

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

FORM 10-Q

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

For the quarterly period ended **September 30, 2018**

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: **000-55655**

NEXEON MEDSYSTEMS INC
(Exact name of registrant as specified in its charter)

Nevada

*(State or other jurisdiction of
incorporation or organization)*

81-0756622

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

**1910 Pacific Avenue, Suite 20000,
Dallas, Texas 75201**
(Address of principal executive offices)

844-919-9990
(Registrant's telephone number)

Indicate by check mark whether the registrant has (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding twelve 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 such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or, an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer
Non-accelerated filer

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 Act). Yes No

As of November 19, 2018, the registrant had 1,965,646 shares of common stock, par value \$0.001 per share, issued and outstanding.

NEXEON MEDSYSTEMS INC

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements that relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as “may,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential”, or “continue,” or the negative of these terms or other comparable terminology. These statements are only predictions, and involve known and unknown risks, uncertainties, and other factors that may cause our or our industry’s actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements.

While these forward-looking statements and any assumptions upon which they are based are made in good faith and reflect our current judgment regarding the direction of our business, actual results may vary from any estimates, predictions, projections, assumptions, or other future performance suggested herein. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

**NEXEON MEDSYSTEMS INC
AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)**

	As of	
	September 30, 2018	December 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	\$ 125,573	\$ 883,962
Accounts receivable	1,709,915	1,877,743
Grants receivable	819,615	804,152
Inventory	2,420,988	2,206,570
Other current assets	106,614	157,621
Total Current Assets	5,182,705	5,930,048
Property, plant and equipment, net	3,449,467	3,569,832
Investments	112,072	112,072
Intangible assets, net	9,833,647	10,739,492
Total Assets	\$ 18,577,891	\$ 20,351,444
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	2,822,693	2,575,399
Accrued liabilities	1,558,501	503,751
Current portion of long-term debt, net of original discount	1,673,667	866,479
Advance grant payments	568,844	935,817
Deferred liabilities	401,478	174,230
Accrued interest	86,088	78,049
Total Current Liabilities	7,111,271	5,133,725
Long-term debt, net of original discount	2,327,666	3,348,730
Total Liabilities	\$ 9,438,937	\$ 8,482,455
Stockholders' Equity		
Common stock - 75,000,000 shares authorized, \$.001 par value; 1,965,646 and 1,970,915 issued and outstanding at September 30, 2018 and December 31, 2017, respectively	1,966	1,971
Additional paid-in capital	15,838,654	15,523,606
Equity instruments to be issued	65,839	65,839
Accumulated deficit	(6,810,662)	(3,743,438)
Accumulated other comprehensive income	43,157	21,011
Total Stockholders' Equity	9,138,954	11,868,989
Total Liabilities and Stockholders' Equity	\$ 18,577,891	\$ 20,351,444

The accompanying notes are an integral part of the unaudited consolidated financial statements.

**NEXEON MEDSYSTEMS INC
AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited)**

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues	\$ 1,977,629	\$ 1,039,679	\$ 7,666,827	\$ 1,147,288
Cost of revenue	1,384,335	709,373	5,533,173	737,664
Gross profit	<u>593,294</u>	<u>330,306</u>	<u>2,133,654</u>	<u>409,624</u>
Selling, general, and administrative expenses	875,016	651,556	2,724,960	1,817,218
Research and development expenses	674,360	287,229	1,881,198	1,659,560
Depreciation and amortization	<u>363,102</u>	<u>326,792</u>	<u>1,095,075</u>	<u>924,790</u>
(Loss) from operations	(1,319,184)	(935,271)	(3,567,579)	(3,991,944)
Other Income (Expense)				
Interest income	—	3,041	—	3,216
Interest income – related party	—	—	—	2,009
Interest expense	(77,873)	(26,792)	(235,869)	(31,762)
Gain on bargain purchase	—	624,211	—	624,211
Loss on stock exchange	—	—	—	(37,788)
Bad debt	—	—	—	(171,946)
Gain on sale of patent	—	—	160,000	—
Foreign exchange loss	<u>—</u>	<u>(89,441)</u>	<u>—</u>	<u>—</u>
Loss before provision (benefit) for taxes	(1,397,057)	(424,252)	(3,643,448)	(3,604,004)
Provision (benefit) for taxes	<u>(5,510)</u>	<u>—</u>	<u>(576,224)</u>	<u>(13,203)</u>
Net (loss)	<u>\$ (1,391,547)</u>	<u>\$ (424,252)</u>	<u>\$ (3,067,224)</u>	<u>\$ (3,590,801)</u>
Other comprehensive income				
Foreign currency translation adjustment	56,704	(81,264)	22,147	5,002
Comprehensive loss	<u>(1,334,843)</u>	<u>(505,516)</u>	<u>(3,045,077)</u>	<u>(3,585,799)</u>
BASIC AND DILUTED PER SHARE DATA:				
Net Loss per common share, basic and diluted	<u>\$ (0.71)</u>	<u>\$ (0.22)</u>	<u>\$ (1.56)</u>	<u>\$ (2.08)</u>
Weighted average common shares outstanding, basic and diluted	<u>1,965,646</u>	<u>1,915,138</u>	<u>1,969,719</u>	<u>1,726,426</u>

The accompanying notes are an integral part of the unaudited consolidated financial statements.

**NEXEON MEDSYSTEMS INC
AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)**

	For the Nine Months Ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	\$ (3,067,224)	\$ (3,590,801)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,095,076	924,786
Stock-based compensation	475,043	217,605
Loss on exchange for stock	—	37,788
Gain on sale of patent	(160,000)	—
Bad debt	—	171,946
Gain on bargain purchase	—	(624,211)
Provision for income taxes	—	(13,203)
Non-cash interest	102,850	11,428
Change in operating assets and liabilities:		
Accounts receivable	111,726	(436,504)
Grants receivable	20,023	(734,790)
Inventory	(291,940)	(153,562)
Other current asset	49,460	103,858
Accounts payable	328,254	495,987
Accrued liabilities	1,122,339	(103,443)
Advance grant payments	(369,221)	(440,739)
Accrued interest payable	8,039	(2,556)
Deferred liabilities	184,679	340
Net cash (used in) operating activities	<u>(390,896)</u>	<u>(4,136,071)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Issuance of notes receivable – related party	—	(59,027)
Cash paid for acquisitions net of cash acquired	—	(957,182)
Additions to property plant and equipment	(63,083)	(13,920)
Net cash used in investing activities	<u>(63,083)</u>	<u>(1,030,129)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	—	1,773,288
Proceeds from debt	358,906	1,839,387
Proceeds from related party	—	34,438
Proceeds from grant advance	(656,256)	235,349
Repayment of debt	—	(57,541)
Net cash (used in) financing activities	<u>(297,350)</u>	<u>3,824,921</u>
Effects of exchange rate changes on cash	<u>(7,060)</u>	<u>(18,717)</u>
Net (decrease) in cash and cash equivalents	(758,389)	(1,359,996)
Cash and cash equivalents at beginning of period	883,962	2,124,795
Cash and cash equivalents at end of period	<u>\$ 125,573</u>	<u>\$ 764,799</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid during period for interest	<u>\$ 122,803</u>	<u>\$ 17,708</u>
Cash paid during period for taxes	<u>3,452</u>	<u>—</u>
SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES:		
Redemption of stock for patent sale	<u>\$ 160,000</u>	<u>\$ —</u>
Original purchase discount on notes	<u>—</u>	<u>274,266</u>

The accompanying notes are an integral part of the unaudited consolidated financial statements.

**NEXEON MEDSYSTEMS INC
AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)**

NOTE 1 – BUSINESS – NATURE OR ORGANIZATION

Unless the context otherwise requires, references to “we,” “our,” “us,” “Nexeon,” or the “Company” in these Notes mean Nexeon MedSystems Inc, a Nevada corporation, on a consolidated basis with its wholly owned subsidiaries, as applicable.

Organization and Operations

Nexeon MedSystems Inc was incorporated in the State of Nevada on December 7, 2015. Nexeon MedSystems Inc is a neuromodulation medical device manufacturing company. As a development-stage enterprise, the Company’s primary purpose is to develop and commercialize its neurostimulation technology platform for the treatment of various disorders via electrical stimulation of tissues associated with the nervous system. The neurostimulation technology platform was acquired through the acquisition of Nexeon MedSystems Belgium, SPRL (“NMB”). During 2016, the Company formed the following wholly owned subsidiaries: Nexeon MedSystems Europe, SARL (“Nexeon Europe”), Nexeon MedSystems Puerto Rico Operating Company Corporation Inc. (“NXPROC”), and Pulsus Medical LLC. Nexeon Europe is the holding company for NXPROC and Nexeon MedSystems Belgium, SPRL (“NMB”). NXPROC is focused on advanced computational biology and deep learning utilization associated with the Internet of Medical Things technology. Pulsus Medical, LLC conducts research and development related to cardiovascular disease technology acquired in its merger with Nexeon MedSystems, Inc., a private Delaware corporation (“NXDE”). On September 1, 2017, through its wholly owned subsidiary Nexeon Europe, the Company completed the acquisition of NMB, along with NMB’s wholly owned subsidiaries Medi-Line, S.A. (“Medi-Line”) and its holding company INGEST, SPRL (“INGEST”), which are incorporated under the laws of Belgium. INGEST is the holding company for Medi-Line. The Company believes Medi-Line provides the medical device manufacturing expertise and experience needed to scale its business. Medi-Line is a leading global source of innovative medical device solutions, with existing customers that include Fortune 50 companies and neurostimulator companies. On September 27, 2017 Nexeon MedSystems Inc began trading on the OTCQB platform under the symbol “NXNN”.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited consolidated financial statements include the accounts of Nexeon MedSystems Inc and its wholly owned subsidiaries NXPROC, Nexeon Europe, Pulsus Medical, LLC, and NMB as of September 30, 2018 and December 31, 2017, and for the three and nine months ended September 30, 2018 and 2017. The financial statements include the accounts of Medi-Line and INGEST as of September 30, 2018 and December 31, 2017 and for the three and nine months ended September 30, 2018 and the month of September 2017 for the three and nine months ended September 30, 2017. The Company’s unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial statements, and with the instructions for Form 10-Q and Article 8 of Regulation S-X of the United States Securities and Exchange Commission (“SEC”). Accordingly, they do not contain all information and footnotes required by accounting principles generally accepted in the United States of America for annual financial statements. These unaudited consolidated financial statements should be read in conjunction with the audited financial statements of the Company, and related notes thereto, which are included in the Company’s Annual Report on Form 10-K as of and for the year ended December 31, 2017. In the opinion of the Company’s management, the accompanying unaudited financial statements contain all the adjustments necessary (consisting only of normal recurring accruals) to present the financial position of the Company as of September 30, 2018, and the results of operations and cash flows for the periods presented. The results of operations for interim periods are not necessarily indicative of the operating results for the full fiscal year or any future period. All significant intercompany accounts and transactions have been eliminated in consolidation.

Management Estimates and Assumptions

The preparation of the Company’s financial statements are in conformity with accounting principles generally accepted in the United States of America, which require management to make 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 expenses during the reporting periods. Management makes these estimates using the best information available at the time the estimates are made; however, actual results could differ materially from these estimates.

Cash and Cash Equivalents

The Company considers those short-term, highly liquid investments with maturities of three months or less as cash and cash equivalents. The Company currently has no cash equivalents.

Long-Lived Assets

Long-lived assets such as property, equipment, and identifiable intangibles are reviewed for impairment whenever facts and circumstances indicate that the carrying value may not be recoverable. When required, impairment losses on assets to be held and used are recognized based on the fair value of the assets. The fair value is determined based on estimates of future cash flows, market value of similar assets, if available, or independent appraisals, if required. If the carrying amount of the long-lived asset is not recoverable from its undiscounted cash flows, an impairment loss is recognized for the difference between the carrying amount and fair value of the asset. When fair values are not available, the Company estimates fair value using the expected future cash flows discounted at a rate commensurate with the risk associated with the recovery of the assets.

Property and Equipment

Property and equipment are stated at cost. Equipment is depreciated using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized based upon the lesser of the term of the lease or the useful life of the asset, and such expense is included in depreciation expense. Repair and maintenance costs are expensed as incurred. The Company capitalizes all furniture and equipment with cost greater than \$1,000 and benefiting more than one accounting period in the period purchased.

Inventories

The value of inventories, comprised solely of finished goods, are stated at the lesser of net realizable value or cost, determined using the first-in, first-out ("FIFO") method. To value inventory, management must estimate excess or obsolete inventory, as well as inventory that is not of saleable quality. This valuation involves an inherent level of risk and uncertainty due to the unpredictability of trends in the industry and customer demand for the Company's products. In assessing the ultimate realization of inventories, management must make judgments as to future demand requirements, and compare those with the current or committed inventory levels. Reserve requirements generally increase as demand decreases due to market conditions and technological and product life-cycle changes. Write-downs of excess and obsolete inventories were \$0 and \$0 in the nine months ended September 30, 2018 and 2017, respectively. Future events and variations in valuation methods or assumptions may cause significant fluctuations in this estimate, and could have a material impact on the Company's results.

Net Income (Loss) Per Share

The Company calculates net income (loss) per share as required by Accounting Standards Codification subtopic 260-10, "Earnings per Share" ("ASC 260-10"). Basic earnings (loss) per share is calculated by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted earnings per share is calculated by dividing net income (loss) by the weighted average number of common shares and dilutive common stock equivalents outstanding. During the periods when they are anti-dilutive, common stock equivalents, if any, are not considered in the computation. Basic and diluted earnings per share were the same for the three and nine months ended September 30, 2018 and 2017, respectively, as the Company has no dilutive securities.

Revenue Recognition

Revenues currently consist of single-use medical devices for the medical and pharmaceutical sectors at Medi-Line and pre-clinical neurostimulation device sales at NMB.

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry specific guidance. This new standard requires a company to recognize revenues when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The FASB subsequently issued the following amendments to ASU No. 2014-09 that have the same effective date and transition date: ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing; ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients; and ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers. The Company adopted these amendments with ASU 2014-09 (collectively, the new revenue standards).

The new revenue standards became effective for the Company on January 1, 2018, and were adopted using the modified retrospective method. The adoption of the new revenue standards as of January 1, 2018 did not change the Company's revenue recognition as the majority of its revenues continue to be recognized when the customer takes control of its product. As the Company did not identify any accounting changes that impacted the amount of reported revenues with respect to its product revenues, no adjustment to retained earnings was required upon adoption.

Under the new revenue standards, the Company recognizes revenues when its customer obtains control of promised goods or services, in an amount that reflects the consideration which it expects to receive in exchange for those goods. The Company recognizes revenues following the five-step model prescribed under ASU No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

Revenues from product sales are recognized when the customer obtains control of the Company's product, which occurs at a point in time, typically upon delivery to the customer. The Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that it would have recognized is one year or less or the amount is immaterial.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes in accordance with ASC Topic 740, "Income Taxes." Under this method, income tax expense is recognized for the amount of: (i) taxes payable or refundable for the current year and (ii) deferred tax consequences of temporary differences resulting from matters that have been recognized in an entity's financial statements or tax returns. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is provided to reduce the deferred tax assets reported if, based on the weight of the available positive and negative evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

ASC Topic 740.10.30 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements, and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC Topic 740.10.40 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Company has no material uncertain tax positions for any of the reporting periods presented.

All tax positions are first analyzed to determine if the weight of available evidence indicates that it is more likely than not that the position will be sustained under audit, including resolution of any related appeals or litigation processes. After the initial analysis, the tax benefit is measured as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

If the Company is required to pay interest on the underpayment of income taxes, the Company recognizes interest expense in the first period the interest becomes due according to the provisions of the relevant tax law.

If the Company is subject to payment of penalties, the Company recognizes an expense for the amount of the statutory penalty in the period when the position is taken on the income tax return. If the penalty was not recognized in the period when the position was initially taken, the expense is recognized in the period when the Company changes its judgment about meeting minimum statutory thresholds related to the initial position taken.

Research and Development Expenses

Research and development expenses are charges to expense as incurred. Research and development expenses include, but are not limited to, product development, clinical and regulatory expenses, payroll and other personnel expenses, materials, supplies, consulting costs, and non-recurring engineering costs. These expenses are assigned to the research, development, and clinical projects to develop the Company's implantable neurostimulation, sensing, and recording technology for a variety of clinical therapeutic applications, and for manufacturing product development.

The Company has been awarded grants subsidies for ongoing research and development projects from the National Institutes of Health Department of Health and Human Services, through the Public Service of Wallonia - Department of Technology Development and the Research Programs Department (the Wallonia region is located in South Brussels, in Belgium), the Cancer Prevention and Research Institute of Texas and the Puerto Rico Science, Technology and Research Trust to support our research projects with potential for commercialization. The Company receives the funding in a combination of advance payments at commencement of a project and through reimbursement requests. Invoices for applicable research, and development expenses as expenses are incurred. These grants and subsidies provide non-dilutive funds that do not include a repayment obligation. Participation by the granting agency typically accounts for 50% to 100% of the project costs in grants or subsidies.

The Company recognizes the amounts receivable in regard to the grant contracts at fair value when there is reasonable assurance that the contract amount will be received and that all the conditions of the specific contract will be complied with in order to properly match the reimbursements with the specific expenditures that the specific contract intends to reimburse. The Company recognizes the amounts received in accordance with the contracts as a reduction of research and development expenses over the periods necessary to match the contract on a systematic basis to the costs that it is intended to compensate. The Company records, on the balance sheet, grants receivable (upon meeting the criteria discussed above) until cash is received. Where the Company receives payments in advance, it is recorded as advance grant payments on the balance sheet, and relieved against research and development expense as the associated costs are incurred.

As of September 30, 2018, the Company has \$819,615 in grants receivable for project expenses invoiced and to be invoiced, but not yet paid, which have been recorded as a reduction of research and development expense in the accompanying statement of operations, and \$568,844 in advance payments received and yet to be expended.

Foreign Currency Translation and Transactions

The Company's reporting currency is the U.S. dollar. The Company's operations in Belgium use their local currencies as their functional currency. The financial statements in foreign currency are translated into U.S. Dollars ("USD") in accordance with ASC Topic 830, Foreign Currency Translation. All assets and liabilities are translated at the period-end currency exchange rate. Stockholders' equity items are translated at the historical rates, and income statement items are translated at the average exchange rate prevailing during the period. Translation adjustments resulting from this process are reported under other comprehensive income ("OCI") in accordance with ASC Topic 220, Reporting Comprehensive Income as a Component of Stockholders' Equity. Foreign exchange transaction gains and losses are reflected in the statement of comprehensive income.

Fair Value Measurements

The Company adopted the provisions of ASC Topic 820, "*Fair Value Measurements and Disclosures*," which defines fair value as used in numerous accounting pronouncements, establishes a framework for measuring fair value, and expands disclosure of fair value measurements.

The estimated fair value of certain financial instruments, including cash and cash equivalents, are carried at historical cost basis, which approximates their fair values because of the short-term nature of these instruments.

ASC 820 defines "fair value" as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

- Level 1 — Quoted prices in active markets for identical assets or liabilities
- Level 2 — Quoted prices for similar assets and liabilities in active markets, or inputs that are observable
- Level 3 — Inputs that are unobservable (for example, cash flow modeling inputs based on assumptions)

The Company currently has no assets or liabilities valued at fair value on a recurring basis.

Investments in Non-Consolidated Subsidiaries

Investments in non-consolidated entities are accounted for using the equity method or cost basis, depending upon the level of ownership and/or the Company's ability to exercise significant influence over the operating and financial policies of the investee. When the equity method is used, investments are recorded at original cost, and adjusted periodically to recognize the Company's proportionate share of the investees' net income or losses after the date of investment. When net losses from an investment accounted for under the equity method exceed its carrying amount, the investment balance is reduced to zero and additional losses are not provided for. The Company resumes accounting for the investment under the equity method if the entity subsequently reports net income and the Company's share of that net income exceeds the share of net losses not recognized during the period the equity method was suspended. Investments are written down only when there is clear evidence that a decline in value that is other than temporary has occurred. The Company accounts for its investment in MicroTransponder, Inc. under the cost method due to the lack of significant influence.

Leases

Leases are reviewed and classified as capital or operating at their inception in accordance with ASC Topic 840, Accounting for Leases. For leases that contain rent escalations, the Company records monthly rent expense equal to the total amount of the payments due in the reporting period over the lease term. The difference between rent expense recorded and the amount paid is credited or charged to deferred rent account when presented on balance sheet.

Acquired Intangibles

Acquired intangibles include patents, patent licenses, trade secrets and know-how, and customer relationships acquired by the Company, which are recorded at fair value and are assigned an estimated useful life, and amortized on a straight-line basis over their estimated useful lives (ranging from 3 to 19 years) for assets with definitive lives. The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its acquired intangibles may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the carrying value of the intangible asset and its fair value, which is determined based on the net present value of estimated future cash flows.

Common stock Purchase Warrants and Other Derivative Financial Instruments

The Company classifies as equity any contracts that require physical settlement or net-share settlement or provide us a choice of net-cash settlement or settlement in our own shares (physical settlement or net-share settlement), provided that such contracts are indexed to our own stock, as defined in ASC 815-40 "*Contracts in Entity's Own Equity*." We classify as assets or liabilities any contracts that require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside our control) or give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). We assess classification of our common stock, par value \$0.001 per share ("Common stock") purchase warrants at each reporting date to determine whether a change in classification between assets and liabilities is required.

Stock-Based Compensation

ASC 718 requires companies to measure all stock compensation awards using a fair value method, and to recognize the related compensation cost in its financial statements. Beginning with the Company's quarterly period that began on January 1, 2016, the Company adopted the provisions of FASB ASC 718, and expenses the fair value of employee stock options and similar awards in the financial statements. The Company accounts for share-based payments in accordance with ASC 718, "*Compensation - Stock Compensation*," which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on the grant date fair value of the award. In accordance with ASC 718-10-30-9, "*Measurement Objective - Fair Value at Grant Date*," the Company estimates the fair value of the award using the Black-Scholes option pricing model for valuation of the share-based payments. The Company believes this model provides the best estimate of fair value due to its ability to incorporate inputs that change over time, such as volatility and interest rates, and to allow for actual exercise behavior of option holders. The simplified method is used to determine compensation expense since historical option exercise experience is limited relative to the number of options issued. The compensation cost is recognized ratably using the straight-line method over the expected vesting period.

The Company accounts for stock-based compensation to other than employees in accordance with FASB ASC 505-50. Equity instruments issued to other than employees are valued at the earlier of a commitment date or upon completion of the services, based on the fair value of the equity instruments, and is recognized as expense over the service period.

During the nine months ended September 30, 2018 and 2017, the Company recognized stock-based compensation expense aggregating \$362,482 and \$217,605, respectively, for Common stock options issued to Company personnel, directors, and consultants. During the nine months ended September 30, 2018 and 2017, the Company paid stock-based compensation consisting of restricted Common stock to non-employees consultants and issued or recorded as Equity instruments to be issued an aggregate of \$112,561 and \$0, respectively.

Recently Issued Accounting Pronouncements

Management does not believe that any recently issued but not yet effective accounting pronouncements, if adopted, would have a material effect on the accompanying financial statements.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the AICPA, and the SEC during the current reporting period did not have, or are not believed by management to have, a material impact on the Company's present or future consolidated financial statements.

NOTE 3 – BUSINESS COMBINATIONS

On September 1, 2017 (the “Acquisition Date”), the Company, through its wholly owned subsidiary Nexeon Europe, completed the acquisition of NMB pursuant to an acquisition agreement (the “Acquisition Agreement”) entered into on January 10, 2017, between Rosellini Scientific, LLC (“RS”), a Texas limited liability company controlled by our chief executive officer, William Rosellini, and Nexeon Europe (the “Acquisition”). RS was the sole shareholder of NMB, owning 107,154 shares (the “NMB Shares”). Pursuant to the Acquisition Agreement, RS granted to Nexeon Europe the exclusive and irrevocable right to purchase the NMB Shares upon the terms and conditions set forth in the Acquisition Agreement (the “Right to Purchase”). The consideration for the Right to Purchase was USD \$1,000 (the “Acquisition Price”). Upon Nexeon Europe exercising the Right to Purchase, the Acquisition Agreement was automatically deemed converted into and considered a share transfer agreement for the purchase of the NMB Shares, and the Acquisition Price became the purchase price of the NMB Shares and was deemed to have been satisfied by Nexeon Europe to RS as of the date of the Acquisition Date.

Due to RS controlling both the Company and NMB, the acquisition has been recorded as a combination of entities under common control, and the results of NMB for the three and nine months ended September 30, 2018 and 2017 are reported retrospectively on a consolidated basis in the Company’s financial statements.

Included in the acquisition of NMB are its wholly owned subsidiaries, Medi-Line and its holding company INGEST. On August 30, 2017, NMB acquired INGEST and Medi-Line for \$1,648,240 (payable as €1,450,000 EUR cash), or \$977.996 (€891,496 EUR) net of cash acquired. As part of the transaction, and prior to the acquisition, Nexeon Europe loaned NMB \$970,400 (€818,075 EUR) pursuant to the existing loan agreement and promissory note, NMB secured a credit facility in the amount of \$330,319 (€275,000 EUR), and Medi-Line loaned NMB \$540,032 (€450,000 EUR). Payment of the purchase price included the settlement of a note payable in the amount of \$120,007 (€100,000 EUR) and a dividend payable in the amount of \$9,901 (€8,250 EUR) to the sellers of INGEST. The balance of the loan and all accrued interest related to the loan agreement and promissory note between Nexeon Europe and NMB, along with the \$540,032 (€450,000 EUR) loan from Medi-Line to NMB, is eliminated through consolidation in the financial statements.

We believe Medi-Line provides the medical device manufacturing expertise and experience needed to scale our business. Medi-Line is a leading global source of innovative medical device solutions, with existing customers that include Fortune 50 companies and neurostimulator companies. Medi-Line seeks to provide high quality and efficiency in the development, engineering, and manufacturing of medical devices for the med-tech and pharmaceutical industries.

The acquisition of INGEST and Medi-Line was accounted for using the acquisition method, and, accordingly, the results of operations of INGEST and Medi-Line were reported in the Company’s financial statements beginning on August 30, 2017, the date of acquisition.

Unaudited Pro Forma Consolidated Results

The following table provides unaudited pro forma results of operations for the three and nine months ended September 30, 2018 and 2017, as if INGEST and Medi-line had been acquired as of January 1, 2017. The pro forma results include the effect of certain purchase accounting adjustments, such as the estimated changes in depreciation and amortization expense on the acquired tangible and intangible assets, and the recognition of grant subsidies. Pro forma results do not include any anticipated cost savings or other effects of the planned integration of INGEST and Medi-Line. Accordingly, such amounts are not necessarily indicative of the results if the acquisition had occurred on the dates indicated, or which may occur in the future.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues	\$ 1,977,629	\$ 1,985,067	\$ 7,666,827	\$ 5,716,007
Net income (loss)	(1,391,547)	(438,503)	(3,067,224)	(3,408,754)
Net income (loss) per common share, basic and diluted	(0.71)	(0.23)	(1.56)	(1.97)

NOTE 4 – GOING CONCERN

The accompanying financial statements have been prepared in conformity with generally accepted accounting principles, which contemplate continuation of the Company as a going concern. The Company has sustained operating losses since inception, and has an accumulated deficit of \$6,810,662 and a working capital deficit of \$1,928,566 at September 30, 2018. In addition, the Company does not have sufficient continuing revenue to cover its future operating expenses. The Company currently has limited liquidity, and has not completed its efforts to establish an additional source of revenues sufficient to cover all of the projected operating costs of the ongoing neurostimulation research and development activities over an extended period of time. These factors, among others, raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern. The Company will need to seek additional financing for continued operations, but there is no guarantee such financing will be available or on terms favorable to the Company. In the third quarter of 2018, the Company began to consolidate its manufacturing facilities in Niel, Belgium with its Medi-Line operations in Liege, Belgium. These operations include a facility, equipment, research and development staff, general and administrative. There is no guarantee these reductions by the Company will alleviate the going concern.

NOTE 5 – LOANS AND LEASES

Loans and leases consist of the following as of September 30, 2018:

Notes Payable

12.00% Senior Secured Convertible Promissory Note:

On August 21, 2017, the Company entered into a securities purchase agreement with Leonite Capital, LLC (“LC”), a Delaware limited liability company, to provide the Company with additional resources to conduct its business. Pursuant to the securities purchase agreement, LC purchased a unit consisting of (i) a note in the principal amount of \$1,120,000 at an original issue discount of \$120,000, (ii) warrants to purchase 35,716 shares of the Company’s Common stock, and (iii) commitment shares equaling 7,143 shares of the Company’s restricted common stock, valued at \$100,000. Interest is at the rate of 12.00% per annum, and the maturity date is 24 months from the date of issue. The note is a senior secured obligation of the Company, with priority over all future indebtedness of the Company. LC shall have the right at any time, at LC’s option, to convert all or any part of the outstanding and unpaid principal amount and accrued and unpaid interest of the note into fully paid and non-assessable shares of Common stock, or any shares of capital stock, subject to beneficial ownership limitations of a maximum of 4.99% of outstanding Common stock of the Company at time of conversion. The conversion price shall be, at the option of LC, \$24.75, subject to a one-time re-pricing 275 days after the closing, or (ii) 80% multiplied by the price per share paid by the investors in a subsequent equity financing. An amount of \$274,266 was recorded on the balance sheet as an original discount including a \$120,000 original discount, \$100,000 in restricted common stock and \$54,266 as the fair value of the warrants issued in the transaction. The \$274,266 will be expensed as interest expense over the 24-month term of the loan. For the LC loan, \$1,120,000 is recorded as Current portion of long-term debt, net of original discount. \$(125,705) of the original discount is recorded as Current portion of long-term debt, net of original discount on the balance sheet.

1.27% Secured bank Loan:

On August 29, 2017, Medi-Line entered into a credit contract with CBC Banque SA (“CBC Banque”) in the original amount of approximately \$2,036,362 (€1,700,000 EUR). The loan is secured by a mortgage on the Medi-Line manufacturing facility, and carries an interest rate of 1.27% per annum, with a seven-year term having monthly payments of interest and principal of approximately \$23,365 (€21,175 EUR). \$297,507 of the outstanding balance is recorded as Current portion of long-term debt, net of original discount on the balance sheet, and \$1,456,086 is recorded as Long-term debt, net of original discount on the balance sheet.

1.27% Secured Bank Loan:

On August 29, 2017, NMB entered into a credit contract with CBC Banque in the original amount of approximately \$329,412 (€275,000 EUR). The loan carries an interest rate of 1.27% per annum, with a seven-year term having monthly payments of interest and principal of approximately \$4,103 (€ 3,425 EUR). The loan is secured by the shares of NMB. \$14,562 of the outstanding balance is recorded as Current portion of long-term debt, net of original discount portion on the balance sheet, and \$285,061 is recorded as Long-term debt, net of original discount on the balance sheet.

0.72% Secured Bank Loan:

On May 7, 2016, Medi-Line entered into a credit contract with CBC Banque in the original amount of approximately \$68,781 (€57,420 EUR). The loan carries an interest rate of 0.72% per annum, with a 48-month term having monthly payments of interest and principal of approximately \$1,454 (€ 1,214 EUR). The loan is secured by the assets of Medi-Line. Proceeds of the loan were used to acquire manufacturing equipment. The loan is secured by the shares of NMB. \$16,745 of the outstanding balance is recorded as Current portion of long-term debt, net of original discount on the balance sheet, and \$13,458 is recorded as Long-term debt, net of original discount on the balance sheet.

Loan Subsidy:

NMB was awarded a loan subsidy through the Public Service of Wallonia in the amount of \$598,665 (€499,779 EUR). Of the total amount awarded, \$179,600 (€149,934 EUR) is categorized as loan, with repayment amounts ranging from \$5,986 to \$23,947 annually from 2018 through 2032. The current portion of the liability is recorded as Current portion of long-term debt, net of original discount on the balance sheet in the amount of \$5,987, and \$173,613 is included as Long-term debt, net of original discount on the balance sheet. The award amounts in excess of the loan amount are invoiced for reimbursement and recorded as a credit to applicable research and development expenses.

Revolving Credit:

The Company has a revolving credit card with BB&T Financial with an outstanding balance of \$12,847 as of September 30, 2018, a credit limit of \$60,000, and a current APR of 25.4%; and a revolving credit card with Comerica Bank with an outstanding balance of \$11,390 as of September 30, 2018, a credit limit of \$11,000, and a current APR of 0%.

Floating Rate Secured Line of Credit:

On February 23, 2018, Medi-Line's line of credit with CBC Banque was amended to increase the advance amount to €300,000 (\$369,561) and to structure the financing as a straight loan with an interest rate of 1.25% above the EURIBOR rate for the period the funds are drawn down. The €300,000 was available for drawdown through April 30, 2018, at which point the facility was reduced to €200,000, and further reduced €100,000 on May 31, 2018. The security includes a pledge of Medi-Line business assets in the amount of €300,000. The outstanding balance as of September 30, 2018 in the amount of \$116,012 is recorded as Current portion of long-term debt, net of original discount on the balance sheet.

Capital Leases**Building Lease:**

On December 13, 2005, Medi-Line entered into a capital lease facility for the financing of the manufacturing facility construction in the amount of \$3,425,880 (€2,860,000 EUR), with a 15-year term. Quarterly lease payments excluding VAT are \$46,730 (€39,202 EUR). The Company has the right to purchase the building at the end of the lease term for three percent (3%) of the original lease amount. \$181,239 of the outstanding balance is recorded as Current portion of long-term debt, net of original discount, and \$426,448 is recorded as Long-term debt, net of original discount on the balance sheet.

Equipment Lease:

On February 4, 2015, the Company entered into a sale-leaseback transaction with Biotech Coaching S.A. for the sale and lease in the original amount of \$131,765 (€110,000 EUR) for medical and clean-room equipment. In March 2015, the Company commenced leasing the equipment, with a 36-month term. Monthly lease payments excluding VAT are \$3,824 (€3,192 EUR). The Company has the right to purchase the equipment at the end of the lease term for a residual value of \$1,579 (€1,318 EUR). The remaining balance of the lease in the amount of \$23,083 is recorded as Current portion of long-term debt, net of original discount on the balance sheet.

	Carrying Amount
Long-Term Debt	
12.00% Senior Convertible Secured Note, amortization begins 2018, 2019 maturity	1,120,000
1.27% Secured Bank Loan, monthly amortization, 2024 maturity	1,753,593
1.27% Secured Bank Loan, monthly amortization, 2024 maturity	272,623
0.72% Secured Bank Loan, monthly amortization, 2020 maturity	30,203
Floating Rate Secured Line of Credit	116,012
Loan Subsidy, amortization begins 2018, 2032 maturity	179,600
Revolving Credit	24,237
Capitalized Building Lease	607,687
Capitalized Equipment Lease	23,083
Less: Original purchase discount, net of amortization	(125,705)
Total Debt	4,001,333
Less: Current portion of debt, net of original discount current portion	(1,673,667)
Total Long-Term Debt	\$ 2,327,666

KBC Accounts Receivable Discounting Agreement:

Medi-Line has an accounts receivable discounting agreement with KBC Commercial Finance, NV ("KBC ComFin") for up to 35% of Medi-Line's customer accounts receivables with no concentration limits per customer. Pursuant to the discounting agreement, Medi-Line will transfer title to KBC ComFin for all receivables that fall under the scope of agreement. The fee for the advance portion of the receivables transferred to KBC ComFin is the two-month LIBOR plus 1.5% on annual basis. As KBC ComFin holds the title to the receivables and assumes the insolvency risk for receivables that are transferred and fall under the scope of the agreement, invoices transferred per the agreement are reduced from Medi-line's customer accounts receivable upon transfer and recorded to a KBC ComFin accounts receivable sub-account and netted against advances and final payments received per the agreement.

NOTE 6 – INCOME TAXES

The Company is incorporated in the United States of America, and is subject to United States federal taxation. No provisions for United States income taxes have been made, as the Company had no U.S. taxable income for the nine months ended September 30, 2018 and 2017. The effective income tax rate for the Company for the three months ended September 30, 2018 and 2017 were 21% and 34%, respectively. One of our subsidiaries generated income, and as of September 30, 2018 we accrued income tax in the amount of \$11,928 according to the Belgian corporate income tax rate and the other operating subsidiaries reported a loss and no tax provision was recorded. Beginning in 2018, the corporate income tax ("CIT") levied in Belgium has been reduced to an effective rate of 29.58%. No state, region, or municipal income tax is levied.

During nine months ended September 30, 2018, the Company's holding company subsidiary, NXEU, was assessed annual corporate taxes in the amount of \$5,038.

As of September 30, 2018, the Company has approximately \$8,485,737 of net operating losses ("NOL") carryovers to offset taxable income, if any, in future years, which expire in fiscal 2036. In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on the assessment, management has established a full valuation allowance against all of the deferred tax assets relating to the NOL period because it is more likely than not that all of the deferred tax assets will not be realized.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law, making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a federal corporate tax rate decrease from 35% to 21% for tax years beginning after December 31, 2017; the transition of U.S international taxation from a worldwide tax system to a territorial system; and a one-time transition tax on the mandatory deemed repatriation of foreign earnings. We have estimated our provision for income taxes in accordance with the Tax Act and guidance available as of the date of this filing, but have kept the full valuation allowance. As a result, we have recorded no United States income tax expense in the nine months ended September 30, 2018.

The Belgian government enacted in December 2017 a significant tax reform law. The new tax legislation contains several key tax provisions, including the reduction of the corporate income tax rate from the current 33.99% to 29.58% in 2018 and 2019, and 25% from 2021. Additionally, the use of net operating losses (which could previously offset 100% of taxable income) is now limited to offset only 70% of taxable income.

On December 27, 2017, NXPROC was granted a tax exemption pursuant to Act number 73-2008 ("ACT 73") by the Government of Puerto Rico, Department of Economic Development and Commerce ("PRIDCO"). The exemption allows NXPROC to obtain tax credits in the amount of fifty percent (50%) of approved applicable research and development expenses of NXPROC. As of July 23, 2018, the Company has received all government approvals and certifications from PRIDCO and received tax credits in the amount of \$732,340, for research and development activity in 2017, which had been posted to Departamento De Hacienda (the Puerto Rican Department of Finance) system and the Company has received \$593,195 in net proceeds from the sale of all available tax credits realizing proceeds of 81% of the face value of the tax credits. For the nine months ended September 30, 2018, the Company recorded a benefit to provision for income taxes in the amount of \$593,195.

NOTE 7 – PROPERTY PLANT and EQUIPMENT

Property plant and equipment at cost and accumulated depreciation as of September 30, 2018 and December 31, 2017 were:

	<u>Estimated useful lives</u>	<u>September 30, 2018</u>	<u>December 31, 2017</u>
Land		\$ 96,884	\$ 96,884
Capitalized building	39 years	3,017,552	3,017,552
Machinery and equipment	5 to 15 years	739,088	677,734
Total property plant and equipment – gross		3,853,524	3,792,170
Less: accumulated depreciation		(404,057)	(222,338)
Total property plant and equipment – net		<u>\$ 3,449,467</u>	<u>\$ 3,569,832</u>

Property plant and equipment depreciation expense for the nine months ended September 30, 2018 was \$186,834, and for the nine months ended September 3, 2017 was \$63,413.

NOTE 8 – INTANGIBLE ASSETS

Intangible assets that have finite useful lives are amortized over their estimated useful lives. Intangible assets as of September 30, 2018 and December 31, 2017 are as follows:

	<u>Estimated useful lives</u>	<u>September 30, 2018</u>	<u>December 31, 2017</u>
Intangible assets with definitive lives:			
Patents, licenses, and intellectual property	4 to 20 years	\$ 10,363,097	\$ 10,363,097
Fair value of customer relationships at acquisition	10 years	600,000	600,000
Less: accumulated amortization		(2,679,450)	(1,773,605)
Patents, licenses, and intellectual property – net		8,283,647	9,189,492
Intangible assets with indefinite lives:			
Fair value of trade secrets and know-how at acquisition		1,550,000	1,550,000

Intangible asset amortization expense for the nine months ended September 30, 2018 was \$909,241, and for the nine months ended September 30, 2017 was \$861,377.

NOTE 9 — INVENTORIES

Inventory balances as of September 30, 2018 and December 31, 2017 are as follow:

	September 30, 2018	December 31, 2017
Raw materials and supplies	\$ 1,688,415	\$ 1,811,749
Work in process	732,573	334,322
Finished goods	—	60,499
Total inventories	<u>\$ 2,420,988</u>	<u>\$ 2,206,570</u>

NOTE 10 — SEGMENTS OF BUSINESS

The Company operates in two distinct business segments within the medical device industry: manufacturing and neurostimulation.

The manufacturing segment includes the manufacturing operations of our wholly owned subsidiary Medi-Line, located in Angleur (Liege), Belgium. Medi-Line manufactures single-use medical devices for the medical and pharmaceutical sectors, including radiopharmacy technology, urology products, and sterilization cases and trays, and designs, develops, and offers worldwide production and supply-chain capabilities for these products to its customers.

The neurostimulation segment includes development, manufacturing, and commercialization of neurostimulation technology for the treatment of various neurological disorders through electrical stimulation of neural tissues. Our first commercial application of the platform will be the Viant™ Deep Brain Stimulation System. Operations for the neurostimulation segment are conducted in the United States, Puerto Rico, Belgium, and Germany.

Other items of revenue not directly related to manufacturing or neurostimulation revenues are categorized as other operating income. Other operating income and expenses not directly related to a specific segment are identified as “other,” and not allocated to segments.

An analysis and reconciliation of the Company’s business segments and geographic information to the respective information in the Condensed Consolidated Financial Statements follows. Revenue by geographic area are presented by allocating revenue from external customers based on where the products are shipped or services are rendered:

Revenue by Segment:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Manufacturing	\$ 1,938,908	\$ 816,325	\$ 7,119,557	\$ 816,325
Neurostimulation	5,003	202,362	400,055	292,936
Other	33,718	20,992	147,215	38,027
Consolidated total	<u>\$ 1,977,629</u>	<u>\$ 1,039,679</u>	<u>\$ 7,666,827</u>	<u>\$ 1,147,288</u>

Income (Loss) Before Income Tax by Segment:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Manufacturing	\$ 48,982	\$ 114,720	\$ 223,100	\$ 114,720
Neurostimulation	(1,386,884)	(1,070,982)	(3,892,894)	(4,144,691)
Other ⁽¹⁾	(59,155)	532,010	26,346	425,967
Consolidated total	<u>\$ (1,397,057)</u>	<u>\$ (424,252)</u>	<u>\$ (3,643,448)</u>	<u>\$ (3,604,004)</u>

⁽¹⁾ Amounts not allocated to segments include interest income (expense) and other income (expense), and amortization of acquisition intangible assets.

Sales by Geographic Area:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Sales Non-domestic locations				
United Kingdom	\$ 886,886	\$ 519,364	\$ 3,530,395	\$ 609,938
Belgium	557,079	229,817	2,286,767	229,817
Switzerland	166,674	59,253	563,641	59,253
Netherlands	184,161	85,763	533,329	85,763
Norway	142,470	120,094	487,640	120,094
Rest of world	6,641	4,396	117,840	4,396
Consolidated sales	1,943,911	1,018,687	7,519,612	1,109,261
Other operating revenue	33,718	20,992	147,215	38,027
Consolidated revenue	\$ 1,977,629	\$ 1,039,679	\$ 7,666,827	\$ 1,147,288

Long-Lived Assets:

	September 30, 2018	December 31, 2017
Manufacturing	\$ 3,422,963	\$ 3,535,516
Neurostimulation	7,774,609	8,643,118
Other	2,085,542	2,130,690
Consolidated total	\$ 13,283,114	\$ 14,309,324

NOTE 11 – EQUITY

We effected a 1-for-14 reverse stock split of our outstanding Common stock, or, the “Reverse Stock Split”, on June 25, 2018 and, unless otherwise indicated, all per share amounts set forth herein have been retroactively restated to reflect the Reverse Stock Split.

The Company issued the following securities during the nine months ended September 30, 2018:

Common Stock Issuances

On March 6, 2018, we issued an aggregate of 1,697 shares of restricted common stock for certain sales and marketing and software consulting services rendered by third-party consultants. The foregoing shares were valued at \$14,840. 583 of these shares were issued to Daniel Powell, the Company’s vice president of sales and marketing at the time of issuance. These shares were issued for services provided by Mr. Powell prior to his employment by the Company.

On April 19, 2018, we issued an aggregate of 7,195 shares of restricted common stock for certain research and development and valuation services provided by third-party consultants. The foregoing shares were valued at \$97,721

Common Stock Redemption

On May 22, 2018, the Company redeemed and cancelled 14,286 shares of its common stock from a former director as consideration for the purchase of certain intellectual property.

Warrants

The Company issued no Warrants for the nine months ended September 30, 2018.

Options Grants – 2016 Plan

The Company may, from time to time, issue certain equity awards pursuant to our 2016 Omnibus Incentive Plan (the “2016 Plan”). The 2016 Plan was adopted by our board of directors on January 2, 2016, and was subsequently approved by our shareholders. On July 8, 2018, the Board of Directors of the Company approved an increase in the number of shares of common stock reserved for issuance pursuant to option grants under the 2016 Plan to 450,000 shares of common stock .

During the nine months ended September 30, 2018, the Company issued stock options to purchase a total of 138,198 shares of the Company's common stock under the 2016 Plan, with exercise prices ranging from \$8.00 to \$20.00 per share, and cancelled stock options to purchase a total of 54,898 shares of the Company's common stock under the 2016 Plan, with exercise prices ranging from \$11.00 to \$17.50 per share, as follows:

- (i) On February 28, 2018 and as compensation for service to the Company as chief executive officer, the Company granted to William Rosellini an incentive stock option to purchase up to 17,858 shares of the Company's restricted common stock with an exercise price of \$10.64. The option to purchase 8,929 shares of common stock was immediately exercisable, and the option to purchase the remaining 8,929 shares of common stock vests on the anniversary of the grant date. The Company also granted a non-qualified stock option to purchase up to 64,286 shares of common stock with an exercise price of \$10.64 per share. The option to purchase 2,679 common shares vests in equal monthly amounts beginning on March 1, 2018. The option to purchase the Company's common stock expires three (3) years from the date they become exercisable pursuant to the grant vesting schedule. The fair value of the options was determined to be \$226,009 using the Black-Scholes Option Pricing Model.
- (ii) On February 28, 2018 and as compensation for service to the Company as president and chief commercial officer, the Company granted to Brian Blischak a non-qualified stock option to purchase up to 4,108 shares of the Company's restricted common stock with an exercise price of \$10.64 per share. The option was immediately exercisable at date of issue. The term of the option shall be for a period of eight (8) years from the date of issue. The fair value of the option was determined to be \$12,855 using the Black-Scholes Option Pricing Model.
- (iii) On February 28, 2018 and as compensation for service to the Company as chief financial officer, the Company granted to Christopher Miller a non-qualified stock option to purchase up to 2,143 shares of the Company's restricted common stock with an exercise price of \$10.64 per share. The option was immediately exercisable at date of issue. The term of the option shall be for a period of three (3) years from the date of issue. The fair value of the option was determined to be \$6,766 using the Black-Scholes Option Pricing Model.
- (iv) On February 28, 2018 and as compensation for service to the Company as vice president sales and marketing, the Company granted to Daniel Powell an incentive stock option to purchase up to 786 shares of the Company's restricted common stock with an exercise price of \$10.64 per share. The option was immediately exercisable at date of issue. The term of the option shall be for a period of three (3) years from the date of issue. The fair value of the option was determined to be \$2,481 using the Black-Scholes Option Pricing Model.
- (v) On February 28, 2018 and as compensation for their service to the Company, the Company granted to non-executive employees incentive stock options to purchase up to 3,301 shares of the Company's restricted common stock with an exercise price of \$10.64 per share. The option to purchase 2,229 shares was immediately exercisable at date of issue, and the option to purchase 1,072 shares of common stock vests in equal monthly amounts beginning on March 1, 2018. The option to purchase the Company's common stock expires three (3) years from the date they become exercisable pursuant to the grant vesting schedule. The fair value of these options was determined to be \$10,420 using the Black-Scholes Option Pricing Model.
- (vi) As compensation for service as a director of the Company, the Company granted to Kent J. George non-qualified stock options to purchase 893 shares of the Company's restricted common stock on each date of March 31, 2018, June 30, 2018 and September 30, 2018 with exercise prices of \$12.11, \$20.00, and \$8.00 per share respectively. The options were immediately exercisable at date of issue. The term of the options shall be for four (4) years from the date of issue. The fair value of the options granted were determined to be \$12,034 using the Black-Scholes Option Pricing Model.
- (vii) As compensation for service as a director of the Company, the Company granted to Michael Neitzel non-qualified stock options to purchase 893 shares of the Company's restricted common stock on each date of March 31, 2018, June 30, 2018 and September 30, 2018 with exercise prices of \$12.11, \$20.00, and \$8.00 per share respectively. The options were immediately exercisable at date of issue. The term of the options shall be for four (4) years from the date of issue. The fair value of the options granted were determined to be \$12,034 using the Black-Scholes Option Pricing Model.
- (viii) As compensation for service as a director of the Company, the Company granted to Wes Dittmer non-qualified stock options to purchase 893 shares of the Company's restricted common stock common stock on each date of June 30, 2018 and on September 30, 2018 with exercise prices of \$20.00 and \$8.00 per share respectively. The options were immediately exercisable at date of issue. The term of the options shall be for four (4) years from the date of issue. The term of the options shall be for four (4) years from the date of issue. The fair value of the options granted were determined to be \$8,439 using the Black-Scholes Option Pricing Model.

- (ix) On July 22, 2018, the Company granted to a new employee at NXPROC incentive stock options to purchase up to 38,572 shares of the Company's restricted common stock with an exercise price of \$11.00 per share with vesting over 48 months. The term of the option was for a period of four (4) years from the date of vesting. The fair value of the option was determined to be \$92,789 using the Black-Scholes Option Pricing Model. Prior to vesting the option to purchase 38,572 shares was cancelled.
- (x) During the three months ended September 30, 2018, incentive stock options to purchase 16,326 shares of the Company's restricted common stock were cancelled pursuant to the 2016 Plan for employee separations from the Company. The range of exercise prices for these cancelled options ranged from \$14.00 to \$17.50.

Unless otherwise stated, the issuance of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or contracts relating to compensation as provided under Rule 701.

The granted options were valued at \$383,828 using the Black-Scholes option pricing model, with the following weighted average assumptions:

Risk-free interest rate	2.44%
Expected life	3.48 years
Expected dividends	0.00%
Expected volatility	56.12%
Fair value of the Company's Common stock	\$10.89

Aggregate options expense recognized for the nine months ended September 30, 2018, was \$362,482.

As of September 30, 2018, there were 103,822 shares available for grant under the 2016 Plan, excluding the 346,178 options outstanding.

As of September 30, 2018, there were incentive stock options outstanding to purchase an aggregate of 175,266 shares of common stock, and non-qualified options outstanding to purchase an aggregate of 170,912 shares of the Company's common stock option activity, both within and outside the 2016 Plan, and Warrant activity for the nine months ended September 30, 2018, are as follows:

	Stock Options		Stock Warrants	
	Shares	Weighted Average Price	Shares	Weighted Exercise Price
Outstanding December 31, 2017	262,878	\$ 15.07	82,926	\$ 19.39
Granted	138,198	10.89	—	—
Canceled	(54,898)	12.53	—	—
Expired	—	—	—	—
Exercised	—	—	—	—
Outstanding at September 30, 2018	346,178	\$ 13.80	82,926	\$ 19.39
Exercisable at September 30, 2018	210,989	\$ 14.17	82,926	\$ 19.39

The range of exercise prices and remaining weighted average life of the options outstanding at September 30, 2018, were \$8.00 to \$28.00 and 1.44 to 7.44 years, respectively.

The range of exercise prices and remaining weighted average life of the Warrants outstanding at September 30, 2018, were \$8.00 to \$28.00 and 1.17 to 3.89 years, respectively.

Unless otherwise stated, the issuance of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or contracts relating to compensation as provided under Rule 701.

NOTE 12 – 2016 OMNIBUS INCENTIVE PLAN

The 2016 Plan was adopted by our board of directors on January 2, 2016 and was subsequently approved by our shareholders. On July 8, 2018, the Board of Directors of the Company approved an increase in the number of shares of common stock reserved for issuance pursuant to option grants under the 2016 Plan to 450,000 shares of common stock. As of September 30, 2018, options to purchase a total of 346,178 shares of the Company's common stock were outstanding under the 2016 Plan with the following exercise prices and terms at grant date:

	As of September 30, 2018			
	Exercise Price	Options to Purchase Shares	Term (yrs)	Options to Purchase Shares
	\$ 8.00	2,679	3	193,851
	10.64	92,482	4	66,075
	12.11	1,786	8	86,252
	14.00	185,518		
	17.50	57,462		
	20.00	2,679		
	25.20	1,786		
	28.00	1,786		
Total Shares		346,178		346,178

The 2016 Plan is administered by the compensation committee which currently consists of three independent directors. The committee performs the requisite duties with respect to awards granted. The committee currently determines to whom awards are made, the timing of any such awards, the type of securities, and number of shares covered by each award, as well as the terms, conditions, performance criteria, restrictions, and other provisions of awards. The committee has the authority to cancel or suspend awards, accelerate the vesting, or extend the exercise period of any awards made pursuant to the 2016 Plan.

Shares Available Under the 2016 Plan

The maximum shares available for issuance under the 2016 Plan are 450,000 shares, subject to adjustment as set forth in the 2016 Plan. Any shares subject to an award that expires, is cancelled or forfeited, or is settled for cash shall, to the extent of such cancellation, forfeiture, expiration, or cash settlement, again become available for awards under the 2016 Plan. The committee can issue awards comprised of restricted stock, stock options, stock appreciation rights, stock units, and other awards, as set forth in the 2016 Plan.

Transferability

Except as otherwise provided in the 2016 Plan, (i) during the lifetime of a participant, only the participant or the participant's guardian or legal representative may exercise an option or stock appreciation right, or receive payment with respect to any other award, and (ii) no award may be sold, assigned, transferred, exchanged, or encumbered, voluntarily or involuntarily, other than by will or the laws of descent and distribution.

Change in Control

In the event of a merger, the surviving or successor entity (or its parent) may continue, assume, or replace outstanding awards as of the date of the relevant transaction, and such awards or replacements therefore shall remain outstanding and be governed by their respective terms. Such awards or replacements can be executed in part on the condition that the contractual obligations represented by the award are expressly assumed by the surviving or successor entity (or its parent), with appropriate adjustments to the number and type of securities subject to the award and the exercise price thereof so as to preserve the intrinsic value of the award existing at the time of the relevant transaction. Alternatively, the surviving or successor entity (or its parent) could issue to a participant a comparable equity-based award that preserves the intrinsic value of the original award existing at the time of the relevant transaction and contains terms and conditions that are substantially similar to those of the award.

If and to the extent that outstanding awards under the 2016 Plan are not continued, assumed, or replaced in connection with a merger or relevant corporate transaction, then all outstanding awards shall become fully vested and exercisable for such period of time prior to the effective date of the relevant transaction as is deemed fair and equitable by the committee, and shall terminate at the effective date of said transaction.

NOTE 13 – RELATED PARTY TRANSACTIONS

During the nine months ended September 30, 2018, the Company had the following transactions with related parties.

Common stock Issuance

On March 8, 2018, the Company issued 583 shares of the Company's restricted Common stock to Daniel Powell, the Company's vice president sales and marketing, for certain sales and marketing consulting services rendered by Mr. Powell prior to his employment by the Company. The foregoing shares were valued at \$5,100.

Options Grants – 2016 Plan

On February 28, 2018, the Company issued the following stock options under the 2016 Plan:

- (i) As compensation for service to the Company as chief executive officer, the Company granted to William Rosellini an incentive stock option to purchase up to 17,858 shares of the Company's restricted common stock with an exercise price of \$10.64. The option to purchase 8,929 shares of common stock was immediately exercisable, and the option to purchase the remaining 8,929 shares of common stock vests on the anniversary of the grant date. The Company also granted a non-qualified stock option to purchase up to 64,286 shares of common stock with an exercise price of \$10.64 per share. The option to purchase 2,679 common shares vests in equal monthly amounts beginning on March 1, 2018. The option to purchase the Company's common stock expires three (3) years from the date they become exercisable pursuant to the grant vesting schedule. The fair value of the options was determined to be \$226,009 using the Black-Scholes Option Pricing Model.
- (ii) As compensation for service to the Company as chief commercialization officer, the Company granted to Brian Blischak a non-qualified stock option to purchase up to 4,108 shares of the Company's restricted common stock with an exercise price of \$10.64 per share. The option was immediately exercisable at date of issue. The term of the option shall be for a period of eight (8) years from the date of issue. The fair value of the option was determined to be \$12,855 using the Black-Scholes Option Pricing Model.
- (iii) As compensation for service to the Company as chief financial officer, the Company granted to Christopher Miller a non-qualified stock option to purchase up to 2,143 shares of the Company's restricted common stock with an exercise price of \$10.64 per share. The option was immediately exercisable at date of issue. The term of the option shall be for a period of three (3) years from the date of issue. The fair value of the option was determined to be \$6,766 using the Black-Scholes Option Pricing Model.
- (iv) As compensation for service to the Company as vice president sales and marketing, the Company granted to Daniel Powell an incentive stock option to purchase up to 786 shares of the Company's restricted common stock with an exercise price of \$10.64 per share. The option was immediately exercisable at date of issue. The term of the option shall be for a period of three (3) years from the date of issue. The fair value of the option was determined to be \$2,481 using the Black-Scholes Option Pricing Model.

On March 31, 2018, the Company issued the following stock options under the 2016 Plan:

- (i) As compensation for service as a director of the Company, the Company granted to Kent J. George a non-qualified stock option to purchase a total of 893 shares of the Company's restricted common stock with an exercise price of \$12.11 per share. The option was immediately exercisable at date of issue. The term of the option shall be for four (4) years from the date of issue. The fair value of the option was determined to be \$3,596 using the Black-Scholes Option Pricing Model.
- (ii) As compensation for service as a director of the Company, the Company granted to Michael Neitzel a non-qualified stock option to purchase a total of 893 shares of the Company's restricted Common stock with an exercise price of \$12.11 per share. The option was immediately exercisable at date of issue. The term of the option shall be for four (4) years from the date of issue. The fair value of the option was determined to be \$3,596 using the Black-Scholes Option Pricing Model.

On June 30, 2018, the Company issued the following stock options under the 2016 Plan:

- (i) As compensation for service as a director of the Company, the Company granted to Kent J. George a non-qualified stock option to purchase a total of 893 shares of the Company's restricted common stock with an exercise price of \$20.00 per share. The option was immediately exercisable at date of issue. The term of the option shall be for four (4) years from the date of issue. The fair value of the option was determined to be \$5,778 using the Black-Scholes Option Pricing Model.
- (ii) As compensation for service as a director of the Company, the Company granted to Michael Neitzel a non-qualified stock option to purchase a total of 893 shares of the Company's restricted common stock with an exercise price of \$20.00 per share. The option was immediately exercisable at date of issue. The term of the option shall be for four (4) years from the date of issue. The fair value of the option was determined to be \$5,778 using the Black-Scholes Option Pricing Model.

- (iii) As compensation for service as a director of the Company, the Company granted to Wes Dittmer a non-qualified stock option to purchase a total of 893 shares of the Company's restricted common stock with an exercise price of \$20.00 per share. The option was immediately exercisable at date of issue. The term of the option shall be for four (4) years from the date of issue. The fair value of the option was determined to be \$5,778 using the Black-Scholes Option Pricing Model.

On July 31, 2018 options to purchase 10,040 shares of the of the Company's restricted common stock granted to Daniel Powell, the vice president of sales and marketing, with an exercise price of \$17.50 were cancelled pursuant the employees separation from the Company and the 2016 Plan.

On September 30, 2018, the Company issued the following stock options under the 2016 Plan:

- (i) As compensation for service as a director of the Company, the Company granted to Kent J. George a non-qualified stock option to purchase a total of 893 shares of the Company's restricted common stock with an exercise price of \$8.00 per share. The option was immediately exercisable at date of issue. The term of the option shall be for four (4) years from the date of issue. The fair value of the option was determined to be \$2,661 using the Black-Scholes Option Pricing Model.
- (ii) As compensation for service as a director of the Company, the Company granted to Michael Neitzel a non-qualified stock option to purchase a total of 893 shares of the Company's restricted common stock with an exercise price of \$8.00 per share. The option was immediately exercisable at date of issue. The term of the option shall be for four (4) years from the date of issue. The fair value of the option was determined to be \$2,661 using the Black-Scholes Option Pricing Model.
- (iii) As compensation for service as a director of the Company, the Company granted to Wes Dittmer a non-qualified stock option to purchase a total of 893 shares of the Company's restricted common stock with an exercise price of \$8.00 per share. The option was immediately exercisable at date of issue. The term of the option shall be for four (4) years from the date of issue. The fair value of the option was determined to be \$2,661 using the Black-Scholes Option Pricing Model.

Unless otherwise stated, the issuance of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or contracts relating to compensation as provided under Rule 701.

NOTE 14 – COMMITMENTS AND CONTINGENCIES

The Company is subject to a patent royalty agreement that requires 3% of net product sales received from commercialization of the 35 patents or other intellectual property acquired in the merger with NXDE to be paid to NXDE, LLC. NXDE, LLC is special purpose entity formed at the time of merger for the purpose of receiving the above-mentioned royalty payments, if any, and is not an affiliate of the Company or NXDE. No sales have been generated from any of the acquired patents or intellectual property.

The Company acquired a non-exclusive license to a portfolio of 86 patents, and is subject to a 6% royalty to Magnus IP GmbH of the net sales of all licensed products sold, licensed, leased, or otherwise disposed of pursuant to the license. No sales have been generated from the licensed intellectual property.

NOTE 15 – CONCENTRATION

For the nine months ended September 30, 2018, two of our customers accounted for approximately 51.6% and 26.7% of sales. For the nine months ended September 30, 2017, three of our customers accounted for approximately 39.4%, 25.9%, and 18.2% of sales

For the nine months ended September 30, 2018, the Company purchased approximately 18.5% of its products from one distributor, as compared to the nine months ended September 30, 2017, the Company purchased approximately 12.5% of its products from one distributor.

For the nine months ended September 30, 2018, three of our customers accounted for 50.0%, 22.8%, and 10.5% of accounts receivable, as compared to the nine months ended September 30, 2017, where two of our customers accounted for 45.2% and 10.6% of accounts receivable.

For the three months ended September 30, 2018, two of our customers accounted for approximately 66.0% and 29.7% of sales. For the three months ended September 30, 2017, three of our customers accounted for approximately 42.9%, 19.8%, and 17.5% of sales.

For the three months ended September 30, 2018, the company did not purchase more than 10% of its products from any single distributor, as compared to the three months ended September 30, 2017, the Company purchased approximately 16.7% and 12.0% respectively of its products from two distributors.

NOTE 16 - SUBSEQUENT EVENTS

None.

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

The following management discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited interim consolidated financial statements and related notes, which are included in Item 1 of this Quarterly Report on Form 10-Q, and with the audited financial statements of the Company, and related notes thereto, for the period ended December 31, 2017, included in our Form 10-K filed with the Securities and Exchange Commission on April 5, 2018.

Overview of Business

We are a medical device company focused on the development, manufacturing, and commercialization of neurostimulation technology for the treatment of various neurological disorders through electrical stimulation of neural tissues. Our neurostimulation technology platform has the potential to provide treatment to patients in several established neurostimulator markets, including deep brain stimulation (DBS), peripheral electrical nerve stimulation (PENS), sacral nerve stimulation (SNS), spinal cord stimulation (SCS), vagus nerve stimulation (VNS), and other emerging neurostimulator markets.

Our first commercial application of our platform will be the Viant™ Deep Brain Stimulation System (or the Viant™ System). We will pursue regulatory approval of the Viant™ System for Parkinson's disease, essential tremor, and dystonia in Europe in the first half of 2019, and for Parkinson's disease in the United States in the second half of 2019. The Viant™ DBS device is designed to deliver best-in-class stimulation with the capability to collect local field potential (LFP) recordings. Using LFP surveys, neurologists will be able to quickly and confidently determine where to stimulate to take full advantage of directional leads. Moreover, our devices are designed to be non-invasively upgradable, enabling both physicians and patients to benefit from the latest technology as it is developed, without the need for implantable pulse generator replacement surgery to take advantage of new features.

The Viant™ System continues to meet critical milestones in its development program. Previous generations of the device have been CE Marked and were manufactured and sold to a joint venture between GlaxoSmithKline. We completed the ISO 13485 certification process, which is a pivotal hurdle prior to regulatory submissions to the CE Mark authorities. Design verification, process validation, and testing requirements are nearly complete, and management expects we will complete the technical file in 2018 (with the exception of some longer-duration biocompatibility and shelf life tests). The Company expects to receive a CE Mark in 2019. As related to the United States, we completed the pre-submission meetings with the United States Food and Drug Administration (FDA) in early 2018 to determine scope of requirements for approval of the Viant™ System. As a result of that meeting, we intend to submit an FDA Premarket Approval (PMA) application without a clinical study. The FDA has changed their approach to referencing other manufacturers' data, which allows us to rely on safety and efficacy data from the nearly 150,000 successful DBS implants that have been completed by other manufacturers.

We have additional opportunities to license the neurostimulator platform to companies focused on enhancements to a comprehensive system offering for closed-loop, chronic disease therapeutics, including advanced computational biology, deep learning utilizing Internet of Medical Things technology, imaging solutions, e-health programs, and big data management and optimization, among others. Once we complete the development of the platform for our DBS application, we will be able to potentially license the platform to capitalize on hundreds of diseases of the nervous system that could be therapeutically addressed with neurostimulation.

We also operate our wholly owned subsidiary, Medi-Line. Medi-Line currently serves over 30 medical device customers in 16 countries, including multi-year contracts with Fortune 500 health care companies. The Belgian manufacturer owns state-of-the-art facilities, which feature two validated clean rooms (one assembly clean room Class ISO 7 or C, and one extrusion/injection molding clean room Class ISO 8 or D) and 600m² of production space. Its capabilities will enable us to reduce risks associated with our commercial launch and speed the development of our neurostimulation products.

As of September 30, 2018, we had an accumulated deficit of \$6,810,662. For the nine months ended September 30, 2018 and 2017, our net loss was \$3,067,224 and \$3,590,801 respectively.

We expect that we will continue to incur significant expenses and increasing operating losses relating to our ongoing activities, particularly as we continue to invest in research and development and initiate clinical trials required to receive regulatory approval for our medical devices in both the United States and the European Union. Additionally, when we initiate a launch of one or more of our products, we expect to incur substantial commercialization expenses related to the manufacture and distribution, as well as sales and marketing, of these products. In addition, the Company is subject to additional costs associated with operating as a public company. Accordingly, we may need to obtain additional funding to continue operations. Such financing may not be available to us on acceptable terms, or at all. In the event we require additional capital and are unable to secure such funding, we could be forced to delay, reduce, or eliminate our research and development activities, as well as any future commercialization of our products.

Prior to the acquisition of Medi-Line and NMB, the Company had not generated any revenues, and we financed our operations primarily with net proceeds from the private placements of our common stock, and from non-dilutive research and development grant awards. The Company's ability to generate revenues in addition to the Medi-Line manufacturing revenues will depend heavily on the successful completion of the requisite clinical trials and studies necessary to achieve approval to begin marketing our contemplated neurostimulation devices from the relevant regulatory authorities in the United States and the European Union.

Business Segments

The manufacturing segment includes the manufacturing operations of our wholly owned subsidiary Medi-Line, located in Angleur (Liege), Belgium. Medi-Line manufactures single-use medical devices for the medical and pharmaceutical sectors, including radiopharmacy technology, urology products, and sterilization cases and trays, and designs, develops, and offers worldwide production and supply-chain capabilities for these products to its customers.

The neurostimulation segment includes development, manufacturing, and commercialization of neurostimulation technology for the treatment of various neurological disorders through electrical stimulation of neural tissues. Our first commercial application of its platform will be the Viant™ Deep Brain Stimulation System. Operations for the neurostimulation segment are conducted in the United States, Puerto Rico, Belgium, and Germany.

Other items of revenue not directly related to manufacturing or neurostimulation revenues are categorized as other operating income. Other operating income and expenses not directly related to a specific segment are identified as "other" and not allocated to segments.

Results of Operations

Consolidated Sales Revenue

For the nine months ended September 30, 2018:

Consolidated revenues increased to \$7,666,827. The change in consolidated revenues consisted of the following segmented revenue activity:

	Nine Months Ended September 30,	
	2018	2017
Manufacturing	\$ 7,119,557	\$ 816,325
Neurostimulation	400,055	292,936
Other	147,215	38,027
Consolidated total	<u>\$ 7,666,827</u>	<u>\$ 1,147,288</u>

Manufacturing segment: Manufacturing sales were \$7,119,557. The prior period comparison for the nine months ended September 30, 2017 includes only one month of sales as the acquisition of Medi-Line occurred on August 30, 2017.

Neurostimulation segment: Neurostimulation sales increased by \$107,119 or 36.6% from the nine months ended September 30, 2017. Neurostimulation sales reflect the sale of neurostimulation devices and sub-components for operation of the devices for pre-clinical use to a single customer. The increase for the nine months ended September 30, 2018 over the nine months ended September 30, 2017 is due to scheduled deliveries pursuant to a development, manufacturing and supply agreement with the customer.

Other: The Company's other operating revenues for the nine months ended September 30, 2018 and 2017 were \$147,215 and \$38,027, respectively. The increase of 287.1% over the prior nine months was primarily due to the inclusion of Medi-Line other operating income for the nine months ended September 30, 2018. Other operating income consists primarily of Belgian government credits for employing staff in the research and development sector.

For the three months ended September 30, 2018:

	Three Months Ended September 30,	
	2018	2017
Manufacturing	\$ 1,938,908	\$ 816,325
Neurostimulation	5,003	202,362
Other	33,718	20,992
Consolidated total	<u>\$ 1,977,629</u>	<u>\$ 1,039,679</u>

Manufacturing segment: Manufacturing sales were \$1,938,908. The prior period comparison for the three months ended September 30, 2017 includes only one month of sales as the acquisition of Medi-Line occurred on August 30, 2017.

Neurostimulation segment: Neurostimulation sales decreased by \$197,359 as only a small sub-component part sale occurred for three months ended September 30, 2018 and no other deliveries were scheduled pursuant to any development, manufacturing and supply agreement with customers for the quarter.

Other: The Company's other operating revenues for the three months ended September 30, 2018 and 2017 were \$33,718 and \$20,992, respectively. The increase of 60.6% over the prior three months was primarily due to the inclusion of Medi-Line other operating income for the three months ended September 30, 2018 and only one month for the three months ended September 30, 2017.

Consolidated Earnings (Loss) Before Provision for Taxes on Income

For the nine months ended September 30, 2018:

Consolidated loss before provision for taxes for the nine months ended September 30, 2018, was \$3,643,448, as compared to a loss of \$3,604,004 for the nine months ended September 30, 2017.

Income (Loss) Before Tax by Segment:

	Nine Months Ended September 30,		Percent Change
	2018	2017	
Manufacturing	\$ 223,100	\$ 114,720	94.5%
Neurostimulation	(3,892,894)	(4,144,691)	(6.1)
Other ⁽¹⁾	26,346	425,967	(93.8)
Consolidated total	<u>\$ (3,643,448)</u>	<u>\$ (3,604,004)</u>	<u>1.09%</u>

⁽¹⁾ Amounts not allocated to segments include interest income (expense) and other income (expense), and amortization of acquisition intangible assets.

Manufacturing segment: Manufacturing segment income before tax as a percent of manufacturing revenues was 3.1%. The prior period comparison for the three months ended September 30, 2017 includes only one month of sales as the acquisition of Medi-Line occurred on August 30, 2017.

Neurostimulation segment: The neurostimulation segment loss before tax as a percent of neurostimulation revenues was (973.1)%. For the nine months ended September 30, 2018 the decrease in loss before tax for the neurostimulation segment was primarily due to \$107,119 increase in device sales and a net decrease of \$166,468 in combined research and development costs and general and administrative costs for the segment for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017.

For the three months ended September 30, 2018:

Consolidated loss before provision for taxes for the three months ended September 30, 2018, was \$1,397,057, as compared to a loss of \$425,252 for the three months ended September 30, 2017.

Income (Loss) Before Tax by Segment:

	Three Months Ended September 30,		Percent Change
	2018	2017	
Manufacturing	\$ 48,982	\$ 114,720	(57.3)%
Neurostimulation	(1,386,884)	(1,070,982)	29.5
Other ⁽¹⁾	(59,155)	532,010	(111.1)
Consolidated total	<u>\$ (1,397,057)</u>	<u>\$ (424,252)</u>	<u>(229.30)%</u>

⁽¹⁾ Amounts not allocated to segments include interest income (expense) and other income (expense), and amortization of acquisition intangible assets.

Manufacturing segment: Manufacturing segment income before tax as a percent of manufacturing revenues was 2.5%. The prior period comparison for the three months ended September 30, 2017 includes only one month of sales as the acquisition of Medi-Line occurred on August 30, 2017.

Neurostimulation segment: For the three months ended September 30, 2018 the increase in loss before tax for the neurostimulation segment was primarily due to no device sales, only component parts sales, for the three months ended September 30, 2018 compared to \$202,362 in device sales for the three months ended September 30, 2017.

Cost of Revenue, Research and Development Expense, and Selling, General, and Administrative Expense

For the nine months ended September 30, 2018:

Cost of revenue, research and development expense, and selling, general, and administrative expense as a percentage of revenue were as follows:

	Nine Months Ended September 30,			
	2018	% Rev	2017	% Rev
Cost of product sold	\$ 5,533,173	72.2%	\$ 737,664	64.3%
Research and development expenses	1,881,198	24.5	1,659,560	144.7
Selling, general, and administrative expenses	2,724,960	35.5%	1,817,218	158.4%

Cost of revenue: Consolidated costs of revenue increased to 72.2% of revenue from 64.3% for the nine months ended September 30, 2018. The increase was driven by the addition of Medi-Line's manufacturing activity for the nine months ended September 30, 2018 compared to one month of activity for Medi-Line for the nine months ended September 30, 2017.

Research and development expenses: Consolidated research and development expenses decreased \$221,638 to 24.5% of revenue from 144.7% for the nine months ended September 30, 2017. The net decrease reflects the addition of research and development activity at Medi-Line and an increase in applicable grant related activity recorded as a reduction to research and development expense.

Selling, general, and administrative expenses increased \$907,742 and decreased to 35.5% of revenue from 158.4% for the nine months ended September 30, 2017. The net increase was driven by the addition of the Medi-Line activity for the nine months ended September 30, 2018 compared to one month of activity for Medi-Line for the nine months ended September 30, 2017.

For the three months ended September 30, 2018:

Cost of revenue, research and development expense, and selling, general, and administrative expense as a percentage of revenue were as follows:

	Three Months Ended September 30,			
	2018	% Rev	2017	% Rev
Cost of product sold	\$ 1,384,335	70.0%	\$ 709,373	68.2%
Research and development expenses	674,360	34.1	287,229	27.6
Selling, general, and administrative expenses	875,016	44.2%	651,556	62.7%

Cost of revenue: Consolidated costs of revenue increased to 70% of revenue from 68.2% for the three months ended September 30, 2017. The increase was driven by the addition of Medi-Line's manufacturing activity and product mix for sales at Medi-Line for the three months ended September 30, 2018.

Research and development expenses: Consolidated research and development expenses increased \$387,131 and decreased to 34.1% of revenue from 27.6% for the three months ended September 30, 2017. The net increase reflects the reduction of research and development credited to grants and the addition of research and development activity at Medi-Line and the percentage decrease reflects the addition of Medi-Line revenues.

Selling, general, and administrative expenses increased \$223,460 and decreased to 44.2% of revenue from 62.7% for the three months ended September 30, 2017. The net increase was driven by the addition of the Medi-Line activity for the three months ended September 30, 2018 compared to one month of activity for Medi-Line for the three months ended September 30, 2017.

It is expected that the Company's Research and development ("R&D") activities and related expenses will increase significantly in the future as we increase the scope and rate of such efforts and begin more expensive development activities, including clinical trials and similar studies as required by the relevant regulatory authorities in our targeted jurisdictions (i.e., the United States and the European Union).

R&D expenses consist of the costs associated with our research and discovery efforts related to the design and development of our proposed medical devices. Primarily, R&D expenses are expected to include, but may not be limited to:

- Facilities, laboratory supplies, equipment, and related expenses;
- Employee-related expenses, which, among other things, includes salaries, benefits, travel, and stock-based compensation;
- External R&D activities incurred under arrangements with third parties, such as contract research organizations, manufacturing organizations, consultants, and possibly a scientific advisory board; and
- License fees and other costs associated with securing and protecting IP.

The Company has been awarded multiple grants and subsidies for its research and development activities, and receives these funds as advance payments and reimbursements for applicable project expenses. The Company recognizes the amounts received in accordance with the contracts as a reduction of research and development expenses over the periods necessary to match the contract on a systematic basis to the costs that it is intended to compensate. The Company records, on the balance sheet, grants receivable (upon meeting the criteria discussed above) until cash is received. For the nine months ended September 30, 2018 and 2017, the Company has recorded a credit to research and development expense in the amount of \$1,054,765 and \$1,631,034 respectively, related to these grants and subsidies.

Selling, general and administrative expenses generally consist of salaries and similar costs associated with employees, including stock-based compensation expense. This category of expenses may also include facility costs and professional fees related to (i) legal and accounting services; (ii) capital formation; (iii) investor and public relations services; and (iv) general corporate consulting services.

It is expected that our selling, general, and administrative expenses will increase in the future as we expand our R&D activities in pursuit of regulatory approval for our contemplated medical devices, and as we increase sales and marketing expenses related to the sales of our neurostimulation devices.

Depreciation and Amortization

Depreciation and amortization expenses consist of amortization of acquired intangibles and depreciation of buildings, capital improvements, capitalized building lease, office equipment, and furniture and fixtures. Property, plant and equipment is depreciated using the straight-line method over the estimated useful lives of the assets.

During the year ended December 31, 2016, the Company acquired \$6,120,000 in patents pertaining to the cardiovascular disease technology acquired in the merger with NXDE, and acquired \$3,190,000 in patent licenses for the underlying patents referred to as the Siemens Patents. NMB holds patents and licenses totaling \$1,053,097 related to our neurostimulation technology and devices. The amortization period for each of the individual patents depends on the legal terms for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. The patents and patent licenses are amortized using the straight-line method over the remaining time until expiration. The majority of these patents and patents underlying the license will expire between 2019 and 2036. Through the acquisition of Medi-Line, the Company acquired intangible assets with a fair value in the amount of \$1,550,000 for trade secrets and know-how and \$600,000 for customer relationships.

For the nine months ended September 30, 2018 and 2017, the Company's depreciation expenses were \$186,834 and \$63,413, respectively. For the nine months ended September 30, 2018 and 2017, the Company's amortization expenses were \$908,241 and \$861,377, respectively.

For the three months ended September 30, 2018 and 2017, the Company's depreciation expenses were \$61,021 and \$38,112, respectively. For the three months ended September 30, 2018 and 2017, the Company's amortization expenses were \$302,081 and \$288,680, respectively.

Interest Income (Expense)

For the three and nine months ended September 30, 2018, the Company's interest expense was \$77,873 and \$235,869 respectively and for the three and nine months ended September 30, 2017, interest expense, net of interest income, was \$26,537 and \$23,751, respectively. Interest expense includes interest on bank loans and credit facilities, interest on leasing, interest on convertible debt, interest on shareholder notes, and non-cash amortizing interest for the original discount of convertible debt in the amount of \$33,876 and \$97,639 for the three and nine months ended September 30, 2018.

Other Income (Expense)

For the three and nine months ended September 30, 2018 the Company recorded other expense, net of other income, in the amount of \$77,873 and \$75,869, respectively. On May 22, 2018 the Company redeemed and cancelled 14,286 shares of its common stock from a former director as consideration for the purchase of certain intellectual property. These shares were valued at \$160,000 and recorded as gain on disposition of patent. For the three and nine months ended September 30, 2017, the Company recorded other income, net of other expense, in the amount of \$511,019 and \$387,940, respectively. In the second quarter of 2017, the Company recorded a charge for the write-off of a loan in the amount of \$171,946 and in the first quarter of 2017 recorded a charge of \$37,788 for the exchange of stock held for investment and in the third quarter of 2017 the Company recorded a gain on bargain purchase for the acquisition of INGEST and Medi-Line in the amount of \$624,211.

Provision for Income Taxes

For the nine months ended September 30, 2018, the Company recorded a provision for Belgian corporate income taxes in the amount of \$11,928 based on the taxable income for Medi-Line. The Company's holding company subsidiary, NXEU, was assessed annual corporate taxes in the amount of \$5,038 during three months ended September 30, 2018. For the nine months ended September 30, 2017 the Company recorded a benefit to provision for income tax in the amount of \$13,203.

On December 27, 2017, NXPROC was granted a tax exemption pursuant to Act number 73-2008 ("ACT 73") by the Government of Puerto Rico, Department of Economic Development and Commerce ("PRIDCO"). The exemption allows NXPROC to obtain tax credits in the amount of fifty percent (50%) of approved applicable research and development expenses of NXPROC. As of July 23, 2018, the Company has received all government approvals and certifications from PRIDCO and received tax credits in the amount of \$732,340, for research and development activity in 2017, which had been posted to Departamento De Hacienda (the Puerto Rican Department of Finance) system and the Company has received \$593,195 in net proceeds from the sale of all available tax credits realizing proceeds of 81% of the face value of the tax credits. For the nine months ended September 30, 2018, the Company recorded a benefit to provision for income taxes in the amount of \$593,195.

Liquidity and Capital Resources

Sources of Liquidity

Prior to the acquisition of NMB and its subsidiary Medi-Line, the Company had not generated any revenues. We have financed our operations to date through private placements, National Institutes of Health awards for research and development projects, and loans from the Company's largest shareholder, RS.

2017 Private Placement & Common Stock Sale

On July 20, 2017, the Company closed on a private placement, pursuant to which it received \$1,165,000 from the sale and issuance of 66,580 shares of restricted common stock. The shares of common stock were offered at \$17.50 per share. In addition, on October 9, 2017, the Company issued 10,715 shares of restricted common stock pursuant to a common stock purchase agreement. The purchase price was \$14.00 per share and the Company received \$150,000.

Research and Development Grants

Our wholly owned subsidiary Pulsus Medical, LLC was awarded \$751,000 of federal research grants applicable to Pulsus Medical, LLC's products, and these funds became available to the Company beginning in the quarter ended September 30, 2017. The Company has been awarded a grant by the Cancer Prevention and Research Institute of Texas, which was approved in the amount of \$392,156 and received \$324,841 in December 2017 and \$67,315 in January 2018.

NMB has been awarded subsidies from the Public Service of Wallonia - Department of Technology Development and the Research Programs Department. As of September 30, 2018, NMB currently has a total of \$491,488, in remaining awarded funds to be received, including a \$361,466 recorded as current accounts receivable and \$130,042 to be reimbursed for future expenses for current projects. NMB has received approval for a grant application from the Public Service of Wallonia in the amount of \$1,263,898. This grant funded research and development project is expected to commence in first quarter of 2019.

Medi-Line has been awarded subsidies from the Public Service of Wallonia - Department of Technology Development and the Research Programs Department. As of September 30, 2018, Medi-Line currently has a total of \$761,839 in remaining awarded funds to be received, including a \$266,320 recorded as current accounts receivable and \$495,519 to be reimbursed for future expenses for current projects. Medi-Line has received approval for a grant application from the Public Service of Wallonia in the amount of \$737,635. This grant funded research and development project is expected to commence in first quarter of 2019.

The Company has received a notice of award from the National Institute of Neurological Disorders and Stroke (NINDS) for the phase I portion in the amount of \$838,241 for funding of an U44 Cooperative Agreement Award (U44NS108148) under the BRAIN Initiative. The award provides more than \$1,554,475 through phase I and phase II of the project to support the development and clinical evaluation of a software tool to improve DBS programming through multi-modal mapping of disease-related neural signals, images/models, and device data. The project budget period began on September 30, 2018. The Puerto Rico Science, Technology, and Research Trust has awarded \$100,000 in matching funds to support the first phase of the project.

2017 Tax Grant

On December 27, 2017, NXPROC was granted a tax exemption pursuant to Act number 73-2008 (“ACT 73”) by the Government of Puerto Rico, Department of Economic Development and Commerce (“PRIDCO”). The exemption allows NXPROC to obtain tax credits in the amount of fifty percent (50%) of approved applicable research and development expenses of NXPROC. These tax credits can be used to offset current year income taxes, or, if no income tax is due, can be sold to companies operating in Puerto Rico to offset their Puerto Rican income tax. In the case of a sale of the tax credits, the tax credits are typically sold at a discount to the dollar value of the credits.

As of July 23, 2018, the Company has received all government approvals and certifications from PRIDCO and received tax credits in the amount of \$732,340, for research and development activity in 2017, which had been posted to Departamento De Hacienda (the Puerto Rican Department of Finance) system and the Company has received \$593,195 in net proceeds from the sale of all available tax credits realizing proceeds of 81% of the face value of the tax credits.

Issuances for Services

During the fiscal years 2016 and 2017 the Company has issued an aggregate of 81,369 shares of common stock for certain research and development, legal, corporate structuring, software development, marketing and valuation consulting services rendered by third-party consultants. The foregoing shares were valued at \$782,645.

During the nine months ended September 30, 2018, the Company issued an aggregate of 8,892 shares of restricted common stock for certain software development, research and development, marketing and valuation services to third-party consultants. The foregoing services were valued at \$112,561.

As of September 30, 2018, we had cash on hand of \$125,573. Based upon our budgeted burn rate, and along with expected grant funding, we currently have operating capital for approximately 2 months. The Company has historically relied on equity or debt financing and federal research and development subsidies to finance its ongoing operations.

During the next 12 months, the Company may elect to issue additional debt or equity either by private placement or a registered offering. There can be no assurance that the Company will be successful in completing any new debt and/or equity financing, or receive assignments of grants. If the Company is unable to secure needed financing, or is unable to secure such financing on terms we find favorable, we may be forced to delay, limit, or terminate product development and/or future product commercialization.

Continued Operations

Until such time, if ever, as we can generate substantial revenues to cover the development and commercialization of our neurostimulation technology platform, we anticipate that we will need to finance our cash needs through a combination of future debt and equity financing, as well as expected non-dilutive research grant awards. Besides certain grant awards, as described above, we do not have any committed external source of funds. To the extent that we secure additional capital through the sale of equity securities or convertible debt, the ownership interest of our stockholders may be diluted, and the terms of any such securities we issue may include liquidation or other preferences that adversely affect the rights of common stockholders. In cases where we secure certain debt financing, if any such is available, we may become subject to certain covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, or declaring dividends. In the event we are unable to secure needed financing, or are unable to secure such financing on terms we find favorable, we may be forced to delay, limit, or terminate product development and/or future commercialization of the same.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements, including arrangements that would affect our liquidity, capital resources, market risk support and credit risk support, or other benefits.

Critical Accounting Policies

Our management's discussion and analysis of the Company's financial condition and results of operations is based on our consolidated financial statements, which were prepared in conformity with generally accepted accounting principles. The preparation of our consolidated financial statements requires us to establish accounting policies and make estimates and assumptions that affect our reported amounts of assets and liabilities at the date of the consolidated financial statements. These consolidated financial statements include some estimates and assumptions that are based on informed judgments and estimates of management. We evaluate our policies and estimates on an ongoing basis, and discuss the development, selection, and disclosure of critical accounting policies with the board of directors. Predicting future events is inherently an imprecise activity, and as such requires the use of judgment. Our consolidated financial statements may differ based upon different estimates and assumptions.

The Company's significant accounting policies are described in more detail in the notes to our consolidated financial statements, above. See *Note 2, Summary of Significant Accounting Policies*, which we believe set forth the most critical accounting policies to aid you in fully understanding and evaluating our financial condition and results of operations.

New Accounting Pronouncements

Management does not believe that any recently issued but not yet effective accounting pronouncements, if adopted, would have a material effect on the accompanying consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risks is limited to changes in interest rates. We do not use derivative financial instruments as part of an overall strategy to manage market risk. We have no investment in debt instruments other than highly liquid short-term investments. Accordingly, we consider our interest rate risk exposure to be insignificant at this time.

Item 4. Controls and Procedures

Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, our Chief Executive Officer and Chief Financial Officer have concluded that as of September 30, 2018, our disclosure controls and procedures were not effective due to the lack of implementation of disclosure internal controls and procedures across all operating entities as a result of the recent acquisitions of foreign subsidiaries, and the integration of those entities.

Changes in Internal Control Over Financial Reporting

During the three months ended September 30, 2018, there was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

Periodically we are a party to various legal actions, both threatened and filed, arising in the normal course of business. While we do not expect that the ultimate resolution of any pending actions will have a material effect on our results of operations, financial position, or cash flows, litigation is subject to inherent uncertainties. As such, there can be no assurance that any pending or threatened legal action, which we currently believe to be immaterial, does not become material in the future.

On October 10, 2018, the Company received a petition and request for disclosure filed in the District Court of Dallas County, Texas naming Mr. Brian Blischak as the plaintiff and Nexeon MedSystems Inc as the defendant. The petition states Nexeon MedSystems Inc hired Mr. Blischak in December of 2016 as President and Chief Commercial Officer. Pursuant to the Employment Agreement between Mr. Blischak and Nexeon MedSystems Inc, Nexeon MedSystems Inc was required to pay Mr. Blischak salary and bonuses in exchange for Mr. Blischak's performance as a corporate executive. Mr. Blischak seeks monetary relief in the amount of \$376,985 for unpaid amounts pursuant to Mr. Blischak's employment agreement with Nexeon MedSystems Inc. Mr. Blischak resigned his position as President and Chief Commercial Officer on November 1, 2018.

Item 1A. Risk Factors

There have been no updates to the Risk Factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, except as set forth below:

We have a history of losses, and we anticipate that we will continue to incur losses in the future. Our auditors have included in their audit report an explanatory paragraph as to substantial doubt as to our ability to continue as a going concern.

We have experienced net losses since our inception. For the year ended December 31, 2017, our net loss was \$2,177,641, compared to a net loss of \$802,463 for the year ended December 31, 2016. For the nine months ended September 30, 2018 and 2017, our net loss was \$3,067,224 and \$3,590,801, respectively. As of December 31, 2017, we had an accumulated deficit of \$3,743,438. As of September 30, 2018, we had an accumulated deficit of \$6,810,662. Our auditors have included in their audit report a "going concern" explanatory paragraph that there is substantial doubt as to our ability to continue as a going concern, which assumes the realization of our assets and the satisfaction of our liabilities and commitments in the normal course of business. We anticipate continuing to incur substantial additional losses over at least the next several years due to, among other factors, expenses related to the following: anticipated research and development activities, investor and public relations, Securities and Exchange Commission (SEC) compliance efforts, and the general and administrative expenses associated with each of these activities. We may never achieve profitability, and, even if we do, we may not be able to sustain being profitable.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidate, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development, and may vary among jurisdictions.

We are subject to anti-bribery, anti-corruption, and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act, as well as export control laws, customs laws, sanctions laws, and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations, and financial condition.

As we grow our international presence and global operations, we will be increasingly exposed to trade and economic sanctions and other restrictions imposed by the United States, the European Union, and other governments and organizations. The U.S. Departments of Justice, Commerce, State, and Treasury, and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the U.S. Foreign Corrupt Practices Act (FCPA), and other federal statutes and regulations, including those established by the Office of Foreign Assets Control (OFAC). Under these laws and regulations, as well as other anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws, and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices (including cessation of business activities in sanctioned countries or with sanctioned persons or entities, and modifications to compliance programs) that may increase compliance costs, and may subject us to fines, penalties, and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition, and results of operations.

We are in the process of implementing policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants, and agents with the FCPA, OFAC restrictions, and other export control, anti-corruption, anti-money-laundering, and anti-terrorism laws and regulations. We cannot assure you, however, that our policies and procedures are or will be sufficient, or that directors, officers, employees, representatives, consultants, and agents have not engaged and will not engage in conduct for which we may be held responsible; nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us, or even result in our being held liable for such conduct. Violations of the FCPA, OFAC restrictions, or other export control, anti-corruption, anti-money laundering, and anti-terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a materially adverse effect on our business, financial condition, and results of operations.

Our chief executive officer beneficially owns a significant percentage of our outstanding capital stock, and will have the ability to significantly influence our affairs.

Our chief executive officer, William Rosellini, beneficially owns approximately 34.14% of our issued and outstanding capital stock, through the holdings of Rosellini Scientific Holdings, LLC (“RSH”), of which he is the sole member and manager. By virtue of his holdings, he may significantly influence, or effectively control, the election of the members of our board of directors, our management, and our affairs, and other corporate transactions (such as mergers, consolidations, or the sale of all or substantially all of our assets) that are submitted to shareholders for approval, and that may not be favorable from our standpoint or that of our other shareholders.

Anti-takeover provisions may impede the acquisition of our Company.

Certain provisions of the Nevada Revised Statutes have anti-takeover effects and may inhibit a non-negotiated merger or other business combination. These provisions are intended to encourage any person interested in acquiring us to negotiate with, and to obtain the approval of, our board of directors in connection with such a transaction. But certain of these provisions may discourage a future acquisition of us, including an acquisition in which the stockholders might otherwise receive a premium for their shares. As a result, stockholders who might desire to participate in such a transaction may not have the opportunity to do so, which could cause our stock price to decline.

Our products may be subject to recalls, even after receiving FDA clearance or approval, which would harm our reputation, business, and financial results.

We will be subject to the medical device reporting regulations, which will require us to report to the FDA if our products may have caused or contributed to a death or serious injury, or have malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to occur. We will also be subject to the correction and removal reporting regulations, which will require us to report to the FDA any field corrections and device recalls or removals that we undertake to reduce a risk to health posed by the device, or to remedy a violation of the Federal Food, Drug and Cosmetic Act (FDCA) caused by the device that may present a risk to health. In addition, the FDA and similar governmental agencies in other countries have the authority to require the recall of our products if there is a reasonable probability that the products would cause serious adverse health consequences or death. A government-mandated or voluntary recall by us could occur as a result of manufacturing defects, labeling deficiencies, packaging defects, or other failures to comply with applicable regulations. Any recall would divert management attention and financial resources and harm our reputation with customers, and could have a materially adverse effect on our financial condition and results of operations.

We are subject to numerous federal and state health care laws and regulations, and failure to comply with such laws and regulations could have an adverse effect on our business and our ability to compete in the marketplace.

There are numerous laws and regulations that govern the means by which companies in the health care industry may market their treatments to health care professionals, and may compete by discounting the prices of their treatments, including, for example, the federal Anti-Kickback Statute, the federal False Claims Act (“FCA”), the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), and state law equivalents to these federal laws that are meant to protect against fraud and abuse (as well as analogous laws in foreign countries). Violations of these laws are punishable by criminal and civil sanctions, including but not limited to (in some instances) civil and criminal penalties, damages, fines, and exclusion from participation in federal and state health care programs, including Medicare and Medicaid. In addition, federal and state laws are also sometimes open to interpretation. Accordingly, we could potentially face legal risks if our interpretation differs from those of enforcement authorities. Further, from time to time we may find ourselves at a competitive disadvantage if our interpretation differs from those of our competitors.

Specifically, anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation, or receipt of any form of remuneration (direct or indirect, in case or in kind) in return for the referral, use, ordering, or recommending of the use of a product or service for which payment may be made by Medicare, Medicaid, or other government-sponsored health care programs. We have entered into consulting agreements, research agreements, and product development agreements with physicians, including some who may order our products or make decisions to use them. In addition, some of these physicians own our stock, which they purchased in arm's-length transactions on terms identical to those offered to non-physicians, or received as stock awards from us as consideration for services performed by them. While these transactions were structured with the intention of complying with all applicable laws, including state anti-referral laws and other applicable anti-kickback laws, it is possible that regulatory or enforcement agencies or courts may in the future view these transactions as prohibited arrangements that must be restructured, or for which we would be subject to other significant civil or criminal penalties. There can be no assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws, or that one or more of our employees or agents will not disregard the rules we have established. Because our strategy relies on the involvement of physicians who consult with us on the design of our potential products, perform clinical research on our behalf, or educate the market about the efficacy and uses of our potential products, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with physicians who refer or order our potential products to be in violation of applicable laws, and determine that we would be unable to achieve compliance with such applicable laws. This could harm our reputation and the reputations of the physicians we engage to provide services on our behalf. In addition, the cost of noncompliance with these laws could be substantial since we could be subject to monetary fines and civil or criminal penalties. We could also be excluded from federally funded health care programs, including Medicare and Medicaid, for noncompliance. Further, even the costs of defending investigations of noncompliance could be substantial.

Also, the FCA imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the federal government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity (i.e., a whistleblower) with knowledge of past or present fraud against the federal government to sue on behalf of the government, and to be paid a portion of the government's recovery, which can include both civil penalties and up to three times the amount of the government's damages (usually the amount reimbursed by federal health care programs). The U.S. Department of Justice ("DOJ") on behalf of the government takes the position that the marketing and promotional practices of life sciences product manufacturers, including the off-label promotion of products, the provision of inaccurate or misleading reimbursement guidance, or the payment of prohibited kickbacks to doctors or other referral sources may cause the submission of improper claims to federal and state health care entitlement programs such as Medicare and Medicaid by health care providers that use the manufacturer's products, which results in a violation of the FCA. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts, and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other health care providers. In addition to federal laws, some states, such as California, Massachusetts, and Vermont, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a health care company may run afoul of one or more of the requirements.

The scope and enforcement of all of these laws is uncertain, and subject to rapid change, especially in light of the lack of applicable precedent and regulations. There can be no assurance that federal or state regulatory or enforcement authorities will not investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a materially adverse effect on our business, financial condition, and results of operations. Any state or federal regulatory or enforcement review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in these laws, whether these changes are retroactive or will have effect on a going-forward basis only.

Our use of sensitive patient information is subject to complex regulations at multiple levels, and we would be adversely affected if we failed to adequately protect this sensitive information.

We process, maintain, and utilize personal health and other confidential and sensitive data. In particular, we have developed a web and mobile application through which our customers can communicate with physicians and others, which may involve sharing patient identifiable health information. The use and disclosure of such information is regulated at the federal, state, and international levels, and these laws, rules, and regulations are subject to change and increased enforcement activity, such as the audit program implemented by the U.S. Department of Health and Human Services under HIPAA. International laws, rules, and regulations governing the use and disclosure of such information are generally more stringent than in the United States, and they vary from jurisdiction to jurisdiction. Noncompliance with any privacy or security laws or regulations, or any security breach, cyber-attack, or cybersecurity breach, as well as any incident involving the theft, misappropriation, loss, or other unauthorized disclosure of, or access to, sensitive or confidential information, whether by us or by another third party, could require us to expend significant resources to remediate any damage, interrupt our operations, and damage our brand and reputation, and could also result in investigations, regulatory enforcement actions, material fines and penalties, loss of customers, litigation, or other actions that could have a materially adverse effect on our business, brand, reputation, cash flows, and operating results.

Our business depends on provider and patient willingness to entrust us with health-related and other sensitive personal information. Events that negatively affect that trust, including inadequate disclosure of our uses of their information, failure to keep our information technology systems and sensitive information secure from significant attack, theft, damage, loss, or unauthorized disclosure or access, whether as a result of our action or inaction, or that of third parties, could adversely affect our brand, reputation, and revenues, and also expose us to mandatory disclosure to the media, litigation (including class action litigation) and other enforcement proceedings, material fines, penalties and/or remediation costs, and compensatory, special, punitive, and statutory damages, as well as consent orders and/or injunctive relief, any of which could adversely affect our business, cash flows, operating results, or financial position. There can be no assurance that any such failure will not occur—or, if any does occur, that we will detect it, or that it can be sufficiently remediated.

The training required for physicians to use our Viant™ System could reduce the market acceptance of our products.

As with any new method or technique, physicians must undergo a thorough training program before they are qualified to perform the surgery to implant our Viant™ System. Physicians could experience difficulty with the technique necessary to successfully insert the device, and may not achieve the technical competency necessary to complete the training program. Even after successfully completing the training program, physicians could still experience difficulty implanting our Viant™ System, and, as a result, limit its use significantly in their practices, or cease utilizing it altogether.

In addition, we may experience difficulty growing the number of physicians who complete our training program if patient demand is low, if the length of time necessary to train each physician is longer than expected, if the capacity of our sales representatives to train physicians is less than expected, or if we are unable to sufficiently grow our sales organization. All of these events would lead to fewer trained physicians qualified to implant our Viant™ System, which could negatively affect our business, financial condition, and results of operations, and impair our ability to grow our business.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

We or the third parties whom we license intellectual property from may become involved in legal proceedings to protect or enforce our intellectual property rights, which could be expensive and time-consuming.

Competitors or others may infringe upon our intellectual property rights. To counteract infringement or unauthorized use, we or third parties whom we license intellectual property from may be required to file patent infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that certain of our intellectual property is not valid or is unenforceable, or the court may refuse to stop the other party from using the technology at issue on the grounds that our intellectual property rights do not cover such technology.

An adverse determination of any litigation or defense proceedings could put our intellectual property at risk of being invalidated or interpreted narrowly, and could put outstanding intellectual property applications at risk of not being granted.

Interference proceedings brought by the United States Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our intellectual property applications. Litigation or interference proceedings may fail, and, even if successful, may result in substantial costs, diversion of resources, and distraction of our management. We or our licensors may not be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as comprehensively as in the United States.

Furthermore, due to the substantial amount of discovery associated with intellectual property litigation, there is a risk that some of our (or our licensors') confidential information could be compromised by disclosure. In addition, during the course of this litigation, there could be public announcement of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, then it could have a substantial adverse effect on the price of our common stock. We or our licensors may not prevail in any litigation or interference proceeding in which we may be involved in the future. Even if we or our licensors do prevail, such legal proceedings would likely be expensive and time-consuming.

If we are unable to protect the confidentiality of our proprietary information and know-how related to any of our product candidates, our competitive position would be impaired and our business, financial condition, and results of operations could be adversely affected.

Some of our technology, including our knowledge regarding the processing of our product candidates, is unpatented, and is maintained by us as trade secrets. In an effort to protect these trade secrets, the information is restricted to our employees, consultants, collaborators, and advisors on a need-to-know basis only. In addition, we require our employees, consultants, collaborators, and advisors to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. These agreements, however, do not ensure protection against improper use or disclosure of confidential information, and these agreements may be breached. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements and other obligations of our employees to assign intellectual property to us may conflict with or be subject to the rights of third parties with whom our employees, consultants, collaborators, or advisors have had previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position, and could have a materially adverse effect on our business, financial condition, and results of operations.

We may become subject to claims of infringement of the intellectual property rights of others, which could prohibit us from developing our treatment, require us to obtain licenses from third parties or to develop non-infringing alternatives, and subject us to substantial monetary damages. We have not obtained and do not intend to obtain any legal opinion with regard to our freedom to practice our technology.

Third parties could assert that our processes, product candidates, or technology infringe upon their patents or other intellectual property rights. Whether a process, product, or technology infringes upon a patent or other intellectual property involves complex legal and factual issues, the determination of which is often uncertain. We cannot be certain that we will not be found to have infringed upon the intellectual property rights of others. Because patent applications may remain unpublished for certain periods of time and may take years to be issued as patents, there may be applications now pending of which we are unaware, and/or that do not currently contain claims of concern but may later result in issued patents that our product candidates, procedures, or processes will infringe upon. There may be existing patents that our product candidates, procedures, or processes infringe upon, of which infringement we are not aware. Third parties could also assert ownership over our intellectual property. Such an ownership claim could cause us to incur significant costs to litigate the ownership issues. If an ownership claim by a third party were upheld as valid, we may be unable to obtain a license from the third party on acceptable terms, to continue to make, use, or sell technology free from claims by that third party of infringement upon the third party's intellectual property. We have not obtained and do not intend to obtain any legal opinion with regard to our freedom to practice our technology at this time.

If we are unsuccessful in actions we bring against the patents of other parties, and it is determined that we infringe upon the patents of third parties, we may be subject to injunctions, or otherwise prevented from commercializing potential products and/or services in the relevant jurisdiction; or may be required to obtain licenses to those patents, or develop or obtain alternative technologies, any of which could harm our business. Furthermore, if such challenges to our patent rights are not resolved in our favor, we could be delayed or prevented from entering into new collaborations, or from commercializing certain product candidates and/or services, which could adversely affect our business and results of operations.

If we are successful in obtaining patent protection, we may not be able to enforce those patent rights against third parties.

Successful challenge of any future patents, such as through opposition, reexamination, *inter partes* review, interference, or derivation proceedings could result in a loss of patent rights in the relevant jurisdiction. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may not be able to protect our intellectual property in countries outside of the United States.

Intellectual property law outside the United States is uncertain, and, in many countries, is currently undergoing review and revisions. The laws of some countries do not protect patent and other intellectual property rights to the same extent as United States laws. Third parties may challenge our patents in foreign countries by initiating proceedings, including pre- and post-grant oppositions and invalidation proceedings. Developments during opposition or invalidation proceedings in one country may directly or indirectly affect a corresponding patent or patent application in another country in an adverse manner. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the United States. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and have a materially adverse effect on our results of operations and financial condition.

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

We effected a 1-for-14 reverse stock split of our outstanding common stock, or, the “Reverse Stock Split”, on June 25, 2018 and, unless otherwise indicated, all per share amounts set forth herein have been retroactively restated to reflect the Reverse Stock Split.

Set forth below is an enumeration of all securities issued by the Company during the three months ended September 30, 2018 that have not been registered under the Securities Act.

Common Stock Issuances

The Company issued no common stock for the three months ended September 30, 2018.

Options Grants – 2016 Plan

During the three months ended September 30, 2018, the Company issued stock options to purchase a total of 41,251 shares of the Company’s common stock and cancelled stock options to purchase a total of 66,247 shares of the Company’s common stock under the 2016 Plan as follows:

- (iv) As compensation for service as a director of the Company, the Company granted to Kent J. George a non-qualified stock option to purchase a total of 893 shares of the Company’s restricted common stock with an exercise price of \$8.00 per share. The option was immediately exercisable at date of issue. The term of the option shall be for four (4) years from the date of issue. The fair value of the option was determined to be \$2,661 using the Black-Scholes Option Pricing Model.
- (v) As compensation for service as a director of the Company, the Company granted to Michael Neitzel a non-qualified stock option to purchase a total of 893 shares of the Company’s restricted common stock with an exercise price of \$8.00 per share. The option was immediately exercisable at date of issue. The term of the option shall be for four (4) years from the date of issue. The fair value of the option was determined to be \$2,661 using the Black-Scholes Option Pricing Model.
- (vi) As compensation for service as a director of the Company, the Company granted to Wes Dittmer a non-qualified stock option to purchase a total of 893 shares of the Company’s restricted common stock with an exercise price of \$8.00 per share. The option was immediately exercisable at date of issue. The term of the option shall be for four (4) years from the date of issue. The fair value of the option was determined to be \$2,661 using the Black-Scholes Option Pricing Model.
- (xi) On July 22, 2018, the Company granted to a new employee at NXPROC incentive stock options to purchase up to 38,572 shares of the Company’s restricted common stock with an exercise price of \$11.00 per share with vesting over 48 months. The term of the option was for a period of four (4) years from the date of vesting. The fair value of the option was determined to be \$92,789 using the Black-Scholes Option Pricing Model. Prior to vesting the option to purchase 38,572 shares was cancelled.
- (xii) During the three months ended September 30, 2018, incentive stock options to purchase 16,326 shares of the Company’s restricted common stock were cancelled pursuant to the 2016 Plan for employee separations from the Company. The range of exercise prices for these cancelled options ranged from \$14.00 to \$17.50.

Unless otherwise stated, the issuance of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or contracts relating to compensation as provided under Rule 701.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.SCH*	XBRL Extension Schema Document
101.CAL*	XBRL Extension Calculation Linkbase Document
101.DEF*	XBRL Extension Definition Linkbase Document
101.LAB*	XBRL Extension Labels Linkbase Document
101.PRE*	XBRL Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith.

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.

Nexeon MedSystems Inc

Dated: November 19, 2018

By: /s/ William Rosellini
William Rosellini
Chief Executive Officer
(Principal Executive Officer)

Dated: November 19, 2018

By: /s/ Christopher R. Miller
Christopher R. Miller
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO RULE 13A-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002**

I, William Rosellini, certify that:

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

Date: November 19, 2018

/s/ William Rosellini

William Rosellini
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO RULE 13A-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002**

I, Christopher Miller, certify that:

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

Date: November 19, 2018

/s/ Christopher Miller

Christopher Miller

Chief Financial Officer

(Principal Financial and Accounting Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Nexeon MedSystems Inc (the "Company") on Form 10-Q for the period ended September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officers of the Company certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of our knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company, as of and for the periods presented in the Report.

Date: November 19, 2018

/s/ William Rosellini

William Rosellini
Chief Executive Officer
(Principal Executive Officer)

/s/ Christopher R. Miller

Christopher R. Miller
Chief Financial Officer
(Principal Financial and Accounting Officer)