

MISONIX INC
Form 10-Q
March 13, 2017

**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
p

For the quarterly period ended September 30, 2016

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
Farmingdale, New York**

11735

Edgar Filing: MISONIX INC - Form 10-Q

(Address of principal executive offices)

(Zip code)

(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 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

" Yes No

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

Large accelerated filer " Accelerated filer Non-accelerated filer " Smaller reporting company "

(Do not check if a smaller reporting company)

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

" Yes No

Indicate the number of shares outstanding of the issuer's common stock as of the latest practicable date: As of March 1, 2017 there were 9,023,354 shares of the registrant's common stock, \$0.01 par value, outstanding.

MISONIX INC.

	Page
<u>PART I — FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements</u>	4
<u>Consolidated Balance Sheets at September 30, 2016 (Unaudited) and June 30, 2016</u>	4
<u>Consolidated Statements of Operations for the Three Months ended September 30, 2016 and 2015 (Unaudited)</u>	5
<u>Consolidated Statement of Shareholders' Equity for the Three Months ended September 30, 2016 (Unaudited)</u>	6
<u>Consolidated Statements of Cash Flows for the Three Months ended September 30, 2016 and 2015 (Unaudited)</u>	7
<u>Notes to Consolidated Financial Statements (Unaudited)</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	20
<u>Item 4. Controls and Procedures</u>	21
<u>PART II — OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	24
<u>Item 1A. Risk Factors</u>	24
<u>Item 6. Exhibits</u>	25
<u>Signatures</u>	26

Explanatory Note

Misonix, Inc. (“Misonix”, the “Company”, “we” or “us”) was not able to file this Quarterly Report on Form 10-Q (the “Q1 10-Q”) for the three months ended September 30, 2016 by its due date. For several months, with the assistance of outside counsel, we have been conducting a voluntary investigation into the business practices of the independent Chinese entity that previously distributed our products in China and the Company’s knowledge of those business practices, which may have implications under the Foreign Corrupt Practices Act (“FCPA”), as well as into various internal controls issues identified during the investigation (the “Investigation”). On September 27, 2016 and September 28, 2016, we voluntarily contacted the Securities and Exchange Commission (“SEC”) and the U.S. Department of Justice (“DOJ”), respectively, to advise both agencies of these potential issues. We have provided and will continue to provide documents and other information to the SEC and the DOJ, and are cooperating fully with these agencies in their investigations of these matters.

Although our Investigation is now complete, additional issues or facts could arise which may expand the scope or severity of the potential violations. We could also receive additional requests from the DOJ or SEC, which may require further investigation. We have no current information derived from the Investigation or otherwise to suggest that our previously reported financial statements and results are incorrect.

Our management has determined, because of the findings from the Investigation, and the Company’s inability to rely on certain personnel, processes and internal controls, that material weaknesses in internal control over financial reporting existed at September 30, 2016. In light of such material weaknesses, management has concluded that the Company’s internal control over financial reporting was ineffective as of September 30, 2016. We have since implemented the changes, controls and procedures as described in Part I - Item 4 “Controls and Procedures” which we believe are necessary to remediate these weaknesses.

On September 15, 2016, we received a deficiency letter from The Nasdaq Stock Market LLC (“Nasdaq”) indicating that the Company, as a result of not filing the Annual Report on Form 10-K (the “10-K”) for the fiscal year ended June 30, 2016 on September 13, 2016 and disclosing that the Company likely would not be able to file the 10-K within the 15-day extension period provided in Rule 12b-25(b) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), was not in compliance with Listing Rule 5250(c)(1) of the Nasdaq Listing Rules (the “Rules”) for continued listing. In addition, on November 10, 2016, we received a second deficiency letter from Nasdaq indicating that the Company, as a result of not filing the Q1 10-Q by November 9, 2016, together with our prior failure to timely file the 10-K, was not in compliance with Listing Rule 5250(c)(1) for continued listing. In the letters, Nasdaq requested that Misonix submit a plan to regain compliance with the Rules by November 14, 2016. On November 14, 2016, Misonix submitted to Nasdaq a plan to regain compliance with the Rules. After reviewing Misonix’s plan to regain compliance, Nasdaq granted an exception to enable the Company to regain compliance with the Rules. Under the terms of the exception, Misonix must file its 10-K and Q1 10-Q on or before March 13, 2017. In the event that Misonix does not satisfy the terms set forth in the extension, Nasdaq will provide written notification that Misonix’s common stock will be delisted. At that time, Misonix may appeal Nasdaq’s determination for a panel review. We filed

the 10-K with the SEC on February 9, 2017.

On February 10, 2017, we received a third deficiency letter from Nasdaq indicating that the Company, as a result of not filing its Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2016 (the “Q2 10-Q”) by February 9, 2017 and disclosing that the Company will not be able to file the Q2 10-Q within the five-day extension period provided in Rule 12b-25(b) under the Exchange Act, together with its prior and ongoing failure to timely file the Q1 10-Q, was not in compliance with Listing Rule 5250(c)(1) for continued listing. We previously submitted a plan to Nasdaq to regain compliance with the Rules and Nasdaq has granted us an exception until March 13, 2017 to regain compliance. We were required to submit to Nasdaq an update to the original compliance plan not later than February 27, 2017, and we have timely submitted this update.

See Part I - Item 4 “Controls and Procedures” and Part II - Item 1 “Legal Proceedings” for additional information regarding these matters.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Misonix, Inc. and Subsidiaries
Consolidated Balance Sheets

	September 30, 2016 (unaudited)	June 30, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,600,821	\$9,049,327
Accounts receivable, less allowance for doubtful accounts of \$96,868 and \$98,868, respectively	3,841,068	3,869,427
Inventories, net	5,177,561	5,822,935
Prepaid expenses and other current assets	469,518	530,564
Total current assets	18,088,968	19,272,253
Property, plant and equipment, net of accumulated amortization and depreciation of \$7,136,072 and \$6,976,282, respectively	2,883,301	2,492,815
Patents, net of accumulated amortization of \$911,637 and \$885,394, respectively	662,794	604,916
Goodwill	1,701,094	1,701,094
Intangible and other assets	287,380	266,603
Deferred income tax	3,422,690	3,394,690
Total assets	\$ 27,046,227	\$27,732,371
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 1,195,749	\$1,402,797
Accrued expenses and other current liabilities	2,160,870	1,887,337
Total current liabilities	3,356,619	3,290,134
Deferred lease liability	9,285	9,262
Deferred income	27,035	31,685
Total liabilities	3,392,939	3,331,081
Commitments and contingencies (Footnote 9)		
Shareholders' equity:		
	79,482	79,482

Edgar Filing: MISONIX INC - Form 10-Q

Common stock, \$.01 par value-shares authorized 20,000,000; 7,948,234 shares issued and 7,809,385 outstanding in each period		
Additional paid-in capital	32,276,402	32,502,521
Accumulated deficit	(7,603,244)	(7,081,361)
Treasury stock, at cost, 138,849 shares in each period	(1,099,352)	(1,099,352)
Total shareholders' equity	23,653,288	24,401,290
Total liabilities and shareholders' equity	\$ 27,046,227	\$ 27,732,371

See Accompanying Notes to Consolidated Financial Statements.

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

	For the three months ended September 30,	
	2016	2015
Net sales	\$6,171,625	\$5,250,985
Cost of goods sold, exclusive of depreciation from consigned product	1,912,007	1,760,699
Gross profit	4,259,618	3,490,286
Operating expenses:		
Selling expenses	3,325,687	2,656,280
General and administrative expenses	1,931,821	1,803,920
Research and development expenses	492,084	399,994
Total operating expenses	5,749,592	4,860,194
Loss from operations	(1,489,974)	(1,369,908)
Other income (expense):		
Interest income	19	19
Royalty income and license fees	944,068	988,170
Other	(1,996)	(6,021)
Total other income	942,091	982,168
Loss from operations before income taxes	(547,883)	(387,740)
Income tax (benefit)/expense	(26,000)	(168,000)
Net loss	\$(521,883)	\$(219,740)
Net loss per share - Basic	\$(0.07)	\$(0.03)
Net loss per share - Diluted	\$(0.07)	\$(0.03)
Weighted average shares - Basic	7,809,385	7,748,509
Weighted average shares - Diluted	7,809,385	7,748,509

See Accompanying Notes to Consolidated Financial Statements.

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

	For the Three Months Ended September 30, 2016						
	Common Stock, \$.01 Par Value		Treasury Stock		Additional	Accumulated	Total
	Number of shares	Amount	Number of shares	Amount	paid-in capital	deficit	stockholders' equity
Balance, June 30, 2016	7,948,234	\$79,482	(138,849)	\$(1,099,352)	\$32,502,521	\$(7,081,361)	\$24,401,290
Net loss	-	-	-	-	-	(521,883)	(521,883)
Stock-based compensation	-	-	-	-	(226,119)	-	(226,119)
Balance, September 30, 2016	7,948,234	\$79,482	(138,849)	\$(1,099,352)	\$32,276,402	\$(7,603,244)	\$23,653,288

See Accompanying Notes to Consolidated Financial Statements.

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

	For the three months ended September 30,	
	2016	2015
Operating activities		
Net loss from operations	\$ (521,883)	\$ (219,740)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization and other non-cash items	226,012	457,309
Deferred income tax benefit	(26,000)	(149,000)
Stock-based compensation	(226,119)	300,743
Deferred income	(4,650)	(12,268)
Deferred lease liability	23	2,316
Changes in operating assets and liabilities:		
Accounts receivable	28,359	788,807
Inventories	164,073	(834,580)
Prepaid expenses and other assets	40,269	82,876
Accounts payable and accrued expenses	64,485	(324,293)
Net cash (used in)/provided by operating activities	(255,431)	92,170
Investing activities		
Acquisition of property, plant and equipment	(108,954)	(85,198)
Additional patents	(84,121)	(21,296)
Net cash used in investing activities	(193,075)	(106,494)
Financing activities		
Proceeds from exercise of stock options	-	136,056
Net cash provided by financing activities	-	136,056
Net (decrease)/increase in cash and cash equivalents	(448,506)	121,732
Cash and cash equivalents at beginning of period	9,049,327	9,623,749
Cash and cash equivalents at end of period	\$ 8,600,821	\$ 9,745,481
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$ 2,053	\$ 76,725
Capitalization of consigned product	\$ 481,272	\$ 326,518

See Accompanying Notes to Consolidated Financial Statements.

MISONIX, INC. and Subsidiaries

Notes to Consolidated Financial Statements

For the Three Months Ended September 30, 2016 and 2015

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

Explanatory Note

Misonix, Inc. (“Misonix” or the “Company”) was not able to file its Quarterly Report on Form 10-Q (the “10-Q”) for the three months ended September 30, 2016 by its due date. For several months, with the assistance of outside counsel, Misonix has been conducting a voluntary investigation into the business practices of its 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 Foreign Corrupt Practices Act (“FCPA”), as well as into various internal controls issues identified during the investigation. On September 27, 2016 and September 28, 2016, Misonix voluntarily contacted the Securities and Exchange Commission (“SEC”) and the U.S. Department of Justice (“DOJ”), respectively, to advise both agencies of these potential issues. Misonix 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 investigations of these matters.

Although the internal investigation is now complete, additional issues or facts could arise which may expand the scope or severity of the potential violations. Misonix could also receive additional requests from the DOJ or SEC, which may require further investigation. Misonix has no current information derived from the internal investigation or otherwise to suggest that its previously reported financial statements and results are incorrect.

Refer to footnote 9, Commitments and Contingencies, for additional information regarding these matters.

Basis of Presentation

These consolidated financial statements 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 year ended June 30, 2016, 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.

Reclassifications

Certain expenses on the Statement of Operations have been reclassified to be consistent with the current year presentation. Historically, the Company had recorded stock compensation expense and bonus expense predominantly within general and administrative expenses. The Company has reclassified the prior years’ presentation to allocate certain of these costs to cost of goods sold, selling expenses and research and development expenses, which is consistent with the classification being used in fiscal 2017. This reclassification had no impact on the Company’s presentation of operating income (loss) and the gross profit impact was not material.

Organization and Business

Misonix designs, manufactures, develops and markets therapeutic ultrasonic devices. These products are used for precise bone sculpting, removal of soft tumors, and tissue debridement in the fields of orthopedic surgery, plastic surgery, neurosurgery, podiatry and vascular surgery. In the United States, the Company sells its products through a network of commissioned agents assisted by Company personnel. Outside of the United States, the Company sells to distributors who then resell the product to hospitals. 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. Cumulative payments through September 30, 2016 were \$1,254,788. No payments were received during the quarter ended September 30, 2016. Payments are generally received once per year, in the Company’s third fiscal quarter.

Major Customers and Concentration of Credit Risk

Included in sales from continuing operations are sales to Cichel (Beijing) Science and Tech Co. Ltd. (“Cichel”) of \$0 and \$243,052, for the three months ended September 30, 2016 and 2015, respectively. Accounts receivable from Cichel were \$0 at September 30, 2016 and June 30, 2016. The Company terminated its agreement with Cichel in the first quarter of fiscal 2017.

Total royalties from Medtronic Minimally Invasive Therapies (“MMIT”) related to their sales of the Company’s ultrasonic cutting products, which use high frequency sound waves to coagulate and divide tissue for both open and laparoscopic surgery, were \$938,000 and \$969,437, for the three months ended September 30, 2016 and 2015, respectively. Accounts receivable from MMIT royalties were approximately \$938,000 and \$973,000 at September 30, 2016 and June 30, 2016, respectively. The license agreement with MMIT expires in August 2017.

At September 30, 2016 and June 30, 2016, the Company’s accounts receivable with customers outside the United States were approximately \$732,000 and \$768,000, respectively, none of which is over 90 days.

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.

Recent Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board (the “FASB”) issued ASU No. 2017-04, *Simplifying the Test for Goodwill Impairment*. Under the new standard, goodwill impairment would be measured as the amount by which a reporting unit’s carrying value exceeds its fair value, not to exceed the carrying value of goodwill. This ASU eliminates existing guidance that requires an entity to determine goodwill impairment by calculating the implied fair value of goodwill by hypothetically assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company will apply this guidance to applicable impairment tests after the adoption date.

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 2019. The Company is currently in the early stages of evaluating this guidance to determine the impact it will have on its financial statements.

In May 2014, the FASB issued guidance on revenue from contracts with customers. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved, in certain circumstances. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. This guidance permits the use of either the retrospective or cumulative effect transition method and is effective for the Company beginning in 2019; early adoption is permitted beginning in 2018. The Company has not yet selected a transition method and is currently evaluating the impact of the guidance on the Company's financial condition, results of operations and related disclosures. The FASB has also issued the following additional guidance clarifying certain issues on revenue from contracts with customers: Revenue from Contracts with Customers - Narrow-Scope Improvements and Practical Expedients and Revenue from Contracts with Customers - Identifying Performance Obligations and Licensing. The Company is currently in the early stages of evaluating this guidance to determine the impact it will have on its 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.

2. Fair Value of Financial Instruments

We follow 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, 2016 and June 30, 2016, all of our cash, trade accounts receivable and trade accounts payable were short term in nature, and their carrying amounts approximate fair value.

3. Inventories

Inventories are summarized as follows:

	September 30, 2016	June 30, 2016
Raw material	\$ 2,859,877	\$ 3,102,175
Work-in-process	761,582	854,631

Edgar Filing: MISONIX INC - Form 10-Q

Finished goods	2,821,807	3,101,234
	6,443,266	7,058,040
Less valuation reserve	1,265,705	1,235,105
	\$ 5,177,561	\$5,822,935

4. Property, Plant and Equipment

Depreciation and amortization of property, plant and equipment totaled approximately \$200,000 and \$312,000, for the three months ended September 30, 2016 and 2015, 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 during the three months ended September 30, 2016 and is expensed over a 3 year period for the three months ended September 30, 2015, and depreciation is charged to selling expenses. The impact of this change in accounting estimate was a reduction in expense of approximately \$180,000 for the three months ended September 30, 2016, compared to what the expense would have been without this change.

5. Goodwill

Goodwill is not amortized. We review 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 discontinued 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 2016 and 2015 as of June 30 of each year. No impairment of goodwill was deemed to exist in fiscal 2016 and 2015.

6. 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 totaled \$662,794 and \$604,916 at September 30, 2016 and June 30, 2016, respectively. Amortization expense for the three months ended September 30, 2016 and 2015 was \$26,000 and \$23,000, respectively.

The following is a schedule of estimated future patent amortization expense as of September 30, 2016:

2017	\$75,532
2018	97,994
2019	89,687
2020	66,258
2021	62,111
Thereafter	271,212
	\$662,794

7. Accrued Expenses and Other Current Liabilities

The following summarizes accrued expenses and other current liabilities:

	September 30, 2016	June 30, 2016
Accrued payroll, payroll taxes and vacation	621,790	648,705
Accrued bonus	100,000	300,000
Accrued commissions	452,000	433,000
Professional fees	447,038	256,130
Deferred income	13,596	20,655
Severance	320,001	-
Other	206,445	228,847
	\$ 2,160,870	\$ 1,887,337

8. Stock-Based Compensation Plans

The compensation cost that has been charged against income for the Company's stock option plans was (\$226,119) of income, which included a reversal of stock compensation from prior periods due to forfeitures of unvested options of \$597,196, and \$301,743 of expense for the three months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, there was approximately \$2,074,029 of total unrecognized compensation cost related to non-vested share-based compensation arrangements to be recognized over a weighted-average period of 2.5 years. Certain share based costs for the quarter ended September 30, 2015 included in general and administrative expenses were reclassified to cost of revenue, selling and research and development expenses to be consistent with the current year's classification.

During the quarter ended September 30, 2016, the Company modified the terms of certain stock options, which resulted in a charge to operations of \$60,747.

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 at date of grant for options granted during the three months ended September 30, 2015 was \$4.73. There were no options granted during the three months ended September 30, 2016. The fair value was estimated based on the weighted average assumptions of:

	For three months ended		
	September 30, 2016	September 30, 2015	
Risk-free interest rates	-	1.80	%
Expected option life in years	-	6.25	
Expected stock price volatility	-	55.35	%
Expected dividend yield	-	0	%

A summary of option activity under the Company's equity plans as of September 30, 2016, and changes during the three months ended September 30, 2016 is presented below:

	Outstanding Shares	Average Exercise Price	Aggregate Intrinsic Value
Vested and exercisable at June 30, 2016	1,790,224	\$ 6.38	\$ 1,675,072
Granted	-	-	
Exercised	-	-	
Forfeited	(325,875)	8.17	
Expired	-	-	
Outstanding as of September 30, 2016	1,464,349	\$ 5.98	\$ 1,701,312
Vested and exercisable at September 30, 2016	957,474	\$ 4.30	\$ 1,683,139

The total fair value of shares vested during the quarter ended September 30, 2016 was \$606,000. The number and weighted-average grant-date fair value of non-vested stock options at the beginning of fiscal 2017 was 976,875 and \$4.81, respectively. The number and weighted-average grant-date fair value of stock options which vested during the quarter ended September 30, 2016 was 144,250 and \$4.20, respectively.

9. 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 \$26,000. The Company also leases certain office equipment and automobiles under operating leases expiring through fiscal 2018.

Class Action Securities Litigation

On September 19, 2016, Richard Scalfani, an individual shareholder of Misonix, filed a lawsuit against the Company and its former CEO and CFO in the U.S. District Court for the Eastern District of New York, alleging violations of the federal securities laws. The complaint alleges that the Company's stock price was artificially inflated between November 5, 2015 and September 14, 2016 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. Scalfani filed the action seeking to represent a putative class of all persons (other than defendants, officers and directors of the Company, and their affiliates) who purchased publicly traded Misonix securities between November 5, 2015 and September 14, 2016. Scalfani seeks an unspecified amount of damages for himself and for the putative class under the federal securities laws.

On November 18, 2016, Scalfani and another individual Misonix shareholder, Tracey Angiuoli, petitioned the Court to be appointed lead plaintiffs for purposes of pursuing the action on behalf of the putative class.

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; there has been no discovery and there is no trial date. The Company is not able to estimate the amount of potential loss it may recognize, if any, from this claim. The Company believes that its insurance coverage is sufficient to cover a potential loss, after payment of the policy retention of \$250,000.

Chinese Distributor

For several months, with the assistance of outside counsel, the Company has been conducting 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.

On September 27, 2016 and September 28, 2016, we 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 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. Since the inception of its distributorship relationship with the prior Chinese distributor in 2012, the Company has generated sales of approximately \$8 million from the relationship.

Further, the Company may suffer other civil penalties or adverse impacts, including lawsuits by private litigants in addition to the lawsuit that has already been filed, or investigations and fines imposed by local authorities. The investigative costs to date are approximately \$1.9 million, of which approximately \$0.6 million was charged to general and administrative expenses during the quarter ended September 30, 2016.

10. Related Party Transactions

Applied BioSurgical, a company owned by the brother of the Company's Chief Executive Officer, Stavros G. Vizirgianakis, is an independent distributor for the Company outside of the United States.

Set forth below is a table showing the Company's net sales for the three months ended September 30 and accounts receivable at September 30 for the indicated time periods below with Applied BioSurgical:

	2016	2015
Sales	\$52,196	\$79,985
Accounts receivable	\$253,699	\$223,029

11. Income Taxes

For the three months ended September 30, 2016 and 2015, the Company recorded an income tax benefit from continuing operations of \$26,000 and \$168,000, respectively.

For the three months ended September 30, 2016 and 2015, the effective rate of (4.7%) and (43.3)%, respectively, on continuing operations varied from the U.S. federal statutory rate primarily due to permanent book tax differences, state taxes and tax credits.

As of September 30, 2016 and June 30, 2016, the Company has no material unrecognized tax benefits or accrued interest and penalties.

12. Licensing Agreements for Medical Technology

In October 1996, the Company entered into a License Agreement with MMIT expiring August 2017, covering the further development and commercial exploitation of the Company's medical technology relating to laparoscopic products, which uses high frequency sound waves to coagulate and divide tissue for both open and laparoscopic surgery. The MMIT license provides for exclusive worldwide marketing and sales rights for this technology. The Company receives a 5% royalty on sales of these products by MMIT. Royalties from this license agreement were \$938,000 and \$969,437 for the three months ended September 30, 2016 and 2015, respectively.

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 is categorized as follows:

	For the Three Months Ended September 30,	
	2016	2015
Total		
Consumables	\$ 4,544,195	\$ 3,490,686
Equipment	1,627,430	1,760,299
Total	\$ 6,171,625	\$ 5,250,985
Domestic		
Consumables	\$ 3,317,929	\$ 2,584,111
Equipment	568,628	483,960

Edgar Filing: MISONIX INC - Form 10-Q

Total	\$ 3,886,557	\$ 3,068,071
International		
Consumables	\$ 1,226,266	\$ 906,575
Equipment	1,058,802	1,276,339
Total	\$ 2,285,068	\$ 2,182,914

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

14. Severance

On August 26, 2016, the Company and the Company's former Chief Executive Officer, Michael McManus ("McManus") entered into a retirement agreement and general release (the "Retirement Agreement"). Pursuant to the Retirement Agreement, on September 2, 2016 Mr. McManus resigned as a Director and the Chairman of the Board of Directors of the Company and retired as President and Chief Executive Officer of the Company. Pursuant to the Retirement Agreement, the Company agreed to (i) pay Mr. McManus' salary through June 30, 2017 at the then current level; (ii) continue to pay premiums for Mr. McManus' and his dependents' coverage under the Company's medical, dental, vision, hospitalization, long term care and life insurance coverage through June 30, 2017 at the then current levels upon timely election by Mr. McManus under the law informally known as COBRA; and (iii) extend the exercisability of previously granted and then currently vested options to purchase shares of Common Stock through June 30, 2017. In addition, Mr. McManus had continued use of the vehicle pursuant to his prior employment agreement through December 31, 2016. In connection with this Retirement Agreement, the Company recorded a charge of \$330,000 during the quarter ended September 30, 2016 to accrue for the cash portion of these benefits, which will be paid during the period ending June 30, 2017. In addition, the Company recorded a non-cash compensation expense of \$61,000 in connection with the modification of the terms of his vested stock options, and recorded a reduction in non-cash compensation expense of \$596,000 relating to the forfeiture of his unvested stock options.

15. Subsequent Events

NASDAQ Deficiency Letters

On September 15, 2016, Misonix received a deficiency letter from The Nasdaq Stock Market LLC (“Nasdaq”) indicating that the Company, as a result of not filing the 10-K on September 13, 2016 and disclosing that the Company likely would not be able to file the 10-K within the 15-day extension period provided in Rule 12b-25(b) under the Securities Exchange Act of 1934, as amended, was not in compliance with Listing Rule 5250(c)(1) of the Nasdaq Listing Rules (the “Rules”) for continued listing. In addition, on November 10, 2016, Misonix received a second deficiency letter from Nasdaq indicating that the Company, as a result of not filing its Quarterly Report on Form 10-Q for the period ended September 30, 2016 (the “Q1 10-Q”) by November 9, 2016, together with its prior failure to timely file the 10-K, was not in compliance with Listing Rule 5250(c)(1) for continued listing. In the letters, Nasdaq requested that Misonix submit a plan to regain compliance with the Rules by November 14, 2016. On November 14, 2016, Misonix submitted to Nasdaq a plan to regain compliance with the Rules. After reviewing Misonix's plan to regain compliance, Nasdaq granted an exception to enable the Company to regain compliance with the Rules. Under the terms of the exception, Misonix must file its 10-K and Q1 10-Q on or before March 13, 2017. In the event that Misonix does not satisfy the terms set forth in the extension, Nasdaq will provide written notification that Misonix's common stock will be delisted. At that time, Misonix may appeal Nasdaq's determination for a panel review. The Company filed the 10-K with the SEC on February 9, 2017.

On February 10, 2017, Misonix received a third deficiency letter from Nasdaq indicating that the Company, as a result of not filing its Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2016 (the “Q2 10-Q”) by February 9, 2017 and disclosing that the Company will not be able to file the Q2 10-Q within the five-day extension period provided in Rule 12b-25(b) under the Exchange Act, together with its prior and ongoing failure to timely file the Q1 10-Q, was not in compliance with Listing Rule 5250(c)(1) for continued listing. The Company previously submitted a plan to Nasdaq to regain compliance with the Rules and Nasdaq has granted the Company an exception until March 13, 2017 to regain compliance. The Company submitted its amended compliance plan to the Nasdaq on February 23, 2017 indicating that the Company expected to file its Q1 10-Q and Q2 10-Q by March 13, 2017.

Employment Agreement - Stavros G. Vizirgianakis

On December 15, 2016, the Company entered into an Employment Agreement (the “Vizirgianakis Agreement”) with Stavros G. Vizirgianakis pursuant to which Mr. Vizirgianakis serves as the Company's full time President and Chief Executive Officer. Mr. Vizirgianakis had been serving on an unpaid basis as interim Chief Executive Officer of the Company since September 2, 2016. Mr. Vizirgianakis continues to serve as a member of the Company's Board of Directors.

Pursuant to the Vizirgianakis Agreement, Mr. Vizirgianakis' initial term of employment runs through September 13, 2019, provided that the term shall be automatically renewed and extended for consecutive one (1) year renewal terms, unless either party sends to the other party a notice of non-renewal at least ninety (90) days prior to the expiration of the initial term or any then-current renewal term. Mr. Vizirgianakis will receive an annual base salary of not less than three hundred sixty thousand dollars (\$360,000) per annum, subject to review by the Board at least annually for increase but not for decrease. Mr. Vizirgianakis is also eligible to receive annual bonuses in the discretion of the Board. The Vizirgianakis Agreement also provides for a one-time \$10,000 moving allowance and reimbursement of counsel fees relating to visa matters and the negotiation of the Vizirgianakis Agreement. If the Company terminates Mr. Vizirgianakis' employment without cause (as defined in the Vizirgianakis Agreement), the Company provides a notice of non-renewal, or Mr. Vizirgianakis terminates his employment for good reason (as defined in the Vizirgianakis Agreement), Mr. Vizirgianakis shall be entitled to receive (i) a lump-sum cash payment from the Company in an amount equal to one and one-half (1.5) times the annual base salary as is in effect immediately prior to the date of such termination, and (ii) continuation of all employee benefits and fringe benefits to which he was entitled under the Vizirgianakis Agreement immediately prior to such termination of employment for a period of eighteen (18) months following the termination of employment. The Vizirgianakis Agreement also contains non-competition and non-solicitation covenants from Mr. Vizirgianakis during the term of employment and for a period of 18 months thereafter.

In conjunction with the execution of the Vizirgianakis Agreement, Mr. Vizirgianakis received grants of an aggregate of 400,000 shares of restricted stock pursuant to the Company's 2014 Equity Incentive Plan (the "Plan") as follows: (i) a grant of 134,000 shares vesting in five equal installments on September 1, 2017, 2018, 2019, 2020 and 2021; (ii) a performance grant of 133,000 shares which vests if both of the following conditions are satisfied simultaneously: (A) at any time prior to the third anniversary of the grant date, the most recent publicly reported trailing four (4) fiscal quarter revenue of the Company (exclusive of the impact of any acquisitions after the grant date) is at least \$35,000,000 and (B) the closing price of the Common Stock is at least \$10.50 per share (subject to adjustment for stock splits, stock dividends and the like) for ten (10) consecutive trading days; and (iii) a performance grant of 133,000 shares which vests if both of the following conditions are satisfied simultaneously: (A) at any time prior to the fifth anniversary of the grant date, the most recent publicly reported trailing four (4) fiscal quarter revenue of the Company (exclusive of the impact of any acquisitions after the grant date) is at least \$48,000,000 and (B) the closing price of the Common Stock is at least \$13.00 per share (subject to adjustment for stock splits, stock dividends and the like) for ten (10) consecutive trading days. The aforementioned performance grants will vest on a change of control in accordance with the Plan only if the applicable share price threshold is met in such transaction.

Director Resignation

On December 15, 2016, T. Guy Minetti, a member of the Company's Board of Directors, resigned from the Board. In connection with his resignation, the Board agreed to extend the exercisability of previously granted and then currently vested options to purchase shares of the Company's common stock through December 15, 2017.

Equity Investment

On October 25, 2016, the Company sold 761,469 shares of Common Stock in a private placement to Stavros G. Vizirgianakis, a director of the Company and its current Chief Executive Officer, at a price per share of \$5.253, representing total cash proceeds to the Company of approximately \$4.0 million.

Investigative Fees

Subsequent to September 30, 2016, the Company has incurred approximately \$1.1 million in fees relating to its FCPA investigation and related activities.

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 February 9, 2017, for the fiscal year ended June 30, 2016 (“2016 Form 10-K”). Item 7 of the 2016 Form 10-K describes the application of our critical accounting policies, for which there have been no significant changes as of September 30, 2016.

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, and other factors discussed in the 2016 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, develops and markets therapeutic ultrasonic devices. These products are used for precise bone sculpting, removal of soft tumors, and tissue debridement in the fields of orthopedic surgery, plastic surgery, neurosurgery, podiatry and vascular surgery. In the United States, the Company sells its products through a network of commissioned agents assisted by Company personnel. Outside of the United States, the Company sells to distributors who then resell the product 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 pieces 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 beginning in fiscal 2017, and a three year period in fiscal 2016. 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 various segments 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 continuing operations.

All of the Company's sales have been derived from the sale of medical device products, which include manufacture and distribution of ultrasonic medical device products. Our sales by category for the quarters ended September 30, 2016 and 2015 are as follows:

	For the Three Months Ended		Net Change	
	September 30,		\$	%
	2016	2015		
Total				
Consumables	\$ 4,544,195	\$ 3,490,686	\$ 1,053,509	30.2 %
Equipment	1,627,430	1,760,299	(132,869)	-7.5 %
Total	\$ 6,171,625	\$ 5,250,985	\$ 920,640	17.5 %
Domestic				
Consumables	\$ 3,317,929	\$ 2,584,111	\$ 733,818	28.4 %
Equipment	568,628	483,960	84,668	17.5 %
Total	\$ 3,886,557	\$ 3,068,071	\$ 818,486	26.7 %
International				
Consumables	\$ 1,226,266	\$ 906,575	\$ 319,691	35.3 %
Equipment	1,058,802	1,276,339	(217,537)	-17.0 %
Total	\$ 2,285,068	\$ 2,182,914	\$ 102,154	4.7 %

Net sales

Net sales increased \$920,640, or 17.5%, to \$6,171,625 in the first quarter of fiscal 2017, from \$5,250,985 in fiscal 2016 in part due to stronger demand for the Company's Consumable products, offset by weaker international Equipment sales. Consumables revenue increased by 30.2% to \$4,544,195 for the first quarter of fiscal 2017, in part due to the Company's continued investment in its sales team and marketing efforts, and comprised 73.4% of total revenue compared with 66.5% in the prior year period. Equipment sales declined by 7.5% to \$1,627,430, resulting from weaker international sales, principally in China, where the Company terminated its relationship with its Chinese distributor in the first quarter of fiscal 2017. In February 2017, the Company executed an agreement with a new Chinese distributor, with initial shipments anticipated to begin in 2017.

Gross profit

Gross profit in the first quarter of fiscal 2017 was 69.0% of sales, which increased from 66.5% in the first quarter of fiscal 2016. The increase resulted from a stronger mix of Consumables revenue which carries a higher gross profit margin than Equipment revenue.

Selling expenses

Selling expenses increased by \$669,407, or 25.2% to \$3,325,687 in the first quarter of fiscal 2017 from \$2,656,280 in the prior year period. The increase is principally related to higher salary and sales commission expenses. The Company continues to invest in sales and marketing in order to gain market share. The Company's strategy to leverage its existing distributor network with product specialists domestically resulted in part in domestic sales growing by 26.7% during the first quarter. This quarterly expense increase was partially offset by a decrease in depreciation of consigned units of \$134,000, resulting from a change in accounting estimate to depreciate these units over five years in fiscal 2017 compared with three years in fiscal 2016.

General and administrative expenses

General and administrative expenses increased by \$127,901, or 7.1% to \$1,931,821 in the first quarter of fiscal 2017 from \$1,803,920 in the prior year period. The increase resulted from a charge of \$330,000 relating to a severance obligation to the Company's former Chief Executive Officer, and a \$460,000 increase in legal fees relating to the Investigation, offset by a reversal of non-cash stock compensation expense of \$596,000 relating to stock options which were forfeited by the Company's former Chief Executive Officer upon his retirement from the Company.

Research and development expenses

Research and development expenses increased by \$92,090, or 23.0% to \$492,084 in the first quarter of fiscal 2017 from \$399,994 in the prior year period. The increase is due generally to higher salary and consulting costs for increased product development activities.

Other income (expense)

Other income decreased \$40,077 to \$942,091 in the first quarter of fiscal 2017 from \$982,168 in the prior year period. The decrease is related to lower royalty income from MMIT. This royalty agreement expires in August 2017.

Income taxes

For the three months ended September 30, 2016 and 2015, the Company recorded an income tax benefit from continuing operations of \$26,000 and \$168,000, respectively. For the three months ended September 30, 2016, the Company recorded a tax benefit with an effective tax rate of (4.7)% compared to (43.3)% for the three months ended September 30, 2015. The decrease relates to an increase in permanent book to tax differences. The effective tax rate for both periods was also affected by state taxes and tax credits.

Liquidity and Capital Resources

Working capital at September 30, 2016 was \$14.7 million. For the three months ended September 30, 2016, cash used in operations was \$255,431, mainly due to the Company's net loss of \$521,883, offset by a \$204,000 reduction in inventories and prepaid expenses. Cash used in investing activities was \$193,075, primarily consisting of the purchase of property, plant and equipment along with filing for additional patents.

On October 25, 2016, the Company sold 761,469 shares of Common Stock in a private placement to Stavros G. Vizirgianakis, a director of the Company and its current Chief Executive Officer, at a price per share of \$5.253, representing total cash proceeds to the Company of approximately \$4.0 million.

As of February 28, 2017, the Company had a cash balance of approximately \$11.9 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 \$1.9 million in investigative costs and is expected to incur additional costs until the matter is fully resolved. Further, the Company could be subject to fines or penalties related to potential violations of the FCPA.

The Company has been receiving an annual royalty from MMIT which has averaged \$3.7 million per year over the last three fiscal years. This royalty will end in August 2017.

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 is 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 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

Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) 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.

As described in Part II - Item 1 "Legal Proceedings" in this 10-Q, in April 2016, the Company's management informed the Board of violations of Company policies and procedures and possible violations of laws and regulations, involving Michael A. McManus, the Company's former President and Chief Executive Officer, and other Company personnel. Subsequently, in mid-May 2016, the Audit Committee of the Board of Directors initiated the investigation of these matters. Special external counsel was retained and conducted the Investigation with the assistance of an advisory firm with forensic accounting expertise. Mr. McManus' employment with the Company ceased on September 2, 2016.

The Investigation resulted in the Company notifying the SEC and DOJ about possible violations of the FCPA and other internal controls matters. These possible violations of laws included knowledge of certain business practices of the independent Chinese entity that distributes the Company's products in China, which practices raised questions under the FCPA.

The Investigation did not identify any financial loss to the Company and did not identify any material misstatements in the Company's financial statements. However, as a result of the Company's Investigation and related activities, it has incurred approximately \$1.8 million of professional fees as of February 28, 2017 and has terminated the agreement with its former distributor in China, which was the Company's largest customer during the prior three fiscal years. In addition, the Company could be subject to disgorgement, fines or penalties related to potential violations of the FCPA

as described in Part II - Item 1 “Legal Proceedings” below.

In connection with the Investigation, the Company carried out an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures as of September 30, 2016. Due to the material weaknesses in internal control over financial reporting as described below in “Internal Control over Financial Reporting”, our current CEO and Interim CFO have concluded that our disclosure controls and procedures were not effective, and were not operating at a reasonable assurance level, as of September 30, 2016.

Internal Control over Financial Reporting

The Company’s management is responsible for establishing and maintaining effective internal control over financial reporting and for assessing the effectiveness of internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting refers to a process designed by, or under the supervision of, our CEO and our CFO and effected by our Board, management and other personnel, 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, and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and members of our Board; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting 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.

A material weakness (as defined in Rule 12b-2 under the Exchange Act) is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. Management conducted an evaluation of the effectiveness of the Company's internal control over financial reporting as of September 30, 2016, 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 has determined, because of the findings from the Investigation, and the Company's inability to rely on certain personnel, processes and internal controls, that material weaknesses existed at September 30, 2016, as described below. In light of such material weaknesses, management has concluded that the Company's internal control over financial reporting was ineffective as of September 30, 2016.

The Company did not have an effective control environment, risk assessment process, information and communication process and monitoring activities. These matters related to ineffective ethical governance, ineffective governance controls, and ineffectively implemented policies and procedures. The aggregation of issues identified within each of these areas resulted in the conclusion that a material weakness existed with respect to the "tone at the top" and effectiveness of governance within the Company. Specifically:

- The Company failed to establish a tone at the top that demonstrated its commitment to integrity and ethical values.

- The Company lacked effective controls and procedures to ensure that all members of management and Board members report to the full Board all possible illegal acts and violations of Company policy.

- The Company lacked effective procedures and controls to ensure that all reimbursement requests are handled in a manner consistent with the Board's authorizations and the Company's policies and procedures.

- The Company did not have effective information and communication and monitoring controls, including a robust whistleblower process, relating to the timely identification and communication of issues among financial reporting personnel, management, the Board, and the independent registered public accounting firm to enable appropriate analysis, financial reporting, and disclosure of such transactions.

In addition, the Company did not properly supervise the preparation and review the calculation of its income tax provision and deferred tax asset. While this control deficiency did not result in a material misstatement of the

Company's financial statements, it could have resulted in misstatements of the aforementioned accounts and disclosures that would not be prevented or detected in a timely manner. Accordingly, our management concluded that this control deficiency also constitutes a material weakness.

The identified control deficiencies did not result in any material misstatements in the Company's financial statements. However, these control deficiencies 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 deficiencies represented material weaknesses in the Company's internal control over financial reporting and our internal control over financial reporting was not effective as of September 30, 2016.

Remediation of Material Weaknesses

The Company continues to work to strengthen our internal control over financial reporting. We are committed to ensuring that such controls are designed and operating effectively. Our Board and management take internal control over financial reporting and the integrity of the Company's financial statements seriously and believe that the remediation steps described below, including with respect to personnel changes, were and are essential steps to establishing and maintaining strong and effective internal control over financial reporting and addressing the tone at the top concerns that contributed to the material weaknesses identified. Some of these remediation steps have taken place as of September 30, 2016. The following actions and plans will be or have been implemented during the fiscal 2017 year:

The Board replaced Mr. McManus effective September 2, 2016 with our then interim and now current CEO, Stavros G. Vizirgianakis. In addition, on September 13, 2016, the Board appointed Joseph P. Dwyer as the Company's interim CFO, reporting to the Company's new CEO and the Audit Committee of the Board. On that date, Richard A. Zarembo ceased serving as the Company's Senior Vice President and CFO and was appointed Senior Vice President, Finance, while remaining as the Company's Secretary and Treasurer.

In November 2016, the Company hired an Interim Chief Compliance Officer who reports directly and regularly to the CEO and the Chairman of the Audit Committee. The Interim Chief Compliance Officer is implementing an improved documentary framework, focusing initially on FCPA compliance and working with the Company's sales and marketing personnel.

The Board, as recommended by the Interim Chief Compliance Officer, reconstituted the Company's internal compliance committee to include the entire senior management team, with the Chief Compliance Officer as Chair and the sales and marketing officers as non-voting members. This action was designed in part to ensure that all members of senior management report all possible illegal acts.

The Company reconstituted the membership of its Board committees. T. Guy Minetti, former Chairman of our Audit Committee, resigned from the Board on December 15, 2016.

The Board reviewed and updated its Committee charters to provide, among other things, a more robust and structured governance process.

The Company updated its Code of Conduct and Ethics and implemented a toll-free whistleblower hotline that is reported directly to the Chairman of the Audit Committee. In addition, the Company has increased communication and will increase training to employees regarding the ethical values of the Company and the requirement to comply with laws, rules, regulations, and Company policies, including the Code of Conduct and Ethics, and the importance of accurate and transparent financial reporting.

Under the supervision of the Board, the Company will emphasize to key leadership the importance of setting appropriate tone at the top and of appropriate behavior with respect to accurate financial reporting, compliance with laws, and adherence to the Company's internal control over financial reporting framework and accounting policies.

The Company terminated the agreement with its former independent distributor of its products in China.

The Company is amending distribution agreements with its international distributors to add more fulsome provisions regarding compliance with laws, including compliance with the FCPA and other applicable anti-bribery provisions.

The Company is instituting a more robust screening process for its independent distributors with respect to legal compliance, including compliance with the FCPA and other applicable anti-bribery provisions.

The Company is implementing a regularly recurring risk assessment process focused on identifying and analyzing risks of financial misstatement due to error and/or fraud, including management override of controls.

The Company is updating its policies and procedures to ensure the proper processing of transactions with senior executives, and to enhance the review and approval for these types of transactions and ensure their proper disclosure, and will train relevant employees on such updated policies.

We have engaged a third-party expert consulting firm specializing in tax and technical accounting and financial reporting issues to assist our management with the review of our tax provisions and the accounting treatment and the financial reporting and disclosure of complex and non-recurring transactions.

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) that occurred during the three months ended September 30, 2016 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. As noted above, the Company began the process of enhancing existing controls and designing and implementing additional controls and procedures in response to the material weaknesses.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

Former Chinese Distributor

For several months, with the assistance of outside counsel, the Company has been conducting the 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.

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

Although our Investigation is complete, additional issues or facts could arise which may expand the scope or severity of the potential violations. The Company could also receive additional requests from the DOJ or SEC, which may require further investigation. 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 we predict the impact on the Company as a result of these matters, which may include the cost of investigations, defense, 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. Since the inception of its distributorship relationship with the prior Chinese distributor in 2012, the Company has generated sales of approximately \$8 million from the relationship.

Further, we may suffer other civil penalties or adverse impacts, including lawsuits by private litigants in addition to the lawsuit that has already been filed, or investigations and fines imposed by local authorities.

Class Action Securities Litigation

On September 19, 2016, Richard Scalfani, an individual shareholder of Misonix, filed a lawsuit against the Company and its former CEO and CFO in the U.S. District Court for the Eastern District of New York, alleging violations of the federal securities laws. The complaint alleges that the Company's stock price was artificially inflated between November 5, 2015 and September 14, 2016 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. Scalfani filed the action seeking to represent a putative class of all persons (other than defendants, officers and directors of the Company, and their affiliates) who purchased publicly traded Misonix securities between November 5, 2015 and September 14, 2016. Scalfani seeks an unspecified amount of damages for himself and for the putative class under the federal securities laws.

On November 18, 2016, Scalfani and another individual Misonix shareholder, Tracey Angiuoli, petitioned the Court to be appointed lead plaintiffs for purposes of pursuing the action on behalf of the putative class.

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; there has been no discovery and there is no trial date.

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, 2016. There have been no material changes from the risk factors disclosed in that Form 10-K.

Item 6. Exhibits

Exhibit No.	Description
31.1	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.
31.2	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.
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: March 13, 2017 By: /s/ Stavros G. Vizirgianakis
Stavros G. Vizirgianakis
Chief Executive Officer

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

Exhibit No.	Description
31.1	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.
31.2	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.
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