance Sheets**

	June 30, 2019	December 31, 2018
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,958,058	\$ 6,780,429
Accounts receivable, net	726,670	1,082,957
Inventories	2,063,431	2,861,864
Prepaid expenses and other current assets	1,101,154	860,915
Total current assets	<u>8,849,313</u>	<u>11,586,165</u>
Fixed assets, net	289,472	407,339
Right to use asset	1,645,668	1,968,062
Other long-term assets	29,824	30,314
Total assets	<u>\$ 10,814,277</u>	<u>\$ 13,991,880</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,017,094	\$ 1,298,084
Accrued expenses	3,081,192	2,236,633
Accrued product returns	741,607	1,101,658
Deferred collaboration income	—	1,956,522
Total current liabilities	<u>4,839,893</u>	<u>6,592,897</u>
Lease obligation, net of current portion	1,116,734	1,301,172
Total liabilities	<u>5,956,627</u>	<u>7,894,069</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Convertible preferred stock	11	18
Common stock, \$0.0001 par value; 100,000,000 shares authorized at June 30, 2019 and December 31, 2018; 9,781,755 and 7,380,463 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	978	738
Additional paid-in capital	197,184,936	197,113,646
Accumulated deficit	(192,328,275)	(191,016,591)
Total stockholders' equity	<u>4,857,650</u>	<u>6,097,811</u>
Total liabilities and stockholders' equity	<u>\$ 10,814,277</u>	<u>\$ 13,991,880</u>

The accompanying notes are an integral part of these interim financial statements.

NeuroMetrix, Inc.
Statements of Operations
(Unaudited)

	Quarters Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues	\$ 2,354,683	\$ 3,751,568	\$ 5,477,618	\$ 8,694,558
Cost of revenues	3,143,787	1,950,304	5,468,018	4,905,564
Gross profit (loss)	(789,104)	1,801,264	9,600	3,788,994
Operating expenses:				
Research and development	1,034,921	1,616,863	1,890,002	2,896,427
Sales and marketing	1,373,949	2,200,852	3,399,237	4,705,593
General and administrative	1,564,555	1,170,634	3,184,045	2,974,777
Total operating expenses	3,973,425	4,988,349	8,473,284	10,576,797
Loss from operations	(4,762,529)	(3,187,085)	(8,463,684)	(6,787,803)
Other income:				
Collaboration income	1,381,818	3,749,999	7,116,667	8,505,704
Other income	18,520	11,014	35,333	22,279
Total other income	1,400,338	3,761,013	7,152,000	8,527,983
Net income (loss)	<u>\$ (3,362,191)</u>	<u>\$ 573,928</u>	<u>\$ (1,311,684)</u>	<u>\$ 1,740,180</u>
Net income (loss) per common share applicable to common stockholders,				
Basic	<u>\$ (0.37)</u>	<u>\$ 0.08</u>	<u>\$ (0.16)</u>	<u>\$ 0.25</u>
Diluted	<u>\$ (0.37)</u>	<u>\$ 0.04</u>	<u>\$ (0.16)</u>	<u>\$ 0.13</u>

The accompanying notes are an integral part of these interim financial statements.

NeuroMetrix, Inc.
Statements of Changes in Stockholders' Equity
(Unaudited)

	Series B – F Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount			
Balance at December 31, 2017	29,479.98	\$ 30	2,706,066	\$ 271	\$ 196,355,142	\$ (191,338,054)	\$ 5,017,389
Stock-based compensation expense	—	—	—	—	371,917	—	371,917
Common stock issued to settle employee incentive compensation obligations	—	—	214,791	21	294,243	—	294,264
Issuance of common stock upon conversion of preferred stock	(11,666.35)	(12)	4,435,874	444	(432)	—	—
Effect of adoption of ASC 606	—	—	—	—	—	297,858	297,858
Net income	—	—	—	—	—	1,740,180	1,740,180
Balance at June 30, 2018	<u>17,813.63</u>	<u>\$ 18</u>	<u>7,356,731</u>	<u>\$ 736</u>	<u>\$ 197,020,870</u>	<u>\$ (189,300,016)</u>	<u>\$ 7,721,608</u>

	Series B – F Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount			
Balance at December 31, 2018	17,513.63	\$ 18	7,380,463	\$ 738	\$ 197,113,646	\$ (191,016,591)	\$ 6,097,811
Stock-based compensation expense	—	—	—	—	64,026	—	64,026
Issuance of common stock upon conversion of preferred stock	(6,258.90)	(7)	2,379,810	238	(231)	—	—
Issuance of common stock under employee stock purchase plan	—	—	21,482	2	7,495	—	7,497
Net loss	—	—	—	—	—	(1,311,684)	(1,311,684)
Balance at June 30, 2019	<u>11,254.73</u>	<u>\$ 11</u>	<u>9,781,755</u>	<u>\$ 978</u>	<u>\$ 197,184,936</u>	<u>\$ (192,328,275)</u>	<u>\$ 4,857,650</u>

The accompanying notes are an integral part of these interim financial statements.

NeuroMetrix, Inc.
Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2019	2018
Cash flows from operating activities:		
Net income (loss)	\$ (1,311,684)	\$ 1,740,180
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Depreciation	107,494	140,989
Stock-based compensation	64,026	371,917
Inventory provision	2,595,884	—
Changes in operating assets and liabilities:		
Accounts receivable	356,287	1,288,332
Inventories	(1,207,451)	(281,617)
Prepaid expenses and other current and long-term assets	(239,749)	609,358
Accounts payable	(287,260)	66,480
Accrued expenses	416,745	(93,651)
Accrued product returns	(360,051)	(645,938)
Deferred collaboration income	(1,956,522)	—
Net cash (used in) provided by operating activities	(1,822,281)	3,196,050
Cash flows from investing activities:		
Purchases of fixed assets	(7,587)	(130,816)
Net cash used in investing activities	(7,587)	(130,816)
Cash flows from financing activities:		
Net proceeds from issuance of stock and warrants	7,497	—
Net cash provided by financing activities	7,497	—
Net (decrease) increase in cash and cash equivalents	(1,822,371)	3,065,234
Cash and cash equivalents, beginning of period	6,780,429	4,043,681
Cash and cash equivalents, end of period	\$ 4,958,058	\$ 7,108,915
Supplemental disclosure of cash flow information:		
Common stock issued to settle employee incentive compensation obligation	\$ —	\$ 294,264

The accompanying notes are an integral part of these interim financial statements.

NeuroMetrix, Inc.
Notes to Unaudited Financial Statements
June 30, 2019

1. Business and Basis of Presentation

Our Business-An Overview

NeuroMetrix, Inc., or the Company, is a commercial stage, innovation driven healthcare company combining neurostimulation and digital medicine to address chronic health conditions including chronic pain, sleep disorders, and diabetes. The Company has two primary products. Quell is an over-the-counter wearable therapeutic device for chronic pain. DPNCheck® is a rapid point-of-care test for diabetic neuropathy which is the most common long-term complication of Type 2 diabetes.

In June 2019 the Company announced a business restructuring aimed at operating costs and cash preservation while continuing to focus on supporting its DPNCheck® product line, managing its existing Quell® business while evaluating alternative therapeutic applications for the core technology, maintaining its strategic collaboration with GlaxoSmithKline, and attempting to negotiate a settlement of the previously disclosed and ongoing Federal Trade Commission (FTC) investigation which is centered on Quell advertising. The restructuring involved a reduction in force, a planned consolidation of all operations in a single location, and the write-down of excess Quell inventory. In connection with the restructuring, the Company recorded in the second quarter of 2019 a restructuring charge of \$2.3 million (See Note 7.). It is likely that the Company will incur future charges associated with settlement of the FTC matter; however, the amount of such charges cannot be reasonably estimated at this time (See Note 8.). In June 2019, the Company also announced that it had retained an investment bank to explore strategic alternatives to enhance shareholder value, including the potential sale or merger of the Company.

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has suffered recurring losses from operations and negative cash flows from operating activities. At June 30, 2019, the Company had an accumulated deficit of \$192.3 million. These factors raise substantial doubt about the Company's ability to continue as a going concern for the one-year period from the date of issuance of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company held cash and cash equivalents of \$5.0 million as of June 30, 2019. The Company believes that these resources, future GSK collaboration milestone payments, and the cash to be generated from future product sales will be sufficient to meet its projected operating requirements through 2019. Accordingly, the Company will need to raise additional funds to support its operating and capital needs in 2020. The Company continues to face significant challenges and uncertainties and, as a result, the Company's available capital resources may be consumed more rapidly than currently expected due to (a) decreases in sales of the Company's products and the uncertainty of future revenues from new products; (b) changes the Company may make to the business that affect ongoing operating expenses; (c) changes the Company may make in its business strategy; (d) regulatory developments affecting the Company's existing products; (e) changes the Company may make in its research and development spending plans; (f) delays in the anticipated timing of achievement of GSK milestones; (g) the final outcome of the FTC civil investigative demand enforcement action involving Quell; and (h) other items affecting the Company's forecasted level of expenditures and use of cash resources. The Company may attempt to obtain additional funding through achievement of milestones under the GSK collaboration, public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources to increase the funds available to fund operations. However, the Company may not be able to secure such funding in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity or debt securities to raise additional funds, its existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of the Company's existing stockholders. If the Company raises additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to its potential products or proprietary technologies, or grant licenses on terms that are not favorable to the Company. Without additional funds, the Company may be forced to delay, scale back or eliminate some of its sales and marketing efforts, research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue its operations. If any of these events occurs, the Company's ability to achieve its development and commercialization goals would be adversely affected.

Unaudited Interim Financial Statements

The accompanying unaudited balance sheet as of June 30, 2019, unaudited statements of operations for the quarters and six months ended June 30, 2019 and 2018, unaudited statements of changes in stockholders' equity for the six months ended June 30, 2019 and 2018 and the unaudited statements of cash flows for the six months ended June 30, 2019 and 2018 have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. The accompanying balance sheet as of December 31, 2018 has been derived from audited financial statements prepared at that date, but does not include all disclosures required by accounting principles generally accepted in the United States of America. In the opinion of management, the financial statements include all normal and recurring adjustments considered necessary for a fair presentation of the Company's financial position and operating results. Operating results for the six months ended June 30, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2018 included in the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission, or the SEC, on January 24, 2019 (File No. 001-33351), or the Company's 2018 Form 10-K.

Revenues

Revenues include product sales, net of estimated returns. Revenue is measured as the amount of consideration the Company expects to receive in exchange for product transferred. Revenue is recognized when contractual performance obligations have been satisfied and control of the product has been transferred to the customer. In most cases, the Company has a single product delivery performance obligation. Accrued product returns are estimated based on historical data and evaluation of current information.

Accounts receivable are recorded net of the allowance for doubtful accounts which represents the Company's best estimate of credit losses. Allowance for doubtful accounts was \$25,000 as of June 30, 2019 and December 31, 2018.

Two customers accounted for 31% and one customer accounted for 20% of total revenues in the quarters and six months ended June 30, 2019, respectively. Two customers accounted for 24% and 29% of total revenues in the quarters and six months ended June 30, 2018, respectively. Three customers accounted for 62% and two customers accounted for 45% of accounts receivable as of June 30, 2019 and December 31, 2018, respectively.

Collaboration income

Collaboration income is recognized within Other income when contractual performance obligations, outside the ordinary activities of the Company, have been satisfied and control has been transferred to a collaboration partner. Collaboration income for each performance obligation is based on the fair value of such performance obligation relative to the total fair value of all performance obligations multiplied by the overall transaction price. A deferred collaboration income liability is recorded when payments are received prior to satisfaction of performance obligations. The Company recognized Collaboration income net of costs, within Other income in the Statement of Operations of \$7,116,667 and \$8,505,704, for the six months ended June 30, 2019 and 2018, respectively.

Stock-based Compensation

Total compensation cost related to non-vested awards not yet recognized at June 30, 2019 was \$139,588. The total compensation costs are expected to be recognized over a weighted-average period of 1.3 years.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during reporting periods. Actual results could differ from those estimates.

Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases (Topic 842)* (“ASU 2016-02”). ASU 2016-02 required that lessees recognize virtually all of their leases on the balance sheet, by recording a right-of-use asset and lease liability. The Company adopted ASU 2016-02, using the modified retrospective method, upon its effective date of January 1, 2019. The impact of adoption was an increase to long-term assets and total liabilities of approximately \$1.9 million as of January 1, 2019.

The following table summarizes the effects of adopting ASU 2016-02 on the Company's balance sheet as of June 30, 2019:

	As reported	Adjustments	Amounts under prior GAAP
Assets			
Prepaid expenses and other current assets	\$ 1,101,154	\$ 26,895	\$ 1,128,049
Total current assets	\$ 8,849,313	\$ 26,895	\$ 8,876,208
Right of use asset	\$ 1,645,668	\$ (1,645,668)	\$ —
Other long-term assets	\$ 29,824	\$ 44,100	\$ 73,924
Total assets	\$ 10,814,277	\$ (1,574,673)	\$ 9,239,604
Liabilities			
Accrued expenses	\$ 3,081,192	\$ (457,939)	\$ 2,623,253
Total current liabilities	\$ 4,839,893	\$ (457,939)	\$ 4,381,954
Lease obligation - net of current portion	\$ 1,116,734	\$ (1,116,734)	\$ —
Total liabilities	\$ 5,956,627	\$ (1,574,673)	\$ 4,381,954

The following table summarizes the effects of adopting ASU 2016-02 on the Company's balance sheet as of December 31, 2018:

	As reported	Adjustments	Amounts under prior GAAP
Assets			
Prepaid expenses and other current assets	\$ 860,915	\$ 44,852	\$ 905,767
Total current assets	\$ 11,586,165	\$ 44,852	\$ 11,631,017
Right of use asset	\$ 1,968,062	\$ (1,968,062)	\$ —
Other long-term assets	\$ 30,314	\$ 44,578	\$ 74,892
Total assets	\$ 13,991,880	\$ (1,878,632)	\$ 12,113,248
Liabilities			
Accrued expenses	\$ 2,236,633	\$ (577,460)	\$ 1,659,173
Total current liabilities	\$ 6,592,897	\$ (577,460)	\$ 6,015,437
Lease obligation - net of current portion	\$ 1,301,172	\$ (1,301,172)	\$ —
Total liabilities	\$ 7,894,069	\$ (1,878,632)	\$ 6,015,437

Adoption of ASU 2016-02 had no impact on the Company's statements of operations, statements of changes in stockholders' equity and statements of cash flows.

2. Comprehensive Income (Loss)

For the quarters and six months ended June 30, 2019 and 2018, the Company had no components of other comprehensive income (loss) other than net income (loss) itself.

3. Net Income (Loss) Per Common Share

Basic and dilutive net income (loss) per common share were as follows:

	Quarters Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net income (loss) applicable to common stockholders	\$ (3,362,191)	\$ 573,928	\$ (1,311,684)	\$ 1,740,180
Weighted average number of common shares outstanding, basic	9,048,235	7,330,479	8,396,249	6,839,778
Dilutive convertible preferred stock	—	6,584,674	—	6,980,585
Weighted average number of common shares outstanding, dilutive	9,048,235	13,915,153	8,396,249	13,820,363
Net income (loss) per common share applicable to common stockholders, basic	\$ (0.37)	\$ 0.08	\$ (0.16)	\$ 0.25
Net income (loss) per common share applicable to common stockholders, diluted	\$ (0.37)	\$ 0.04	\$ (0.16)	\$ 0.13

Shares underlying the following potentially dilutive weighted average number of common stock equivalents were excluded from the calculation of diluted net (loss) income per common share because their effect was anti-dilutive for each of the periods presented:

	Quarters Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Options	482,656	466,025	485,559	401,778
Warrants	459,375	459,375	459,375	459,375
Convertible preferred stock	4,915,974	—	5,567,960	—
Total	5,858,005	925,400	6,512,894	861,153

4. Inventories

Inventories consist of the following:

	June 30, 2019	December 31, 2018
Purchased components	\$ 1,226,434	\$ 1,767,674
Finished goods	836,997	1,094,190
	\$ 2,063,431	\$ 2,861,864

As of June 30, 2019 inventory reserves for excess stock totaled \$2,181,819 with \$2,030,000 allocated to purchased components and \$151,819 allocated to finished goods.

5. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2019	December 31, 2018
Lease obligation, current portion	\$ 582,940	\$ 577,460
Supplier excess commitments	590,000	160,000
Professional services	566,000	391,000
Technology fees	450,000	450,000
Advertising and promotion	380,000	171,000
Compensation expense	162,990	223,756
Warranty reserve	103,000	129,837
Relocation costs	100,000	—
Other	146,262	133,580
	<u>\$ 3,081,192</u>	<u>\$ 2,236,633</u>

6. Leases

Operating Leases

In June 2018, the Company extended the lease on its Woburn, Massachusetts manufacturing facilities (the “Woburn Lease”) through September 2025. The Woburn Lease has a monthly base rent of \$13,918 and a 5-year extension option. In September 2014, the Company entered into a 7-year operating lease agreement with one 5-year extension option for its corporate office and product development activities in Waltham, Massachusetts (the “Waltham Lease”). The term of the Waltham Lease commenced on February 20, 2015 and includes fixed payment obligations that escalate over the initial lease term. Average monthly base rent under the Waltham lease is \$41,074.

Future minimum lease payments under non-cancellable operating leases as of June 30, 2019 are as follows:

2019	\$ 315,609
2020	641,193
2021	653,164
2022	247,347
2023	165,785
2024	165,785
2025	117,431
Total minimum lease payments	<u>\$ 2,306,314</u>
Weighted-average discount rate, 14.6%	\$ 606,640
Lease obligation, current portion	582,940
Lease obligation, net of current portion	<u>1,116,734</u>
	<u>\$ 2,306,314</u>

Total recorded rent expense was \$332,049 and \$307,420, for the six months ended June 30, 2019 and 2018, respectively. The Company records rent expense on its facility leases on a straight-line basis over the lease term.

7. Business Restructuring

In June 2019 the Company reported a business restructuring incorporating several different elements and involving a charge against operations of approximately \$2.3 million. This restructuring included a reduction in force affecting eleven employees and severance costs of \$224,773. It also includes a planned consolidation of the Company's corporate office and engineering labs into its Woburn manufacturing facility resulting in estimated relocation and idle asset costs of approximately \$225,000. In addition, the Company incurred a Quell inventory-related costs totaling \$1,895,884 in order to cover the write down of excess parts to their net realizable value of \$1,485,884 and accrued costs related to parts purchase commitments of \$410,000.

The severance and relocation obligations relating to the business restructuring outstanding as of June 30, 2019 are presented below.

	June 30, 2019
Severance obligations:	
Provision	\$ 224,773
Amounts paid out	(192,515)
Total	<u>32,258</u>
Relocation costs:	
Provision	225,000
Total	<u>225,000</u>
Balance - June 30, 2019	<u>\$ 257,258</u>

Within the Company's Statements of Operations for the quarter and six months ended June 30, 2019, Quell inventory-related costs of \$1,895,884 were recorded within costs of revenues, \$201,514 of severance and relocation costs were recorded within research and development, \$129,812 of severance and relocation costs were recorded within sales and marketing, and \$118,447 of severance and relocation costs were recorded within general and administrative.

8. Contingencies

As previously disclosed, in 2017, the Company received a Civil Investigative Demand ("CID") from the Federal Trade Commission (the "FTC"). The CID requested information in connection with an FTC review for compliance of the Company's advertising about its product Quell with Sections 5 and 12 of the Federal Trade Commission Act (the "FTC Act"). During 2017 and 2018, the Company provided responses to those requests. The Company met with the staff of the FTC (the "Staff") on three occasions between March and July 2019 to discuss the Company's responses to FTC inquiries, and the Company has provided additional information in response to further requests from the FTC. As part of those discussions, the parties are engaged in a dialogue regarding the possible structuring of a settlement of this matter, which is likely to include a monetary judgment that would be payable to the FTC. The Company and the FTC will also be negotiating the scope and terms of a proposed consent order (the "Order"), which is expected to prohibit the Company from making certain claims in the Company's advertising about Quell, as will likely be defined by the Order.

The Company is currently awaiting feedback from the Staff on the latest discussions and responses to Staff inquiries, and intends to continue the dialogue with the Staff regarding a resolution of this matter. The ultimate outcome cannot be reasonably estimated at this time; however, the Company believes that a material financial loss is probable.

9. Fair Value Measurements

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis for the periods presented and indicates the fair value hierarchy of the valuation techniques it utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates, and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability.

	Fair Value Measurements at June 30, 2019 Using			
	June 30, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$ 3,004,775	\$ 3,004,775	\$ —	\$ —
Total	\$ 3,004,775	\$ 3,004,775	\$ —	\$ —

	Fair Value Measurements at December 31, 2018 Using			
	December 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$ 4,284,928	\$ 4,284,928	\$ —	\$ —
Total	\$ 4,284,928	\$ 4,284,928	\$ —	\$ —

10. Credit Facility

The Company is party to a Loan and Security Agreement, as amended (the "Credit Facility"), with a bank. As of June 30, 2019, the Credit Facility permitted the Company to borrow up to \$2.5 million on a revolving basis. The Credit Facility was amended most recently in June 2019 and expires in September 2019. Amounts borrowed under the Credit Facility will bear interest equal to the prime rate plus 0.5%. Any borrowings under the Credit Facility will be collateralized by the Company's cash, accounts receivable, inventory, and equipment. The Credit Facility includes traditional lending and reporting covenants. These include certain financial covenants applicable to liquidity that are to be maintained by the Company. As of June 30, 2019, the Company was in compliance with these covenants and had not borrowed any funds under the Credit Facility. However, \$226,731 of the amount under the Credit Facility is restricted to support letters of credit issued in favor of the Company's landlords. Consequently, the amount available for borrowing under the Credit Facility as of June 30, 2019 was approximately \$2.3 million.

11. Stockholders' Equity

Preferred stock and convertible preferred stock consist of the following:

	6/30/2019	12/31/2018
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at June 30, 2019 and December 31, 2018; no shares issued and outstanding at June 30, 2019 and December 31, 2018	\$ —	\$ —
Series B convertible preferred stock, \$0.001 par value; 147,000 shares designated at June 30, 2019 and December 31, 2018; 200 shares issued and outstanding at June 30, 2019 and December 31, 2018	\$ 1	\$ 1
Series D convertible preferred stock, \$0.001 par value; 21,300 shares designated at June 30, 2019 and December 31, 2018; 11,054.73 and 14,052.93 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	\$ 10	\$ 14
Series E convertible preferred stock, \$0.001 par value; 7,000 shares designated at June 30, 2019 and December 31, 2018; zero and 3,260.70 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	\$ —	\$ 3

2019 equity activity

During the six months ended June 30, 2019, 2,998.20 shares of the Series D Preferred Stock were converted into a total of 1,140,000 shares of Common Stock and 3,260.70 shares of the Series E Preferred Stock were converted into a total of 1,239,810 shares of Common Stock.

2018 equity activity

During the six months ended June 30, 2018, the Company issued shares of fully vested common stock in partial settlement of outstanding management incentive compensation. The issuance involved 214,791 shares with an aggregate value of \$294,264, reflecting the \$1.37 closing price of the Company's common stock as reported on the Nasdaq Capital Market on April 12, 2018.

During the six months ended June 30, 2018, 3,739.3 shares of the Series E Preferred Stock were converted into a total of 1,421,787 shares of Common Stock and 7,927.05 shares of the Series F Preferred Stock were converted into a total of 3,014,087 shares of Common Stock.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion of our financial condition and results of operations in conjunction with our financial statements and the accompanying notes to those financial statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. For a description of factors that may cause our actual results to differ materially from those anticipated in these forward-looking statements, please refer to the below section of this Quarterly Report on Form 10-Q titled "Cautionary Note Regarding Forward-Looking Statements." Unless the context otherwise requires, all references to "we", "us", the "Company", or "NeuroMetrix" in this Quarterly Report on Form 10-Q refer to NeuroMetrix, Inc.

Overview

NeuroMetrix is a commercial stage, innovation driven healthcare company combining neurostimulation and digital medicine to address chronic health conditions including chronic pain, sleep disorders, and diabetes. Our core expertise in biomedical engineering has been refined over nearly two decades of designing, building and marketing medical devices that stimulate nerves and analyze nerve response for diagnostic and therapeutic purposes. We created the market for point-of-care nerve testing and were first to market with sophisticated wearable technology for management of chronic pain. We have an experienced management team and Board of Directors. Our business is fully integrated with in-house capabilities spanning product research and development, manufacturing, regulatory affairs and compliance, sales and marketing, and customer support. We derive revenues from the sale of medical devices and after-market consumable products and accessories. Our products are sold in the United States and select overseas markets and are cleared by the U.S. Food and Drug Administration (FDA) and regulators in foreign jurisdictions where appropriate. We have two principal product lines:

- Wearable neurostimulation therapeutic devices
- Point-of-care neuropathy diagnostic tests

Chronic pain is a significant public health problem. It is defined by the National Institutes of Health as any pain lasting more than 12 weeks. This contrasts with acute pain which is a normal bodily response to injury or trauma. Chronic pain may be triggered by an injury or there may be an ongoing cause such as disease or illness. There may also be no clear cause. In individuals suffering from chronic pain, pain signals continue to be transmitted in the nervous system over extended periods of time often leading to other health problems. These can include fatigue, sleep disturbance, decreased appetite, and mood changes which cause difficulty in carrying out important activities and can contribute to disability and despair. In general, chronic pain cannot be cured. Treatment of chronic pain is focused on reducing pain and improving function. The goal is effective pain management.

Chronic pain affects over 100 million adults in the United States and more than 1.5 billion people worldwide. The estimated incremental impact of chronic pain on health care costs in the United States is over \$250 billion per year and lost productivity is estimated to exceed \$300 billion per year. The most common approach to chronic pain management is pain medication. This includes over-the-counter (OTC) internal and external analgesics as well as prescription pain medications, both non-opioid and opioid. The approach to treatment is individualized, drug combinations may be employed, and the results are often hit or miss. Side effects and the potential for addiction are real and the risks are substantial. Increasingly, federal, state and private-payer restrictions are being imposed on prescription opioids as a response to those risks. Reflecting the complexity of chronic pain and the difficulty in treating it, we believe that inadequate relief leads 25% to 50% of pain sufferers to seek alternatives to prescription pain medications. These alternatives include nutritional supplements, acupuncture, chiropractic care, non-prescription analgesics, electrical stimulators, braces, sleeves, pads and other items. In total these pain relief products and services account for approximately \$20 billion in annual spending in the United States.

Nerve stimulation is a well-established category of treatment for chronic pain. This treatment approach is available through implantable spinal cord stimulation requiring surgery with its attendant risks. Non-invasive approaches involving transcutaneous electrical nerve stimulation (TENS) have achieved limited efficacy in practice due to device limitations, ineffective dosing and low patient adherence. Our Quell wearable technology for chronic pain addresses these limitations and has resulted in quality of life improvements for a majority of chronic pain sufferers who have used the product, which we have determined through post-market analysis of user data submitted to us for research purposes via the Quell App, clinical studies, and user reviews.

Diabetes is a worldwide epidemic with an estimated affected population of over 400 million people. Within the United States there are over 30 million people with diabetes and another 80 million people with pre-diabetes. The annual direct cost of

treating diabetes in the United States exceeds \$100 billion. Although there are dangerous acute manifestations of diabetes, the primary burden of the disease is in its long-term complications which include cardiovascular disease, nerve disease and resulting conditions such as foot ulcers which may require amputation, eye disease leading to blindness, and kidney failure. The most common long-term complication of diabetes affecting over 50% of the diabetic population is nerve disease or diabetic neuropathy. Diabetic peripheral neuropathy (DPN) is the primary trigger for diabetic foot ulcers which may progress to the point of requiring amputation. People with diabetes have a 15-25% lifetime risk of foot ulcers and approximately 15% of foot ulcers lead to amputation. Foot ulcers are the most expensive complication of diabetes with a typical cost of \$5,000 to \$50,000 per episode. In addition, between 16% and 26% of people with diabetes suffer from chronic pain in their feet and lower legs.

Early detection of DPN is important because there are no treatment options once the nerves have degenerated. Today's diagnostic methods for DPN range from a simple monofilament test for lack of sensory perception in the feet to a nerve conduction study performed by a specialist. Our DPNCheck technology provides a rapid, low cost, quantitative test for peripheral nerve disease, including DPN. It addresses an important medical need and is particularly effective in mass screenings of populations that are likely susceptible to DPN. DPNCheck has been validated in numerous clinical studies.

In 2018, the Company entered into a collaboration with GlaxoSmithKline ("GSK"). The GSK collaboration established a framework for the joint development of the next generation of Quell, recently launched in the United States in September 2018, and to be launched by GSK internationally, and the assignment of areas of marketing responsibility. The initial term of the GSK collaboration runs through 2020. Through June 30, 2019, GSK has paid the Company \$19.5 million in milestone payments. GSK has committed to future performance milestone payments totaling up to \$5.5 million and agreed to co-fund Quell development costs starting in 2019.

Results of Operations

Comparison of Quarters Ended June 30, 2019 and 2018

Revenues

	Quarters Ended June 30,		Change	% Change
	2019	2018		
	(in thousands)			
Revenues	\$ 2,354.7	\$ 3,751.6	\$ (1,396.9)	(37.2)%

Revenues include sales from Quell, DPNCheck and our legacy neurodiagnostic products. During the second quarter of 2019 total revenues decreased by \$1.4 million, or 37.2%, from the second quarter of 2018. Quell revenues of \$0.8 million were the largest contributor to the decrease in total revenue. Quell revenues were \$1.2 million, or 60.6%, below the comparable 2018 period primarily due to the reduction of advertising promotion and curtailment of most retail and direct response television distribution channels. DPNCheck revenues were \$1.3 million in both the second quarters of 2019 and 2018. Our legacy products contributed \$0.3 million and \$0.4 million of revenue in the second quarters of 2019 and 2018, respectively.

Cost of Revenues and Gross Profit

	Quarters Ended June 30,		Change	% Change
	2019	2018		
	(in thousands)			
Cost of revenues	\$ 3,143.8	\$ 1,950.3	\$ 1,193.5	61.2 %
Gross profit (loss)	\$ (789.1)	\$ 1,801.3	\$ (2,590.4)	(143.8)%

Our gross margin was (33.5)% in the second quarter of 2019 versus 48.0% in the same period in the prior year. The negative gross margin in 2019 results from a charge of \$1.9 million to write down Quell inventory to net realizable value. Excluding this charge the gross profit margin was 47.0% and 48.0% for the second quarters of 2019 and 2018, respectively.

Operating Expenses

	Quarters Ended June 30,		Change	% Change
	2019	2018		
	(in thousands)			
Operating expenses:				
Research and development	\$ 1,034.9	\$ 1,616.9	\$ (582.0)	(36.0)%
Sales and marketing	1,373.9	2,200.9	(827.0)	(37.6)%
General and administrative	1,564.6	1,170.6	394.0	33.7 %
Total operating expenses	<u>\$ 3,973.4</u>	<u>\$ 4,988.4</u>	<u>\$ (1,015.0)</u>	(20.3)%

Research and Development

Research and development expense in the second quarter of 2019 decreased by 36.0% from the same period in the prior year due to GSK's co-funding \$0.5 million in certain development costs and \$0.1 million decrease in Quell outside engineering costs, partially offset by \$0.2 million in employee severance and relocation costs associated with the business restructuring.

Sales and Marketing

Sales and marketing expense in the second quarter of 2019 decreased by 37.6% from the same period in the prior year due to a reduction in advertising and promotion spending by \$0.6 million. In addition, personnel costs decreased by \$0.3 million, partially offset by \$0.1 million in employee severance and relocation costs associated with the business restructuring.

General and Administrative

General and administrative expense in the second quarter of 2019 increased by 33.7% from the same period in the prior year primarily due to an increase of \$0.3 million in outside professional service costs and \$0.1 million in employee severance and relocation costs associated with the business restructuring.

Collaboration income

	Quarters Ended June 30,		Change	% Change
	2019	2018		
	(in thousands)			
Collaboration income	<u>\$ 1,381.8</u>	<u>\$ 3,750.0</u>	<u>\$ (2,368.2)</u>	(63.2)%

Collaboration income includes milestones achieved and funded by GSK under our Quell Collaboration.

Other income

	Quarters Ended June 30,		Change	% Change
	2019	2018		
	(in thousands)			
Other income	<u>\$ 18.5</u>	<u>\$ 11.0</u>	<u>\$ 7.5</u>	68.2%

Other income primarily includes interest income.

Comparison of Six Months Ended June 30, 2019 and 2018

Revenues

	Six Months Ended June 30,		Change	% Change
	2019	2018		
	(in thousands)			
Revenues	\$ 5,477.6	\$ 8,694.6	\$ (3,217.0)	(37.0)%

Revenues include sales from Quell, DPNCheck and our legacy neurodiagnostic products. During the six months ended June 30, 2019 total revenues decreased by \$3.2 million, or 37.0%, from the six months ended June 30, 2018. Quell revenues of \$2.5 million in the six months ended June 30, 2019 were the largest contributor to the decrease in total revenue. Quell revenues were \$3.1 million, or 55.6%, below the comparable 2018 period primarily due to the reduction of advertising promotion and curtailment of most retail and direct response television distribution channels. DPNCheck revenues were \$2.4 million in the six months ended June 30, 2019 and 2018. Our legacy products contributed \$0.6 million and \$0.7 million of revenue in the six months ended June 30, 2019 and 2018, respectively.

Cost of Revenues and Gross Profit

	Six Months Ended June 30,		Change	% Change
	2019	2018		
	(in thousands)			
Cost of revenues	5,468.0	4,905.6	562.4	11.5 %
Gross profit (loss)	9.6	3,789.0	(3,779.4)	(99.7)%

Our gross profit margin was 0.2% in the six months ended June 30, 2019 versus 43.6% in the same period in the prior year. The lower gross profit margin in 2019 results from charges in the first and second quarters of 2019 totaling \$2.6 million to write down Quell inventory to net realizable value. Excluding these charges the gross profit margin was 47.6% and 43.6% for the first six months of 2019 and 2018, respectively, which reflects the increased weighting within revenue of the higher margin DPNCheck business.

Operating Expenses

	Six Months Ended June 30,		Change	% Change
	2019	2018		
	(in thousands)			
Operating expenses:				
Research and development	\$ 1,890.0	\$ 2,896.4	\$ (1,006.4)	(34.7)%
Sales and marketing	3,399.2	4,705.6	(1,306.4)	(27.8)%
General and administrative	3,184.0	2,974.8	209.2	7.0 %
Total operating expenses	\$ 8,473.2	\$ 10,576.8	\$ (2,103.6)	(19.9)%

Research and Development

Research and development expense in the six months ended June 30, 2019 decreased by 34.7% from the same period in the prior year due to GSK's co-funding of \$1.0 million in certain development costs and a \$0.1 million decrease in Quell outside engineering costs, partially offset by \$0.2 million in employee severance and relocation costs associated with the business restructuring.

Sales and Marketing

Sales and marketing expense in the six months ended June 30, 2019 decreased by 27.8% from the same period in the prior year reflecting a reduction in advertising and promotion spending by \$1.7 million. This was partially offset by a \$0.2 million increase in marketing consulting fees and \$0.1 million in employee severance and relocation costs associated with the business restructuring.

General and Administrative

General and administrative expense in the six months ended June 30, 2019 increased by 7.0% from the same period in the prior year primarily due to a \$0.4 million increase in professional services costs and \$0.1 million in employee severance and relocation costs associated with the business restructuring, partially offset by a \$0.2 million decrease in stock-based compensation expense.

Collaboration income

	Six Months Ended June 30,		Change	% Change
	2019	2018		
	(in thousands)			
Collaboration income	\$ 7,116.7	\$ 8,505.7	\$ (1,389.0)	(16.3)%

Collaboration income includes milestones achieved and funded by GSK under our Quell Collaboration.

Other income

	Six Months Ended June 30,		Change	% Change
	2019	2018		
	(in thousands)			
Other income	\$ 35.3	\$ 22.3	\$ 13.0	58.6%

Other income primarily includes interest income.

Liquidity and Capital Resources

Our principal source of liquidity is cash and cash equivalents of \$5.0 million at June 30, 2019. Funding for our operations largely depends on revenues from the sale of our commercial products for chronic pain and neuropathy, and on achievement of milestones under the GSK collaboration. A low level of market interest in Quell or DPNCheck, a decline in our consumables sales, unanticipated increases in our operating costs, or unanticipated setbacks toward the achievement of the GSK milestones would have an adverse effect on our liquidity and cash.

	June 30, 2019	December 31, 2018	Change	% Change
	(\$ in thousands)			
Cash and cash equivalents	\$ 4,958.1	\$ 6,780.4	\$ (1,822.3)	(26.9)%

During the six months ended June 30, 2019, our cash and cash equivalents decreased by \$1.8 million reflecting \$6.6 million cash used in operating activities, partially offset by the net proceeds of \$4.8 million provided by the GSK collaboration.

We are party to a Loan and Security Agreement with a bank. As of June 30, 2019 this credit facility permitted us to borrow up to \$2.5 million on a revolving basis. Amounts borrowed under the credit facility bear interest equal to the prime rate plus 0.5% and are collateralized by cash, accounts receivable, inventory, and equipment. The credit facility includes traditional lending and reporting covenants. We were in compliance with these covenants at June 30, 2019.

In managing working capital, we focus on two important financial measurements:

	Quarters Ended June 30,		Year Ended
	2019	2018	December 31, 2018
Days sales outstanding (days)	33	32	39
Inventory turnover rate (times per year)	5.5	3.6	3.5

Days sales outstanding reflect customer payment terms which vary from payment on order to 60 days from invoice date. Our inventory turnover rate in the second quarter of 2019 of 5.5 times includes the effect of a \$1.9 million inventory provision recorded in the quarter. Excluding this provision, our turnover rate declined to 1.1 during the quarter ended June 30, 2019. This reflected lower Quell sales and increased inventory on hand.

The following sets forth information relating to our sources and uses of our cash:

	Six Months Ended June 30,	
	2019	2018
	(in thousands)	
Net cash used in operating activities (excluding collaboration income)	\$ (6,582.4)	\$ (5,309.6)
Net cash provided by collaboration income	4,760.1	8,505.7
Net cash (used in) provided by operating activities	<u>\$ (1,822.3)</u>	<u>\$ 3,196.1</u>

During the six months ended June 30, 2019, our operating activities consumed \$6.6 million of cash offset by \$4.8 million of collaboration income.

We have suffered recurring losses from operations and negative cash flows from operating activities. These factors raise substantial doubt about our ability to continue as a going concern for the one-year period from the date of issuance of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. We held cash and cash equivalents of \$5.0 million as of June 30, 2019. We believe that these resources, future GSK collaboration milestone payments, and the cash to be generated from future product sales will be sufficient to meet our projected operating requirements through 2019. Accordingly, we will need to raise additional funds to support our operating and capital needs in 2020. We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to (a) decreases in sales of our products; (b) changes we may make to the business that affect ongoing operating expenses; (c) changes we may make in our business strategy; (d) regulatory developments affecting our existing products; (e) changes we may make in our research and development spending plans; (f) delays in the timing of achieving GSK milestones; (g) the final outcome of the Federal Trade Commission civil investigative demand enforcement action involving Quell; and (h) other items affecting our forecasted level of expenditures and use of cash resources. We may attempt to obtain additional funding through achievement of milestones under the GSK collaboration, public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources. However, we may not be able to secure such funding in a timely manner or on favorable terms, if at all. We filed a shelf registration statement on Form S-3 with the SEC covering shares of our common stock and other securities for sale, giving us the opportunity to raise funding when needed or otherwise considered appropriate at prices and on terms to be determined at the time of any such offerings. However, pursuant to the instructions to Form S-3, we only have the ability to sell shares under the shelf registration statement, during any 12-month period, in an amount less than or equal to one-third of the aggregate market value of our common stock held by non-affiliates. If we raise additional funds by issuing equity or debt securities, either through the sale of securities pursuant to a registration statement or by other means, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Without additional funds, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected.

Our common stock is quoted on the Nasdaq Capital Market under the symbol “NURO.” One of the requirements for continued listing on the Nasdaq Capital Market is maintenance of a minimum closing bid price of \$1.00. The closing bid price of our common stock on the Nasdaq Global Market was \$0.45 on July 12, 2019.

On June 3, 2019, we received a notice from the Listing Qualifications Department of the Nasdaq Stock Market indicating that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share required for continued inclusion in the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). The notification letter states that pursuant to Nasdaq Listing Rule 5810(c)(3)(A), the Company will be afforded 180 calendar days, or until December 2, 2019, to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of the Company’s common stock must maintain a minimum bid closing price of at least \$1.00 per share for a minimum of ten consecutive business days. If we do not regain compliance by December 2, 2019, Nasdaq will provide written notification to us that our common stock will be delisted. At that time, we may appeal Nasdaq’s delisting determination to a Nasdaq Listing Qualifications Panel. Alternatively, we may be eligible for an additional 180 day grace period if we satisfy all of the requirements, other than the minimum bid price requirement, for listing on The Nasdaq Capital Market set forth in Nasdaq Listing Rule 5505. The notification letter has no effect at this time on the listing of our common stock on the Nasdaq Capital Market. We intend to actively monitor the bid price for our common stock between now and December 2, 2019.

Off-Balance Sheet Arrangements, Contractual Obligation and Contingent Liabilities and Commitments

As of June 30, 2019, we did not have any off-balance sheet financing arrangements.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases (Topic 842)* (“ASU 2016-02”). ASU 2016-02 required that lessees recognize virtually all of their leases on the balance sheet, by recording a right-of-use asset and lease liability. We adopted ASU 2016-02, using the modified retrospective method, upon its effective date of January 1, 2019. The impact of adoption was an increase to long-term assets and total liabilities of approximately \$1.9 million as of January 1, 2019.

Cautionary Note Regarding Forward-Looking Statements

The statements contained in this Quarterly Report on Form 10-Q, including under the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and other sections of this Quarterly Report, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including, without limitation, statements regarding our or our management’s expectations, hopes, beliefs, intentions or strategies regarding the future, such as our estimates regarding anticipated operating losses, future revenues and projected expenses, our future liquidity and our expectations regarding our needs for and ability to raise additional capital; our ability to manage our expenses effectively and raise the funds needed to continue our business; our belief that there are unmet needs for the management of chronic pain and in the diagnosis or treatment of diabetic neuropathy; our expectations surrounding Quell and DPNCheck; our expected timing and our plans to develop and commercialize our products; our ability to meet our proposed timelines for the commercial availability of our products; our ability to obtain and maintain regulatory approval of our existing products and any future products we may develop; regulatory and legislative developments in the United States and foreign countries; the performance of our third-party manufacturers; our ability to obtain and maintain intellectual property protection for our products; the successful development of our sales and marketing capabilities; the size and growth of the potential markets for our products and our ability to serve those markets; our plan to make Quell more broadly available through retail distribution; the final outcome of the FTC civil investigative demand enforcement action, which is ongoing; our estimate of our customer returns of our products; the rate and degree of market acceptance of any future products; our reliance on key scientific management or personnel; the payment and reimbursement methods used by private or government third party payers; and other factors discussed elsewhere in this Quarterly Report on Form 10-Q. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “plan” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this quarterly report are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled “Risk Factors” in our Annual Report on Form 10-K. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We do not use derivative financial instruments in our investment portfolio and have no foreign exchange contracts. Our financial instruments consist of cash and cash equivalents. We consider investments that, when purchased, have a remaining maturity of 90 days or less to be cash equivalents. The primary objectives of our investment strategy are to preserve principal, maintain proper liquidity to meet operating needs, and maximize yields. To minimize our exposure to an adverse shift in interest rates, we invest mainly in cash equivalents and short-term investments with a maturity of twelve months or less and maintain an average maturity of twelve months or less. We do not believe that a notional or hypothetical 10% change in interest rate percentages would have a material impact on the fair value of our investment portfolio or our interest income.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures. Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of June 30, 2019, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(b) Changes in Internal Controls. There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the quarter ended June 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

While we are not currently a party to any material legal proceedings other than the FTC matter noted below, we could become subject to legal proceedings in the ordinary course of business. We do not expect any such potential items to have a significant impact on our financial position.

Item 1A. Risk Factors

There have been no material changes in the risk factors described in “Item 1A. Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2018 other than the updated risk factors noted below.

We are subject to Federal Trade Commission regulatory oversight. Exercise of this regulatory oversight could lead to an outcome which would constrain our marketing of Quell, cause us to incur significant costs and penalties, and adversely affect our financial results.

Under the Federal Trade Commission Act (“FTC Act”), the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in substantial administrative or judicial penalties, including civil penalties, or injunctions affecting the manner in which we would be able to market Quell in the future.

As previously disclosed, in 2017 we received a Civil Investigative Demand (“CID”) from the FTC. The CID requested information in connection with an FTC review for compliance of our representations about Quell with Sections 5 and 12 of the FTC Act. During 2017 and 2018, we provided responses to those requests. We met with the staff (the “Staff”) of the FTC on three occasions between March and July 2019 to discuss our responses to FTC inquiries, and we have provided additional information in response to further requests from the FTC. As part of those discussions, the parties are engaged in a dialogue regarding the possible structuring of a settlement of this matter, which is likely to include a monetary judgment that would be payable to the FTC. We and the FTC will also be negotiating the scope and terms of a proposed consent order (the “Order”), which is expected to prohibit us from making certain claims in our advertising about Quell, as will likely be defined by the Order.

We are currently awaiting feedback from the Staff on the latest discussions and responses to Staff inquiries, and intend to continue the dialogue with the Staff regarding a resolution of this matter. The ultimate outcome cannot be reasonably estimated at this time; however, the Company believes that a material financial loss is probable.

We are focused on the commercialization within the United States of Quell, our over-the-counter, or OTC, wearable device for chronic pain. We cannot assure you that we will be successful in this field or that our current commercial product for peripheral neuropathy, DPNCheck, or the product candidates or product enhancements in our development pipeline, will be successful.

We are focused on the commercialization within the United States of Quell, our OTC wearable device for pain relief. Quell is based on our prescription product for pain relief, SENSUS. Quell has been on the market since June 2015 and we have shipped over 180,000 Quell devices through the end of 2018. We are also focused on the growth of DPNCheck, which was launched in 2011, and is a quantitative nerve conduction test for systemic neuropathies such as DPN. Our future prospects are closely tied to our success with Quell and DPNCheck, which, in turn, depend upon market acceptance and growth in future revenues and margins. We cannot assure you that our commercialization strategy will be successful. If our strategy is not successful, it could materially affect our revenues and results of operations.

We recently completed an in-depth review of our Quell strategy, which has provided important insights on our target markets, points of differentiation in customer messaging, and possible changes in product pricing and positioning. We may make changes to our commercialization strategy with respect to Quell as a result, and the effect of any changes we may make is uncertain. Further, there may be changes to our commercialization strategy that would be desirable from an operational perspective that we are unable to make due to constraints on our resources or otherwise.

Our future success could be adversely affected by a number of factors, including:

- inability to efficiently create market demand for Quell at profitable pricing levels through our TV and digital marketing efforts, or any other marketing efforts we may adopt;
- changes we may make to our pricing and marketing strategy with respect to Quell or our other products;
- manufacturing issues with Quell or our other products;
- inability to increase adoption of DPNCheck within the Medicare Advantage market and Outside the United States (OUS) markets;
- regulatory inquiries or issues affecting our products;
- unfavorable changes to current Medicare, Medicare Advantage and commercial payer payment policies;
- changes to payor policies under the Patient Protection and Affordable Care Act;
- the outcome of the ongoing FTC investigation regarding Quell;
- unfavorable experiences by patients and physicians using Quell and our other products; and,
- physicians' or patients' reluctance to alter their existing practices and adopt the use of our devices.

If we are unable to expand exposure and market demand for Quell and DPNCheck, our ability to increase our revenues will be limited and our business prospects will be adversely affected.

If we fail to continue to meet all applicable Nasdaq Capital Market requirements and the Nasdaq Stock Market determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock, impair the value of your investment and harm our business.

Our common stock is currently listed on the Nasdaq Capital Market. In order to maintain that listing, we must satisfy minimum financial and other requirements. On June 3, 2019, we received a notice from the Listing Qualifications Department of the Nasdaq Stock Market indicating that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share required for continued inclusion on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). The notification letter states that pursuant to Nasdaq Listing Rule 5810(c)(3)(A) the Company will be afforded 180 calendar days, or until December 2, 2019, to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of the Company's common stock must maintain a minimum bid closing price of at least \$1.00 per share for a minimum of ten consecutive business days. If we do not regain compliance by December 2, 2019, Nasdaq will provide written notification to us that our common stock will be delisted. At that time, we may appeal Nasdaq's delisting determination to a Nasdaq Listing Qualifications Panel. Alternatively, we may be eligible for an additional 180 day grace period if we satisfy all of the requirements, other than the minimum bid price requirement, for listing on the Nasdaq Capital Market set forth in Nasdaq Listing Rule 5505.

While we intend to engage in efforts to regain compliance, and thus maintain our listing, there can be no assurance that we will be able to regain compliance during the applicable time periods set forth above. If we fail to continue to meet all applicable Nasdaq Capital Market requirements in the future and Nasdaq determines to delist our common stock, the delisting could substantially decrease trading in our common stock and adversely affect the market liquidity of our common stock; adversely affect our ability to obtain financing on acceptable terms, if at all, for the continuation of our operations; and harm our business. Additionally, the market price of our common stock may decline further and stockholders may lose some or all of their investment. The closing bid price of our common stock on the Nasdaq Capital Market was \$0.45 on July 12, 2019.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

As previously disclosed, in 2017 we received a Civil Investigative Demand (“CID”) from the Federal Trade Commission (“FTC”). The CID requested information in connection with an FTC review for compliance of our representations about Quell with Sections 5 and 12 of the FTC Act. During 2017 and 2018, we provided responses to those requests. We met with the staff (the “Staff”) of the FTC on three occasions between March and July 2019 to discuss our responses to FTC inquiries, and we have provided additional information in response to further requests from the FTC. As part of those discussions, the parties are engaged in a dialogue regarding the possible structuring of a settlement of this matter, which is likely to include a monetary judgment that would be payable to the FTC. We and the FTC will also be negotiating the scope and terms of a proposed consent order (the “Order”), which is expected to prohibit us from making certain claims in our advertising about Quell, as will likely be defined by the Order. We are currently awaiting feedback from the Staff on the latest discussions and responses to Staff inquiries, and intend to continue the dialogue with the Staff regarding a resolution of this matter. The ultimate outcome cannot be reasonably estimated at this time; however, the Company believes that a material financial loss is probable.

The Company intends to repurchase, from time to time, warrants to purchase its common stock that are traded on Nasdaq under the symbol NUROW. The Company may expend up to \$25,000 in making these purchases on Nasdaq from time to time. Through June 30, 2019, the Company spent \$2,391 to repurchase 38,506 warrants to purchase its common stock.

Item 6. Exhibits

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this quarterly report, which Exhibit Index is incorporated herein by this reference.

SIGNATURES

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

NEUROMETRIX, INC.

July 18, 2019

/s/ SHAI N. GOZANI, M.D., PH. D.

Shai N. Gozani, M.D., Ph. D.
Chairman, President and Chief Executive Officer

July 18, 2019

/s/ THOMAS T. HIGGINS

Thomas T. Higgins
Senior Vice President, Chief Financial Officer and Treasurer

EXHIBIT INDEX

Exhibit No.	Description
10.1	Twelfth Modification to Loan and Security Agreement with Comerica Bank, dated June 21, 2019. Filed herewith.
31.1	Certification of Principal Executive Officer Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended, and pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002. Filed herewith.
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, and pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350. Furnished herewith.
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets at June 30, 2019 and December 31, 2018, (ii) Statements of Operations for the quarter and six months ended June 30, 2019 and 2018, (iii) Statements of Changes in Stockholders' Equity for the six months ended June 30, 2019 and 2018, (iv) Statements of Cash Flows for the six months ended June 30, 2019 and 2018, and (v) Notes to Financial Statements.

TWELFTH MODIFICATION TO LOAN AND SECURITY AGREEMENT

This Eleventh Modification to Loan and Security Agreement (this "Modification") dated June 21, 2019, is entered into by and between **Neurometrix, Inc.**, a Delaware corporation ("Borrower"), and **Comerica Bank** ("Bank").

RECITALS

Bank and Borrower previously entered into a Loan and Security Agreement dated March 5, 2010, as amended by the following:

the First Modification to Loan and Security Agreement dated March 1, 2011,
the Second Modification to Loan and Security Agreement dated February 15, 2012,
the Third Modification to Loan and Security Agreement dated April 19, 2012,
the Fourth Modification to Loan and Security Agreement dated January 28, 2013,
the Fifth Modification to Loan and Security Agreement dated January 31, 2014,
the Sixth Modification to Loan and Security Agreement dated January 23, 2015,
the Seventh Modification to Loan and Security Agreement dated January 14, 2016,
the Eighth Modification to Loan and Security Agreement dated December 29, 2016,
the Ninth Modification to Loan and Security Agreement dated January 17, 2018,
the Tenth Modification to Loan and Security Agreement dated January 14, 2019 and
the Eleventh Modification to Loan and Security Agreement dated March 25, 2019 (collectively "Agreement").

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as set forth below.

AGREEMENT

1. Incorporation by Reference. The Recitals and the documents referred to therein are incorporated herein by this reference. Except as otherwise noted, the terms not defined herein shall have the meanings set forth in the Agreement.
2. Modification to the Agreement. Subject to the satisfaction of the conditions precedent as set forth in Section 3 hereof, the Agreement is hereby modified as set forth below.
 - (a) The following defined term, which is set forth in Exhibit A of the Agreement, is given the following amended definition:

'Revolving Maturity Date' means **September 30, 2019.**"

3. Legal Effect.

(a) Except as expressly set forth herein, the execution, delivery, and performance of this Modification shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Bank under the Agreement, as in effect prior to the date hereof. Borrower ratifies and reaffirms the continuing effectiveness of all promissory notes, guaranties, security agreements, environmental agreements, and all other instruments, documents and agreements entered into in connection with the Agreement.

(a) Borrower represents and warrants that the representations and warranties contained in the Agreement are true and correct as of the date of this Modification, and that no Event of Default has occurred and is continuing.

(b) The effectiveness of this Modification and each of the documents, instruments and agreements entered into in connection with this Modification is conditioned upon receipt by Bank of:

(i) this Modification and any other documents which Bank may require to carry out the terms hereof; and

(ii) payment of any Bank expenses incurred through the date of this Modification.

4. No Other Changes. Except as specifically provided in this Modification, it does not vary the terms and provisions of any of the Loan Documents. This Modification shall not impair the rights, remedies, and security given in and by the Loan Documents. The terms of this Modification shall control any conflict between its terms and those of the Agreement.

5. Integration. This is an integrated Modification and supersedes all prior negotiations and agreements regarding the subject matter hereof. All amendments hereto must be in writing and signed by the parties.

6. Release and Waiver. Borrower waives, discharges, and forever releases Bank, Bank's employees, officers, directors, attorneys, stockholders, and their successors and assigns, from and of any and all claims, causes of action, allegations or assertions that Borrower has or may have had at any time up through and including the date of this Amendment, against any or all of the foregoing, regardless of whether any such claims, causes of action, allegations or assertions were known to Borrower or whether any such claims, causes of action, allegations or assertions arose as result of Bank's actions or omissions in connection with the Loan Agreement, any other Loan Document, any amendments, extensions or modifications thereto, or Bank's administration of the Indebtedness or otherwise. It is further understood and agreed that any and all rights under the provisions of Section 1542 of the California Civil Code are expressly waived by Borrower. Section 1542 of the California Civil Code provides as follows:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.]

7. Counterparts. This Modification may be executed in one or more counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same Agreement, and shall become effective when one or more counterparts have been signed by each of the parties hereto and delivered to the other party.

[end of Modification; signature page follows]

IN WITNESS WHEREOF, the parties have agreed to this Twelfth Modification to Loan and Security Agreement as of the date first set forth above.

BANK: BORROWER:

Comerica Bank NeuroMetrix, Inc. a Delaware corporation

By: /s/ Bryan W. Kana By: /s/ Thomas T. Higgins

Bryan W. Kana Printed Name: Thomas T. Higgins

Its: Vice President Its: CFO

CERTIFICATION

I, Shai N. Gozani, M.D., Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NeuroMetrix, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 18, 2019

/s/ SHAI N. GOZANI, M.D., PH.D.

Shai N. Gozani, M.D., Ph.D.

Chairman, President and Chief Executive Officer

CERTIFICATION

I, Thomas T. Higgins, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NeuroMetrix, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 18, 2019

/s/ THOMAS T. HIGGINS

Thomas T. Higgins

Senior Vice President, Chief Financial Officer and Treasurer

CERTIFICATION

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of NeuroMetrix, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report for the quarter ended June 30, 2019 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ SHAI N. GOZANI, M.D., PH.D.

Shai N. Gozani, M.D., Ph.D.

Chairman, President and Chief Executive Officer

/s/ THOMAS T. HIGGINS

Thomas T. Higgins

Senior Vice President, Chief Financial Officer and Treasurer

July 18, 2019

This certification is being furnished and not filed, and shall not be incorporated into any document for any purpose, under the Securities Exchange Act of 1934 or the Securities Act of 1933.