

NeuroMetrix, Inc.
Form 10-Q
April 20, 2018

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 March 31, 2018

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 04-3308180
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

1000 Winter Street, Waltham, Massachusetts 02451
(Address of principal executive offices) (Zip Code)
(781) 890-9989
(Registrant's telephone number, including area code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Yes No

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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 the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 7,356,731 shares of common stock, par value \$0.0001 per share, were outstanding as of April 13, 2018.

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 April 13, 2018.

NeuroMetrix, Inc.
Form 10-Q
Quarterly Period Ended March 31, 2018

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

NeuroMetrix, Inc.

Balance Sheets

	March 31, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$6,097,792	\$4,043,681
Accounts receivable, net	1,588,720	1,049,329
Inventories	1,858,652	2,142,561
Prepaid expenses and other current assets	952,985	1,867,803
Total current assets	10,498,149	9,103,374
Fixed assets, net	431,656	440,842
Other long-term assets	43,158	55,008
Total assets	\$10,972,963	\$9,599,224
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$384,065	\$733,305
Accrued expenses and compensation	2,361,257	2,362,124
Accrued product returns	1,405,117	666,375
Deferred revenue	—	820,031
Total current liabilities	4,150,439	4,581,835
Total liabilities	4,150,439	4,581,835
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock	—	—
Convertible preferred stock	18	30
Common stock, \$0.0001 par value; 100,000,000 shares authorized at March 31, 2018 and December 31, 2017; 7,141,940 and 2,706,066 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	714	271
Additional paid-in capital	196,695,736	196,355,142
Accumulated deficit	(189,873,944)	(191,338,054)
Total stockholders' equity	6,822,524	5,017,389
Total liabilities and stockholders' equity	\$10,972,963	\$9,599,224

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

NeuroMetrix, Inc.
 Statements of Operations
 (Unaudited)

	Quarters Ended March 31,	
	2018	2017
Revenues	\$4,942,990	\$4,306,122
Cost of revenues	2,955,260	2,697,602
Gross profit	1,987,730	1,608,520
Operating expenses:		
Research and development	1,279,564	903,284
Sales and marketing	2,504,741	2,597,712
General and administrative	1,804,143	1,421,782
Total operating expenses	5,588,448	4,922,778
Loss from operations	(3,600,718)	(3,314,258)
Other income:		
Collaboration income	4,755,705	—
Other income	11,265	81,858
Total other income	4,766,970	81,858
Net income (loss)	1,166,252	(3,232,400)
Net income (loss) applicable to common stockholders:		
Deemed dividends attributable to preferred shareholders	—	(4,041,682)
Net income (loss) applicable to common stockholders	\$1,166,252	\$(7,274,082)
Net income (loss) per common share applicable to common stockholders,		
Basic	\$0.18	\$(7.27)
Diluted	\$0.08	\$(7.27)

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

NeuroMetrix, Inc.
 Statements of Cash Flows
 (Unaudited)

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities:		
Net income (loss)	\$1,166,252	\$(3,232,400)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation	55,444	61,579
Stock-based compensation	341,026	66,496
Change in fair value of warrant liability	—	(77,601)
Changes in operating assets and liabilities:		
Accounts receivable	814,108	(211,240)
Inventories	283,909	55,379
Prepaid expenses and other current and long-term assets	343,177	236,859
Accounts payable	(369,665)	(329,980)
Accrued expenses and compensation	(868)	121,822
Accrued product returns	(553,439)	(161,856)
Deferred revenue	—	116,968
Net cash provided by (used in) operating activities	2,079,944	(3,353,974)
Cash flows from investing activities:		
Purchases of fixed assets	(25,833)	—
Net cash used in investing activities	(25,833)	—
Cash flows from financing activities:		
Net proceeds from issuance of stock and warrants	—	6,302,000
Net cash provided by financing activities	—	6,302,000
Net increase in cash and cash equivalents	2,054,111	2,948,026
Cash and cash equivalents, beginning of period	4,043,681	3,949,135
Cash and cash equivalents, end of period	\$6,097,792	\$6,897,161

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

NeuroMetrix, Inc.
Notes to Unaudited Financial Statements
March 31, 2018

1. Business and Basis of Presentation

Our Business-An Overview

NeuroMetrix, Inc., or the Company, is a commercial stage, innovation driven healthcare company combining bioelectrical and digital medicine to address chronic health conditions including chronic pain, sleep disorders, and diabetes. The Company's lead product is Quell, an over-the-counter wearable therapeutic device for chronic pain. Quell is integrated into a digital health platform that helps patients optimize their therapy and decrease the impact of chronic pain on their quality of life. The Company also markets DPNCheck®, a rapid point-of-care test for diabetic neuropathy, which is the most common long-term complication of Type 2 diabetes. The Company maintains an active research effort and has several pipeline programs. The Company is located in Waltham, Massachusetts and was founded as a spinoff from the Harvard-MIT Division of Health Sciences and Technology in 1996.

In January 2018, the Company entered into a collaboration (the "Collaboration") with GlaxoSmithKline ("GSK"). The Collaboration set up a framework for the joint development of the next generation of Quell and the assignment of areas of marketing responsibility. The initial term of the Collaboration runs through 2020. GSK paid the Company \$5.0 million upon entering the Collaboration, committed to future performance milestone payments totaling up to \$21.5 million, and agreed to co-fund Quell development costs starting in 2019.

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. In recent years, the Company has suffered recurring losses from operations and negative cash flows from operating activities. At March 31, 2018, the Company had an accumulated deficit of \$189.9 million. The Company held cash and cash equivalents of \$6.1 million as of March 31, 2018. The Company believes that these resources, together with the cash to be generated from expected product sales and the potential achievement of development milestones under the Collaboration with GSK, will be sufficient to meet its projected operating requirements into 2019. 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; (b) delays in achieving Quell development milestones and related payments from GSK; (c) changes the Company may make to the business that affect ongoing operating expenses; (d) changes the Company may make in its business strategy; (e) regulatory developments or inquiries affecting the Company's existing products and products under development; (f) changes the Company may make in its research and development spending plans; and (g) other items affecting the Company's forecasted level of expenditures and use of cash resources. Accordingly, the Company may need to raise additional funds to support its operating and capital needs in 2019 and beyond. 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 intends to obtain additional funding through 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 financing 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 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.

Certain prior period amounts have been adjusted to reflect the Company's 1-for-8 reverse stock split effected May 11, 2017.

Unaudited Interim Financial Statements

The accompanying unaudited balance sheet as of March 31, 2018, unaudited statements of operations for the quarters ended March 31, 2018 and 2017 and the unaudited statements of cash flows for the three months ended March 31, 2018 and 2017 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, 2017 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 quarter ended March 31, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2017 included in the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission, or the SEC, on February 8, 2018 (File No. 001-33351), or the Company's 2017 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. It 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. Product returns are estimated based on historical data and evaluation of current information.

Accounting Standards Update ("ASU") No. 2014-9, Revenue from Contracts with Customers ("ASU 2014-9"), is a comprehensive revenue recognition standard that superseded nearly all existing revenue recognition guidance. The Company adopted this standard effective January 1, 2018, using the modified retrospective method. Upon adoption, the Company discontinued revenue deferral under the sell-through model and commenced recording revenue upon delivery to distributors, net of estimated returns. Generally, the new standard results in earlier recognition of revenues.

Adoption of ASU 2014-09 impacted the previously reported results for the quarter ended March 31, 2017 as follows:

	As reported		After adoption
	Quarter Ended March 31, 2017	ASU 2014-09 Impact	Quarter Ended March 31, 2017
Revenues	\$4,306,122	\$7,654	\$4,313,776
Cost of revenues	\$2,697,602	\$26,029	\$2,723,631
Gross profit	\$1,608,520	\$(18,375)	\$1,590,145
Net loss applicable to common stockholders	\$(7,274,082)	\$(18,375)	\$(7,292,457)
Net loss per common share applicable to common stockholders, basic and diluted	\$(7.27)	\$(0.02)	\$(7.29)

Adoption of ASU 2014-09 impacted the previously reported balance sheet as of December 31, 2017 as follows:

	As reported	ASU	After adoption
	December 31, 2017	2014-09 Impact	December 31, 2017
Accounts receivable, net	\$1,049,329	\$1,353,499	\$2,402,828
Prepaid expenses and other current assets	\$1,867,803	\$(583,491)	\$1,284,312
Total current assets	\$9,103,374	\$770,008	\$9,873,382
Accrued product returns	\$666,375	\$1,292,181	\$1,958,556
Deferred revenue	\$820,031	\$(820,031)	\$—
Total current liabilities	\$4,581,835	\$472,150	\$5,053,985
Accumulated deficit	\$(191,338,054)	\$297,858	\$(191,040,196)
Total stockholders' equity	\$5,017,389	\$297,858	\$5,315,247

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 March 31, 2018 and December 31, 2017.

Two customers accounted for 32% and one customer accounted for 17% of total revenue for the quarters ended March 31, 2018 and 2017, respectively. Customers that individually account for greater than 10% of accounts receivables totaled 46% and 66% of accounts receivables as of March 31, 2018 and December 31, 2017, respectively.

Collaboration

In January 2018, the Company entered into the Collaboration with GSK. The Company sold to GSK the rights to Company's Quell technology for markets outside of the United States, including certain patents and related assets, and agreed to complete development milestones for the next-generation Quell technology. The Company retained exclusive ownership of Quell technology in the U.S. market. GSK agreed to payments totaling up to \$26.5 million of which \$5.0 million was paid at closing and the balance due upon achievement of defined development and commercialization milestones. In addition, the parties agreed to jointly fund future Quell technology development during an initial period starting in 2019. Upon closing, the Company recognized Collaboration income of \$4,755,705, net of costs, within Other income in the Statement of Operations for the quarter ended March 31, 2018.

Stock-based Compensation

Total compensation cost related to nonvested awards not yet recognized at March 31, 2018 was \$314,025. The total compensation costs are expected to be recognized over a weighted-average period of 2.4 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.

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Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2016-2, Leases (Topic 842) (“ASU 2016-2”). ASU 2016-2 requires that lessees will need to recognize virtually all of their leases on the balance sheet, by recording a right-of-use asset and lease liability. The provisions of this guidance are effective for annual periods beginning after December 31, 2018, and for interim periods therein. The Company is in the process of evaluating the new standard and assessing the impact, if any, ASU 2016-2 will have on the Company’s financial statements and which adoption method will be used.

2. Comprehensive Income (Loss)

For the quarters ended March 31, 2018 and 2017, the Company had no components of other comprehensive income or 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 March	
	31,	
	2018	2017
Net income (loss) applicable to common stockholders	\$1,166,252	\$(7,274,082)
Weighted average number of common shares outstanding, basic	6,345,719	1,000,988
Dilutive convertible preferred stock	7,380,895	—
Weighted average number of common shares outstanding, dilutive	13,726,614	1,000,988
Net income (loss) per common share applicable to common stockholders, basic	\$0.18	\$(7.27)
Net income (loss) per common share applicable to common stockholders, diluted	\$0.08	\$(7.27)

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

	Quarters Ended	
	March 31,	
	2018	2017
Options	336,817	97,891
Warrants	459,375	4,392,152
Convertible preferred stock	—	2,413,464
Total	796,192	6,903,507

4. Inventories

Inventories consist of the following:

	March 31,	December
	2018	31, 2017
Purchased components	\$568,930	\$505,293
Finished goods	1,289,722	1,637,268
	\$1,858,652	\$2,142,561

5. Accrued Expenses and Compensation

Accrued expenses and compensation consist of the following:

	March 31, 2018	December 31, 2017
Accrued compensation	\$ 1,029,747	\$786,184
Technology fees	450,000	450,000
Professional services	341,000	603,000
Warranty reserve	177,152	127,361
Advertising and promotion	99,400	160,800
Other	263,958	234,779
	\$2,361,257	\$2,362,124

6. Commitments and Contingencies

Operating Lease

In August 2014, the Company entered into a 5-year operating lease agreement with one 5-year extension option for manufacturing and order fulfillment facilities in Woburn, Massachusetts (the "Woburn Lease"). The Woburn Lease commenced December 15, 2014 and has a monthly base rent of \$7,815. 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 7-year lease is approximately \$37,788. These payment obligations were accrued and recognized over the term of occupancy. Under the Waltham Lease, the landlord was responsible for making certain improvements to the leased space at an agreed upon cost to the landlord. Total costs for the landlord improvements exceeded the agreed upon cost by \$275,961. The landlord billed that excess cost to the Company as additional rent which has been included in other long term assets at March 31, 2018. This additional rent has been included in the net calculation of lease payments, so that rent expense is recognized on a straight-line basis over the term of occupancy.

7. Fair Value Measurements

The Fair Value Measurements and Disclosures Topic of the Codification defines fair value, establishes a framework for measuring fair value in applying generally accepted accounting principles, and expands disclosures about fair value measurements. This Codification topic identifies two kinds of inputs that are used to determine the fair value of assets and liabilities: observable and unobservable. Observable inputs are based on market data or independent sources while unobservable inputs are based on the Company's own market assumptions. Once inputs have been characterized, this Codification topic requires companies to prioritize the inputs used to measure fair value into one of three broad levels. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values identified by Level 2 inputs utilize observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities. Fair values identified by Level 3 inputs are unobservable data points and are used to measure fair value to the extent that observable inputs are not available. Unobservable inputs reflect the Company's own assumptions about the assumptions that market participants would use at pricing the asset or liability.

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 March 31, 2018					
Using					
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable (Level 2)	Other Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets:					
Cash equivalents	\$3,784,877	\$3,784,877	\$	—	\$ —
Total	\$3,784,877	\$3,784,877	\$	—	\$ —

Fair Value Measurements at December 31, 2017					
Using					
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable (Level 2)	Other Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets:					
Cash equivalents	\$1,744,965	\$1,744,965	\$	—	\$ —
Total	\$1,744,965	\$1,744,965	\$	—	\$ —

8. Credit Facility

The Company is party to a Loan and Security Agreement, as amended (the "Credit Facility"), with a bank. As of March 31, 2018, 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 January 2018, and expires in January 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 March 31, 2018, 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 facilities landlords. Consequently, the amount available for borrowing under the Credit Facility as of March 31, 2018 was approximately \$2.3 million.

9. Stockholders' Equity

Preferred stock and convertible preferred stock consist of the following:

	March 31, 2018	December 31, 2017
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at March 31, 2018 and December 31, 2017; no shares issued and outstanding at March 31, 2018 and December 31, 2017	\$ —	\$ —
Series B convertible preferred stock, \$0.001 par value, 147,000 shares designated at March 31, 2018 and December 31, 2017, and 500 shares issued and outstanding at March 31, 2018 and December 31, 2017	\$ 1	\$ 1
Series D convertible preferred stock, \$0.001 par value, 21,300 shares designated at March 31, 2018 and December 31, 2017, 14,052.93 shares issued and outstanding at March 31, 2018 and December 31, 2017	\$ 14	\$ 14
Series E convertible preferred stock, \$0.001 par value, 7,000 shares designated at March 31, 2018 and December 31, 2017, respectively, and 3,260.70 and 7,000 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	\$ 3	\$ 7
Series F convertible preferred stock, \$0.001 par value, 10,621 shares designated at March 31, 2018 and December 31, 2017, zero and 7,927.05 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	\$ —	\$ 8

2018 equity activity

During the three months ended March 31, 2018, 3,739.3 shares of the Series E Preferred Stock were converted into a total of 1,421,787 shares of Common Stock. As of March 31, 2018, 3,260.70 shares of Series E Preferred Stock remained outstanding.

During the three months ended March 31, 2018, 7,927.05 shares of the Series F Preferred Stock were converted into a total of 3,014,087 shares of Common Stock. As of March 31, 2018, zero shares of Series F Preferred Stock remained outstanding.

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 bioelectrical and digital medicine to address chronic health conditions including chronic pain, sleep disorders, and diabetes. Our business is fully integrated with in-house capabilities spanning product 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 selected overseas markets, and are cleared by the U.S. Food and Drug Administration, or FDA, and regulators in foreign jurisdictions where appropriate. We have two principal product lines:

- Wearable neuro-stimulation therapeutic devices
- Point-of-care neuropathy diagnostic tests

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.

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, in contrast to acute pain, which is a normal bodily response to injury or trauma. Chronic pain conditions include painful diabetic neuropathy, or PDN, arthritis, fibromyalgia, sciatica, musculoskeletal pain, cancer pain and many others. 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. 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 contributing 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 is widespread. It affects over 100 million adults in the United States and more than 1.5 billion people worldwide. The global market for pain management drugs and devices alone was valued at \$35 billion in 2012. 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. Estimated out-of-pocket spending in the United States on chronic pain is \$20 billion per year.

The most common approach to chronic pain is pain medication. This includes over-the-counter drugs (such as Advil and Motrin), and prescription drugs including anti-convulsants (such as Lyrica and Neurontin) and anti-depressants (such as Cymbalta and Elavil). Topical creams may also be used (such as Zostrix and Bengay). With severe pain, narcotic pain medications may be prescribed (such as codeine, fentanyl, morphine, and oxycodone). 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.

Reflecting the difficulty in treating chronic pain, we believe that inadequate relief leads 25% to 50% of pain sufferers to turn to the over-the-counter market for supplements or alternatives to prescription pain medications. These include non-prescription medications, topical creams, lotions, electrical stimulators, dietary products, braces, sleeves, pads and other items. In total they account for over \$4 billion in annual spending in the United States on pain relief products.

High frequency nerve stimulation is an established treatment for chronic pain supported by numerous clinical studies demonstrating efficacy. In simplified outline, the mechanism of action involves intensive nerve stimulation to activate the body's central pain inhibition system resulting in widespread analgesia, or pain relief. The nerve stimulation activates brainstem

pain centers leading to the release of endogenous opioids that act primarily through the delta opioid receptor to reduce pain signal transmission through the central nervous system. This therapeutic approach is available through deep brain stimulation and through implantable spinal cord stimulation, both of which require surgery and have attendant risks. Non-invasive approaches to neuro-stimulation (transcutaneous electrical nerve stimulation, or TENS) have achieved limited efficacy in practice due to device limitations, ineffective dosing and low patient compliance.

Quell is our OTC wearable device for pain relief. Quell revenues for fiscal years 2017 and 2016 were approximately \$12.4 million and \$7.4 million, respectively. Quell revenues for the three months ended March 31, 2018 were approximately \$3.5 million. Following commercial launch through March 31, 2018, approximately 152,545 Quell devices plus electrodes and accessories were shipped to consumers. Quell utilizes our patented 100% drug-free neuro-stimulation technology to provide relief from chronic pain, such as nerve pain due to diabetes, fibromyalgia, arthritic pain, and lower back and leg pain. This advanced wearable device is lightweight and can be worn during the day while active, and at night while sleeping. It has been cleared by the U.S. Food and Drug Administration (the “FDA”) for treatment of chronic intractable pain without a doctor’s prescription. Users of the device have the option of using their smartphones to control pain therapy and to track sleep, activity, gait and therapy parameters. Quell is distributed in North America via e-commerce, including the Company’s website (www.quellrelief.com) and Amazon, via direct response television including QVC, via retail merchandisers including Best Buy, CVS, and others and via health care professionals such as pain management physician practices and podiatry practices. Distribution is supported by television promotion to expand product awareness.

DPNCheck is our diagnostic test for peripheral neuropathies. DPNCheck revenues for fiscal years 2017 and 2016 were approximately \$3.1 million, and \$2.5 million, respectively. DPNCheck revenues for the three months ended March 31, 2018 were approximately \$1.2 million. Our U.S. sales efforts focus on Medicare Advantage providers who assume financial responsibility and the associated risks for the health care costs of their patients. We believe that DPNCheck presents an attractive clinical case with early detection of neuropathy allowing for earlier clinical intervention to help mitigate the effects of neuropathy on both patient quality of life and cost of care. Also, the diagnosis and documentation of neuropathy provided by DPNCheck helps clarify the patient health profile which, in turn, may have a direct, positive effect on the Medicare Advantage premium received by the provider. DPNCheck is marketed in Japan by our distribution partner Fukuda Denshi; in China by OMRON Medical (Beijing) Ltd.; and in Mexico by Scienta Farma.

Our products consist of a medical device used in conjunction with a consumable electrode or biosensor. Other accessories and consumables are also available to customers. Our commercial objective is to build an installed base of active customer accounts that regularly order aftermarket products to meet their needs. We successfully implemented this model when we started our business with the NC-stat system and applied it to subsequent product generations including ADVANCE. Our more recently developed products, Quell, SENSUS and DPNCheck, conform to this model.

Results of Operations

Comparison of Quarters Ended March 31, 2018 and 2017

Revenues

The following table summarizes our revenues:

Quarters Ended		Change %	Change
2018	2017		
March 31,			

(in thousands)

Revenues \$4,943.0 \$4,306.1 \$636.9 14.8 %

Revenues include sales from Quell, DPNCheck and our legacy neurodiagnostic products. During the first quarter of 2018 total revenues increased by approximately \$0.6 million, or 14.8%, from the first quarter of 2017. Quell revenues increased approximately \$0.4 million, or 12.6%, to approximately \$3.5 million in the quarter ended March 31, 2018 from approximately \$3.1 million in the same period in 2017. DPNCheck revenues increased approximately \$0.4 million, or 43.1%, to approximately \$1.2 million in the quarter ended March 31, 2018 from approximately \$0.8 million in the same period in 2017. DPNCheck domestic revenues were \$1.1 million and \$0.6 million in the quarters ended March 31, 2018 and 2017, respectively, an increase of \$0.5 million. Our legacy neurodiagnostic and therapeutic products contributed approximately \$0.3 million in revenue for the first quarter of 2018, as compared to approximately \$0.4 million in the first quarter of 2017.

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Upon adoption of the new revenue recognition standard ASU 2014-9, we discontinued revenue deferral under the sell-through model and commenced recording revenue upon delivery to distributors, net of estimated returns. Generally, the new standard results in earlier recognition of revenues. Had the accounting principles of ASU 2014-9 been applied in the first quarter of 2017 revenues would have been unchanged from the amount of \$4.3 million previously reported.

Cost of Revenues and Gross Profit

The following table summarizes our cost of revenues and gross profit:

	Quarters Ended					
	March 31,					
	2018	2017	Change	%	Change	%
	(in thousands)					
Cost of revenues	\$2,955.3	\$2,697.6	\$257.7	9.6	%	
Gross profit	\$1,987.7	\$1,608.5	\$379.2	23.6	%	

Our cost of revenues increased \$0.3 million, or 9.6% to approximately \$3.0 million in the first quarter of 2018 from \$2.7 million in the comparable period in 2017. The gross profit rate increased to 40.2% in the first quarter of 2018 from 37.4% in the first quarter of 2017. Gross profit rates improved for both Quell and DPNCheck, partially offset by higher overhead costs and the effects of the declining legacy business.

Operating Expenses

The following table summarizes our operating expenses:

	Quarters Ended					
	March 31,					
	2018	2017	Change	%	Change	%
	(in thousands)					
Operating expenses:						
Research and development	\$1,279.6	\$903.3	\$376.3	41.7	%	
Sales and marketing	2,504.7	2,597.7	(93.0)	(3.6)	%	
General and administrative	1,804.1	1,421.8	382.3	26.9	%	
Total operating expenses	\$5,588.4	\$4,922.8	\$665.6	13.5	%	

Research and Development

Research and development expenses for the quarters ended March 31, 2018 and 2017 were approximately \$1.3 million and \$0.9 million, respectively. The increase of approximately \$0.4 million relates primarily to a \$0.3 million increase in Quell development spending, partially offset by a \$0.1 million decrease in clinical study spending.

Sales and Marketing

Sales and marketing expenses were approximately \$2.5 million and \$2.6 million for the quarters ended March 31, 2018 and March 31, 2017, respectively. The spending reflected a \$0.1 million decrease in promotional spending.

General and Administrative

General and administrative expenses were approximately \$1.8 million and \$1.4 million for the quarters ended March 31, 2018 and March 31, 2017, respectively. The increase of approximately \$0.4 million primarily reflected an additional \$0.2 million in professional services expense and an additional \$0.2 million in stock-based compensation.

Collaboration income

Quarters			
Ended March			
31,			
2018	2017	Change	% Change
(in thousands)			

Collaboration income	\$4,755.7	\$	-\$4,755.7	100.0	%
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In January 2018, we entered into agreements (the “Collaboration”) with GlaxoSmithKline (“GSK”) in which the Company sold to GSK rights to the Company’s Quell technology for markets outside of the United States, including certain patents and related assets, and agreed to complete development milestones for the next-generation Quell technology. The Company retained exclusive ownership of Quell technology in the U.S. market. GSK agreed to payments totaling up to \$26.5 million of which \$5.0 million was paid at closing and the balance due upon achievement of defined development and commercialization milestones. In addition, the parties agreed to jointly fund future Quell technology development during an initial period starting in 2019. Upon closing, the Company recorded Collaboration income of \$4.8 million, net of costs, for the quarter ended March 31, 2018.

Other income

Quarters			
Ended			
March 31,			
2018	2017	Change	% Change
(in thousands)			

Other income	\$11.3	\$81.9	\$(70.6)	(86.2)	%
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Other income includes interest income and warrant liability fair value changes. The change in fair value of warrant liability was zero and \$77,601 for the quarters ended March 31, 2018 and 2017, respectively.

Net income (loss) per common share applicable to common stockholders, basic and diluted

The net income (loss) per common share applicable to common stockholders, basic and diluted, were \$0.18 and \$0.08, respectively, for the quarter ended March 31, 2018 and \$(7.27), both basic and diluted for the quarter ended March 31, 2017. Weighted average shares outstanding used in computing per share amounts are included in Note 3 to the Financial Statements. In the quarter ended March 31, 2017, per share amounts reflected a deemed dividend attributable to preferred stockholders of \$4.0 million, or \$4.04 per share, related to our Q1 2017 equity offering; plus our net loss of \$3.2 million, or \$3.23 per share.

Liquidity and Capital Resources

Our principal source of liquidity is our cash resources which, as of March 31, 2018, totaled \$6.1 million. Funding for our operations largely depends on the success of our commercial products for chronic pain and neuropathy, and on milestone achievement 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. The following table sets forth information relating to our cash resources:

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	March 31, 2018	December 31, 2017	Change	% Change
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(\$ in thousands)

Cash and cash equivalents	\$6,097.8	\$4,043.7	\$2,054.1	50.8 %
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The Company is party to a Loan and Security Agreement with a bank. As of March 31, 2018 this credit facility permitted the Company to borrow up to \$2.5 million on a revolving basis. Amounts borrowed under the credit facility will bear interest equal to the prime rate plus 0.5% and will be collateralized by our cash, accounts receivable, inventory, and equipment. The

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credit facility also includes traditional lending and reporting covenants and, as of March 31, 2018, we were in compliance with these covenants.

During the three months ended March 31, 2018, cash and cash equivalents increased by \$2.1 million reflecting proceeds from closing the GSK Collaboration offset by net cash usage from business operations.

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

	Quarters Ended		Year Ended
	March 31,	March 31,	December 31,
	2018	2017	2017
Days sales outstanding (days)	36	31	37
Inventory turnover rate (times per year)	5.9	8.9	6.5

Customer payment terms vary from payment-on-order for Quell e-commerce sales to 60 days from invoice date.

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

	Three Months Ended	
	March 31,	
	2018	2017
	(in thousands)	
Net cash used in operating activities (excluding collaboration income)	\$(2,675.8)	\$(3,354.0)
Net cash provided by collaboration income	4,755.7	—
Net cash provided by (used in) operating activities	\$2,079.9	\$(3,354.0)
Net cash used in investing activities	\$(25.8)	\$—
Net cash provided by financing activities	\$—	\$6,302.0

Our operating activities, excluding collaboration income, consumed \$2.7 million of cash for the three months ended March 31, 2018, which reflected our operating net loss of \$3.6 million. This operating loss included non-cash stock compensation expense of approximately \$0.3 million. In addition, operating activities included decreases in accounts receivable of \$0.8 million and in prepaid expenses and other current and long-term assets of \$0.3 million, partially offset by decreases in accrued product returns of \$0.6 million and in accounts payable of \$0.4 million.

We held cash and cash equivalents of \$6.1 million as of March 31, 2018. We believe that these resources, together with the cash to be generated from expected product sales and the potential achievement of development milestones under the Collaboration will be sufficient to meet our projected operating requirements into 2019. 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) delays in achieving Quell development milestones and related payments from GSK; (c) changes we may make to the business that affect ongoing operating expenses; (d) changes we may make in our business strategy; (e) regulatory developments or inquiries affecting our existing products and products under development; (f) changes we may make in our research and development spending plans; and (g) other items affecting our forecasted level of expenditures and use of cash resources. Accordingly, we may need to raise additional funds to support our operating and capital needs in 2019 and beyond. 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 may attempt to obtain additional funding through 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 financing in a timely manner or on favorable terms, if at all. We filed a shelf registration statement on Form S-3 with the U.S. Securities and Exchange Commission (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 applicable SEC rules, 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.

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

As of March 31, 2018, we did not have any off-balance sheet financing arrangements.

See Note 6, Commitments and Contingencies, of our Notes to Unaudited Financial Statements for information regarding commitments and contingencies.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update No. 2016-2, Leases (Topic 842) (“ASU 2016-2”). ASU 2016-2 requires that lessees recognize virtually all of their leases on the balance sheet, by recording a right-of-use asset and lease liability. The provisions of this guidance are effective for annual periods beginning after December 31, 2018, and for interim periods therein. The Company is in the process of evaluating the new standard and assessing the impact, if any, ASU 2016-2 will have on the Company’s financial statements and which adoption method will be used.

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 expectations regarding achievement of milestones under the GSK Collaboration; our future liquidity and our expectations regarding our needs for and ability to raise additional capital; our ability to manage our expenses effectively; our belief that there are unmet needs for the management of chronic pain and in the diagnosis and 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 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; 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 March 31, 2018, 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 March 31, 2018 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, 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, 2017.

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

In 2017 the Company received a Civil Investigative Demand (“CID”) from the United States Federal Trade Commission (“FTC”). The CID requests information in connection with an FTC review for compliance of the Company’s representations about Quell with Sections 5 and 12 of the FTC Act. The Company is in the process of producing documents and information in response to the CID. To the knowledge of the Company, no complaint has been filed against the Company; however, no assurance can be given as to the timing or outcome of the investigation.

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 March 31, 2018, the Company spent \$2,237 to repurchase 36,006 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.

April 20, 2018 /s/SHAI N. GOZANI, M.D., PH. D.

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

Chairman, President and Chief Executive Officer

April 20, 2018 /s/THOMAS T. HIGGINS

Thomas T. Higgins

Senior Vice President, Chief Financial Officer and Treasurer

EXHIBIT INDEX

Exhibit No.	Description
<u>31.1</u>	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.
<u>31.2</u>	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.
<u>32</u>	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 March 31, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets at March 31, 2018 and December 31, 2017, (ii) Statements of Operations for the quarters ended March 31, 2018 and 2017, (iii) Statements of Cash Flows for the three months ended March 31, 2018 and 2017, and (iv) Notes to Financial Statements.