

MISONIX INC
Form 10-Q
November 08, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

OR

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

For the transition period from _____ to _____.

Commission File Number: **1-10986**

MISONIX, INC.

(Exact name of registrant as specified in its charter)

New York

11-2148932

(State or other jurisdiction of incorporation or organization) *(IRS Employer Identification No.)*

1938 New Highway

11735

Farmingdale, New York

(Zip code)

(Address of principal executive offices)

(631) 694-9555

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Indicate the number of shares outstanding of the issuer's common stock as of the latest practicable date: As of October 23, 2018 there were 9,533,303 shares of the registrant's common stock, \$0.01 par value, outstanding.

MISONIX, INC.

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PART I — FINANCIAL INFORMATION**Item 1. Financial Statements****Misonix, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets**

	September 30, 2018 (Unaudited)	June 30, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$9,322,811	\$10,979,455
Accounts receivable, less allowance for doubtful accounts of \$200,000 and \$200,000, respectively	5,535,271	5,245,549
Inventories, net	4,920,350	5,019,886
Prepaid expenses and other current assets	583,314	611,647
Total current assets	20,361,746	21,856,537
Property, plant and equipment, net of accumulated amortization and depreciation of \$9,355,964 and \$9,023,235, respectively	4,346,826	4,188,378
Patents, net of accumulated amortization of \$1,097,252 and \$1,063,393, respectively	773,668	757,447
Goodwill	1,701,094	1,701,094
Contract assets	960,000	—
Intangible and other assets	468,013	517,295
Total assets	\$28,611,347	\$29,020,751
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$2,082,704	\$1,794,098
Accrued expenses and other current liabilities	2,344,903	2,812,172
Total current liabilities	4,427,607	4,606,270
Deferred income	13,303	13,303
Total liabilities	4,440,910	4,619,573
Commitments and contingencies		
Shareholders' equity:		
	94,822	94,305

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Common stock, \$.01 par value-shares authorized 40,000,000; 9,481,251 and 9,430,466 shares issued and outstanding in each period

Additional paid-in capital	41,192,701	39,772,973
Accumulated deficit	(17,117,086)	(15,466,100)
Total shareholders' equity	24,170,437	24,401,178
Total liabilities and shareholders' equity	\$28,611,347	\$29,020,751

See Accompanying Notes to Consolidated Financial Statements.

Misonix, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(Unaudited)

	For the three months ended September 30,	
	2018	2017
Revenues		
Product	\$9,361,164	\$7,280,723
Total revenue	9,361,164	7,280,723
Cost of goods sold	2,750,543	2,177,355
Gross profit	6,610,621	5,103,368
Operating expenses:		
Selling expenses	4,735,005	3,570,713
General and administrative expenses	3,183,384	2,573,131
Research and development expenses	1,304,766	901,274
Total operating expenses	9,223,155	7,045,118
Loss from operations	(2,612,534)	(1,941,750)
Other income (expense):		
Interest income	19,813	13
Royalty income	—	452,971
Other	(18,265)	(4,458)
Total other income	1,548	448,526
Loss from operations before income taxes	(2,610,986)	(1,493,224)
Income tax (benefit)	—	(281,000)
Net loss	\$(2,610,986)	\$(1,212,224)
Net loss per share:		
Basic	\$(0.29)	\$(0.14)
Diluted	\$(0.29)	\$(0.14)
Weighted average shares - Basic	9,100,123	8,958,405
Weighted average shares - Diluted	9,100,123	8,958,405

See Accompanying Notes to Consolidated Financial Statements.

Misonix, Inc. and Subsidiaries
Condensed Consolidated Statement of Shareholders' Equity
(Unaudited)

	Common Stock, \$.01 Par Value		Treasury Stock	Additional paid-in capital	Accumulated deficit	Total shareholders' equity
	Number of shares	Amount	Number of shares Amount			
Balance, June 30, 2018	9,430,466	\$94,305	— \$ —	\$39,772,973	\$(15,466,100)	\$24,401,178
Cumulative effect of the adoption of ASC 606 - revenue recognition					\$960,000	960,000
Net loss	—	—	—	—	(2,610,986)	(2,610,986)
Proceeds from exercise of stock options	51,660	517	—	— 415,230		415,747
Stock-based compensation	—	—	—	— 1,004,498	—	1,004,498
Balance, September 30, 2018	9,482,126	\$94,822	— \$ —	\$41,192,701	\$(17,117,086)	\$24,170,437

See Accompanying Notes to Consolidated Financial Statements.

Misonix, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	For the three months ended September 30,	
	2018	2017
Operating activities		
Net loss	\$(2,610,986)	\$(1,212,224)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	366,588	326,420
Disposals of property, plant and equipment	—	112,704
Deferred income tax (benefit)	—	(281,000)
Stock-based compensation	1,004,498	625,293
Deferred income	—	(6,436)
Changes in operating assets and liabilities:		
Accounts receivable	(289,722)	979,878
Inventories	(104,135)	(649,440)
Prepaid expenses and other current assets	28,333	416,438
Intangible, contract and other assets	49,282	—
Accounts payable, accrued expenses and other current liabilities	(178,663)	(1,285,333)
Net cash used in operating activities	(1,734,805)	(973,700)
Investing activities		
Acquisition of property, plant and equipment	(287,506)	(85,129)
Additional patents	(50,080)	(26,403)
Net cash used in investing activities	(337,586)	(111,532)
Financing activities		
Proceeds from exercise of stock options	415,747	56,202
Net cash provided by financing activities	415,747	56,202
Net decrease in cash and cash equivalents	(1,656,644)	(1,029,030)
Cash and cash equivalents at beginning of period	10,979,455	11,557,071
Cash and cash equivalents at end of period	\$9,322,811	\$10,528,041
Supplemental disclosure of cash flow information:		
Cash paid for:		
Income taxes	\$7,678	\$—
Transfer of inventory to property, plant and equipment for consignment of product	\$203,671	\$435,849

See Accompanying Notes to Consolidated Financial Statements.

Misonix, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

For the Three Months Ended September 30, 2018 and 2017 (unaudited)

1. Basis of Presentation, Organization and Business and Summary of Significant Accounting Policies

Basis of Presentation

These condensed consolidated financial statements of Misonix, Inc. (“Misonix” or the “Company”) include the accounts of Misonix and its 100% owned subsidiaries. All significant intercompany balances and transactions have been eliminated.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these financial statements do not include all the information and footnotes required by U.S. GAAP for complete financial statements. As such, they should be read with reference to the Company’s Annual Report on Form 10-K for the fiscal year ended June 30, 2018, which provides a more complete explanation of the Company’s accounting policies, financial position, operating results, business properties and other matters. In the opinion of management, these financial statements reflect all adjustments considered necessary for a fair statement of interim results.

Organization and Business

Misonix designs, manufactures and markets minimally invasive therapeutic ultrasonic medical devices. These products are used for precise bone sculpting, removal of soft and hard tumors, and tissue debridement, primarily in the areas of neurosurgery, orthopedic surgery, plastic surgery, wound care and maxillo-facial surgery. In the United States, our products are marketed primarily through a hybrid sales approach. This includes direct sales representatives, managed by regional sales managers, along with independent distributors. Outside the United States, we sell BoneScalpel and SonaStar to specialty distributors who purchase products from us to resell to their clinical customer bases. We sell to all major markets in the Americas, Europe, Middle East, Asia Pacific and Africa. The Company operates as one business segment.

High Intensity Focused Ultrasound Technology

The Company sold its rights to the high intensity focused ultrasound technology to SonaCare Medical, LLC (“SonaCare”) in May 2010. The Company may receive up to approximately \$5.8 million in payment for the sale. SonaCare will pay the Company 7% of the gross revenues received from its sales of the (i) prostate product in Europe and (ii) kidney and liver products worldwide, until the Company has received payments of \$3 million, and thereafter 5% of the gross revenues, up to an aggregate payment of \$5.8 million, all subject to a minimum annual royalty of \$250,000. No payments were received for the three months ended September 30, 2018 and 2017. Cumulative royalties through September 30, 2018 were \$2,542,579.

Major Customers and Concentration of Credit Risk

Included in revenues are sales to the Company distributor of Bone Scalpel in China of approximately \$1,500,000 and \$0, for the three months ended September 30, 2018 and 2017, respectively. Accounts receivable from this customer were \$10,000 and \$0 at September 30, 2018 and June 30, 2018, respectively.

Total royalties from Medtronic Minimally Invasive Therapies (“MMIT”) related to their sales of the Company’s ultrasonic cutting and sculpting products, which use high frequency sound waves to coagulate and divide tissue for both open and laparoscopic surgery, were \$0 and \$453,000 for the three months ended September 30, 2018 and 2017, respectively. Accounts receivable from MMIT royalties were \$0 at September 30, 2018 and \$0 at June 30, 2018. The license agreement with MMIT expired in August 2017.

At September 30, 2018 and June 30, 2018, the Company's accounts receivable with customers outside the United States were approximately \$1,689,000 and \$1,630,000, respectively, \$370,000 of which is over 90 days at September 30, 2018.

Earnings Per Share

Earnings per share ("EPS") is calculated using the two class method, which allocates earnings among common stock and participating securities to calculate EPS when an entity's capital structure includes either two or more classes of common stock or common stock and participating securities. Unvested share-based payment awards that contain non-forfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities. As such, unvested restricted stock of the Company are considered participating securities. The dilutive effect of options and their equivalents (including non-vested stock issued under stock based compensation plans), is computed using the "treasury" method.

Basic income per common share is based on the weighted average number of common shares outstanding during the period. Diluted income per common share includes the dilutive effect of potential common shares outstanding. The following table sets forth the reconciliation of weighted average shares outstanding and diluted weighted average shares outstanding:

	For the three months ended September 30,	
	2018	2017
Basic weighted average shares outstanding	9,100,123	8,958,405
Dilutive effect of restricted stock awards (participating securities)	—	—
Denominator for basic earnings per share	9,100,123	8,958,405
Dilutive effect of stock options	—	—
Diluted weighted average shares outstanding	9,100,123	8,958,405

Diluted EPS for the three months ended September 30, 2018 and 2017 as presented is the same as basic EPS as the inclusion of the effect of common share equivalents then outstanding would be anti-dilutive. Accordingly, excluded from the calculation of diluted EPS are the dilutive effect of options to purchase 632,301 and 668,751 shares of common stock for the three months ended September 30, 2018 and 2017, respectively. Also excluded from the calculation of earnings per share for the three months ended September 30, 2018 and 2017 are the unvested restricted

stock awards which were issued in December 2016.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued ASC Update No. 2014-09, Revenue from Contracts with Customers (Topic 606), which was subsequently updated. The purpose of the updated standard is to provide enhancements to the quality and consistency of revenue recognition between companies using U.S. GAAP and International Financial Reporting Standards. The new five-step recognition model introduces the core principle of recognizing revenue in an amount that reflects the consideration to which the entity expects to be entitled in exchange for the promised goods or services, which includes additional footnote disclosures to describe the nature, amount, timing and uncertainty of revenue, certain costs and cash flow arising from customers.

As amended, ASU 2014-09 requires the Company to use either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients; or (ii) a modified retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption. This standard became effective for the Company on July 1, 2018 and the Company adopted the new pronouncement under the modified retrospective approach.

In February 2016, the FASB issued guidance on lease accounting requiring lessees to recognize a right-of-use asset and a lease liability for long-term leases. The liability will be equal to the present value of lease payments. This guidance must be applied using a modified retrospective transition approach to all annual and interim periods presented and is effective for the Company beginning in fiscal 2020. The Company is currently in the early stages of evaluating this guidance to determine the impact it will have on its consolidated financial statements.

In August 2016, the FASB issued guidance on the Statement of Cash Flows Classification of certain cash receipts and cash payments (a consensus of the Emerging Issues Task Force). This guidance addresses the following eight specific cash flow issues: Debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies (including bank-owned life insurance policies); distributions received from equity method investees; beneficial interests in securitization transactions; and separately identifiable cash flows and application of the predominance principle. This guidance became effective for the Company beginning in fiscal 2019. As this guidance only affects the classification within the statement of cash flows, ASU 2016-15 did not have a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations: Clarifying the Definition of a Business* ("ASU 2017-01"). ASU 2017-01 clarifies the definition of a business for determining whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. ASU 2017-01 is effective for annual periods and interim periods within those annual periods beginning after December 15, 2017, and early adoption is permitted. The Company adoption of ASU 2017-01 did not have a material effect on the Company's consolidated financial statements.

There are no other recently issued accounting pronouncements that are expected to have a material effect on the Company's financial position, results of operations or cash flows.

Critical Accounting Policies and Use of Estimates

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and judgments that affect the reported amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are used for but not limited

to establishing the allowance for doubtful accounts, valuation of inventory, depreciation, asset impairment evaluations and establishing deferred tax assets and related valuation allowances, and stock-based compensation. Actual results could differ from those estimates.

2. Revenue Recognition

On July 1, 2018 the Company adopted Topic 606 using the modified retrospective method applied to those contracts which were not completed as of the adoption date. The reported results for the quarter ended September 30, 2018 reflect the application of Topic 606 guidance while the reported results for fiscal year 2018 were prepared under the guidance of Topic 605, "Revenue Recognition". The adoption of Topic 606 resulted in a cumulative prior period adjustment in the amount of \$960,000 related to the Company's License and Exclusive Manufacturing Agreement described below, but the remainder of the adoption did not have a material impact on the timing or amount of revenue recognized.

The impacts of adopting ASC Topic 606 on the Company's consolidated balance sheets as of July 1, 2018 were as follows:

	As Reported	ASC 606 Adjustments	As Adjusted Under ASC 606
Long-term contract assets	\$—	\$ 960,000	\$960,000
Total Shareholders' equity	\$24,401,178	\$ 960,000	\$25,361,178

The Company has made the following accounting policy elections and elected to use certain practical expedients, as permitted by the FASB, in applying Topic 606: 1) the Company accounts for amounts collected from customers for sales and other taxes net of related amounts remitted to tax authorities; 2) the Company expenses costs to obtain a contract as they are incurred if the expected period of benefit, and therefore the amortization period, is one year or less; 3) the Company accounts for shipping and handling activities that occur after control transfers to the customer as a fulfillment cost rather than an additional promised service and these fulfillment costs fall within selling, general and administrative expenses; 4) the Company does not assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer; 5) the Company will utilize the right-to-invoice practical expedient with regard to the recognition of revenue upon the purchase of consumable goods in connection with a product placement/consignment arrangement.

The Company determines revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, a performance obligation is satisfied

Contracts and Performance Obligations

The Company accounts for a contract with a customer when there is an approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of the consideration is probable. The Company's performance obligations consist mainly of transferring control of products and related services identified in the contracts, purchase orders or invoices. For each contract, the Company considers the obligation to transfer products or bundled products and services to the customer, of which each is distinct in the context of the contract, to be performance obligations. The Company historically has not made provisions for returns and allowances as they have not been material to the operations of the Company.

Transaction Price and Allocation to Performance Obligations

Transaction prices of products are typically based upon contracted rates as specified on the purchase order for the purchase of consumables which represents the standalone selling price as determined through the sale of products and or bundled products or services separately in similar circumstances to similar customers. The Company determines the effects of variable consideration, inclusive of any constraints, in determining the transaction price with regard to their contracts with customers.

Recognition of Revenue

The Company satisfies performance obligations over time, or at a point in time, upon which control transfers to the customer.

Revenue derived from the shipping and billing of product is recorded upon shipment, when transfer of control for products shipped F.O.B. shipping point. Products shipped F.O.B. destination point are recorded as revenue when received at the point of destination when the transfer of control is completed. Shipments under agreements with distributors are not subject to return, and payment for these shipments is not contingent on sales by the distributor. Accordingly, the Company recognizes revenue on shipments to distributors in the same manner as with other customers under the ship and bill process.

Revenue derived from the rental of equipment is recorded on a monthly basis over the term of the lease. Shipments of consumable products to these rental customers is recorded as orders are received and shipments are made F.O.B. destination or F.O.B. shipping point.

Revenue derived from consignment agreements is earned as consumables product orders are fulfilled. Therefore, revenue is recognized as shipments are made F.O.B shipping point or F.O.B destination.

Revenue derived from service and maintenance contracts is recognized evenly over the life of the service agreement as the services are performed.

Contract Specific Performance Obligations and Significant Judgements

Product Placement/Consignment Agreements

The Company's product placement/consignment agreements include the placement of a generator at the customer's place of business and pricing related to the purchase of consumables for use in conjunction with the generator. These agreements have no stated minimum consumable purchase quantities nor a stated term. The Company considers the transaction price in these arrangements to be fully constrained variable consideration because it is dependent on future sales of consumables to the customer. The Company has determined that the pattern of purchase of consumables by a customer is consistent with the benefit received by the customer for the use of the generator and therefore the Company has a right to consideration based upon the pattern of consumable purchases placed through purchase orders by the customer. The Company's invoices to these customers have short-term payment terms and are aligned with the transfer of goods and services to the customer and the Company recognizes revenue based upon their right to invoice customers.

License and Manufacturing Agreement

On October 19, 2017, the Company entered into a License and Exclusive Manufacturing Agreement (the “Agreement”) with Hunan Xing Hang Rui Kang Bio-technologies Co., Ltd, a Chinese corporation (the “Licensee”) under which Misonix has licensed certain manufacturing and distribution rights to its SonaStar product line in China, Hong Kong and Macau in exchange for payments consisting of initial payments totaling \$5,000,000 for the transfer of functional intellectual property and initial stocking orders of product, and minimum royalty payments of \$2,000,000 per calendar year for three years beginning in 2019, based upon the manufacture of products by the Licensee. \$5,000,000 of initial revenue was collected and recorded for the quarter ended March 31, 2018 under ASC 605. Upon the adoption of Topic 606, the Company evaluated this contract under the provisions of the new revenue standard. The Company determined that the satisfied performance obligations and allocation of the transaction price related to the \$5,000,000 received prior to adoption was consistent with the provisions of ASC 606 and also recorded a transitional adjustment to accumulated deficit in the amount of \$960,000 as follows:

Minimum royalty revenue provided by the contract	\$6,000,000
Implicit price concession	(5,040,000)
Adoption adjustment to accumulated deficit under ASC 606	\$960,000

Although the contract includes minimum royalties, the Company concluded that a significant portion of those guaranteed minimums are actually variable consideration subject to the constraint because the Company has provided an implicit price concession. Specifically, the fact that production of the product in China is not assured and the Licensee must develop a manufacturing process, coupled with the fact that new technology related to this product is expected to be available for sale domestically, may result in the Licensee not earning sufficient revenue in order to pay the minimum royalties. Therefore, the Company has determined variable consideration through utilization of the most likely method based upon forecasts and projections of shipment of products.

The Company will monitor facts and circumstances over time and adjust management's most likely estimate of variable consideration on a quarterly basis.

Disaggregation of Revenue

The Company generates revenue from the sale and leasing of medical equipment and from the sale of consumable products used with such equipment in surgical procedures as well as through product licensing arrangements. In the United States, the Company's products are marketed primarily through a hybrid sales approach which includes direct sales representatives, managed by regional sales managers, along with independent distributors. Outside the United States, the Company sells BoneScalpel and SonaStar to specialty distributors who purchase products to resell to their clinical customer bases. The Company sells to all major markets in the Americas, Europe, Middle East, Asia Pacific, and Africa. Revenue is disaggregated from contracts between products under ship and bill arrangements and licensing agreements, and by geography, which the Company believes best depicts how the nature, amount, timing and uncertainty of revenues and cash flows are affected by economic factors. The Company also provides an immaterial amount of service revenue which is recognized over time, but not stated separately because the amounts are immaterial.

The following table disaggregates the Company's product revenue by classification and location:

	For the three months ended September 30,	
	2018	2017
Total		
Consumables	\$6,339,108	\$5,379,589
Equipment	3,022,056	1,901,134
Total	\$9,361,164	\$7,280,723

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Domestic:		
Consumables	\$4,825,599	\$4,134,918
Equipment	578,919	592,424
Total	\$5,404,518	\$4,727,342

International:		
Consumables	\$1,513,509	\$1,244,671
Equipment	2,443,137	1,308,710
Total	\$3,956,646	\$2,553,381

There was no license revenue for the periods presented.

The following table disaggregates the Company's revenue by geographic location:

	Three months ended September 30,	
	2018	2017
United States	\$5,404,518	\$4,727,342
International	3,956,646	2,553,381
Total Product Revenue	\$9,361,164	\$7,280,723

Contract Assets

The timing of revenue recognition, customer invoicing, and collections produces accounts receivable and contract assets on the Company's consolidated balance sheet. Contract liabilities are not material to the operations of the Company as of September 30, 2018. The Company invoices in accordance with contract payment terms. Customer invoices represent an unconditional right of consideration. When revenue is recognized in advance of customer invoicing a contract asset is recorded. Unpaid customer invoices are reflected as accounts receivable.

The contract asset represents an asset in conjunction with the Company's License and Manufacturing Agreement related to the most likely variable consideration associated with the royalty provisions in the contract. The asset is recorded as a long-term asset as the Company believes that payment will be made on this asset in a duration to exceed one year.

Selling Costs

Incremental direct costs of obtaining a contract primarily include sales commissions paid to sales personnel and outside sales representatives in connection with sales of products under ship and bill scenarios or through product placement scenarios. The expected period of benefit of these costs is one year or less and therefore the Company has elected the practical expedient to expense such costs in the period in which they are incurred. Typically, these costs represent shipping and handling costs and the Company accounts for these costs as fulfillment costs and are expensed as incurred. Costs in fulfilling a contract are only capitalized as an asset if they relate directly to an existing contract or specific anticipated contract, they generate or enhance resources of the entity that will be used to satisfy performance obligations in the future, and they are expected to be recovered. The Company has not identified any such costs.

3. Fair Value of Financial Instruments

The Company follows a three-level fair value hierarchy that prioritizes the inputs to measure fair value. This hierarchy requires entities to maximize the use of "observable inputs" and minimize the use of "unobservable inputs." The three levels of inputs used to measure fair value are as follows:

Level 1: Quoted prices (unadjusted) for identical assets or liabilities in active markets as of the measurement date.

Level 2: Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

Level 3: Significant unobservable inputs that reflect assumptions that market participants would use in pricing an asset or liability.

At September 30, 2018 and June 30, 2018, all of the Company's cash and cash equivalents, trade accounts receivable and trade accounts payable were short term in nature, and their carrying amounts approximate fair value.

4. Inventories

Inventories are summarized as follows:

	September 30, 2018	June 30, 2018
Raw material	\$3,057,058	\$3,540,205
Work-in-process	186,186	180,442
Finished goods	2,121,364	1,743,497
	5,364,608	5,464,144
Less valuation reserve	(444,258)	(444,258)
	\$4,920,350	\$5,019,886

5. Property, Plant and Equipment

Depreciation and amortization of property, plant and equipment was \$333,000 and \$296,000 for the three months ended September 30, 2018 and 2017, respectively. Inventory items included in property, plant and equipment are depreciated using the straight line method over estimated useful lives of 3 to 5 years. Depreciation of generators which are consigned to customers is expensed over a 5 year period, and depreciation is charged to selling expenses.

6. Goodwill

Goodwill is not amortized. The Company reviews goodwill for impairment annually and whenever events or changes indicate that the carrying value of an asset may not be recoverable. These events or circumstances could include a significant change in the business climate, legal factors, operating performance indicators, competition, or sale or disposition of significant assets or products. Application of these impairment tests requires significant judgments, including estimation of cash flows, which is dependent on internal forecasts, estimation of the long term rate of growth for the Company's business, the useful lives over which cash flows will occur and determination of the Company's weighted average cost of capital. The Company primarily utilizes the Company's market capitalization and a discounted cash flow model in determining the fair value which consists of Level 3 inputs. Changes in the projected cash flows and discount rate estimates and assumptions underlying the valuation of goodwill could materially affect the determination of fair value at acquisition or during subsequent periods when tested for impairment. The Company completed its annual goodwill impairment tests for fiscal 2018 and 2017 as of June 30 of each year. There were no triggering events identified during the quarter ended September 30, 2018.

7. Patents

The costs of acquiring or processing patents are capitalized at cost. These amounts are being amortized using the straight-line method over the estimated useful lives of the underlying assets, which is approximately 17 years. Patents, net of accumulated amortization, totaled \$773,668 and \$757,447 at September 30, 2018 and June 30, 2018, respectively. Amortization expense for the three months ended September 30, 2018 and 2017 was \$34,000 and \$30,000, respectively. The following is a schedule of estimated future patent amortization expenses by fiscal year as of September 30, 2018:

2019	\$96,335
2020	\$106,103
2021	\$99,932
2022	\$67,385
2023	\$66,315

8. Accrued Expenses and Other Current Liabilities

The following summarizes accrued expenses and other current liabilities:

	September 30, 2018	June 30, 2018
Accrued payroll, payroll taxes and vacation	\$633,656	\$351,435
Accrued bonus	170,596	552,988
Accrued commissions	484,226	742,807
Professional fees	36,000	102,065
Deferred foreign taxes	401,000	401,000
Vendor, tax and other accruals	619,425	661,877
	\$2,344,903	\$2,812,172

9. Stock-Based Compensation Plans

Stock Option Awards

For the three months ended September 30, 2018 and 2017, the compensation cost relating to stock option awards that has been charged against income for the Company's stock option plans was \$278,121 and \$398,359 respectively. As of September 30, 2018, there was \$2,996,027 of total unrecognized compensation cost related to non-vested share-based compensation arrangements to be recognized over a weighted-average period of 2.7 years.

Stock options typically expire 10 years from the date of grant and vest over service periods, which typically are 4 years. All options are granted at fair market value, as defined in the applicable plans.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. The expected volatility represents the historical price changes of the Company's stock over a period equal to that of the expected term of the option. The Company uses the simplified method for determining the option term. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant. The expected dividend yield is based upon historical and projected dividends. The

Company has historically not paid dividends, and is not expected to do so in the near term.

The weighted average fair value per share at date of grant for options granted during the three months ended September 30, 2018 was \$8.62. There were options to purchase 137,000 and 172,500 shares granted during the three months ended September 30, 2018 and 2017, respectively. The fair value was estimated based on the weighted average assumptions of:

	For three months ended September 30, 2018		2017	
Risk-free interest rates	2.87	%	1.86	%
Expected option life in years	6.25		5.72	
Expected stock price volatility	55.39	%	59.52	%
Expected dividend yield	0	%	0	%

A summary of option activity under the Company's equity plans as of September 30, 2018, and changes during the three months ended September 30, 2018 is presented below:

	Outstanding Shares	Average Exercise Price	Aggregate Intrinsic Value
Outstanding at June 30, 2018	1,330,193	\$ 8.47	\$5,369,557
Granted	137,000	15.55	
Exercised	(51,660)	8.05	
Forfeited	(55,627)	9.16	
Expired	(15,000)	2.66	
Outstanding as of September 30, 2018	1,344,906	\$ 9.31	\$12,364,220
Vested and exercisable at September 30, 2018	710,280	\$ 8.04	\$7,428,351

The total fair value of stock options vested during the three months ended September 30, 2018 was \$526,729. The number and weighted-average grant-date fair value of non-vested stock options at the beginning of fiscal 2018 was 648,877 and \$5.08, respectively. The number and weighted-average grant-date fair value of stock options which vested during the three months ended September 30, 2018 was 95,624 and \$5.51, respectively.

Restricted Stock Awards

On December 15, 2016, the Company issued 400,000 shares of restricted stock to its Chief Executive Officer. These awards vest over a period of up to five years, subject to meeting certain service, performance and market conditions. These awards were valued at approximately \$3.6 million. Compensation expense recorded in the three months ended September 30, 2018 and 2017 related to these awards was \$726,377 and \$226,934 respectively. As of September 30, 2018, there was approximately \$1,552,272 of total unrecognized compensation cost related to non-vested restricted stock awards to be recognized over a weighted-average period of 3.06 years. The awards contain a combination of vesting terms which include time vesting, performance vesting relating to revenue achievement, and market vesting related to obtaining certain levels of Company stock prices. At September 30, 2018, the Company has estimated that it is probable that the performance conditions will be met. The awards were valued using a Monte Carlo valuation model using a stock price at the date of grant of \$9.60, a term of 3 to 5 years, a risk free interest rate of 1.6% to 2.1% and a volatility factor of 66.5%. As of September 30, 2018, 186,600 shares from this set of awards have vested.

During the three months ended September 30, 2018, the performance conditions of one of these restricted stock awards were met, resulting in the full amortization of this award during the quarter. The number of restricted stock awards which vested was 133,333 and the related compensation expense during the quarter was \$573,686.

10. Commitments and Contingencies

Leases

The Company has entered into several non-cancellable operating leases for the rental of certain manufacturing and office space, equipment and automobiles expiring in various years through 2021. The principal building lease provides for a monthly rental of approximately \$28,000.

Former Chinese Distributor - FCPA

With the assistance of outside counsel, the Company conducted a voluntary investigation into the business practices of the independent Chinese entity that previously distributed its products in China and the Company's knowledge of those business practices, which may have implications under the FCPA, as well as into various internal controls issues identified during the investigation (the "Investigation").

On September 27, 2016 and September 28, 2016, the Company voluntarily contacted the SEC and the DOJ, respectively, to advise both agencies of these potential issues. The Company has provided and will continue to provide documents and other information to the SEC and the DOJ, and is cooperating fully with these agencies in their ongoing investigations of these matters.

Although the Company's investigation is complete, additional issues or facts could arise which may expand the scope or severity of the potential violations. The Company has no current information derived from the investigation or otherwise to suggest that its previously reported financial statements and results are incorrect.

At this stage, the Company is unable to predict what, if any, action the DOJ or the SEC may take or what, if any, penalties or remedial measures these agencies may seek. Nor can the Company predict the impact on the Company as a result of these matters, which may include the imposition of fines, civil and criminal penalties, which are not currently estimable, as well as equitable remedies, including disgorgement of any profits earned from improper conduct and injunctive relief, limitations on the Company's conduct, and the imposition of a compliance monitor. The DOJ and the SEC periodically have based the amount of a penalty or disgorgement in connection with an FCPA action, at least in part, on the amount of profits that a company obtained from the business in which the violations of the FCPA occurred. During its distributorship relationship with the prior Chinese distributor from 2010 through 2016, the Company generated revenues of approximately \$8 million.

Further, the Company may suffer other civil penalties or adverse impacts, including lawsuits by private litigants in addition to the lawsuits that already have been filed, or investigations and fines imposed by local authorities. The investigative costs to date are approximately \$3.1 million, of which approximately \$0.1 million and \$0.2 million was charged to general and administrative expenses during the three months ended September 30, 2018 and 2017 respectively.

Former Chinese Distributor – Litigation

On April 5, 2017, the Company's former distributor in China, Cikel (Beijing) Science & Technology Co., Ltd., filed a lawsuit against the Company and certain officers and directors of the Company in the United States District Court for the Eastern District of New York, alleging that the Company improperly terminated its contract with the former distributor. The complaint sought various remedies, including compensatory and punitive damages, specific performance and preliminary and post judgment injunctive relief, and asserted various causes of action, including breach of contract, unfair competition, tortious interference with contract, fraudulent inducement, and conversion. On October 7, 2017, the court granted the Company's motion to dismiss all of the tort claims asserted against it, and also granted the individual defendants' motion to dismiss all claims asserted against them. The only claim currently remaining in the case is for breach of contract against the Company; the plaintiff has moved to amend its complaint to add tort claims, which the Company has opposed. The Company believes it has various legal and factual defenses to the allegations in the complaint, and intends to vigorously defend the action. The case is at its earliest stages; discovery is just beginning and there is no trial date.

Stockholder Derivative Litigation

On June 6, 2017, Irving Feldbaum, an individual shareholder of Misonix, filed a lawsuit in the U.S. District Court for the Eastern District of New York. The complaint alleges claims against the Company's board of directors, its former CEO and CFO, certain of its former directors, and the Company as a nominal defendant for alleged violations of Section 14(a) of the Securities Exchange Act of 1934 and state law claims for breach of fiduciary duty, waste of corporate assets, and unjust enrichment. The complaint alleges that the Company incurred damages as a result of alleged false and misleading statements in the Company's securities filings concerning the Company's business, operations, and prospects and the Company's internal control over financial reporting. The complaint also alleges that the Company's February 4, 2016 Proxy Statement contained false and misleading statements regarding executive compensation. The complaint seeks the recovery of damages on behalf of the Company and the implementation of changes to corporate governance procedures. On June 16, 2017, Michael Rubin, another individual shareholder of Misonix, filed a case alleging similar claims in the same district court. On July 21, 2017, the district court consolidated the two actions for all purposes. On July 16, 2018, the Company and counsel for Mr. Feldbaum and Mr. Rubin informed the District Court that the parties had reached a settlement in principle. There are aspects of the settlement that remain to be negotiated and documented, and the settlement is subject to approval by the District Court after notice to the Company's shareholders.

11. Related Party Transactions

OrthoXact Proprietary Limited (“OrthoXact”) (formerly Applied BioSurgical) is an independent distributor for the Company in South Africa. The chief executive officer of OrthoXact is also the brother of Stavros G. Vizirgianakis, the CEO of Misonix, Inc.

Set forth below is a table showing the Company’s net revenues for the three months ended September 30 and accounts receivable at September 30 for the indicated time periods below with OrthoXact:

	For the three months ended September 30, 2018 2017	
Sales	\$296,881	\$169,340
Accounts receivable	\$236,478	\$154,475

12. Income Taxes

For the three months ended September 30, 2018 and 2017, the Company recorded income tax expense (benefit), as follows:

	For the three months ended September 30, 2018 2017	
Income tax benefit	\$(427,000)	\$(281,000)
Valuation allowance on deferred tax asset	427,000	—
Net income tax benefit	\$—	\$(281,000)

For the three months ended September 30, 2018 and 2017, the effective rate of 0% and 18.8%, respectively, varied from the U.S. federal statutory rate primarily due to the recording of a full valuation allowance on the remaining deferred tax assets, permanent book tax differences relating principally to stock compensation expense and tax credits, and the impact of the Tax Cuts and Jobs Act of 2017.

Tax Cuts and Jobs Act of 2017

The Tax Cuts and Jobs Act of 2017, enacted on December 22, 2017, contains significant changes to U.S. tax law, including lowering the U.S. corporate income tax rate to 21%, implementing a territorial tax system, and imposing a one-time tax on deemed repatriated earnings of foreign subsidiaries.

Valuation Allowance on Deferred Tax Assets

Deferred tax assets refer to assets that are attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets in essence represent future savings of taxes that would otherwise be paid in cash. The realization of the deferred tax assets is dependent upon the generation of sufficient future taxable income, including capital gains. If it is determined that the deferred tax assets cannot be realized, a valuation allowance must be established, with a corresponding charge to net income.

In accordance with ASC Topic 740, the Company establishes valuation allowances for deferred tax assets that, in its judgment are not more likely-than-not realizable. The guidance requires entities to evaluate all available positive and negative evidence, including cumulative results in recent periods, weighted based on its objectivity, in determining whether its deferred tax assets are more likely than not realizable.

The Company regularly assesses its ability to realize its deferred tax assets. While the Company had positive cumulative pretax income as of June 30, 2017, based on actual results for fiscal 2018 and the Company's current forecast for fiscal 2019 the Company is in a three-year cumulative loss position at September 30, 2018, and it expects to be in a cumulative pretax loss position as of September 30, 2019. Management evaluated available positive evidence, including the continued growth of the Company's revenues and gross profit margins, its recent SonaStar technology license to its Chinese partner and the reduction in investigative and professional fees recognized in fiscal 2017, along with available negative evidence, including the Company's continuing investment in building its next generation Nexus platform and its continuing investment in building a direct sales force, while at the same time paying commissions to its domestic sales distributors. After weighing both the positive and negative evidence, management concluded that the Company's deferred tax assets are not more likely-than-not realizable. Accordingly, the Company recorded a full valuation allowance against its deferred tax assets as of December 31, 2017 and has continued to record valuation allowances against its deferred tax assets through September 30, 2018. The Company will continue to assess its ability to utilize its net operating loss carryforwards, and will reverse this valuation allowance when sufficient evidence is achieved to allow the realizability of such deferred tax assets.

As of September 30, 2018 and June 30, 2018, the Company had no material unrecognized tax benefits or accrued interest and penalties.

13. Segment Reporting

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision-maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance of the segment. The Company has concluded that its Chief Executive Officer is the CODM as he is the ultimate decision maker for key operating decisions, determining the allocation of resources and assessing the financial performance of the Company. These decisions, allocations and assessments are performed by the CODM using consolidated financial information. Consolidated financial information is utilized by the CODM as the Company's current product offering primarily consists of minimally invasive therapeutic ultrasonic medical devices. The Company's products are relatively consistent and manufacturing is centralized and consistent across product offerings. Based on these factors, key operating decisions and resource allocations are made by the CODM using consolidated financial data and as such the Company has concluded that it operates as one segment.

Worldwide revenue for the Company's products and license revenue is categorized as follows:

For the three months ended	Net Change	
September 30,	\$	%

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	2018	2017		
Domestic	\$5,404,518	\$4,727,342	\$677,176	14.3%
International	3,956,646	2,553,381	1,403,265	55.0%
Total	\$9,361,164	\$7,280,723	\$2,080,441	28.6%

Substantially all of the Company's long-lived assets are located in the United States.

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

This Management’s Discussion and Analysis of Financial Condition and Results of Operations of Misonix and its subsidiaries, which we refer to as the “Company”, “Misonix”, “we”, “our” and “us”, should be read in conjunction with the accompanying unaudited financial statements included in Part I – Item 1 “Financial Statements” of this Report and Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the “SEC”) on September 13, 2018, for the fiscal year ended June 30, 2018 (“2018 Form 10-K”). Item 7 of the 2018 Form 10-K describes the application of our critical accounting policies, for which there have been no significant changes during the three months ended September 30, 2018.

Forward Looking Statements

With the exception of historical information contained in this Form 10-Q, content herein may contain “forward looking statements” that are made pursuant to the Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995. These statements are based on management’s current expectations and are subject to uncertainty and changes in circumstances. We cannot guarantee that any forward looking statements will be accurate, although we believe that we have been reasonable in our expectations and assumptions. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from our expectations and projections. These factors include general economic conditions, delays and risks associated with the performance of contracts, risks associated with international sales and currency fluctuations, uncertainties as a result of research and development, acceptable results from clinical studies, including publication of results and patient/procedure data with varying levels of statistical relevance, risks involved in introducing and marketing new products, regulatory compliance, potential acquisitions, consumer and industry acceptance, litigation and/or contemplated 510(k) filings, the ability to achieve and maintain profitability in our business lines, the pending FCPA investigation and other factors discussed in the 2018 Form 10-K, subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We disclaim any obligation to update any forward-looking statements.

Overview

Misonix designs, manufactures and markets minimally invasive therapeutic ultrasonic medical devices. These products are used for precise bone sculpting, removal of soft and hard tumors, and tissue debridement, primarily in the areas of neurosurgery, orthopedic surgery, plastic surgery, wound care and maxillo-facial surgery. In the United States, the Company sells its products through its direct sales force, in addition to a network of commissioned agents assisted by Company personnel. Outside of the United States, the Company generally sells to distributors who then resell the products to hospitals. The Company operates as one business segment.

In the United States, the Company is taking a more aggressive approach to taking market share, expanding the market and increasing its share of recurring disposable revenue by using a consignment model, whereby the Company will consign the equipment (which is defined as a generator, hand units and accessories) (the "Equipment") and sell to customers higher margin disposable, single use items (the "Consumables") on a recurring basis. Title remains with the Company with respect to consigned Equipment, which is depreciated and charged to selling expenses over a five year period. Outside of the United States, the Company has principally not yet adopted a consignment model. The Company's overall goal is to increase the utilization rate of Equipment which will increase the total number of procedures and maximize the sale of Consumables to our customers, with the goal of becoming the standard of care in the medical procedures we focus on.

Results of Operations

The following discussion and analysis provides information which the Company's management believes is relevant to an assessment and understanding of the Company's results of operations and financial condition. This discussion should be read in conjunction with the consolidated financial statements and notes thereto appearing elsewhere herein. Unless otherwise specified, this discussion relates solely to the Company's operations.

All of the Company's revenues have been derived from the sale of medical device products, which include manufacture and distribution of ultrasonic medical device products.

Three months ended September 30, 2018 and 2017

Our revenues by category for the three months ended September 30, 2018 and 2017 are as follows:

	For the three months ended		Net change	
	September 30,		\$	%
	2018	2017		
Total				
Consumables	\$6,339,108	\$5,379,589	\$959,519	17.8%
Equipment	3,022,056	1,901,134	1,120,922	59.0%
Total	\$9,361,164	\$7,280,723	\$2,080,441	28.6%
Domestic:				
Consumables	\$4,825,599	\$4,134,918	\$690,681	16.7%
Equipment	578,919	592,424	(13,505)	-2.3%
Total	\$5,404,518	\$4,727,342	\$677,176	14.3%
International:				
Consumables	\$1,513,509	\$1,244,671	\$268,838	21.6%
Equipment	2,443,137	1,308,710	1,134,427	86.7%
Total	\$3,956,646	\$2,553,381	\$1,403,265	55.0%

Revenues

Total revenue increased 28.6% or \$2.1 million to \$9.4 million in the first quarter of fiscal 2019, from \$7.3 million in the first quarter of fiscal 2018.

The revenue increase is principally attributable to a 17.8% or \$1.0 million increase in consumables revenue, in addition to a 59.0% or \$1.1 million increase in equipment revenue. The BoneScalpel and SonicOne product lines both performed well during the quarter.

There was no license revenue during the first quarter of fiscal 2019 or fiscal 2018.

Gross profit

Gross profit from product revenue in the first quarter of fiscal 2019 was 70.6% of revenue, slightly higher from 70.1% in the first quarter of fiscal 2018, resulting from product mix.

Selling expenses

Selling expenses increased by \$1.2 million, or 32.6% to \$4.7 million in the first quarter of fiscal 2019 from \$3.6 million in the prior year period. The increase is principally related to higher compensation costs and travel related expenses resulting from the continued buildout of the Company's direct sales force, along with higher trade show and sales training expenses.

General and administrative expenses

General and administrative expenses increased by \$0.6 million, or 23.7% to \$3.2 million in the first quarter of fiscal 2019 from \$2.6 million in the prior year period. This increase is principally related to a non-cash compensation charge of \$475,000 related to an acceleration of vesting on an existing restricted stock award, where market conditions were met to allow for the early vesting of the award. In addition, the Company incurred higher regulatory professional fees of \$240,000, in part for new product registrations, and incurred a \$150,000 severance charge during the quarter. These expense increases were partially offset by cost reductions put into place over the past year.

Research and development expenses

Research and development expenses increased by \$0.4 million or 45% to \$1.3 million in the first quarter of fiscal 2019 from \$0.9 million in the prior year period. The Company is investing in the design and development of its next generation platform product, Nexus, which is expected to be available in fiscal 2019. During the first quarter of fiscal 2019, approximately \$0.6 million was charged to research and development expenses related to this product.

Other income (expense)

Other income was \$1,548 in the first quarter of fiscal 2019 compared with \$0.4 million in the prior year period. This decrease related to the royalty income from MMIT in the prior year. This royalty agreement expired in August 2017.

Income taxes

For the three months ended September 30, 2018 and 2017, the Company recorded an income tax expense (benefit) of \$0 and (\$281,000), respectively. For the three months ended September 30, 2018 and 2017, the effective rate of 0% and 18.8%, respectively, varied from the U.S. federal statutory rate due to changes in the Company's projected pretax book income.

Income tax expense for the quarter ended September 30, 2018 includes a \$427,000 valuation allowance against the Company's deferred tax asset recorded in the quarter. In accordance with the guidance of ASC Topic 740, management concluded that in its judgment, the Company's deferred tax assets at September 30, 2018 are not more likely-than-not realizable. The components of the tax provision are as follows:

	For the three months ended September 30,	
	2018	2017
Income tax benefit	\$(427,000)	\$(281,000)
Valuation allowance on deferred tax asset	427,000	—
Net income tax benefit	\$—	\$(281,000)

Liquidity and Capital Resources

Working capital at September 30, 2018 was \$15.9 million. For the three months ended September 30, 2018, cash used in operations was \$1.7 million, mainly due a use of \$0.5 million for working capital and the loss from operations during the quarter.

Cash used in investing activities was \$0.3 million, primarily consisting of the purchase of property, plant and equipment along with filing for additional patents.

Cash provided by financing activities was \$0.4 million, resulting from stock option exercises.

As of September 30, 2018, the Company had cash and cash equivalents of approximately \$9.3 million and believes it has sufficient cash to finance operations for at least the next 12 months.

Relating to the internal investigation described herein, the Company has incurred approximately \$3.1 million in investigative costs through September 30, 2018 and is not expected to incur significant additional investigative costs to resolve this matter. Further, the Company could be subject to fines or penalties related to potential violations of the FCPA.

The Company is investing in the design and development of its next generation platform product, which is expected to be available in fiscal 2019 of which \$0.6 million in development costs have been incurred during the three months ended September 30, 2018.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on the Company's financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to the Company.

Other

In the opinion of management, inflation has not had a material effect on the operations of the Company.

Recent Accounting Pronouncements

See Note 1 to our consolidated financial statements included herein.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market Risk:

The principal market risks (i.e., the risk of loss arising from adverse changes in market rates and prices) to which the Company is exposed are interest rates on cash and cash equivalents.

Interest Rate Risk:

The Company earns interest on cash balances and pays interest on any debt incurred. In light of the Company's existing cash, results of operations and projected borrowing requirements, the Company does not believe that a 10% change in interest rates would have a significant impact on its consolidated financial position.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

All internal control systems, no matter how well designed and tested, have inherent limitations, including, among other things, the possibility of human error, circumvention or disregard. Therefore, even those systems of internal control that have been determined to be effective can provide only reasonable assurance that the objectives of the control system are met and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Material Weakness

In the 2018 Form 10-K, we disclosed that management conducted an evaluation of the effectiveness of our internal control over financial reporting as of June 30, 2018, based on the criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based upon this evaluation, management determined, because of a lack of consistency in the approval of manual journal entries to the general ledger, a material weakness existed at June 30, 2018, as described below. In light of such material weakness, management concluded that our internal control over financial reporting was ineffective as of June 30, 2018.

The Company's financial procedures require that when preparing a journal entry for posting to the general ledger, such journal entry requires the review and written approval of the appropriate finance personnel, other than the individual creating the journal entry. The Company identified a number of instances where journal entries did not contain evidence of the proper written approval. To remediate the design of this control, the Company has converted its entire operation, effective July 1, 2018, onto a new NetSuite ERP system, from its legacy ERP system. The legacy system required a higher number of manual journal entries, compared with the new system which will require fewer manual journal entries because of the level of system integration and sophistication. In addition, the Company has

implemented procedures to ensure that all journal entries are properly approved including a review at month end by the CFO to ensure that all journal entries are properly authorized.

The identified control deficiency did not result in any material misstatements in our financial statements. However, this control deficiency created a reasonable possibility that a material misstatement to the consolidated financial statements would not be prevented or detected on a timely basis. Accordingly, we concluded that the control deficiency represented a material weakness in our internal control over financial reporting and our internal control over financial reporting was not effective.

Evaluation at September 30, 2018

We carried out an evaluation, under the supervision and with the participation of management, of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2018. Based on this evaluation, our CEO and CFO have concluded that our disclosure controls and procedures were not effective as of September 30, 2018. While the Company believes it has remediated the design of the control described above, it is still in the process of testing its operating effectiveness.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2018 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

Former Chinese Distributor - FCPA

With the assistance of outside counsel, the Company conducted a voluntary investigation into the business practices of the independent Chinese entity that previously distributed its products in China and the Company's knowledge of those business practices, which may have implications under the FCPA, as well as into various internal controls issues identified during the investigation (the "Investigation").

On September 27, 2016 and September 28, 2016, the Company voluntarily contacted the SEC and the DOJ, respectively, to advise both agencies of these potential issues. The Company has provided and will continue to provide documents and other information to the SEC and the DOJ, and is cooperating fully with these agencies in their ongoing investigations of these matters.

Although the Company's investigation is complete, additional issues or facts could arise which may expand the scope or severity of the potential violations. The Company has no current information derived from the investigation or otherwise to suggest that its previously reported financial statements and results are incorrect.

At this stage, the Company is unable to predict what, if any, action the DOJ or the SEC may take or what, if any, penalties or remedial measures these agencies may seek. Nor can the Company predict the impact on the Company as a result of these matters, which may include the imposition of fines, civil and criminal penalties, which are not currently estimable, as well as equitable remedies, including disgorgement of any profits earned from improper conduct and injunctive relief, limitations on the Company's conduct, and the imposition of a compliance monitor. The DOJ and the SEC periodically have based the amount of a penalty or disgorgement in connection with an FCPA action, at least in part, on the amount of profits that a company obtained from the business in which the violations of the FCPA occurred. During its distributorship relationship with the prior Chinese distributor from 2010 through 2016, the Company generated revenues of approximately \$8 million.

Further, the Company may suffer other civil penalties or adverse impacts, including lawsuits by private litigants in addition to the lawsuits that already have been filed, or investigations and fines imposed by local authorities. The investigative costs to date are approximately \$3.1 million, of which approximately \$0.1 million and \$0.2 million was

charged to general and administrative expenses during the three months ended September 30, 2018 and 2017, respectively.

Former Chinese Distributor – Litigation

On April 5, 2017, the Company's former distributor in China, Cikel (Beijing) Science & Technology Co., Ltd., filed a lawsuit against the Company and certain officers and directors of the Company in the United States District Court for the Eastern District of New York, alleging that the Company improperly terminated its contract with the former distributor. The complaint sought various remedies, including compensatory and punitive damages, specific performance and preliminary and post judgment injunctive relief, and asserted various causes of action, including breach of contract, unfair competition, tortious interference with contract, fraudulent inducement, and conversion. On October 7, 2017, the court granted the Company's motion to dismiss all of the tort claims asserted against it, and also granted the individual defendants' motion to dismiss all claims asserted against them. The only claim currently remaining in the case is for breach of contract against the Company; the plaintiff has moved to amend its complaint to add tort claims, which the Company has opposed. The Company believes it has various legal and factual defenses to the allegations in the complaint, and intends to vigorously defend the action. The case is at its earliest stages; discovery is just beginning and there is no trial date.

Stockholder Derivative Litigation

On June 6, 2017, Irving Feldbaum, an individual shareholder of Misonix, filed a lawsuit in the U.S. District Court for the Eastern District of New York. The complaint alleges claims against the Company's board of directors, its former CEO and CFO, certain of its former directors, and the Company as a nominal defendant for alleged violations of Section 14(a) of the Securities Exchange Act of 1934 and state law claims for breach of fiduciary duty, waste of corporate assets, and unjust enrichment. The complaint alleges that the Company incurred damages as a result of alleged false and misleading statements in the Company's securities filings concerning the Company's business, operations, and prospects and the Company's internal control over financial reporting. The complaint also alleges that the Company's February 4, 2016 Proxy Statement contained false and misleading statements regarding executive compensation. The complaint seeks the recovery of damages on behalf of the Company and the implementation of changes to corporate governance procedures. On June 16, 2017, Michael Rubin, another individual shareholder of Misonix, filed a case alleging similar claims in the same district court. On July 21, 2017, the district court consolidated the two actions for all purposes. On July 16, 2018, the Company and counsel for Mr. Feldbaum and Mr. Rubin informed the District Court that the parties had reached a settlement in principle. There are aspects of the settlement that remain to be negotiated and documented, and the settlement is subject to approval by the District Court after notice to the Company's shareholders.

Item 1A. Risk Factors.

Risks and uncertainties that, if they were to occur, could materially adversely affect our business or that could cause our actual results to differ materially from the results contemplated by the forward-looking statements contained in this Report and other public statements were set forth in the Item 1A. – "Risk Factors" section of our Form 10-K for the fiscal year ended June 30, 2018. There have been no material changes from the risk factors disclosed in that Form 10-K.

Item 6. Exhibits

Exhibit No.	Description
<u>31.1</u>	<u>Chief Executive Officer—Certification pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>31.2</u>	<u>Chief Financial Officer—Certification pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>

32.1 Chief Executive Officer—Certification pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2 Chief Financial Officer—Certification pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS XBRL Instance Document

101.SCH XBRL Taxonomy Extension Scheme Document

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF XBRL Taxonomy Extension Definition Linkbase Document

101.LAB XBRL Taxonomy Extension Label Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

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.

MISONIX, INC.

Dated: November 8, 2018 By: /s/ Stavros G. Vizirgianakis
Stavros G. Vizirgianakis
Chief Executive Officer

By: /s/ Joseph P. Dwyer
Joseph P. Dwyer
Chief Financial Officer