

NeuroMetrix, Inc.
Form 10-Q
April 25, 2019

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, 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 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, a smaller reporting company, or a 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

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Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 8,820,273 shares of common stock, par value \$0.0001 per share, were outstanding as of April 22, 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 April 22, 2019.

NeuroMetrix, Inc.
Form 10-Q
Quarterly Period Ended March 31, 2019

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

NeuroMetrix, Inc.

Balance Sheets

	March 31, 2019 (Unaudited)	December 31, 2018 (a)
Assets		
Current assets:		
Cash and cash equivalents	\$7,200,795	\$6,780,429
Accounts receivable, net	972,352	1,082,957
Inventories	2,494,268	2,861,864
Prepaid expenses and other current assets	962,727	860,915
Total current assets	11,630,142	11,586,165
Fixed assets, net	375,561	407,339
Right to use asset	1,870,979	1,968,062
Other long-term assets	30,081	30,314
Total assets	\$13,906,763	\$13,991,880
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$557,861	\$1,298,084
Accrued expenses and compensation	3,036,301	2,236,633
Accrued product returns	726,892	1,101,658
Deferred collaboration income	181,818	1,956,522
Total current liabilities	4,502,872	6,592,897
Lease obligation, net of current portion	1,211,480	1,301,172
Total liabilities	5,714,352	7,894,069
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Convertible preferred stock	15	18
Common stock, \$0.0001 par value; 100,000,000 shares authorized at March 31, 2019 and December 31, 2018; 8,310,463 and 7,380,463 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	831	738
Additional paid-in capital	197,157,649	197,113,646
Accumulated deficit	(188,966,084)	(191,016,591)
Total stockholders' equity	8,192,411	6,097,811
Total liabilities and stockholders' equity	\$13,906,763	\$13,991,880

(a) Amounts adjusted due to adoption of lease accounting standard (Note 1)

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

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NeuroMetrix, Inc.
 Statements of Operations
 (Unaudited)

	Quarters Ended March	
	31, 2019	2018
Revenues	\$3,122,935	\$4,942,990
Cost of revenues	2,324,231	2,955,260
Gross profit	798,704	1,987,730
Operating expenses:		
Research and development	855,081	1,279,564
Sales and marketing	2,025,288	2,504,741
General and administrative	1,619,490	1,804,143
Total operating expenses	4,499,859	5,588,448
Loss from operations	(3,701,155)	(3,600,718)
Other income:		
Collaboration income	5,734,849	4,755,705
Other income	16,813	11,265
Total other income	5,751,662	4,766,970
Net income	\$2,050,507	\$1,166,252
Net income per common share applicable to common stockholders,		
Basic	\$0.26	\$0.18
Diluted	\$0.15	\$0.08

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 of	Number 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	—	—	—	—	341,026	—	341,026
Issuance of common stock upon conversion of preferred stock	(11,666.35)	(12)	4,435,874	443	(431)	—	—
Effect of adoption of ASC606	—	—	—	—	—	297,858	297,858
Net income	—	—	—	—	—	1,166,252	1,166,252
Balance at March 31, 2018	17,813.63	\$ 18	7,141,940	\$ 714	\$ 196,695,736	\$(189,873,944)	\$ 6,822,524

	Series B – F Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount of	Number Shares	Amount			
Balance at December 31, 2018	17,813.63	\$ 18	7,380,463	\$ 738	\$ 197,113,646	\$(191,016,591)	\$ 6,097,811
Stock-based compensation expense	—	—	—	—	44,093	—	44,093
Issuance of common stock upon conversion of preferred stock	(2,445.90)	(3)	930,000	93	(90)	—	—
Net income	—	—	—	—	—	2,050,507	2,050,507
Balance at March 31, 2019	15,367.73	\$ 15	8,310,463	\$ 831	\$ 197,157,649	\$(188,966,084)	\$ 8,192,411

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

NeuroMetrix, Inc.
 Statements of Cash Flows
 (Unaudited)

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net income	\$2,050,507	\$1,166,252
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	31,778	55,444
Stock-based compensation	44,093	341,026
Inventory provision	700,000	—
Changes in operating assets and liabilities:		
Accounts receivable	110,605	814,108
Inventories	(182,404)	283,909
Prepaid expenses and other current and long-term assets	(101,579)	343,177
Accounts payable	(740,223)	(369,665)
Accrued expenses and compensation	657,059	(868)
Accrued product returns	(374,766)	(553,439)
Deferred collaboration income	(1,774,704)	—
Net cash provided by operating activities	420,366	2,079,944
Cash flows from investing activities:		
Purchases of fixed assets	—	(25,833)
Net cash used in investing activities	—	(25,833)
Net increase in cash and cash equivalents	420,366	2,054,111
Cash and cash equivalents, beginning of period	6,780,429	4,043,681
Cash and cash equivalents, end of period	\$7,200,795	\$6,097,792

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

NeuroMetrix, Inc.
Notes to Unaudited Financial Statements
March 31, 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 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 the assignment of areas of marketing responsibility. The initial term of the GSK collaboration runs through 2020. Through March 31, 2019, GSK has paid the Company \$18.7 million, committed to future performance milestone payments totaling up to \$6.2 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. The Company has suffered recurring losses from operations and negative cash flows from operating activities. At March 31, 2019, the Company had an accumulated deficit of \$189.0 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 \$7.2 million as of March 31, 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 may 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 Federal Trade Commission 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 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 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 March 31, 2019, unaudited statements of operations for the quarters ended March 31, 2019 and 2018, unaudited statements of changes in stockholders' equity for the three months ended March 31, 2019 and 2018 and the unaudited statements of cash flows for the three months ended March 31, 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 three months ended March 31, 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 March 31, 2019 and December 31, 2018.

Two customers accounted for 32% and 32% of total revenues in the quarters ended March 31, 2019 and 2018, respectively. Two customers accounted for 44% and 45% of accounts receivable as of March 31, 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 \$5,734,849 and \$4,755,705, for the quarters ended March 31, 2019 and 2018, respectively.

Stock-based Compensation

Total compensation cost related to non-vested awards not yet recognized at March 31, 2019 was \$208,741. The total compensation costs are expected to be recognized over a weighted-average period of 1.8 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 March 31, 2019:

	As reported	Adjustments	Amounts under prior GAAP
Prepaid expenses and other current assets	\$962,727	\$44,852	\$1,007,579
Total current assets	\$11,630,142	\$44,852	\$11,674,994
Right of use asset	\$1,870,979	\$(1,870,979)	\$—
Other long-term assets	\$30,081	\$34,363	\$64,444
Total assets	\$13,906,763	\$(1,791,764)	\$12,114,999
Accrued expenses	\$3,036,301	\$(580,284)	\$2,456,017
Total current liabilities	\$4,502,872	\$(580,284)	\$3,922,588
Lease obligation - net of current portion	\$1,211,480	\$(1,211,480)	\$—
Total liabilities	\$5,714,352	\$(1,791,764)	\$3,922,588

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
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
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

For the quarters ended March 31, 2019 and 2018, the Company had no components of other comprehensive income other than net income itself.

3. Net Income Per Common Share

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

	Quarters Ended March 31,	
	2019	2018
Net income applicable to common stockholders	\$2,050,507	\$1,166,252
Weighted average number of common shares outstanding, basic	7,741,463	6,345,719
Dilutive convertible preferred stock	6,222,746	7,380,895
Weighted average number of common shares outstanding, dilutive	13,964,209	13,726,614
Net income per common share applicable to common stockholders, basic	\$0.26	\$0.18
Net income per common share applicable to common stockholders, diluted	\$0.15	\$0.08

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

	Quarters Ended March 31,	
	2019	2018
Options	488,494	336,817
Warrants	459,375	459,375
Total	947,869	796,192

4. Inventories

Inventories consist of the following:

	March 31, 2019	December 31, 2018
Purchased components	\$1,710,368	\$1,767,674
Finished goods	783,900	1,094,190
	\$2,494,268	\$2,861,864

The Company recorded an inventory related provision of \$700,000 in the quarter ended March 31, 2019 to adjust Quell Classic inventory to net realizable value. The provision was assigned in the amounts of \$335,000 and \$165,000 within purchased components and finished goods, respectively. The remaining \$200,000 related to components located at contract manufacturers was recorded in accrued expenses.

5. Accrued Expenses and Compensation

Accrued expenses and compensation consist of the following:

	March 31, 2019	December 31, 2018
Professional services	\$863,000	\$391,000
Lease obligation, current portion	580,284	577,460
Compensation	467,522	213,756
Technology fees	450,000	450,000
Contract manufacturer	320,000	160,000
Warranty reserve	116,000	129,837
Advertising and promotion	61,200	171,000
Other	178,295	143,580
	\$3,036,301	\$2,236,633

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 March 31, 2019 are as follows:

2019	\$473,413
2020	641,193
2021	653,164
2022	247,347
2023	165,785
2024	165,785
2025	117,431
Total minimum lease payments	\$2,464,118

Weighted-average discount rate, 14.6%	\$672,354
Lease obligation, current portion	580,284
Lease obligation, net of current portion	1,211,480
	\$2,464,118

Total recorded rent expense was \$166,024 and \$156,703, for the quarters ended March 31, 2019 and 2018, respectively. The Company records rent expense on its facility leases on a straight-line basis over the lease term.

7. 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 March 31, 2019				
	Using				
March 31, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Other Inputs	Significant Unobservable Inputs (Level 3)	
Assets:					
Cash equivalents	\$4,966,621	\$4,966,621	\$	—	\$ —
Total	\$4,966,621	\$4,966,621	\$	—	\$ —

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

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, 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 March 2019 and expires in June 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, 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 March 31, 2019 was approximately \$2.3 million.

9. Stockholders' Equity

Preferred stock and convertible preferred stock consist of the following:

	March 31, 2019	December 31, 2018
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at March 31, 2019 and December 31, 2018; no shares issued and outstanding at March 31, 2019 and December 31, 2018	\$ —	\$ —
Series B convertible preferred stock, \$0.001 par value; 147,000 shares designated at March 31, 2019 and December 31, 2018; 200 shares issued and outstanding at March 31, 2019 and December 31, 2018	\$ 1	\$ 1
Series D convertible preferred stock, \$0.001 par value; 21,300 shares designated at March 31, 2019 and December 31, 2018; 13,526.93 and 14,052.93 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	\$ 13	\$ 14
Series E convertible preferred stock, \$0.001 par value; 7,000 shares designated at March 31, 2019 and December 31, 2018; 1,340.80 and 3,260.70 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	\$ 1	\$ 3

2019 equity activity

During the three months ended March 31, 2019, 526.00 shares of the Series D Preferred Stock were converted into a total of 200,000 shares of Common Stock and 1,919.90 shares of the Series E Preferred Stock were converted into a total of 730,000 shares of Common Stock.

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 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 March 31, 2019, GSK has paid the Company \$18.7 million in milestone payments GSK has committed to future performance milestone payments totaling up to \$6.2 million, and agreed to co-fund Quell development costs starting in 2019.

Results of Operations

Comparison of Quarters Ended March 31, 2019 and 2018

Revenues

Quarters Ended		Change	% Change
March 31,			
2019	2018		
(in thousands)			
Revenues	\$3,122.9	\$4,943.0	\$(1,820.1) (36.8)%

Revenues include sales from Quell, DPNCheck and our legacy neurodiagnostic products. During the first quarter of 2019 total revenues decreased by \$1.8 million, or 36.8%, from the first quarter of 2018. Quell revenues of \$1.6 million were the largest contributor to total revenue. They were \$1.8 million, or 52.6%, 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 \$1.2 million in the first quarters of 2019 and 2018. Our legacy products contributed \$0.3 million of revenue in the first quarters of 2019 and 2018.

Cost of Revenues and Gross Profit

	Quarters Ended			
	March 31,			
	2019	2018	Change	% Change
	(in thousands)			
Cost of revenues	\$2,324.2	\$2,955.3	\$(631.1)	(21.4)%
Gross profit	\$798.7	\$1,987.7	\$(1,189.0)	(59.8)%

Our gross profit margin was 25.6% in the first quarter of 2019 versus 40.2% in the same period in the prior year. The lower gross profit margin in 2019 is due in part to a charge of \$0.7 million to write down Quell Classic inventory to net realizable

value. Excluding this charge the gross profit margin for the first quarter of 2019 was 48% which reflects the higher margin benefit from Quell 2.0 as well as the increased share of the revenue from the DPNCheck business.

Operating Expenses

	Quarters Ended			
	March 31,			
	2019	2018	Change	% Change
	(in thousands)			
Operating expenses:				
Research and development	\$855.1	\$1,279.6	\$(424.5)	(33.2)%
Sales and marketing	2,025.3	2,504.7	(479.4)	(19.1)%
General and administrative	1,619.5	1,804.1	(184.6)	(10.2)%
Total operating expenses	\$4,499.9	\$5,588.4	\$(1,088.5)	(19.5)%

Research and Development

Research and development expense in the first quarter of 2019 decreased by 33.2% from the same period in the prior year due to co-funding of certain Quell development projects under the GSK Collaboration.

Sales and Marketing

Sales and marketing expense in the first quarter of 2019 declined by 19.1% from the same period in the prior year due to the reduction of advertisement promotion during the quarter and corresponding drop in advertising spending by \$0.8 million. This was partially offset by increased marketing consulting fees of \$0.3 million.

General and Administrative

General and administrative expense declined by 10.2% from the same period in the prior year primarily due to a decrease of \$0.2 million in stock-based compensation expense.

Collaboration income

	Quarters Ended			
	March 31,			
	2019	2018	Change	% Change
	(in thousands)			
Collaboration income	\$5,734.8	\$4,755.7	\$979.1	20.6%

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

Other income

Quarters
Ended
March 31,

	2019	2018	Change	% Change
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(in thousands)

Other income	\$16.8	\$11.3	\$5.5	48.7 %
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Other income primarily includes interest income.

Liquidity and Capital Resources

Our principal source of liquidity is cash and cash equivalents of \$7.2 million at March 31, 2019. Funding for our operations largely depends on revenues from the sale of our commercial products for chronic pain and neuropathy, and on achievement