SECURITIES & EXCHANGE COMMISSION EDGAR FILING

ENDRA Life Sciences Inc.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2017

OR

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

COMMISSION FILE NUMBER 001-37969

ENDRA LIFE SCIENCES INC.

(Exact name of registrant as specified in its charter)

Delaware	**26-0579295**
(State of incorporation)	*(I.R.S. Employer Identification No.)*

3600 Green Court, Suite 350, Ann Arbor, MI 48105-1570

(Address of principal executive office) (*Zip code*)

(734) 335-0468

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☐ (Do not check if smaller reporting company)	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 ☑

As of June 13, 2017, there were 3,907,027 shares of our Common Stock, par value $0.0001 per share, outstanding.

ENDRA LIFE SCIENCES INC.
FORM 10-Q
FOR THE THREE MONTHS ENDED MARCH 31, 2017

INDEX

PART I - FINANCIAL INFORMATION	PAGE
Item 1. Financial Statements	1
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3. Quantitative and Qualitative Disclosure About Market Risk	19
Item 4. Controls and Procedures	19
PART II – OTHER INFORMATION	
Item 1. Legal Proceedings	20
Item 1A. Risk Factors	20
Item 2. Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities	41
Item 3. Defaults Upon Senior Securities	42
Item 4. Mine Safety Disclosures	42
Item 5. Other Information	42
Item 6. Exhibits	42
SIGNATURES	42
EXHIBIT INDEX	44

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

ENDRA Life Sciences Inc.
Condensed Balance Sheets

Assets	March 31, 2017 (Unaudited)	December 31, 2016
Assets		
Cash	$ 133,679	$ 144,953
Prepaid expenses	1,139	-
Inventory	40,237	40,105
Deferred offering costs	75,000	-
Other current assets	15,593	10,535
Total Current Assets	265,648	195,593
Other Assets		
Fixed assets, net	279,478	295,168
Total Assets	$ 545,126	$ 490,761
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable and accrued liabilities	$ 623,129	$ 434,552
Notes payable	50,000	50,000
Convertible notes payable, related party, net of discount	102,562	99,804
Convertible notes payable, net of discount	1,149,141	800,172
Total Current Liabilities	1,924,832	1,384,528
Total Liabilities	1,924,832	1,384,528
Stockholders' Deficit		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued or outstanding	-	-
Common stock, $0.0001 par value; 50,000,000 shares authorized; 723,335 and 723,335 shares issued and outstanding	72	72
Stock payable	90,000	81,000
Additional paid in capital	11,790,318	11,543,634
Accumulated deficit	(13,260,096)	(12,518,473)
Total Stockholders' Deficit	(1,379,706)	(893,767)
Total Liabilities and Stockholders' Deficit	$ 545,126	$ 490,761

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

ENDRA Life Sciences Inc.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
Operating Expenses		
Research and development	$ 95,814	$ 95,237
Sales and marketing	1,124	4,433
General and administrative	263,760	273,786
Total operating expenses	360,698	373,456
Operating loss	(360,698)	(373,456)
Other Expenses		
Loss on warrant exercise	-	(5,823)
Other expense	(380,926)	(199)
Total other expenses	(380,926)	(6,022)
Loss from operations before income taxes	(741,623)	(379,478)
Provision for income taxes	-	-
Net Loss	$ (741,623)	$ (379,478)
Net loss per share – basic and diluted	$ (1.03)	$ (0.52)
Weighted average common shares – basic and diluted	723,335	723,335

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

ENDRA Life Sciences Inc.
Condensed Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
Cash Flows from Operating Activities		
Net loss	$ (741,623)	$ (379,478)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	15,690	16,181
Common stock and options issued for services	29,697	78,240
Additional warrants issued during exchange	-	5,823
Interest on discount of convertible debt	351,727	-
Imputed interest on promissory notes	987	-
Changes in operating assets and liabilities:		
Increase in prepaid expenses	(1,139)	-
Increase in inventory	(132)	(3,781)
Increase in deferred offering costs	(75,000)	-
Increase in other asset	(5,058)	-
Increase in accounts payable and accrued liabilities	188,577	229,257
Net cash used in operating activities	(236,274)	(53,757)
Cash Flows from Investing Activities:		
Net cash used in investing activities	-	-
Cash Flows from Financing Activities		
Proceeds from issuance of common stock	-	5,000
Proceeds from notes payable	-	50,000
Proceeds from convertible notes	225,000	-
Net cash provided by financing activities	225,000	55,000
Net Increase/(Decrease) in cash	(11,274)	1,243
Cash, beginning of period	144,953	19,128
Cash, end of period	$ 133,679	$ 20,371
Supplemental disclosures:		
Interest paid	$ -	$ -
Income tax paid	$ -	$ -
Supplemental disclosures of non-cash Items:		
Discount on convertible notes	$ 225,000	$ -
Common shares to be issued for accrued salaries - related parties	$ -	$ 60,910

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

Note 1 – Nature of the Business

ENDRA Life Sciences Inc. ("ENDRA" or the "Company") was incorporated on July 18, 2007 as a Delaware corporation.

ENDRA is developing a medical imaging technology based on the thermoacoustic effect that improves the sensitivity and specificity of clinical ultrasound.

On May 8, 2017, the Company effected a one-for-3.5 reverse stock split (the "Reverse Split") of the Company's common stock, with no reduction in authorized capital stock. In the Reverse Split, every 3.5 outstanding shares of common stock became one share of common stock. See Note 9 below.

All common stock and stock incentive plan information in these financial statements has been restated to reflect the Reverse Split.

Note 2 – Summary of Significant Accounting Policies

Use of Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Management makes estimates that affect certain accounts including deferred income tax assets, accrued expenses, fair value of equity instruments and reserves for any other commitments or contingencies. Any adjustments applied to estimates are recognized in the period in which such adjustments are determined.

Basis of Presentation

The accompanying unaudited financial statements and related notes have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to such rules and regulations. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three-month period ended March 31, 2017 are not necessarily indicative of the results that may be expected for the year ended December 31, 2017. The balance sheet at December 31, 2016 has been derived from the audited financial statements at such date. For further information, refer to the financial statements and footnotes thereto included in ENDRA Life Sciences Inc. annual financial statements for the year ended December 31, 2016 included in Amendment No. 10 to the Company's Registration Statement on Form S-1 filed with the SEC on May 1, 2017.

Cash and Cash Equivalents

The Company considers all cash on hand and in banks, including accounts in book overdraft positions, certificates of deposit and other highly-liquid investments with maturities of three months or less, when purchased, to be cash and cash equivalents. As of March 31, 2017 and December 31, 2016, the Company had no cash equivalents.

Inventory

The Company's inventory is stated at the lower of cost or estimated realizable value, with cost primarily determined on a weighted-average cost basis on the first-in, first-out ("FIFO") method. The Company periodically determines whether a reserve should be taken for devaluation or obsolescence of inventory. As of March 31, 2017 and December 31, 2016 no such reserve was taken.

Capitalization of Fixed Assets

The Company capitalizes expenditures related to property and equipment, subject to a minimum rule, that have a useful life greater than one year for: (1) assets purchased; (2) existing assets that are replaced, improved or the useful lives have been extended; or (3) all land, regardless of cost. Acquisitions of new assets, additions, replacements and improvements (other than land) costing less than the minimum rule in addition to maintenance and repair costs, including any planned major maintenance activities, are expensed as incurred.

Capitalization of Intangible Assets

The Company records the purchase of intangible assets not purchased in a business combination in accordance with the ASC Topic 350.

Revenue Recognition

The Company recognizes revenue in accordance with the requirements of ASC 605-10-599, which directs that it should recognize revenue when (1) persuasive evidence of an arrangement exists (contracts); (2) delivery has occurred; (3) the seller's price is fixed or determinable (per the customer's contract); and (4) collectability is reasonably assured (based upon our credit policy). For products sold to end users revenue is recognized when title has passed to the customer and collectability is reasonably assured; and no further efforts are required. Future revenue from anticipated new products will follow this same policy.

Advertising Expense

The cost of advertising is expensed as incurred. Advertising expense for the three months ended March 31, 2017 was approximately $93. Advertising expense for the three months ended March 31, 2016 was approximately $180.

Income Taxes

The Company utilizes ASC 740, "Income Taxes," which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the tax basis of assets and liabilities and their financial reporting amounts based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. A valuation allowance is recorded when it is "more likely-than-not" that a deferred tax asset will not be realized.

The Company generated a deferred tax asset through net operating loss carry-forwards. However, a valuation allowance of 100% has been established due to the uncertainty of the Company's realization of the net operating loss carry forward prior to its expiration.

Research and Development Costs

The Company follows ASC 730-10, "Research and Development". Research and development costs are charged to the statement of operations as incurred. During the three months ended March 31, 2017 and 2016, the Company incurred $95,814 and $95,237 of expenses related to research and development costs, respectively.

Net Earnings (Loss) Per Common Share

The Company computes earnings per share under ASC Subtopic 260-10, Earnings Per Share ("ASC 260-10"). Basic earnings (loss) per share is computed by dividing the net income (loss) attributable to the common stockholders (the numerator) by the weighted average number of shares of common stock outstanding (the denominator) during the reporting periods. Diluted loss per share is computed by increasing the denominator by the weighted average number of additional shares that could have been outstanding from securities convertible into common stock (using the "treasury stock" method), unless their effect on net loss per share is anti-dilutive. There were 1,526,005 and 1,346,441 potentially dilutive shares, which include outstanding common stock options, warrants, and convertible notes, as of March 31, 2017 and December 31, 2016.

The potential shares, which are excluded from the determination of basic and diluted net loss per share as their effect is anti-dilutive, are as follows:

	March 31, 2017	December 31, 2016
Options to purchase common stock	151,881	151,881
Warrants to purchase common stock	151,563	152,812
Convertible notes	1,222,561	1,041,748
Potential equivalent shares excluded	1,526,005	1,346,441

Fair Value Measurements

Disclosures about fair value of financial instruments require disclosure of the fair value information, whether or not recognized in our balance sheet, where it is practicable to estimate that value. As of March 31, 2017 and December 31, 2016, the amounts reported for cash, accrued liabilities and accrued interest approximated fair value because of their short maturities.

In accordance with ASC Topic 820, "Fair Value Measurements and Disclosures," we measure certain financial instruments at fair value on a recurring basis. ASC Topic 820 defines fair value, established a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC Topic 820 established a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). These tiers include:

- Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets;
- Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

Share-based Compensation

The Company's 2016 Omnibus Incentive Plan, which has been approved by its board of directors, permits the grant of share options and shares to its employees, consultants and non-employee members of the board of directors for up to 1,345,074 shares of common stock, of which approximately 500,000 remain available to be granted. The Company records share-based compensation in accordance with the provisions of the Share-based Compensation Topic of the FASB Codification. The guidance requires the use of option-pricing models that require the input of highly subjective assumptions, including the option's expected life and the price volatility of the underlying stock. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option valuation model, and the resulting charge is expensed using the straight-line attribution method over the vesting period. The Company has elected to use the calculated value method to account for the options it issued in 2017 and 2016. A nonpublic entity that is unable to estimate the expected volatility of the price of its underlying share may measure awards based on a "calculated value," which substitutes the volatility of appropriate public companies (representative of the company's size and industry) as a bench mark for the volatility of the entity's own share price. Currently, there is no active market for the Company's common shares. The Company has used the historical closing values of these companies to estimate volatility, which was calculated to be 90%.

Stock compensation expense recognized during the period is based on the value of share-based awards that were expected to vest during the period adjusted for estimated forfeitures. The estimated fair value of grants of stock options and warrants to non-employees of the Company is charged to expense, if applicable, in the financial statements. These options vest in the same manner as the employee options granted under each of the option plans as described above.

Beneficial Conversion Feature

If the conversion feature of conventional convertible debt provides for a rate of conversion that is below market value, this feature is characterized as a beneficial conversion feature ("BCF"). A BCF is recorded by the Company as a debt discount pursuant to ASC Topic 470-20 "Debt with Conversion and Other Options." In those circumstances, the convertible debt is recorded net of the discount related to the BCF and the Company amortizes the discount to interest expense over the life of the debt using the effective interest method.

Debt Discount

The Company determines if the convertible debenture should be accounted for as liability or equity under ASC 480, Liabilities — Distinguishing Liabilities from Equity. ASC 480 applies to certain contracts involving a company's own equity, and requires that issuers classify the following freestanding financial instruments as liabilities. Mandatorily redeemable financial instruments, obligations that require or may require repurchase of the issuer's equity shares by transferring assets (e.g., written put options and forward purchase contracts), and certain obligations where at inception the monetary value of the obligation is based solely or predominantly on:

- A fixed monetary amount known at inception, for example, a payable settleable with a variable number of the issuer's equity shares with an issuance date fair value equal to a fixed dollar amount;

- Variations in something other than the fair value of the issuer's equity shares, for example, a financial instrument indexed to the S&P 500 and settleable with a variable number of the issuer's equity shares; or

- Variations inversely related to changes in the fair value of the issuer's equity shares, for example, a written put that could be net share settled. If the entity determined the instrument meets the guidance under ASC 480 the instrument is accounted for as a liability with a respective debt discount. The Company records debt discounts in connection with raising funds through the issuance of promissory notes (see Note 6). These costs are amortized to noncash interest expense over the life of the debt. If a conversion of the underlying debt occurs, a proportionate share of the unamortized amounts is immediately expensed.

Going Concern

The Company's financial statements are prepared using accounting principles generally accepted in the United States ("U.S. GAAP") applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company has a limited operating history and had a cumulative net loss from inception to March 31, 2017 of $13,260,096. The Company has a working capital deficit of $1,659,184 as of March 31, 2017. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and to allow it to continue as a going concern. The accompanying financial statements for the period ended March 31, 2017, have been prepared assuming the Company will continue as a going concern. The Company believes its cash resources are insufficient to meet its anticipated needs during the next twelve months. The Company will require additional financing to fund its future planned operations, including research and development and commercialization of its products.

The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it establishes a revenue stream and becomes profitable. Management's plans to continue as a going concern include raising additional capital through sales of equity securities and borrowing. However, management cannot provide any assurances that the Company will be successful in accomplishing any of its plans. If the Company is not able to obtain the necessary additional financing on a timely basis, the Company will be forced to delay or scale down some or all of its development activities or perhaps even cease the operation of its business. The ability of the Company to continue as a going concern is dependent upon its ability to successfully secure other sources of financing and attain profitable operations. There is substantial doubt about the ability of the Company to continue as a going concern within one year after the date that the financial statements are issued. The accompanying financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers. ASU 2014-09 is a comprehensive revenue recognition standard that will supersede nearly all existing revenue recognition guidance under current U.S. GAAP and replace it with a principle based approach for determining revenue recognition. Under ASU 2014-09, revenue is recognized when a customer obtains control of promised goods or services and is recognized in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The FASB has recently issued ASU 2016-08, ASU 2016-10, ASU 2016-11, ASU 2016-12, and ASU 2016-20, all of which clarify certain implementation guidance within ASU 2014-09. ASU 2014-09 is effective for interim and annual periods beginning after December 15, 2017. Early adoption is permitted only in annual reporting periods beginning after December 15, 2016, including interim periods therein. The standard can be adopted either retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the cumulative catch-up transition method). The Company is currently in the process of analyzing the information necessary to determine the impact of adopting this new guidance on its financial position, results of operations, and cash flows. The Company plans to adopt the provisions of this statement in the first quarter of fiscal 2018.

In February 2016, the FASB issued ASU No. 2016-02, Leases. ASU 2016-02 requires a lessee to record a right of use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. ASU 2016-02 is effective for all interim and annual reporting periods beginning after December 15, 2018. Early adoption is permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest period presented in the financial statements. The Company is currently evaluating the expected impact that the standard could have on its financial statements and related disclosures.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future financial statements.

Note 3 – Inventory

As of March 31, 2017 and 2016, inventory consisted of raw materials to be used in the assembly of a Nexus 128 system. As of March 31, 2017 and 2016, no orders were pending for such units.

Note 4 – Fixed Assets

As of March 31, 2017 and December 31, 2016, fixed assets consisted of the following:

	March 31, 2017	December 31, 2016
Computer equipment and fixtures	$ 571,318	$ 571,318
Accumulated depreciation	(291,840)	(276,150)
Fixed assets, net	$ 279,478	$ 295,168

Depreciation expense for the three months ended March 31, 2017 and 2016 was $15,690 and $16,181, respectively.

Note 5 – Current Liabilities

As of March 31, 2017 and December 31, 2016, current liabilities consisted of the following:

	March 31, 2017	December 31, 2016
Accounts payable	$ 303,172	$ 227,744
Accrued payroll	187,758	105,258
Accrued employee benefits	32,063	29,552
Accrued interest	100,136	71,998
Notes payable	50,000	50,000
Convertible notes, related party, net of discount	102,562	99,804
Convertible notes, net of discount	1,149,141	800,172
Total	$ 1,924,832	$ 1,384,528

On January 28, 2016, the Company entered into promissory notes with three investors for a total amount of $50,000. The notes matured one year from the issue date, accrue no interest and are payable at maturity. The Company accounted for imputed interest of $986 for the three months ended March 31, 2017, which was calculated at a rate of 8% per annum, consistent with other notes issued by the Company. During the period ending March 31, 2017 the Company and the promissory note holders agreed to extend the maturity date of all three notes to July 31, 2017, on the same terms as previously agreed. Subsequent to the period ended March 31, 2017, the promissory notes were repaid in full to all holders.

During 2016, the Company entered into convertible promissory notes with approximately 60 investors for a total principal amount of $1,386,448, $132,000 of which were purchased by related parties (the “2016 Notes”). On March 15, 2017, the Company extended the 2016 Notes offering by $250,000. The extension was made available only to existing noteholders and obtained subscriptions for $225,000. Pursuant to the terms of the 2016 Notes, noteholders holding a majority of the outstanding principal amount of the 2016 Notes elected to convert the principal and accrued interest on all outstanding 2016 Notes into shares of the Company’s common stock at a conversion price of $1.40 per share immediately prior to the Company’s initial public offering. 1,232,859 shares of the Company’s common stock were issued upon such conversion (see Note 9). In connection with the issuance of the 2016 Notes, the Company recorded a debt discount at an initial aggregate value of $1,611,448, of which $351,727 was amortized during the three months ended March 31, 2017, resulting in a debt discount balance of $359,745 as of March 31, 2017.

The Company accrued interest expense of $28,138 for the period ended March 31, 2017, $2,604 of which was payable for the notes due to related parties.

Note 6 – Capital Stock

At March 31, 2017, the authorized capital of the Company consisted of 60,000,000 shares of capital stock, consisting of 50,000,000 shares of common stock with a par value of $0.0001 per share, and 10,000,000 shares of preferred stock with a par value of $0.0001 per share.

There was $9,000 of stock to be issued during the three months ended March 31, 2017 for services. There was $90,000 of stock payable as of March 31, 2017.

As of March 31, 2017, there were 732,335 shares of common stock issued and outstanding (or 2,531,808, prior to taking into account the Reverse Split (see Note 9)) and no preferred stock outstanding.

Note 7 – Stock Options and Warrants

A summary of option activity under the Company option plans as of March 31, 2017, and changes during the period then ended is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Balance outstanding at December 31, 2016	151,881	$ 10.01	2.47
Granted	-	-	-
Exercised	-	-	-
Forfeited	-	-	-
Cancelled or expired	-	-	-
Balance outstanding at March 31, 2017	151,881	$ 10.01	2.22
Exercisable at March 31, 2017	127,995	$ 10.01	2.03

The following table summarizes all stock warrant activity for the three months ended March 31, 2017:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Balance outstanding at December 31, 2016	152,812	$ 18.94	3.30
Granted	-	-	-
Exercised	-	-	-
Forfeited	-	-	-
Expired	(1,249)	10.01	-
Balance outstanding at March 31, 2017	151,563	$ 19.01	3.08
Exercisable at March 31, 2017	151,563	$ 19.01	3.08

Note 8 – Commitments & Contingencies

From time to time the Company may become a party to litigation in the normal course of business. Management believes that there are no current legal matters that would have a material effect on the Company's financial position or results of operations.

On November 11, 2007, the Company entered into an at-will employment agreement with its Chief Operating Officer (now its Chief Technology Officer). The employment agreement required annual base salary payments of $200,000 per year, with a bonus potential of 20% of the then current base salary. In addition, the executive was granted an option to purchase 29,429 shares of Company's common stock exercisable at $10.01 per share, vesting in 3 equal annual installments on each anniversary of its three year term. The agreement also provided for severance compensation if terminated other than for cause (as defined therein) of 6 months of the then applicable base salary if the COO had been employed at least 6 months, and compensation equal to 12 months of the then applicable base salary if employed over 12 months.

Effective May 12, 2017, the Company and its Chief Technology Officer entered into a new employment agreement (see Note 9).

On August 28, 2014, the Company entered into a services agreement with StoryCorp Consulting dba Wells Compliance Group ("StoryCorp") for financial reporting and compliance services. David R. Wells is the owner of this firm and is the Company's Chief Financial Officer. The services agreement called for monthly payments of $5,000, and accrued an additional $3,000 per month in fees to be paid by common stock at the time of a public offering. The accrued balance due under the cash portion as of March 31, 2017 and December 31, 2016 was $15,000 and $25,000 respectively, and the accrued balance due under the stock portion was $90,000 and $81,000, respectively.

Effective May 12, 2017, the Company entered into a consulting agreement with StoryCorp Consulting that superseded the services agreement (see Note 9).

Effective January 1, 2015, we entered into an office lease agreement with Green Court, LLC, a Michigan limited liability company, for approximately 3,657 rentable square feet of space, for the initial monthly rent of $5,986, which commenced on January 1, 2015 for an initial term of 60 months. Under the terms of the lease the Company has an option on the same space for an additional 60-month term. Future minimum payments under this lease are as follows:

2017	$	56,486
2018		77,348
2019		79,269
Total	$	213,103

For the three month periods ended March 31, 2017 and 2016, the Company incurred rent expense of $18,968 and $18,165, respectively.

On April 16, 2015, the Company entered into an at-will employment agreement with its Chief Executive Officer. The employment agreement required annual base salary payments of $250,000 per year with a bonus potential of 50% of the then current base salary. In addition, the executive was granted an option to purchase 35,499 shares of Company's common stock exercisable at $10.01 per share, vesting in 3 equal annual installments on each anniversary of its three year term. The agreement also provided for severance compensation if terminated other than for cause (as defined therein) of 6 months of the then applicable base salary if the CEO has been employed at least 6 months, and compensation equal to 12 months of the then applicable base salary if employed over 12 months.

Effective May 12, 2017, the Company and its Chief Executive Officer entered into a new employment agreement (see Note 9).

Note 9 – Subsequent Events

Reverse Stock Split

On May 8, 2017, the Company filed a certificate of amendment (the "Certificate of Amendment") to its certificate of incorporation with the Secretary of State of the State of Delaware to effect a one-for-3.5 reverse stock split (the "Reverse Split") of the Company's common stock, with no reduction in authorized capital stock. Pursuant to the terms of the Certificate of Amendment, the Reverse Split became effective at 11:59 p.m. Eastern Time on May 8, 2017. In the Reverse Split, every 3.5 outstanding shares of common stock became one share of common stock. No fractional shares were issued in connection with the Reverse Split. Subject to the terms of the Certificate of Amendment, stockholders who were otherwise entitled to receive a fractional share of common stock received one whole share of common stock.

The Reverse Split was previously approved by holders of a majority of the Company's issued and outstanding common stock. All common stock and stock incentive plan information in these financial statements has been restated to reflect this split.

Conversion of Convertible Notes

In connection with the funding of the Company's initial public offering of its units (the "IPO"), on May 12, 2017, the principal and interest due under the Company's convertible notes, in an aggregate amount of $1,726,079, was converted into 1,232,859 shares of the Company's common stock. The purchasers of the convertible notes are subject to lock-up requirements with respect to the conversion shares for periods that expire on May 9, 2018.

Initial Public Offering of Units

The Company's Registration Statement on Form S-1, as amended (Reg. No. 333-214724), was declared effective by the Securities and Exchange Commission (the "SEC") on May 8, 2017, and the Company's Registration Statement on Form S-1 (Reg. No. 333-217788), which was filed on May 8, 2017 with the SEC pursuant to Rule 462(b) of the Securities Act of 1933, as amended (the "Securities Act"), became effective upon filing. These registration statements registered the securities offered in the IPO. In the IPO, the Company sold 1,932,000 units at a price to the public of $5.00 per unit, including the full exercise of the underwriters' option to purchase additional units. The IPO closed on May 12, 2017 and the underwriters exercised their overallotment option as of May 22, 2017, as a result of which the Company raised net proceeds of approximately $8.6 million after deducting approximately $773,000 in underwriting discounts, commissions and expenses and approximately $297,000 in offering expenses payable by the Company. National Securities Corporation and Dougherty & Company LLC were the underwriters of the IPO. No payments were made by the Company to its directors or officers or persons owning ten percent or more of its common stock or to their associates, or to the Company's affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

IPO Underwriters' Warrants

In connection with the closing of the IPO, the Company issued to the underwriters and their designees warrants to purchase an aggregate of 154,560 shares of the Company's common stock (the "Underwriters' Warrants") at an exercise price of $6.25 per share with an expiration date of May 8, 2022. The Underwriters' Warrants become exercisable on November 8, 2017.

Employment and Consulting Agreements

Effective as of May 12, 2017 upon the closing of the IPO, the Company entered into amended and restated employment agreements with Francois Michelon, its Chief Executive Officer and Chairman of its Board of Directors, and Michael Thornton, its Chief Technology Officer. Mr. Michelon's employment agreement provides for an annual base salary of $325,000 and eligibility for an annual cash bonus up to a percentage of such base salary (in 2016, up to 35% of his base salary then in effect). Mr. Thornton's employment agreement provides for an annual base salary of $245,000 and eligibility for an annual cash bonus up to a percentage of such base salary (in 2016, up to 22% of his base salary then in effect). The employment agreements also provide for eligibility to receive benefits substantially similar to those of the Company's other senior executive officers.

Pursuant to the employment agreements, Mr. Michelon and Mr. Thornton were each granted stock options to purchase a number of shares of the Company's common stock, that, taken together with the number of shares such officer already held, equal 5.0% of the Company's total issued and outstanding shares of common stock on a fully diluted basis following the IPO and underwriters' exercise of their overallotment option. The stock options have a weighted average exercise price of approximately $4.96, and vest in three equal annual installments beginning on May 12, 2019.

Effective as of May 12, 2017, the Company entered into a consulting agreement with StoryCorp, pursuant to which David Wells will continue to provide services to the Company as its Chief Financial Officer. Pursuant to the consulting agreement, the Company will pay to StoryCorp a monthly fee of $9,000. Additionally, pursuant to the consulting agreement, the Company granted to Mr. Wells a stock option to purchase 15,000 shares of common stock in connection with the closing of the IPO, having an exercise price per share equal to $5.00 (the price per unit to the public in the IPO) and vesting in twelve equal quarterly installments, and will grant to Mr. Wells a stock option to purchase the same number of shares of common stock with the same terms on each annual anniversary of the date of the consulting agreement. The consulting agreement supersedes the consulting agreement previously in effect between the Company and StoryCorp.

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

Forward-Looking Statements

As used in this Quarterly Report on Form 10-Q (this "Form 10-Q"), unless the context otherwise requires, the terms "we," "us," "our," "ENDRA" and the "Company" refer to ENDRA Life Sciences Inc., a Delaware corporation. The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our historical financial statements and related notes thereto in this Form 10-Q. This Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "could," "seek," "intend," "plan," "estimate," "anticipate" or other comparable terms. All statements other than statements of historical facts included in this Form 10-Q regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expectations for revenues, cash flows and financial performance, the anticipated results of our development efforts and the timing for receipt of required regulatory approvals and product launches. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: our ability to develop a commercially feasible technology; receipt of necessary regulatory approvals; our ability to find and maintain development partners, market acceptance of our technology, the amount and nature of competition in our industry; our ability to protect our intellectual property; and the other risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of this Form 10-Q. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Overview

We have commercialized an enhanced ultrasound technology for the pre-clinical research market and are leveraging that expertise to develop technology for increasing the capabilities of clinical diagnostic ultrasound, to broaden patient access to the safe diagnosis and treatment of a number of significant medical conditions in circumstances where expensive X-ray computed tomography ("CT") and magnetic resonance imaging ("MRI") technology is unavailable or impractical.

Since 2010, we have marketed and sold our Nexus 128 system, which combines light-based thermoacoustics and ultrasound, to address the imaging needs of researchers studying disease models in pre-clinical applications. Sales of the Nexus 128 system were approximately $1.4 million in 2015 and $515,000 in 2016. Our Nexus 128 system is used in a number of leading global academic research centers, including Stanford University, The University of Michigan, Shanghai Jiao Tong University, and Purdue University. We expect to continue to sell our Nexus 128 system to maintain a base level of revenue, but believe the market potential for our clinical systems is much higher.

Building on our expertise in thermoacoustics, we developed a next-generation technology platform — Thermo Acoustic Enhanced Ultrasound, or TAEUS — which is intended to enhance the capability of clinical ultrasound technology and support the diagnosis and treatment of a number of significant medical conditions that currently require the use of expensive CT or MRI imaging or where imaging is not practical using existing technology.

Unlike the near-infrared light pulses used in our Nexus 128 system, our TAEUS technology uses radio frequency ("RF") pulses to stimulate tissues, using a small fraction of the energy transmitted into the body during an MRI scan. The use of RF energy allows our TAEUS technology to penetrate deep into tissue, enabling the imaging of human anatomy at depths equivalent to those of conventional ultrasound. The RF pulses are absorbed by tissue and converted into ultrasound signals, which are detected by an external ultrasound receiver and a digital acquisition system that is part of the TAEUS system. The detected ultrasound is processed into images using our proprietary algorithms and overlaid in real time onto conventional gray-scale ultrasound images.

We expect that the first-generation TAEUS application will be a standalone ultrasound accessory designed to cost-effectively quantify fat in the liver and stage progression of non-alcoholic fatty liver disease, or ("NAFLD"), which can only be achieved today with impractical surgical biopsies or MRI scans. Subsequent TAEUS offerings are expected to be implemented via a second generation hardware platform that can run multiple clinical software applications that we will offer TAEUS users for a one-time licensing fee – adding ongoing customer value to the TAEUS platform and a growing software revenue stream for our Company.

Each of our TAEUS platform applications will require regulatory approvals before we are able to sell or license the application. Based on certain factors, such as the installed base of ultrasound systems, availability of other imaging technologies, such as CT and MRI, economic strength and applicable regulatory requirements, we intend to seek initial approval of our applications for sale in the European Union, followed by the United States and China.

Financial Operations Overview

Revenue

To date our revenue has been generated by the placement and sale of our Nexus 128 system for use in pre-clinical applications.

Cost of Goods Sold

Our cost of goods sold is related to our direct costs associated with the development and shipment of our thermoacoustic imaging systems placed in pre-clinical settings.

Research and Development Expenses

Our research and development expenses primarily include wages, fees and equipment for the development of our TAEUS technology platform and our proposed applications. Additionally, we incur certain costs associated with the protection of our products and inventions through a combination of patents, licenses, applications and disclosures.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of advertising, marketing and consulting expenses and headcount. Currently, our marketing efforts for our pre-clinical business are through distributors in China, the European Union, Australia, Korea and the United Kingdom, our website, and attendance of key industry meetings. In connection with the commercialization of our TAEUS applications, we expect to build a small sales and marketing team to train and support global ultrasound distributors, as well as execute traditional marketing activities such as promotional materials, electronic media and participation in industry conferences.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related expenses for our management and personnel, and professional fees, such as accounting, consulting and legal.

Critical Accounting Policies and Estimates

Use of Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Management makes estimates that affect certain accounts including deferred income tax assets, accrued expenses, fair value of equity instruments and reserves for any other commitments or contingencies. Any adjustments applied to estimates are recognized in the period in which such adjustments are determined.

Share-based Compensation

Our 2016 Omnibus Incentive Plan which has been approved by our board of directors, permits the grant of share options and shares to our employees, consultants and non-employee members of our board of directors for up to 1,345,074 shares of common stock. We record share-based compensation in accordance with the provisions of the Share-based Compensation Topic of the FASB Codification. The guidance requires the use of option-pricing models that require the input of highly subjective assumptions, including the option's expected life and the price volatility of the underlying stock. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option valuation model which uses certain assumptions related to risk-free interest rates, expected volatility, expected life of the common stock options, and future dividends, and the resulting charge is expensed using the straight-line attribution method over the vesting period.

Stock compensation expense recognized during the period is based on the value of share-based awards that were expected to vest during the period adjusted for estimated forfeitures. The estimated fair value of grants of stock options and warrants to non-employees is charged to expense, if applicable, in the financial statements.

Recent Accounting Pronouncements

See Note 2 of the financial statements for a discussion of recently issued accounting standards.

Results of Operations

Three Months Ended March 31, 2017 and 2016

Revenues

We had no revenue for the three months ended March 31, 2017, and March 31, 2016.

Research and Development

Research and development expenses were $95,814 for the three months ended March 31, 2017, as compared to $95,237 for the three months ended March 31, 2016, an increase of $577, or 1%. The costs include primary wages, fees and equipment for the development of our TAEUS product line. Research and development expenses were unchanged from the same period for the prior year and consisted mostly of wages and employment related expenses.

Sales and Marketing

Sales and marketing expenses were $1,124 for the three months ended March 31, 2017, as compared to $4,433 for the three months ended March 31, 2016, a decrease of $3,309, or 75%. The decrease was primarily due to reduced commissions paid on the sale of our Nexus 128 system. Currently our marketing efforts for our pre-clinical business are through distributors in China, the European Union, Australia and the United Kingdom, our website and attendance of key industry meetings. Our future clinical business will involve hiring and training additional staff to support our sales efforts. As we seek to complete the development and commercialization of our TAEUS applications, we intend to build a small sales and marketing team to train and support global ultrasound distributors, as well as execute traditional marketing activities such as promotional materials, electronic media and participation in industry conferences.

General and Administrative

Our general and administrative expenses for the three months ended March 31, 2017 were $263,760, a decrease of $10,026, or 4%, compared to $273,786 for the three months ended March 31, 2016. General and administrative expenses decreased due to a decrease in headcount, offset by one-time expenses related to the IPO. Our wage and related expenses for the three months ended March 31, 2017 were $126,766, compared to $159,400 for the three months ended March 31, 2016. Wage and related expenses in the three month period ended March 31, 2017 included $20,697 of stock compensation expense related to the issuance and vesting of options, compared to $69,240 of stock compensation expense for 2016. Our professional fees for the three months ended March 31, 2017 were $72,472, compared to $56,425 for the three months ended March 31, 2016. We expect that our general and administrative expenses will increase significantly as a result of our becoming a public company.

Net loss

As a result of the foregoing, for the three months ended March 31, 2017, we recorded a net loss of $741,623 compared to a net loss of $379,478 for the three months ended March 31, 2016.

Liquidity and Capital Resources

To date, we have generated only limited revenues from sales of our Nexus 128 system. We have funded our operations to date through private and public sales of our securities. As of March 31, 2017, we had $133,679 in cash. In May 2017, we completed our initial public offering (the “IPO”), raising net proceeds of approximately $8.6 million after deducting offering expenses of approximately $773,000 in underwriting discounts, commissions and expenses and approximately $297,000 in offering expenses payable by the Company.

The financial statements included in this Form 10-Q have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As reflected in the accompanying financial statements, during the three months ended March 31, 2017, the Company incurred a net loss of $741,623 used cash in operations of $236,274, and at March 31, 2017, the Company had a stockholders’ deficit of $1,379,706. These and other factors raise substantial doubt about the Company’s ability to continue as a going concern for one year from the issuance of the financial statements. The financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

Operating Activities

During the three months ended March 31, 2016, the Company used $53,757 of cash in operating activities primarily as a result of its net loss of $379,478, offset in part by net changes in operating assets and liabilities of $225,477, $16,181 in depreciation and amortization expense, $78,240 in non-cash stock compensation expense, and additional warrants issued during the warrant exchange program of $5,823.

During the three months ended March 31, 2017, the Company used $236,274 of cash in operating activities primarily as a result of its net loss of $741,623, offset by amortization of discount of convertible debt of $351,727, share-based compensation of $29,697, $15,690 in depreciation and amortization expenses, and net changes in operating assets and liabilities of $107,247.

Investing Activities

There were no investing activities for the three months ended March 31, 2017 and 2016.

Financing Activities

During the three months ended March 31, 2016, financing activities provided $55,000, including $5,000 from common stock issued for cash, and $50,000 in proceeds from notes payable.

During the three months ended March 31, 2017, financing activities provided $225,000 in proceeds from issuance of convertible notes.

Funding Requirements

We have not completed development of our TAEUS technology platform applications. We expect to continue to incur significant expenses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- advance the engineering design and development of our NAFLD TAEUS application;
- prepare applications required for marketing approval of our NAFLD TAEUS application in the European Union and the United States;
- seek to hire a small internal marketing team to engage and support channel partners and clinical customers for our NAFLD TAEUS application;
- commence marketing of our NAFLD TAEUS application;
- advance development of our other TAEUS applications; and
- add operational, financial and management information systems and personnel, including personnel to support our product development, planned commercialization efforts and our operation as a public company.

We believe that our existing cash, taking into account the net proceeds of our IPO, will be sufficient for us to fund the development and regulatory approval and to prepare for the commercialization of our NAFLD TAEUS application in the European Union. It is possible that we will not achieve the progress that we expect because the actual costs and timing of completing the development and regulatory approvals for a new medical device are difficult to predict and are subject to substantial risks and delays. We have no committed external sources of funds. We do not expect that our existing cash will be sufficient for us to complete the commercialization of our NAFLD TAEUS application or to complete the development of any other TAEUS application and we will need to raise substantial additional capital for those purposes. As a result, we will need to finance our future cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in the section entitled “Risk Factors” and elsewhere in this Form 10-Q. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Until we can generate a sufficient amount of revenue from our TAEUS platform applications, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or applications or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Off Balance Sheet Transactions

We do not have any off balance sheet transactions.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

The information required by Item 3 is not required to be provided by issuers that satisfy the definition of “smaller reporting company” under Securities and Exchange Commission rules.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Form 10-Q, management performed, with the participation of our principal executive officer and principal financial officer, an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”). Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission’s forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosures. Based on the evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2017, our disclosure controls and procedures were not effective.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. We identified the following material weakness as of March 31, 2017: insufficient personnel resources within the accounting function to segregate the duties over financial transaction processing and reporting.

To remediate our internal control weaknesses, management intends to implement the following measures, as finances allow:

- We will add sufficient accounting personnel or outside consultants to properly segregate duties and to effect a timely, accurate preparation of the financial statements.
- Upon the hiring of additional accounting personnel or outside consultants, we will develop and maintain adequate written accounting policies and procedures.

The additional hiring is contingent upon our efforts to obtain additional funding and the results of our operations. Management expects to secure funds in the coming fiscal year but provides no assurances that it will be able to do so.

Changes in Internal Control over Financial Reporting

There was no change to our internal controls or in other factors that could affect these controls during the three month period ended March 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. However, our management is currently seeking resolutions to improve our controls and procedures in an effort to remediate the deficiency described above.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any pending legal proceedings that we believe will have a material adverse effect on our business or financial conditions. We may, however, be subject to various claims and legal actions arising in the ordinary course of business from time to time.

Item 1A. Risk Factors

Investing in our securities involves a high degree of risk. You should carefully consider the following risks and all other information contained in this Quarterly Report on Form 10-Q, including our financial statements and the related notes, before investing in our securities. The risks and uncertainties described below supplement, or to the extent inconsistent, supersede those disclosed in our final Prospectus for our initial public offering as filed with the Securities and Exchange Commission on May 10, 2017. The risks and uncertainties described below are not the only ones we face, but include the most significant factors currently known by us that make investing in our securities speculative or risky. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, also may become important factors that affect us. If any of the following risks materialize, our business, financial condition and results of operations could be materially harmed. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to Our Business

We have a history of operating losses, and we may never achieve or maintain profitability.

We have a limited operating history upon which investors may evaluate our prospects. We have only generated limited revenues to date and have a history of losses from operations. As of March 31, 2017, we had an accumulated deficit of approximately $1,379,706. We will require additional capital to complete the commercialization of our planned TAEUS applications and to meet our growth and profitability targets. We expect to expend significant resources on hiring of personnel, payroll and benefits, continued scientific and potential product research and development, potential product testing and pre-clinical and clinical investigations, intellectual property development and prosecution, marketing and promotion, capital expenditures, working capital, and general and administrative expenses. We also expect to incur costs and expenses related to consulting, laboratory development, hiring of scientists and other operational personnel, and expenses associated with the development of relationships with strategic partners.

Our Thermo Acoustic Enhanced Ultrasound, or ("TAEUS"), technology is still in development and we do not have any applications for our TAEUS technology approved for sale. Applications for our TAEUS technology may never be approved, generate significant revenue or become commercially viable. Our ability to generate significant revenues and, ultimately, achieve profitability will depend on whether we can obtain additional capital when we need it, complete the development of our technology, receive required regulatory approvals for our TAEUS applications and find customers who will purchase our future products or strategic partners that will incorporate our technology into their products. Even if we develop commercially viable applications for our TAEUS technology, which may include licensing, we may never recover our research and development expenses and we may never be able to produce material revenues or operate on a profitable basis.

Our efforts may never result in the successful development of commercial applications based on our TAEUS technology.

Due to the limited tissue penetration capability of light-based thermoacoustic technology, we believe that there is a limited clinical market for our current Nexus 128 product, which is focused on laboratory specimen analysis. As a result, we are currently focused on the development of products based on our TAEUS technology. We have not yet completed the development of any applications based on such technology. Our research and development efforts remain subject to all of the risks associated with the development of new products based on emerging technologies, including, without limitation, unanticipated technical or other problems, the inability to develop a product that may be sold at an acceptable price point and the possible insufficiency of funds needed in order to complete development of these products. Technical problems may result in delays and cause us to incur additional expenses that would increase our losses. If we cannot complete, or if we experience significant delays in developing applications based on, our TAEUS technology, particularly after incurring significant expenditures, our business may fail.

Our success is substantially dependent on the success of applications for our TAEUS platform.

To date we have generated only limited sales of our existing Nexus 128 product and our ability to generate meaningful revenues in the future will depend on the successful development and commercialization of our TAEUS platform applications. The commercial success of our TAEUS platform applications and our ability to generate revenues will depend on many factors, including the following:

- our successful development of applications for our TAEUS technology, such as those we intend to pursue for the diagnosis of Non-Alcohol Fatty Liver Disease, or ("NAFLD"), and the monitoring of thermal ablation surgery, and the acceptance in the marketplace by physicians and patients of such applications;
- the successful design and manufacturing of a device or devices which enable the use of our TAEUS technology by physicians on their patients;
- receipt of necessary regulatory approvals;
- sufficient coverage or reimbursement by third-party payors;
- our ability to successfully market our products;
- our ability to demonstrate that our TAEUS applications have advantages over competing products and procedures;
- the amount and nature of competition from competing or alternative imaging products; and
- our ability to establish and maintain commercial manufacturing, distribution and sales force capabilities.

We have limited data regarding the efficacy of our TAEUS platform applications. If our applications do not perform in accordance with our expectations, we are unlikely to successfully commercialize our applications, even if they receive regulatory approval.

Our success depends in large part on the medical and third-party payor community's acceptance of our TAEUS applications. As a result, even if we receive regulatory approval for our applications, we believe that we will need to obtain additional clinical data from users of our applications to persuade medical professions to use our applications. We may conduct post-approval clinical testing to obtain such additional data. Clinical testing is expensive, can take a significant amount of time to complete and can have uncertain outcomes. We have not yet conducted any clinical studies and there can be no assurance that the results of any such studies will be positive. Our failure to conduct successful clinical studies could have a material, adverse impact on our business.

Our limited operating history makes it difficult to evaluate our business, predict our future results or forecast our financial performance and growth.

We were incorporated in 2007 and began commercializing our initial pre-clinical Nexus 128 product in 2010. Our limited operating history makes it difficult to evaluate our business, predict our future results or forecast our financial performance and growth. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

We may not remain commercially viable if there is an inadequate level of reimbursement by governmental programs and other third-party payors.

Medical imaging products are purchased principally by hospitals, physicians and other healthcare providers around the world that typically bill various third-party payors, including governmental programs (*e.g.*, Medicare and Medicaid in the United States), private insurance plans and managed care programs, for the services provided to their patients.

Third-party payors and governments may approve or deny coverage for certain technologies and associated procedures based on independently determined assessment criteria. Reimbursement decisions by payors for these services are based on a wide range of methodologies that may reflect the services' assessed resource costs, clinical outcomes and economic value. These reimbursement methodologies and decisions confer different, and sometimes conflicting, levels of financial risk and incentives to healthcare providers and patients, and these methodologies and decisions are subject to frequent refinements. Third-party payors are also increasingly adjusting reimbursement rates, often downwards, indirectly challenging the prices charged for medical products and services. There can be no assurance that our products will be covered by third-party payors, that adequate reimbursement will be available or, even if payment is available, that third-party payors' coverage policies will not adversely affect our ability to sell our products profitably.

We will depend on third parties to design, manufacture and seek regulatory approval of our TAEUS applications. If any third party fails to successfully design, manufacture and gain regulatory approval of our TAEUS applications, our business will be materially harmed.

We currently intend to outsource the design and manufacturing of applications utilizing our TAEUS technology rather than manufacture our TAEUS applications ourselves. We will have limited control over the efforts and resources that any third-party original equipment manufacturer ("OEM"), will devote to developing and manufacturing our TAEUS applications. In addition, we currently expect to depend on OEMs to acquire CE marks for the device or devices that they develop and manufacture which are necessary to permit marketing of those devices in the European Union.

An OEM may not be able to successfully design and manufacture the products it develops based on our TAEUS technology, may not devote sufficient time and resources to support these efforts or may fail in gaining the required regulatory approvals of our TAEUS applications. The failure by an OEM in its efforts to design, manufacture or gain regulatory approval of our TAEUS applications could substantially harm the value of our TAEUS technology, brand and business.

If we are unable to manage the anticipated growth of our business, our future revenues and operating results may be harmed.

Because of our small size, growth in accordance with our business plan, if achieved, will place a significant strain on our financial, technical, operational and management resources. As we expand our activities, there will be additional demands on these resources. The failure to continue to upgrade our technical, administrative, operating and financial control systems or the occurrence of unexpected expansion difficulties, including issues relating to our research and development activities and retention of experienced scientists, managers and technicians, could have a material adverse effect on our business, financial condition and results of operations and our ability to timely execute our business plan. If we are unable to implement these actions in a timely manner, our results may be adversely affected.

Competition in the medical imaging market is intense and we may be unable to successfully compete.

In general, competition in the medical imaging market is very significant and characterized by extensive research and development and rapid technological change. Competitors in this market include very large companies with significantly greater resources than we have. To successfully compete in this market we will need to develop TAEUS applications for particular applications that offer significant advantages over alternative imaging products and procedures for such applications.

Developments by other medical imaging companies of new or improved products, processes or technologies may make our products or proposed products obsolete or less competitive. Alternative medical imaging devices may be more accepted or cost-effective than our products. Competition from these companies for employees with experience in the medical imaging industry could result in higher turnover of our employees. If we are unable to respond to these competitive pressures, we could experience delayed or reduced market acceptance of our products, higher expenses and lower revenue. If we are unable to compete effectively with current or new entrants to these markets, we will be unable to generate sufficient revenue to maintain our business.

Changes in the healthcare industry could result in a reduction in the size of the market for our products or may require us to decrease the selling price for our products, either of which could have a negative impact on our financial performance.

Trends toward managed care, healthcare cost containment, and other changes in government and private sector initiatives in Europe, the United States and China are placing increased emphasis on lowering the cost of medical services, which could adversely affect the demand for or the prices of our products. For example:

- major third-party payors of hospital and non-hospital based healthcare services could revise their payment methodologies and impose stricter standards for reimbursement of imaging procedures charges and/or a lower or more bundled reimbursement;
- there has been a consolidation among healthcare facilities and purchasers of medical devices who prefer to limit the number of suppliers from whom they purchase medical products, and these entities may decide to stop purchasing our products or demand discounts on our prices;
- there is economic pressure to contain healthcare costs in markets throughout the world; and
- there are proposed and existing laws and regulations in international and domestic markets regulating pricing and profitability of companies in the healthcare industry.

These trends could lead to pressure to reduce prices for our products and could cause a decrease in the demand for our products in any given market that could adversely affect our revenue and profitability, which could harm our business.

We have limited selling, marketing and manufacturing resources, which may restrict our success in commercializing our TAEUS technology.

We currently do not have a sales, marketing, customer support or manufacturing team dedicated to our TAEUS clinical applications. To grow our business as planned, we must expand our sales, marketing, customer support and manufacturing capabilities. We must also establish satisfactory arrangements for the manufacture and distribution of our TAEUS applications, which will involve the development of our commercial infrastructure and/or collaborative commercial arrangements and partnerships. We may be unable to attract, retain and manage the specialized workforce and collaborative manufacturing and distribution arrangements necessary to successfully commercialize our products. In addition, developing these functions is time consuming and expensive. We intend to partner with others to assist us with some or all of these functions. However, we may be unable to find appropriate third parties with whom to enter into these arrangements. Furthermore, if we do enter into these arrangements, these third parties may not perform as expected.

If we experience problems in our relationships with our distributors, our ability to sell our products could be limited.

Because we are a small company with limited resources, we expect to depend on distributors to help promote market acceptance and demand for our products. Distributors that are in the business of selling other medical products may not devote a sufficient level of resources and support required to generate awareness of our products and grow or maintain product sales. If our distributors are unwilling or unable to market and sell our products, or if they do not perform to our expectations, we could experience delayed or reduced market acceptance and sales of our products. In addition, disagreements with our distributors or non-performance by these third parties could lead to costly and time-consuming litigation or arbitration and disrupt distribution channels for a period of time and require us to re-establish a distribution channel.

We have and may in the future form or seek additional strategic alliances, collaborations or enter into licensing arrangements, and we may not realize the benefits of such alliances, collaborations or licensing arrangements.

On April 22, 2016, we entered into a Collaborative Research Agreement with GE Healthcare under which GE Healthcare has agreed to support our efforts to commercialize our TAEUS technology for use in an NAFLD application by, among other things, providing equipment and technical advice and facilitating introductions to GE Healthcare clinical ultrasound customers. This agreement does not commit GE Healthcare to a long-term relationship and it may disengage with us at any time. This agreement has a term of one year and is subject to termination by either party upon not less than 60 days' notice. On April 21, 2017, we and GE Healthcare entered into an amendment to our agreement, extending its term by one year to April 22, 2018.

We intend in the future to form or seek additional strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our technologies and applications.

Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. If we license technologies or applications, we may not be able to realize the benefit of such transactions. Further, strategic alliances and collaborations are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our technologies and applications or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon the development of an application, repeat or conduct new clinical trials, or require a new formulation of an application for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our applications and technologies;
- a collaborator with marketing and distribution rights to one or more applications may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our technologies and applications, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable applications or technologies; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our applications or technologies, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our applications could delay the development and commercialization of our technologies and applications in certain geographies or for certain applications, which would harm our business prospects, financial condition and results of operations.

We intend to market our TAEUS applications, if approved, globally, in which case we will be subject to the risks of doing business outside of the United States.

Because we intend to market our TAEUS applications, if approved, globally, our business may be subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in local jurisdictions;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection in certain countries;
- trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the United States Department of Commerce and fines, penalties or suspension or revocation of export privileges;
- effects of applicable local tax structures and potentially adverse tax consequences; and
- significant adverse changes in currency exchange rates.

We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business.

Our success largely depends upon the continued services of our executive management team and key employees and the loss of one or more of our executive officers or key employees could harm us and directly impact our financial results. Our employees may terminate their employment with us at any time. Our executive management team has significant experience and knowledge of medical devices and ultrasound systems, and the loss of any team member could impair our ability to design, identify, and develop new intellectual property and new scientific or product ideas. Additionally, if we lose the services of any of these persons, we would likely be forced to expend significant time and money in the pursuit of replacements, which may result in a delay in the implementation of our business plan and plan of operations. We can give no assurance that we could find satisfactory replacements for these individuals on terms that would not be unduly expensive or burdensome to us.

To execute our growth plan, we must attract and retain highly qualified personnel. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing medical devices and for sales executives, especially with industry expertise. We may experience difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we have. In addition, we invest significant time and expense in training our employees, which increases their value to competitors who may seek to recruit them. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the U.S. Food, Drug and Cosmetics Act, or the FD&C Act, and similar laws of other countries, and rules and regulations of the U.S. Food and Drug Administration, or the FDA, and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; comply with manufacturing standards we establish; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain European, Chinese or FDA approval of any of our products and begin commercializing those products in Europe, China or the United States, respectively, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Misdiagnosis, warranty and other claims initiated against us and product field actions could increase our costs, delay or reduce our sales and damage our reputation, adversely affecting our financial condition.

Our business exposes us to the risk of malpractice, warranty or product liability claims inherent in the sale and support of medical device products, including those based on claims that the use or failure of one of our products resulted in a misdiagnosis or harm to a patient. Such claims may cause financial loss, damage our reputation by raising questions about our products' safety and efficacy, adversely affect regulatory approvals and interfere with our efforts to market our products. Although to date we have not been involved in any medical malpractice or product liability litigation, we may incur significant liability if such litigation were to occur. We may also face adverse publicity resulting from product field actions or regulatory proceedings brought against us. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability or related claims, we may incur substantial liabilities or be required to limit distribution of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and negative media attention;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize a product at all or for particular applications; and
- a decline in the price of our securities.

Although we currently maintain liability insurance in amounts we believe are commercially reasonable, any liability we incur may exceed our insurance coverage. Our insurance policies may also have various exclusions, and we may be subject to a claim for which we have no coverage. Liability insurance is expensive and may cease to be available on acceptable terms, if at all. A malpractice, warranty, product liability or other claim or product field action not covered by our insurance or exceeding our coverage could significantly impair our financial condition. In addition, a product field action or a liability claim against us could significantly harm our reputation and make it more difficult to obtain the funding and commercial relationships necessary to maintain our business.

Our internal computer systems, or those used by third-party manufacturers or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future manufacturers and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our products could be delayed.

Unfavorable economic conditions may have an adverse impact on our business.

Unfavorable changes in economic conditions, including inflation, recession, or other changes in economic conditions, may result in lower consumer healthcare spending as well as physician and hospital spending and availability of credit. If demand for medical devices or budgets for capital improvements decline, our revenue could be adversely affected. Additionally, if our suppliers face challenges in obtaining credit, in selling their products or otherwise in operating their businesses, they may become unable to continue to offer the materials we use to manufacture our products, which could result in sales disruption.

We may face significant challenges if global economic conditions remain unstable or worsen, including reduced demand for our products and services, increased order cancellations, longer sales cycles and slower adoption of new technologies; increased difficulty in collecting accounts receivable and increased risk of excess and obsolete inventories; increased price competition in our served markets; increased prices in components as a result of higher commodities prices; supply chain interruptions, which could disrupt our ability to produce our products; and increased risk of impairment of investments, goodwill and intangible and long-lived assets.

The United Kingdom's vote to leave the European Union will have uncertain effects and could adversely affect us.

The United Kingdom held a referendum on June 23, 2016 in which a majority of voters voted to exit the European Union, commonly referred to as "Brexit". Negotiations are expected to commence to determine the future terms of the United Kingdom's relationship with the European Union, including, among other things, the terms of trade between the United Kingdom and the European Union. The effects of Brexit will depend on any agreements the United Kingdom makes to retain access to E.U. markets either during a transitional period or more permanently. Brexit could adversely affect European and worldwide economic and market conditions and could contribute to instability in global financial and foreign exchange markets, including volatility in the value of the Sterling and Euro. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which E.U. laws to replace or replicate. Any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, results of operations, financial condition and cash flows.

Risks Related to Intellectual Property and Other Legal Matters

If we are unable to protect our intellectual property, then our financial condition, results of operations and the value of our technology and products could be adversely affected.

Much of our value arises out of our proprietary technology and intellectual property for the design, manufacture and use of medical imaging systems, including development of our TAEUS applications. We rely on patent, copyright, trade secret and trademark laws to protect our proprietary technology and limit the ability of others to compete with us using the same or similar technology. Third parties may infringe or misappropriate our intellectual property, which could harm our business.

We currently maintain a patent portfolio consisting of one current granted patent and twelve pending patent applications in the United States and foreign jurisdictions relating to our technology. In addition, we currently license eight granted patents and three pending patent applications in the United States and foreign jurisdictions. We or our licensor may fail to maintain these patents, may determine not to pursue litigation against entities that are infringing upon these patents, or may pursue such enforcement less aggressively than we ordinarily would.

Policing unauthorized use of our intellectual property is difficult, costly and time-intensive. We may fail to stop or prevent misappropriation of our technology, particularly in countries where the laws may not protect our proprietary rights to the same extent as do the laws of the United States. Proceedings to enforce our patent and other intellectual property rights in non-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. If we cannot prevent other companies from using our proprietary technology or if our patents are found invalid or otherwise unenforceable, we may be unable to compete effectively against other manufacturers of ultrasound systems, which could decrease our market share. In addition, the breach of a patent licensing agreement by us may result in termination of a patent license.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to our patent activities, we rely upon, among other things, unpatented proprietary technology, processes, trade secrets and know-how. Any involuntary disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third parties. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. To the extent that any of our staff was previously employed by other pharmaceutical, medical technology or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their former employee's therapeutic development activities for us.

We may in the future be a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell our TAEUS applications.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Other medical imaging market participants, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use product names. We may become a party to patent or trademark infringement or trade secret claims and litigation as a result of these and other third party intellectual property rights being asserted against us. The defense and prosecution of these matters are both costly and time consuming. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third party's patent or trademark or of misappropriating a third party's trade secret.

Further, if such patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney fees and court costs. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our TAEUS applications to avoid infringement.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or USPTO, may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re-examination, inter partes review, or opposition proceedings, before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our TAEUS applications or using product names, which would have a significant adverse impact on our business.

Additionally, we may need to commence proceedings against others to enforce our patents or trademarks, to protect our trade secrets or know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. These proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. We may not be able to stop a competitor from marketing and selling products that are the same or similar to our products or from using product names that are the same or similar to our product names, and our business may be harmed as a result.

Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our TAEUS platform, brand and business.

Risks Related to Government Regulation

Failure to comply with laws and regulations could harm our business.

Our business is or in the future may be subject to regulation by various federal, state, local and foreign governmental agencies, including agencies responsible for monitoring and enforcing employment and labor laws, workplace safety, environmental laws, consumer protection laws, anti-bribery laws, import/export controls, securities laws and tax laws and regulations. In certain jurisdictions, these regulatory requirements may be more stringent than those in the United States. Noncompliance with applicable regulations or requirements could subject us to investigations, sanctions, mandatory recalls, enforcement actions, adverse publicity, disgorgement of profits, fines, damages, civil and criminal penalties or injunctions and administrative actions. If any governmental sanctions, fines or penalties are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, operating results and financial condition could be harmed. In addition, responding to any action will likely result in a significant diversion of management's attention and our resources and substantial costs. Enforcement actions and sanctions could further harm our business, operating results and financial condition.

If we fail to obtain and maintain necessary regulatory clearances or approvals for our TAEUS applications, or if clearances or approvals for future applications and indications are delayed or not issued, our commercial operations will be harmed.

The medical devices that we manufacture and market are subject to regulation by numerous worldwide regulatory bodies, including the FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing development, testing, manufacturing, labeling, marketing and distribution of medical devices. Devices are generally subject to varying levels of regulatory control, based on the risk level of the device. Governmental regulations specific to medical devices are wide-ranging and govern, among other things:

- product design, development and manufacture;
- laboratory, pre-clinical and clinical testing, labeling, packaging storage and distribution;
- premarketing clearance or approval;
- record keeping;
- product marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

In the European Union, we will be required to comply with applicable medical device directives (including the Medical Devices Directive and the Active Implantable Medical Devices Directive) and obtain CE mark certification in order to market medical devices. The CE mark is applied following approval from an independent notified body or declaration of conformity. It is an international symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. We believe that our TAEUS applications will qualify for sale in the European Union as Class IIa medical devices. Existing regulations do not require clinical trials to obtain CE marks for Class IIa medical devices. However, in 2012 the European Commission proposed a new regulatory scheme that, if implemented, will impose significant additional obligations on medical device companies. Expected changes include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by government accredited groups for some types of medical devices, and tightened and streamlined quality management system assessment procedures. It is anticipated that this new regulatory scheme may be implemented prior to receipt of the CE mark for our NAFLD TAEUS application but we believe that applicable transition rules should allow us to avoid their application in that case. However, such new rules could impose additional requirements, such as a requirement to conduct clinical trials, on future CE mark applications we make.

We are also required to comply with the regulations of each other country where we commercialize products, such as the requirement that we obtain approval from the FDA and the China Food and Drug Administration before we can launch new products in the United States and China, respectively.

International sales of medical devices manufactured in the United States that are not approved by the FDA for use in the United States, or that are banned or deviate from lawful performance standards, are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the United States due to differing regulatory requirements; however, other countries, such as China for example, require approval in the country of origin first.

Before a new medical device or a new intended use for an existing product can be marketed in the United States, a company must first submit and receive either 510(k) clearance or premarketing approval, or PMA, from the FDA, unless an exemption applies. The typical duration to receive a 510(k) approval is approximately nine to twelve months from the date of the initial 510(k) submission and the typical duration to receive a PMA approval is approximately two years from the date of submission of the initial PMA application, although there is no guarantee that the timing will not be longer.

We expect all of our products to be classified as Class II medical devices that may be approved by means of a 510(k) clearance. In the past, the 510(k) pathway for product marketing has required only proof of substantial equivalence in technology for a given indication with a previously cleared device. Recently, there has been a trend of the FDA requiring additional clinical work to prove efficacy in addition to technological equivalence and basic safety. Whether clinical data is provided or not, the FDA may decide to reject the substantial equivalence argument we present. If that happens, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the “de novo” process, which may determine that the new device is of low to moderate risk and that it can be appropriately be regulated as a Class I or II device. Thus, although at this time we do not anticipate that we will be required to do so, it is possible that one or more of our other products may require approval through the 510(K) de novo process or by means of a PMA.

We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Therefore, even if we believe we have successfully developed our TAEUS technology, we may not be permitted to market TAEUS applications in the United States if we do not obtain FDA regulatory clearance to market such applications. Delays in obtaining clearance or approval could increase our costs and harm our revenues and growth.

In addition, we are required to timely file various reports with the FDA, including reports required by the medical device reporting regulations that require us to report to certain regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publically available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition would be harmed.

Our TAEUS applications may require recertification or new regulatory clearances or premarket approvals and we may be required to recall or cease marketing our TAEUS applications until such recertification or clearances are obtained.

Most countries outside of the United States require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and, where needed, conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

In the United States, material modifications to the intended use or technological characteristics of our TAEUS applications will require new 510(k) clearances or premarket approvals or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval.

We may not be able to obtain recertification or additional 510(k) clearances or premarket approvals for our applications or for modifications to, or additional indications for, our TAEUS technology in a timely fashion, or at all. Delays in obtaining required future governmental approvals would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. If foreign regulatory authorities or the FDA require additional approvals, we may be required to recall and to stop selling or marketing our TAEUS applications, which could harm our operating results and require us to redesign our applications. In these circumstances, we may be subject to significant enforcement actions.

If we or our suppliers fail to comply with the FDA's Quality System Regulations or other regulatory bodies' equivalent regulations, our manufacturing operations could be delayed or shut down and TAEUS platform sales could suffer.

Our manufacturing processes and those of our third party suppliers will be required to comply with the FDA's Quality System Regulations and other regulatory bodies' equivalent regulations, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our TAEUS applications. We will also be subject to similar state requirements and licenses. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we fail such an inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse inspection could result in, among other things, a shut-down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our products, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our product and cause our results of operations to suffer.

Our TAEUS applications may in the future be subject to product recalls that could harm our reputation.

Governmental authorities in Europe, the United States and China have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. Recalls of our TAEUS applications would divert managerial attention, be expensive, harm our reputation with customers and harm our financial condition and results of operations. A recall announcement would negatively affect the price of our securities.

Healthcare reform measures could hinder or prevent our planned products' commercial success.

There have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could harm our future revenues and profitability and the future revenues and profitability of our potential customers. In the European Union, although there have not been any recent amendments to the relevant regulatory legislation, there are ongoing discussions regarding amending the current regulatory framework for medical devices. Moreover, because the Medical Devices Directive requires only minimum harmonization in the European Union, member countries may alter their enforcement of the directives or amend their national regulatory rules. We cannot predict what healthcare initiatives, if any, will be implemented by the European Union or E.U. member countries, or the effect any future legislation or regulation will have on us.

In the United States, federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or Affordable Care Act, was enacted in 2010. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things, imposes an excise tax of 2.3% on the sale of most medical devices, including ours, and any failure to pay this amount could result in the imposition of an injunction on the sale of our products, fines and penalties.

It remains unclear whether changes will be made to the Affordable Care Act, or whether it will be repealed or materially modified. We cannot assure you that the Affordable Care Act, as currently enacted or as amended or discontinued in the future, will not harm our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability; and
- the availability of capital.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. Other jurisdictions such as the European Union have similar laws. The regulations that will affect how we operate include:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;

- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal Physician Payment Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The Affordable Care Act, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal and similar foreign healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could harm our ability to operate our business and our results of operations.

Compliance with environmental laws and regulations could be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability.

Our research and development and manufacturing operations may involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. In addition, our research and development and manufacturing operations produce biological waste materials, such as human and animal tissue, and waste solvents, such as isopropyl alcohol. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third part property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

Risks Related to Owning Our Securities, Our Financial Results and Our Need for Financing

Our quarterly and annual results may fluctuate significantly, may not fully reflect the underlying performance of our business and may result in decreases in the price of our securities.

Our operating results will be affected by numerous factors such as:

- variations in the level of expenses related to our proposed products;
- status of our product development efforts;
- execution of collaborative, licensing or other arrangements, and the timing of payments received or made under those arrangements;
- intellectual property prosecution and any infringement lawsuits to which we may become a party;
- regulatory developments affecting our products or those of our competitors;
- our ability to obtain and maintain FDA clearance and approval from foreign regulatory authorities for our products, which have not yet been approved for marketing;
- market acceptance of our TAEUS applications;
- the availability of reimbursement for our TAEUS applications;
- our ability to attract new customers and grow our business with existing customers;
- the timing and success of new product and feature introductions by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations;
- changes in our pricing policies or those of our competitors;
- general economic, industry and market conditions;
- the hiring, training and retention of key employees, including our ability to expand our sales team;
- litigation or other claims against us;
- our ability to obtain additional financing; and
- advances and trends in new technologies and industry standards.

Any or all of these factors could adversely affect our cash position, requiring us to raise additional capital which may be on unfavorable terms and result in substantial dilution.

If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our securities may decrease.

As a public company, we are be required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act of 2002, (the "Sarbanes-Oxley Act"), requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our annual report for the year ending December 31, 2018, provide a management report on our internal control over financial reporting, which must be attested to by our independent registered public accounting firm to the extent we are no longer an “emerging growth company,” as defined by the Jumpstart Our Businesses Act of 2012 (the "JOBS Act").

Currently, we have material weaknesses in our internal control over financial reporting and, as a result, we may not detect errors on a timely basis and our financial statements may be materially misstated. We are in the process of designing and implementing our internal control over financial reporting, which process will be time consuming, costly and complicated. However, we are a small organization with limited management resources. In addition to serving as our Chief Financial Officer, David Wells provides financial consulting services to several other companies. These other consulting services could prevent Mr. Wells from dedicating sufficient time and attention to us, which could limit our ability to maintain effective internal controls over financial reporting.

Until such time as we are no longer an “emerging growth company” or a smaller reporting company, our auditors will not be required to attest as to our internal control over financial reporting. If we continue to identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective or, once required, if our independent registered public accounting firm is unable to attest that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our securities could decrease. We could also become subject to stockholder or other third-party litigation as well as investigations by the stock exchange on which our securities are listed, the Securities and Exchange Commission (the "SEC"), or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions or other remedies.

We may not be able to secure financing on favorable terms, or at all, to meet our future capital needs and our failure to obtain financing when needed could force us to delay, reduce or eliminate our product development programs and commercialization efforts.

We believe that our current cash, including the net proceeds from our initial public offering, and expected revenues from operations will be sufficient for us to fund the development and regulatory approval and to initiate the commercialization of our NAFLD TAEUS application in the European Union. However, , we expect that we will need to finance the full commercialization of this application in the European Union and to complete the development of any other TAEUS application through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives.

To date, we have financed our operations primarily through sales of our Nexus 128 system and net proceeds from the issuance of securities. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. In the future, we may require additional capital in order to (i) continue to conduct research and development activities; (ii) conduct clinical studies; (iii) fund the costs of seeking regulatory approval of TAEUS applications; (iv) expand our sales and marketing infrastructure; (v) acquire complementary business technology or products; or (vi) respond to business opportunities, challenges, increased regulatory obligations or unforeseen circumstances. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the costs, timing and outcomes of regulatory reviews associated with our future products, including TAEUS applications;
- the costs and expenses of expanding our sales and marketing infrastructure;
- the costs and timing of developing variations of our TAEUS applications and, if necessary, obtaining regulatory clearance of such variations;
- the degree of success we experience in commercializing our products, particularly our TAEUS applications;
- the extent to which our TAEUS applications are adopted by hospitals for use by primary care physicians, hepatologists, radiologists and oncologists for diagnosis of fatty liver disease and the thermal ablation of lesions;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the extent and scope of our general and administrative expenses;
- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals, including the potential that the FDA or comparable regulatory authorities may require that we perform more studies than those that we currently expect;
- the amount of sales and other revenues from technologies and products that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party reimbursement;
- selling and marketing costs associated with our potential products, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions and/or the development of other products;
- the costs of operating as a public company;
- the cost and timing of completion of commercial-scale, outsourced manufacturing activities; and
- the time and cost necessary to respond to technological and market developments.

We may raise funds in equity or debt financings or enter into credit facilities in order to access funds for our capital needs. Any debt financing obtained by us in the future would cause us to incur debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. If we raise additional funds through issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution in their percentage ownership of our Company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. General market conditions or the market price of our common stock may not support capital raising transactions such as a public or private offering of our common stock or other securities. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or products or to grant licenses on terms that may not be favorable to us.

If we are unable to raise capital when needed, we may be required to curtail the development of our technology or materially curtail or reduce our operations. We could be forced to sell or dispose of our rights or assets. Any inability to raise adequate funds on commercially reasonable terms could have a material adverse effect on our business, results of operation and financial condition, including the possibility that a lack of funds could cause our business to fail and liquidate with little or no return to investors.

We may be subject to securities litigation, which is expensive and could divert management attention.

The price of our securities may be volatile, and in the past companies that have experienced volatility in the market price of their securities have been subject to an increased incidence of securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We are an "emerging growth company" under the JOBS Act and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our securities less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the price of our securities may be more volatile.

We will remain an "emerging growth company" for up to five years after the date of our initial public offering, although we will lose that status sooner if our annual revenues exceed $1 billion, if we issue more than $1 billion in non-convertible debt in a three year period, or if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the price of our securities and trading volume could decline.

The trading market for our securities is influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few analysts commence research coverage of us, or one or more of the analysts who cover us issues an adverse opinion about our company, the price of our securities would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our securities or trading volume to decline.

We have not paid dividends in the past and have no immediate plans to pay dividends.

We plan to reinvest all of our earnings, to the extent we have earnings, in order to further develop our technology and potential products and to cover operating costs. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We cannot assure you that we will, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend.

Concentration of ownership among our existing executive officers, directors and significant stockholders may prevent new investors from influencing significant corporate decisions.

All decisions with respect to the management of the Company will be made by our board of directors and our officers, who beneficially own approximately 6.3% of our common stock, as calculated in accordance with Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This control could have the effect of delaying or preventing a change of control of the Company or changes in management, which in turn could have a material adverse effect on the market price of the Company's securities or prevent stockholders from realizing a premium over the market price for their securities.

We incur significant costs as a result of becoming a public company that reports to the SEC and our management is required to devote substantial time to meet compliance obligations.

As a public company listed in the United States, we incur significant legal, accounting and other expenses. We are subject to reporting requirements of the Exchange Act and the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and Nasdaq that impose significant requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. In addition, in 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that contribute to our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and also place undue strain on our personnel, systems and resources. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. In addition, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

A significant portion of our total outstanding shares of common stock is restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our securities to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of securities intend to sell shares, could reduce the market price of our common stock. We currently have outstanding 3,907,027 shares of common stock. Of these outstanding shares, approximately 1,975,027 are restricted under securities laws or as a result of lock-up agreements but will be able to be resold in the near future. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to 180- and 365-day lock-up periods under certain lock-up agreements.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plan, could result in dilution of the percentage ownership of our stockholders and could cause the price of our securities to fall.

We expect that significant capital will be needed in the future to continue our planned operations. To the extent we raise capital by issuing common stock, convertible securities or other equity securities, our stockholders may experience substantial dilution, and new investors could gain rights superior to our existing stockholders.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.

Certain provisions of our Fourth Amended and Restated Certificate of Incorporation (our “Certificate of Incorporation”) and bylaws and applicable provisions of Delaware law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. The provisions in our Certificate of Incorporation and bylaws:

- authorize our board of directors to issue preferred stock without stockholder approval and to designate the rights, preferences and privileges of each class; if issued, such preferred stock would increase the number of outstanding shares of our capital stock and could include terms that may deter an acquisition of us;
- limit who may call stockholder meetings;
- do not provide for cumulative voting rights; and
- provide that all vacancies may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum.

In addition, section 203 of the Delaware General Corporation Law limits our ability to engage in any business combination with a person who beneficially owns 15% or more of our outstanding voting stock unless certain conditions are satisfied. This restriction lasts for a period of three years following any such person's share acquisition. These provisions may have the effect of entrenching our management team and may deprive stockholders of the opportunity to sell their shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified by the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Item 2. Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities

Convertible Notes

In March 2017, we extended our 2016 offering of convertible promissory notes by $250,000. The extension was made available only to existing noteholders and $225,000 of the offering was subscribed. The class of promissory notes converted into shares of our common stock immediately prior to the completion of our initial public offering at an effective conversion price of $1.40 per share, after the one-for-3.5 reverse stock split that the Company effected on May 8, 2017 (the "Reverse Split"). Except as otherwise noted in this Quarterly Report on Form 10-Q, all share numbers are presented on a post Reverse Split basis. In connection with the issuances of the foregoing securities, the Company relied on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, for transactions not involving a public offering. We used the funds received from the issuance of these convertible notes for working capital.

Use of Proceeds from Offering of Registered Securities

On May 8, 2017, our Registration Statement on Form S-1, as amended (Reg. No. 333-193522) was declared effective by the SEC and, on May 8, 2017, our Registration Statement on Form S-1 (Reg. No. 333-217788) became effective upon filing with the SEC each such Registration Statement was filed in connection with our initial public offering, pursuant to which we sold 1,932,000 units, each consisting of one share of our common stock and a warrant to purchase one share of our common stock, at a price to the public of $5.00 per unit, which amount includes the full exercise of the underwriters' option to purchase additional units. The common stock and warrants comprising each unit are not immediately separable and will begin trading separately on July 10, 2017, which is the first day following the 60th day after the date of the final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on May 10, 2017 (the "Prospectus"), or such earlier date as may be determined by National Securities Corporation, as representative of the underwriters of the offering. Each warrant is exercisable for a share of our common stock at a price of $6.25 per share. The offering closed on May 12, 2017 and the underwriters exercised their overallotment option as of May 22, 2017, as a result of which we raised net proceeds of approximately $8.6 million after deducting approximately $773,000 in underwriting discounts, commissions and expenses and approximately $297,000 in offering expenses payable by us. National Securities Corporation and Dougherty & Company LLC were the underwriters for the offering. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

There has been no material change in the planned use of proceeds from our initial public offering as described in the Prospectus.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The exhibits required to be filed as a part of this report are listed in the Exhibit Index.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

ENDRA LIFE SCIENCES INC.
(Registrant)

Date: June 21, 2017

By: /s/ Francois Michelon
Name: Francois Michelon
Title: Chief Executive Officer and Chairman
(Principal Executive Officer)

EXHIBIT INDEX

Exhibit Number	Description
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on May 12, 2017)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-214724), as amended, originally filed on November 21, 2016)
4.1	Specimen Certificate representing shares of common stock of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-214724), as amended, originally filed on November 21, 2016)
4.2	Form of Warrant Agreement and Warrant comprising a part of the Registrant's units issued in its initial public offering (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-214724), as amended, originally filed on November 21, 2016)
4.3	Form of Underwriters' Warrant issued to certain designees of the underwriters in the Registrant's 2017 initial public offering (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-214724), as amended, originally filed on November 21, 2016)
4.4	Form of Unit Certificate (incorporated by reference to Exhibit 4.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-214724), as amended, originally filed on November 21, 2016)
4.5	Form of Convertible Promissory Note (incorporated by reference to Exhibit 4.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-214724), as amended, originally filed on November 21, 2016)
31.1	Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14a and pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
31.2	Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14a and pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
32.1	Certification of Periodic Report by Chief Executive Officer and Chief Financial Officer pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith)
101.INS	XBRL Instance Document (filed herewith)
101.SCH	XBRL Taxonomy Schema (filed herewith)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase (filed herewith)
101.DEF	XBRL Taxonomy Extension Definition Linkbase (filed herewith)
101.LAB	XBRL Taxonomy Extension Label Linkbase (filed herewith)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase (filed herewith)

EXHIBIT 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Francois Michelon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ENDRA Life Sciences Inc. ;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

   Date: June 21, 2017

/s/ Francois Michelon
Name: Francois Michelon
Title: Chief Executive Officer and Chairman

EXHIBIT 31.2

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David R. Wells, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ENDRA Life Sciences Inc. ;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

   Date: June 21, 2017

/s/ David R. Wells

Name: David R. Wells
Title: Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of ENDRA Life Sciences Inc. (the "Company") on Form 10-Q for the period ended March 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Francois Michelon, Chief Executive Officer and Chairman of the Company, and David Wells, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to ENDRA Life Sciences Inc. and will be retained by ENDRA Life Sciences Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Francois Michelon
Name: Francois Michelon
Title: Chief Executive Officer and Chairman
Date: June 21, 2017

/s/ David R. Wells
Name: David R. Wells
Title: Chief Financial Officer
Date: June 21, 2017