SECURITIES & EXCHANGE COMMISSION EDGAR FILING

DTHERA SCIENCES

Form: 10-Q

Date Filed: 2018-11-14

Corporate Issuer CIK: 1586372

Table of Contents

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 September 30, 2018

Or

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

Commission File Number: 333-191175

DTHERA SCIENCES

(Exact name of registrant as specified in its charter)

Nevada	**90-0925768**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
7310 Miramar Rd., Suite 350, San Diego, CA	**92126**
(Address of principal executive offices)	**(Zip Code)**

(858) 215-6360

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant 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). Yes x No o

Indicate by check mark whether the registrant has been subject to such filing requirements for the past 90 days. Yes o No x

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

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	☒	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. o

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

The number of shares outstanding of the registrant's common stock on November 12, 2018, was 2,667,602.

TABLE OF CONTENTS

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

DTHERA SCIENCES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
CURRENT ASSETS		
Cash	$ 1,567,877	$ 303,483
Restricted cash	20,000	20,000
Inventory	70,945	–
Prepaid expenses	608,483	95,176
Deferred cost of revenue	9,655	–
Deposits	4,270	2,500
TOTAL CURRENT ASSETS	2,281,230	421,159
LONG TERM ASSETS		
Property and equipment, net	45,599	77,365
Software development costs, net	245,292	–
TOTAL LONG-TERM ASSETS	290,891	77,365
TOTAL ASSETS	$ 2,572,121	$ 498,524
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 984,424	$ 436,472
Deferred revenue	12,287	1,800
Notes payable, net	559,582	–
Convertible notes payable, net	1	–
Derivative liabilities	1,106,711	–
TOTAL CURRENT LIABILITIES	2,663,005	438,272
TOTAL LIABILITIES	2,663,005	438,272
STOCKHOLDERS' EQUITY (DEFICIT)		
Common stock 600,000,000 shares authorized; $0.001 par value; 2,667,602 and 2,352,166 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	2,668	2,352
Additional paid in capital	7,583,279	4,594,847
Accumulated deficit	(7,676,831)	(4,536,947)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(90,884)	60,252
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 2,572,121	$ 498,524

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

DTHERA SCIENCES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	For the Three Months Ended September 30, 2018	For the Three Months Ended September 30, 2017	For the Nine Months Ended September 30, 2018	For the Nine Months Ended September 30, 2017
REVENUES	$ 6,485	$ –	$ 6,485	$ –
COST OF REVENUES				
Cost of revenues	95,885	–	95,885	–
Impairment of inventory	16,019	–	16,019	–
TOTAL COST OF REVENUES	111,904	–	111,904	–
GROSS PROFIT	(105,419)	–	(105,419)	–
OPERATING EXPENSES				
General and administrative	912,161	97,259	1,994,319	1,584,466
Sales and marketing	273,545	93,240	609,692	188,415
Research and development	64,377	66,940	142,565	158,274
TOTAL OPERATING EXPENSES	1,250,083	257,439	2,746,576	1,931,155
OPERATING LOSS	(1,355,502)	(257,439)	(2,851,995)	(1,931,155)
OTHER INCOME (EXPENSES)				
Interest expense	(49,323)	–	(51,440)	(185,847)
Change in fair value of derivative liabilities	75,309	–	75,309	142,835
Loss on extinguishment of debt	–	–	–	(91,593)
Loss on disposal of fixed assets	–	–	(6,170)	–
Derivative expense	(305,398)	–	(305,398)	–
TOTAL OTHER EXPENSES	(279,412)	–	(287,699)	(134,605)
NET LOSS	$ (1,634,914)	$ (257,439)	$ (3,139,694)	$ (2,065,760)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING				
Basic and diluted	2,572,762	1,510,462	2,500,169	954,805
Loss per common share				
Basic and diluted	$ (0.64)	$ (0.17)	$ (1.26)	$ (2.16)

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

DTHERA SCIENCES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Nine Months Ended September 30,
(Unaudited)

	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (3,139,694)	$ (2,065,760)
Adjustments for non-cash items:		
Amortization of debt discount	41,118	172,655
Depreciation and amortization	31,079	766
Loss on disposal of fixed assets	6,170	–
Impairment of inventory	16,019	–
Loss on extinguishment of debt	–	91,593
Derivative expense	305,398	–
Gain on derivative liability	(75,309)	(142,835)
Common stock issued for services	123,632	–
Fair value of options vested	388,855	399,049
Changes in operating assets and liabilities:		
Deferred cost of revenue	(9,655)	–
Inventory	(1,901)	–
Prepaid expenses	(513,307)	(10,167)
Deposits	(1,770)	–
Accounts payable and accrued liabilities	547,954	(45,482)
Deferred revenue	10,487	646
NET CASH USED IN OPERATING ACTIVITIES	(2,270,924)	(1,599,535)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(76,117)	(49,866)
Development of software	(259,721)	–
NET CASH USED IN INVESTING ACTIVITIES	(335,838)	(49,866)
CASH FLOWS FROM FINANCING ACTIVITIES		
Common stock issuance	2,024,350	1,215,750
Exercise of stock options	31,806	–
Proceeds from notes payable	900,000	50,000
Proceeds from convertible notes	915,000	–
Payments on convertible notes	–	(240,000)
Payments on notes payable	–	(70,000)
Payments on notes payable, related party	–	(209)
Redemption of preferred stock	–	(82,690)
NET CASH PROVIDED BY FINANCING ACTIVITIES	3,871,156	1,786,853
NET CHANGE IN CASH	1,264,394	137,452
CASH AT BEGINNING OF PERIOD	323,483	12,191
CASH AT END OF PERIOD	$ 1,587,877	$ 149,643
Cash paid for interest	$ 2,063	$ 19,890
Cash received for interest earned	$ 25	$ –
Cash paid for taxes	$ 800	$ 800
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Transfer of property and equipment to inventory	$ 85,063	$ –
Adoption of ASU 2018-07	$ 190	$ –
Debt discounts recorded on notes payable	$ 456,535	$ –
Debt discounts recorded on convertible notes	$ 1,100,000	$ –
Common stock issued with convertible notes	$ 38,378	$ –
Common stock issued in extinguishment of debt	$ –	$ 183,260

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

NOTE 1– CONDENSED FINANCIAL STATEMENTS

Organization and Description of Business

Dthera Sciences, a Nevada corporation ("the Company"), is a leading digital therapeutic company focusing on the elderly. The San Diego-based company is working to improve the lives of seniors and individuals suffering from neurodegenerative diseases, as well as those who care for them. Dthera has two core products: DTHR-ALZ, a development-stage product that has been granted Breakthrough Device designation by the FDA for the mitigation of the symptoms of agitation and depression associated with major neurocognitive disorder of the Alzheimer's type; and ReminX™, a consumer health product and general wellness device exempt from FDA regulations available for purchase for individuals suffering from social isolation and dementia.

Consolidated Financial Statements

The accompanying financial statements have been prepared by the Company without audit. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position, results of operations, and cash flows at September 30, 2018, and for all periods presented herein, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been condensed or omitted. It is suggested that these condensed financial statements be read in conjunction with the financial statements and notes thereto included in the Company's December 31, 2017, audited financial statements. The results of operations for the periods ended September 30, 2018 and 2017, are not necessarily indicative of the operating results for the full years.

NOTE 2 – GOING CONCERN

The Company's financial statements are prepared using U.S. GAAP applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. As of the date of this Report, the Company had an accumulated deficit of $7,676,831, and to date has only minimal revenues which to date have been insufficient to cover its operating costs. These factors raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. As of the date of this Report, the Company had not yet established an ongoing source of revenues sufficient to cover its operating costs and allow it to continue as a going concern.

The future of the Company as an operating business will depend on its ability to (1) obtain sufficient capital contributions and/or financing as may be required to sustain its operations, and (2) achieve adequate revenues from its operations. Management's plan to address these issues includes, (a) continuing to exercise of tight cost controls to conserve cash, (b) obtaining additional financing, (c) placing revenue producing products into place, and (d) identifying and executing on additional revenue generating opportunities.

There can be no guarantee that the Company will be unable to achieve the above results or to obtain adequate financing on terms considered satisfactory to the Company, or at all.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Preparation

The Company's financial statements are prepared using the accrual basis of accounting in accordance with U.S. GAAP. The Company has a December 31 fiscal year end.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates are made in relation to the fair value of certain financial instruments.

Principles of Consolidation

The consolidated financial statements include the accounts of Dthera Sciences and its subsidiaries. All significant inter-company accounts and transactions have been eliminated.

Inventory

The Company reported inventory related to its ReminX tablets as of September 30, 2018. The Company adopted FIFO as its inventory valuation method and reports inventory at the lower of cost or net realizable value.

Software Development

The Company accounts for internal use software development costs in accordance with authoritative guidance related to accounting for the costs of application and web software developed or obtained for internal use. Software development costs that are incurred in the preliminary development stage are expensed as incurred. Once certain criteria have been met ("application development stage"), direct costs incurred in developing or obtaining computer software are capitalized. Costs in the post-implementation/operation stage, including costs related to training and software maintenance, are expensed as incurred. Some costs in post-implementation stage can be capitalized if the modifications add additional functionality in the future. The application development stage begin in the first fiscal quarter of 2018 and the post-implementation/operation stage was reached in the third fiscal quarter of 2018.

Research and Development

The Company engages in new software and hardware development efforts. Research and development expenses relating to possible future software and hardware are expensed as incurred. Research and development expenses were $64,377 and $142,565 for the three and nine months ended September 30, 2018, respectively, and $66,940 and $158,274 for the three and nine months ended September 30, 2017, respectively.

Revenue

The Company generates revenue from the sale of device consisting of a digital tablet specifically designed for seniors with proprietary software. As the nature of the Company's performance obligation to its customers is to provide digital reminiscence therapy, which requires both the tablet and the software, the Company determined it has a single performance obligation. The Company recognizes revenue upon satisfaction of the single performance obligation ratably over the contract period as the customer receives and consumes the benefits derived from the Company's performance as the Company performs.

Derivative Instruments

The Company evaluates its convertible notes and warrants to determine whether those contracts, or components of those contracts, qualify as derivatives to be separately accounted for. To the extent the conversion price of notes issued is based on a variable that is not an input to the fair value of a "fixed-for-fixed" option as defined under FASB ASC Topic No. 815 – 40, the fair value of the notes is recognized as a derivative instrument at the issuance date.

The classification of derivative instruments is re-assessed at the end of each financial reporting period. Each derivative is measured at the transaction date and will be remeasured by a third-party specialist and reported at fair value with changes reported through profit and loss each financial reporting date until the liabilities are settled. Upon conversion or exercise of a derivative instrument, the instrument is marked to fair value at the conversion date and the fair value is classified as equity.

The Company uses a Monte Carlo simulation to value its derivatives due to the path-dependent nature of certain potential exercise price adjustments.

The Company does not use derivative instruments to hedge exposure to cash flow or fair value risks.

Reclassification

Certain balances in previously issued financial statements have been reclassified to be consistent with the current period presentation. Professional Fees and Depreciation are presented with General and Administrative expenses. Research and Development costs and Sales and Marketing expenses have been presented separately from General and Administrative expenses. Related Party Advances are presented with Accounts Payable and Accrued Liabilities and Restricted Cash is presented separately from Cash.

Loss Per Common Share

Basic loss per Common Share is computed by dividing losses attributable to Common shareholders by the weighted-average number of shares of Common Stock outstanding during the period.

Diluted loss per Common Share is computed by dividing loss attributable to Common shareholders by the weighted-average number of Shares of Common Stock outstanding during the period increased to include the number of additional Shares of Common Stock that would have been outstanding if the potentially dilutive securities had been issued. Potentially dilutive securities include outstanding stock options and warrants. The dilutive effect of potentially dilutive securities is reflected in diluted earnings per share by application of the treasury stock method. Under the treasury stock method, an increase in the fair market value of the Company's Common Stock can result in a greater dilutive effect from potentially dilutive securities.

For the nine months ended September 30, 2018 and 2017, all of the Company's potentially dilutive securities (options, warrants, and conversion features) were excluded from the computation of diluted earnings per share as they were anti-dilutive. The total numbers of potentially dilutive Common Shares that were excluded were 790,945 and 396,437 for the nine months ended September 30, 2018 and 2017, respectively.

Reverse stock split

On September 25, 2018, the Company effectuated a reverse stock-split of its issued and outstanding common stock at a ratio of one-for-20 (the "Listing Reverse Split"). The Company filed a Certificate of Amendment to its Articles of Incorporation with the Secretary of State of the State of Nevada to effectuate the Listing Reverse Split. The Listing Reverse Split did not affect the number of authorized shares of common stock. A proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the exercise or conversion of the Company's outstanding equity awards, options and warrants to purchase shares of common stock and outstanding convertible notes. The accompanying condensed consolidated financial statements and notes give retroactive effect to the Listing Reverse Split for all periods presented.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 (updated by ASU 2017-13 and 2018-01) provides guidance for lessees and lessors and requires a right-of-use asset and a lease liability to be recognized in the Statement of Financial Position. Disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. As such, qualitative disclosures and specific quantitative disclosures are required. A modified retrospective approach is required and several practical expedients are available. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 with early adoption permitted. The Company does not anticipate ASU 2016-02 will have a material impact on its financial statements as its only contract for which the Company is a lessee is a short-term lease for its office space.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows, Restricted Cash ("ASU 2016-18") to address diversity in practice in the classification and presentation of changes in restricted cash on the statement of cash flows. Under ASU 2016-18, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning and ending cash amounts shown on the statement of cash flows. The update was effective for the Company January 1, 2018 and was applied using a retrospective transition method.

In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718) ("ASU 2018-07"). ASU 2018-07 provides for improvements to nonemployee share-based payment accounting by expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The awards will be measured at grant date, consistent with accounting for employee share-based payment awards. The measurement date has been redefined as the date at which the grantor and grantee reach a mutual understanding of the key terms and conditions of the award. The requirement to reassess classification of equity-classified awards upon vesting has been eliminated. ASU 2018-07 will have a material impact on the Company's financial statements as a significant number of options were granted to nonemployees. The Company adopted ASU 2018-07 July 1, 2018.

NOTE 4 – INVENTORY

The following presents the inventory activity during the period:

	2018
Inventory, December 31, 2017	**$ –**
Tablets transferred from property and equipment	85,063
Purchases	68,450
Sales	(66,549)
Impairment	(16,019)
Inventory, September 30, 2018	**$ 70,945**

Prior to the rollout of ReminX, the Company planned to lease tablets to customers and recover the tablet at the end of the lease term. As such, the Company reported its tablet assets within property and equipment. In the third quarter of 2018, the Company changed its strategy and determined it would sell the tablets to customers pursuant to a short-term financing arrangement. Upon the change in strategy, the Company reclassified its tablets to inventory.

During the three and nine months ended September 30, 2018, the Company expensed $16,019 to write down the net realizable value of the inventory to expected sales price. The charge was recognized in cost of sales.

NOTE 5 – PREPAID EXPENSES

Prepaid expenses consisted of the following:

	September 30, 2018	December 31, 2017
Tablets	$ 467,640	$ –
Professional services	73,841	9,354
Commissions	18,000	–
Study	15,000	–
Marketing services	11,692	77,655
Subscription	11,000	6,667
Freight	6,000	–
Insurance	5,310	–
Rent	–	1,500
Total prepaid expenses	**$ 608,483**	**$ 95,176**

During the nine months ended September 30, 2018, the Company made prepayments to its equipment manufacturer to procure the raw materials and to perform the subassembly of the tablets to be sold. The Company does not have any ownership rights to the assets until the finished goods are received, therefore the prepayment of tablets is classified as a Prepaid Tablets until receipt occurs.

NOTE 6 – PROPERTY AND EQUIPMENT

The Company's property and equipment were comprised of the following as of September 30, 2018, and December 31, 2017:

	September 30, 2018	December 31, 2017
Computer and Equipment	$ 8,025	$ 10,237
Assets Used to Fulfill Contract Obligations	–	70,195
Tooling for ReminX hardware	56,500	–
Less: Accumulated Depreciation	(18,926)	(3,067)
Net Property and Equipment	$ 45,599	$ 77,365

Depreciation expense for the three and nine months ended September 30, 2018 was $14,795 and $16,650, respectively. Depreciation expense for the three and nine months ended September 30, 2017, was $333 and $766, respectively. The Company recorded a loss on disposal of fixed assets in the nine months ended September 30, 2018 of $6,170, with no related expense in the three months ended September 30, 2018 or in the three and nine months ended September 30, 2017.

The Company transferred its Assets Used to Fulfill Contract Obligations to Inventory in the third fiscal quarter of 2018 as the Company determined it would sell, rather than lease, its ReminX tablets.

The Company capitalized $56,500 for tooling for its ReminX hardware in the third quarter of 2018 and estimated the useful life of the tooling was one year. The Company recognized $14,125 of depreciation expense in cost of revenue related to the tooling in the three and nine months ended September 30, 2018 with no comparable charge in the comparative period.

NOTE 7 – SOFTWARE DEVELOPMENT COSTS

The Company's capitalized application development stage costs related to computer software development under ASC 350-40 *"Intangibles-Goodwill and Other-Internal-Use Software"* as the Company reached the application development stage in the first quarter of 2018. The total software development costs capitalized as of September 30, 2018 is $259,721.

The Company began amortizing the software August 1, 2018 after the rollout of the ReminX product. The Company recognized amortization of $14,429 in the three and nine months ended September 30, 2018, reported in cost of revenue on the Statement of Operations.

The Company considered the applicability of ASC 985-20 for accounting for its internally developed software. The customer does not have a contractual right to take possession of the software, and the software is only available on ReminX tablets (i.e. the Company has not made ReminX software available for use on third-party hardware subsequent to the rollout of the ReminX product on proprietary hardware). The software resides on the Company's hardware and is accessed on an as-needed basis over the Internet. As such, the software is subject to a hosting arrangement and is therefore not within the scope of ASC 985.

NOTE 8 – DEBT

Notes payable

The following notes payable were outstanding as of September 30, 2018, with no comparable balances as of December 31, 2017:

Ref	Amount	Interest rate	Net debt discount	Carrying value of debt	Accrued and unpaid interest	Total
1	$ 50,000	14.4%	$ –	$ 50,000	$ 1,321	$ 51,321
2	50,000	12.0%	–	50,000	1,578	51,578
3	50,000	12.0%	–	50,000	1,561	51,561
5	275,000	OID	(139,151)	135,849	–	135,849
6	550,000	OID	(276,267)	273,733	2,564	276,297
Total	$ 975,000		$ (415,418)	$ 559,582	$ 7,024	$ 566,606

(1) On May 11, 2018, the Company issued a short-term promissory note to an unrelated party for $50,000 due 30 days from the date of issuance. The note bore an interest rate of 14.4% per annum, and the Company had the right to pre-pay with no penalty or premium. The Company's obligation to repay the note was secured by the grant of a security interest in the assets of the Company. On June 10, 2018, the Company extended the term of the above short-term promissory note of $50,000 to October 31, 2018. All other terms remained the same. This note was subsequently repaid. See Subsequent Events Footnote 13 for additional details.

(2) On June 28, 2018, the Company issued a short-term promissory note to an unrelated party for $50,000 due 90 days from the date of issuance. The note bore interest at a rate of 12% per annum, and the Company had the right to pre-pay with no penalty or premium. The Company's obligation to repay the note was secured by the grant of a security interest in the assets of the Company. This note was extended on August 28, 2018 to October 31, 2018 and was subsequently repaid. See Subsequent Events Footnote 13 for additional details.

(3) On July 2, 2018, the Company issued a short-term note to a related party for $50,000 due 90 days from the date of issuance. The note bore interest at a rate of 12% per annum, and the Company had the right to pre-pay with no penalty or premium. In November 2018, the Company modified the loan as part of its crossover funding, which will automatically convert to common shares upon uplisting. See Subsequent Events Footnote 13 for additional details.

(4) On July 2, 2018, the Company issued a short-term note to a related party for $100,000 due 60 days from the date of issuance. The note bore an interest rate of 12% per annum, and the Company had the right to pre-pay with no penalty or premium. The Company's obligation to repay the note was secured by the grant of a security interest in the assets of the Company. This note was extinguished as a part of the following note.

(5) On September 17, 2018, the Company issued a short-term 10% original issue discount ("OID") note to a related party with a face amount of $550,000 and a purchase price of $500,000, $400,000 of which was received in cash and $100,000 was paid through the extinguishment of an existing promissory note, referenced above. The note is due and payable January 17, 2019 and is secured by the Company's assets. Upon closing of the crossover funding, the note will automatically convert to a convertible note which will convert into common shares upon uplisting. In connection with the note, the Company issued 25,000 shares of common stock and 50,000 warrants to purchase 50,000 additional shares. The initial debt discount recorded was $301,775, based on the relative fair value of the warrants and common stock issued, as well as OID interest. The debt discount will be accreted according to the effective interest method over the contractual term of the note. The warrants qualified for equity classification and were reported within Additional Paid-In Capital as of September 30, 2018.

(6) On September 14, 2018, the Company issued a short-term 10% OID note to a related party with a face amount of $275,000 and a purchase price of $250,000. The note is due and payable January 14, 2019 and is secured by the Company's assets. Upon closing of the crossover funding, the note will automatically convert to a convertible note which will convert into common shares upon uplisting. In connection with the note, the Company issued 12,500 shares of common stock and 25,000 warrants. The initial debt discount recorded was $154,760, based on the relative fair value of the warrants and common stock issued, as well as OID interest. The debt discount will be accreted according to the effective interest method over the contractual term of the note. The warrants qualified for equity classification and were reported within Additional Paid-In Capital as of September 30, 2018.

Convertible note

The following convertible note was outstanding as of September 30, 2018, with no comparable balances as of December 31, 2017:

Ref	Amount	Interest rate	Net debt discount	Carrying value of debt	Accrued and unpaid interest	Total
7	1,100,000	OID	(1,099,999)	1	–	1
Total	$ 1,100,000		$ (1,099,999)	$ 1	$ –	$ 1

(7) On September 21, 2018, the Company issued a short term 10% OID convertible note to an unrelated party with a face amount of $1.1 million and a purchase price of $1.0 million. The convertible note is secured by the Company's assets. Of the face amount of this note, $550,000 automatically converts to common shares upon uplisting and $550,000 is convertible into common shares at a conversion price of $10.00 per share at any time after uplisting or certain other events. The Company analyzed the conversion feature of the agreement for derivative accounting considerations under ASC 815-15 "Derivatives and Hedging" and determined the embedded conversion feature should be classified as a derivative because the exercise price of the convertible note is subject to a variable conversion rate upon default and default includes matters outside the control of the Company. Accordingly, the Company bifurcated the conversion feature of the note and recorded a derivative liability pursuant to ASC 815. In connection with the note, the Company issued 50,000 shares of common stock and warrants to purchase 100,000 additional shares. The warrants did not qualify for equity classification based on the Company's inability to assert there will be sufficient authorized and unissued shares of common stock to fulfill its obligation to settle the contract in shares should the warrants be exercised. Therefore, the warrants are reported as a derivative liability as of September 30, 2018. The initial fair value of the warrants and conversion feature were $792,191 and $389,829, respectively. The fair values of the warrants and conversion feature were remeasured as of the end of the financial reporting period and were determined to equal $718,539 and $388,172, respectively. The initial debt discount recorded was $1.1 million which will be accreted according to the effective interest method over the contractual term of the note. The excess fair value at initial measurement was recorded as derivative expense on the Statement of Operations. Refer to Note 12 for additional information regarding the fair value measurement of the warrants and beneficial conversion feature.

NOTE 9 – COMMON STOCK

As of September 30, 2018, the Company was authorized to issue 600,000,000 shares of $0.001 par value per share Common Stock, of which 2,667,602 and 2,352,166 shares were issued outstanding as of September 30, 2018, and December 31, 2017, respectively.

During the nine months ended September 30, 2018, the Company issued 199,093 shares of Common Stock for $2,024,350 in cash in connection with a private placement offering.

During the nine months ended September 30, 2018, option holders exercised 14,843 options at $2.14 per share of common stock for $31,806.

During the nine months ended September 30, 2018, the Company issued an aggregate of 87,500 shares of stock in connection with the issuance of debt instruments as noted above. The fair value allocated to the commitment shares on a relative fair value basis was $194,216, which was recorded as a debt discount on the Statement of Financial Position.

During the nine months ended September 30, 2018, the Company issued 14,000 shares of common stock in exchange for strategic advisory and marketing services. The fair value of the stock compensation was $123,632 of which $50,898 and $63,957 was recognized in general and administrative expenses for the three and nine months ended September 30, 2018, respectively, with the remainder in prepaid assets for future services.

NOTE 10 – STOCK OPTIONS AND WARRANTS

Stock Purchase Options

On March 21, 2018, the Company's Board of Directors voted to grant to sixteen individuals options to purchase up to an aggregate of 75,000 shares of the Company's common stock. The terms of the options are as follows: the options vest one-third on the first anniversary of the date of grant; one-third on the second anniversary of the date of grant; and one-third on the third anniversary of the date of grant; the options have a contractual life of eight years from the date of grant; and the exercise price is $13.00, which was the market price of the options on the date of the grant. Included in the grants were options to purchase up to 12,500 shares to the Company's President and Chief Executive Officer, and options to purchase up to 12,500 shares to the Company's Chief Technical Officer. The options were not issued pursuant to a stock option or stock incentive plan.

On April 6, 2018, the Company's Board of Directors approved the grant of 12,500 shares of the Company's common stock to the newest member of the Board of Directors. The terms of the options are as follows: the options vest one-third on the first anniversary of the date of grant; one-third on the second anniversary of the date of grant; and one-third on the third anniversary of the date of grant; the options have a contractual life of eight years from the date of grant; and the exercise price is $13.00.

On June 13, 2018, the Company's Board of Directors approved the grant of 3,000 options to purchase shares of the Company's common stock, to a consultant in exchange for services. The options granted had an exercise price of $9.00 per share. One-sixth of the options shall vest each month for six months, the first one-sixth will vest in June 2018 and the last one-sixth will vest in November 2018. The grants expire on the eighth anniversary of the date of grant.

On June 28, 2018, the Company's Board of Directors approved the grant of an aggregate of 12,500 options to purchase shares of the Company's common stock, consisting of grants of 6,250 options to two Board Members of the Company. The options granted had an exercise price of $8.40 per share, and vest one-third on each of the first, second, and third anniversaries of the date of grant, and expire on the eighth anniversary of the date of grant.

On June 29, 2018, the Company's Board of Directors approved the grant of an aggregate of 30,000 options to purchase shares of the Company's common stock, consisting of grants of 1,250 options to 24 employees and consultants to the Company who had been instrumental in helping the Company get to the point of the initial rollout. The options granted had an exercise price of $8.40 per share, and vest one-third on each of the first, second, and third anniversaries of the date of grant, and expire on the eighth anniversary of the date of grant.

The Company early adopted ASU 2018-07 in the third quarter of 2018. As such, the outstanding options issued to non-employees were measured using the Black-Scholes valuation model as of July 1, 2018 and will be amortized ratably over the remaining service period. An adjustment was made to retained earnings in the amount of $190 in connection with the adoption of the updated accounting guidance. Stock options issued to employees are valued on the date of issuance and amortized over the service period until they fully vest over a 3-year vesting period. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the services received. As of September 30, 2018, the compensation expense totaled $2,001,102 to be recognized over the vesting period. The Company recorded $174,050 and $388,855 of stock-based compensation expense in the three and nine months ended September 30, 2018, respectively. The Company recorded a reversal of $652,489 in the three months ended September 30, 2017 due to a decrease in the value of the underlying stock. The Company recorded $399,049 of stock-based compensation expense in the nine months ended September 30, 2017.

As of September 30, 2018, the Company had $ 1,219,425 in unrecognized expense related to future vesting of stock options.

The following table summarizes the changes in options outstanding of the Company during the nine months ending September 30, 2018:

	Number of Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding, December 31, 2017	69,118	$ 5.75		
Granted	133,000	$ 11.44		
Exercised	(14,843)	$ 2.14		
Cancelled	(13,750)	$ 11.75		
Outstanding, September 30, 2018	**173,525**	**$ 9.95**	**7.43**	**$ 144,996**
Exercisable, September 30, 2018	**52,147**	**$ 6.88**	**7.05**	**$ 109,774**

Stock Purchase Warrants

During the nine months ended September 30, 2018, the Company issued 175,000 warrants in connection with its debt agreements.

The following table summarizes the changes in warrants outstanding during the nine months ended September 30, 2018:

	Number of Warrants	Weighted Average Exercise Price per Share
Outstanding, December 31, 2017	327,719	$ 9.00
Warrants issued pursuant to debt agreements	175,000	13.00
Outstanding, September 30, 2018	502,719	$ 10.39
Exercisable, September 30, 2018	100,000	$ 13.00

The warrants issued in 2017 are contractually exercisable two years after the grant date and expire four years after the grant date. There is a 30-day mandatory exercise period triggered by the Company's stock trading on a national exchange at a price of more than $50.00 per share for 30 consecutive trading days. If warrants are not exercised within 30 days of the mandatory exercise period termination, the warrants will be forfeited.

With respect to the warrants issued in 2018, 75,000 warrants are contractually exercisable 180 days after the grant date and expire five years after the grant date. The remaining 100,000 warrants are contractually exercisable immediately upon issuance and expire five years after the grant date.

NOTE 11 – REVENUE RECOGNITION

The Company provides digital reminiscence therapy to users suffering from neurodegenerative diseases and social isolation in a single operating segment. Sales are related to a beta version of the company's product that incorporated the Company's proprietary software but not the proprietary hardware and the newly rolled out ReminX product. ReminX is a consumer health product and general wellness device exempt from FDA regulations that is designed for seniors suffering from social isolation and living with dementia. ReminX is comprised of three key components: A ReminX computer tablet (proprietary hardware), an AI chatbot, and a family feedback loop (proprietary software). The initial commercial rollout of ReminX began in the three months ending September 2018.

	Revenue recognized in the three months ended September 30, 2018	Revenue recognized in the nine months ended September 30, 2018
Beta version	4,122	4,122
ReminX	2,363	2,363
Total Revenue	**$ 6,485**	**$ 6,485**

The balances of the contract liabilities from contracts with customers as of September 30, 2018 and December 31, 2017 were as follows:

	Contract liabilities included in deferred revenue
Balance as of January 1, 2017	1,800
Balance as of September 30, 2018	12,287
Change	$ 10,487

Contract liabilities are recorded when subscription payments are collected in advance of delivery of subscription services. The change in contract liabilities primarily relates to customer activity associated with the prepaid pricing option including the receipt of cash payments and the satisfaction of performance obligations.

Of the revenue recognized in the three and nine months ended September 30, 2018, $3,945 and $1,800 were reported in deferred revenue as of June 30, 2018, and December 31, 2017, respectively.

As of September 30, 2018, the aggregate amount of transaction price allocated to remaining performance obligations was $12,287. The performance obligations will be satisfied within the next 12 months.

The Company adopted the practical expedient to recognize as expense when incurred incremental costs to obtain contracts as all contracts are 12 months or less. Deferred contract costs incurred to fulfill the contract will be amortized ratably over the 12-month contract period. Amortization of deferred contract costs was $57,687 for the three and nine months ended September 30, 2018.

A significant portion of the revenue recognized in the three and nine months ended September 30, 2018 arises from transactions with customers for services provided during beta testing on third-party tablets prior to the rollout of ReminX.

NOTE 12 - FAIR VALUE MEASUREMENTS

Measurement at fair value approximates amounts that would be received to sell an asset or transfer a liability in an orderly transaction between market participants. The Company uses the Black-Scholes options pricing option model to measure the fair value of stock options and Monte Carlo simulations to measure the fair value of derivative liabilities. The derivative liabilities arise from certain conversion features of convertible debt and certain warrants issued in connection with the convertible debt. The table below presents the Company's instruments measured at fair value as of September 30, 2018:

	Level 1	Level 2	Level 3	Total
Fair value of options	$ –	$ –	$ –	$ –
Fair value of derivative liabilities	$ –	$ –	$ 1,106,711	$ 1,106,711

The table below presents the Company's instruments measured at fair value as of December 31, 2017:

	Level 1	Level 2	Level 3	Total
Fair value of options	$ –	$ –	$ 960,518	$ 960,518

Derivative liabilities

The following table presents the change in the fair value of the derivative liabilities:

	2018
Fair value of instruments measured at fair value, December 31, 2017	$ –
Initial recognition of a derivative liability	1,182,020
Change in fair value of derivative liability	(75,309)
Fair value of instruments measured at fair value, September 30, 2018	$ 1,106,711

The terms of the warrants provide that in the event the Company issues shares at a price per share lower than the exercise price in effect, the exercise price will be reduced to equal the per share price of the new securities. Similarly, the terms of the convertible note provide that in the event the Company issues new shares at a price lower than the conversion price in effect, the conversion price will be reduced to equal the per share price of the new securities. Due to the path-dependent nature of potential price adjustments, it is necessary to value the instruments using a Monte Carlo simulation. The inputs used for the valuation are as follows:

	Initial measurement		As of September 30, 2018	
	Warrants	Conversion feature	Warrants	Conversion feature
Valuation date	9/21/2018	9/21/2018	9/30/2018	9/30/2018
Expected term	5 years	0.50 years	4.98 years	0.48 years
Stock price	$ 10.00	$ 10.00	$ 8.99	$ 8.99
Exercise price	$ 13.00	$ 10.00	$ 13.00	$ 10.00
Volatility	107.2%	107.3%	107.6%	108.2%
Risk-free rate	2.95%	2.38%	2.94%	2.34%

The volatility assumption was measured from the volatility of guideline public companies using a historical period commensurate with the remaining expected term of the applicable instrument.

NOTE 13 - SUBSEQUENT EVENTS

In accordance with ASC 855, Company's management reviewed all material events through the date of this filing and determined that there were the following material subsequent events to report:

Financing

In October 2018, the Company repaid two promissory notes and all accrued and unpaid interest thereon in the amount of $102,971.

In October 2018, the Company modified a $50,000 loan as part of its crossover funding, which will automatically convert to common shares upon uplisting. The note bears interest at a rate of 6% per annum and may be prepaid at any time at 125% of the outstanding principal at the time of repayment, plus accrued and unpaid interest.

Stock Options

In October 2018, the Company's Board of Directors approved the grant of 20,000 options to purchase shares of the Company's common stock. The options granted had an exercise price of $4.10 per share, and vest one-third on each of the first, second, and third anniversaries of the date of grant, and expire on the eighth anniversary of the date of grant.

In October 2018, the Company's Board of Directors approved the grant of 12,500 options to purchase shares of the Company's common stock to contractors. The options granted had an exercise price of $4.10 per share, and vest one-third on each of the first, second, and third anniversaries of the date of grant, and expire on the eighth anniversary of the date of grant.

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

Management's Discussion and Analysis of Financial Condition and Results of Operations analyzes the major elements of our balance sheets and statements of income. This section should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2017, and our interim financial statements and accompanying notes to these financial statements. All amounts are in U.S. dollars.

Forward-Looking Statement Notice

This quarterly report on Form 10-Q of Dthera Sciences ("we" or the "Company") contains forward-looking statements about our expectations, beliefs or intentions regarding, among other things, our product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, we or our representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "intend," "plan," "may," "should" or "anticipate" or their negatives or other variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical or current matters. These forward-looking statements may be included in, but are not limited to, various filings made by us with the SEC, press releases or oral statements made by or with the approval of one of our authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, those set forth in our most recent annual report referenced below.

This report identifies important factors which could cause our actual results to differ materially from those indicated by the forward-looking statements, particularly those set forth under Item 1A – Risk Factors as disclosed in the Annual Report on Form 10-K as filed with the Securities and Exchange Commission on April 2, 2018, and as augmented below.

All forward-looking statements attributable to us or persons acting on our behalf speak only as of the date of this report and are expressly qualified in their entirety by the cautionary statements included in this report. We undertake no obligations to update or revise forward-looking statements to reflect events or circumstances that arise after the date made or to reflect the occurrence of unanticipated events. In evaluating forward-looking statements, you should consider these risks and uncertainties.

Overview of the Company

Dthera Sciences, based in San Diego, CA, is a leading digital therapeutic company focusing on the elderly. Dthera Sciences is working to improve the lives of seniors and individuals suffering from neurodegenerative diseases, as well as those who care for them. Dthera has two core products: DTHR-ALZ, a development-stage product that has been granted Breakthrough Device designation by the FDA for the mitigation of the symptoms of agitation and depression associated with major neurocognitive disorder of the Alzheimer's type; and ReminX™, a consumer health product and general wellness device exempt from FDA regulations available for purchase for individuals suffering from social isolation and dementia.

On September 21, 2017, our shares of common stock were approved for trading on the OTCQB® Venture Market.

Our principal offices are located at 7310 Miramar Road, Suite 350, San Diego, CA, 92126.

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act (the "JOBS Act").

Dthera Business; Products

We have two core products: DTHR-ALZ, a development-stage product that has been granted Breakthrough Device designation by the FDA for the mitigation of the symptoms of agitation and depression associated with major neurocognitive disorder of the Alzheimer's type; and ReminX™, a consumer health product and general wellness device exempt from FDA regulations available for purchase for individuals suffering from social isolation and living with dementia. DTHR-ALZ, and to a certain extent ReminX, use elements of a behavioral intervention called Reminiscence Therapy. The commercialization and the commercial rollout of ReminX recently began in the fall of 2018, and DTHR-ALZ is an early development stage product.

The DTHR-ALZ product

DTHR-ALZ is a development-stage medical device that has been granted Breakthrough Device designation by the FDA for the mitigation of the symptoms of agitation and depression associated with major neurocognitive disorder of the Alzheimer's type. Under the Breakthrough Devices program, established by a provision of the 21st Century Cures Act of 2016, the FDA works with medical device developers to expedite development assessment and review in order to give patients more timely access to diagnostic and therapeutic medical devices. Under the 21st Century Cures Act, a “Breakthrough Device” is a medical device that may be more effective at treating or diagnosing a life-threatening or irreversibly debilitating disease or condition compared to the current standard of care and represents a breakthrough technology (1) for which no approved or cleared alternatives exist, (2) offers significant advantages over existing approved or cleared alternatives, or (3) the availability of the device is in the best interest of patients.. To our knowledge, we are only the second digital therapeutics company to obtain Breakthrough Device designation from the FDA.

Our management anticipates that DTHR-ALZ, if cleared or approved by FDA, will be the first non-pharmacological prescription treatment for the symptoms of agitation and depression associated with major neurocognitive disorder of the Alzheimer’s type.

DTHR-ALZ is based on the Dthera Reminiscence Platform (“DRP”), which also supports ReminX. DTHR-ALZ and ReminX are distinct products with distinct intended uses. DTHR-ALZ will make medical claims relating to the treatment of agitation and depression, in patients with major neurocognitive disorder of the Alzheimer’s type, whereas ReminX is a consumer health product and general wellness device exempt from FDA regulations that does not make medical claims and is marketed to individuals experiencing social isolation and living with dementia. DTHR-ALZ is also distinct in that it has higher processing power, enhanced facial expression recognition, and more robust feedback loop that collectively allow the device to focus on positive memories and to customize and optimize therapy in a way that a person or drug cannot

We expect DTHR-ALZ to require a pivotal clinical trial to receive FDA clearance. We are in the early stages on working with our advisors to develop a draft clinical development plan, which will be shared with the FDA for their feedback as part of the Breakthrough Devices program, using the pre-submission process. It is not anticipated that DTHR-ALZ will receive FDA clearance in 2019.

The ReminX product

ReminX is a consumer health product and general wellness device exempt from FDA regulations that is designed for seniors suffering from social isolation and living with dementia. Using elements of Reminiscence Therapy, the product is designed to provide individuals with the opportunity to reconnect with life’s memories and to remotely engage with their loved ones by receiving recent stories from family members and events. The product allows multiple family members and friends to collaborate in the care of and engagement of seniors, regardless of where they live. ReminX is comprised of three key components: A ReminX computer tablet, an AI chatbot, and a family feedback loop. The initial commercial rollout of ReminX began in the fall of 2018, and we are currently testing various sales models. There have been early sales of the ReminX product, but we have not yet generated a material amount of revenue from these sales.

We have assessed the regulatory status of ReminX under the law and FDA regulations and guidance documents. We have concluded that for certain of its intended uses, broadly summarized as alleviating social isolation in people who may or may not have a particular disease state, ReminX is a consumer health product that does not make medical claims. Under the 21st Century Cures Act of 2016, “a software function that is intended … for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition” is not a device under the Federal Food, Drug, and Cosmetic Act and thus is not subject to FDA regulation. For its other intended uses, to help people live well with Alzheimer’s and other forms of dementia, we have concluded that ReminX is a device under Federal Food, Drug, and Cosmetic Act but meets the definition of a “general wellness” device under an FDA guidance document published in 2016. In that guidance, FDA states that it will not exercise regulatory authority over general wellness devices, and therefore such devices are not required to comply with otherwise applicable FDA requirements for premarket review and approval or clearance and post-market regulatory requirements for devices, including, but not limited to: registration and listing and premarket notification requirements, labeling requirements, good manufacturing practice requirements, and Medical Device Reporting. However, there can be no guarantee that the FDA will agree with our conclusions or assessments relating to ReminX and the regulatory issues described above.

Plan of Operations

We expect to market and sell our two core assets through partnerships and direct sales.

Results of Operations – Three and Nine Months Ended September 30, 2018, Compared to the Three and Nine Months Ended September 30, 2017

Revenue

Revenue totaled $6,485 for the three and nine months ended September 30, 2018, with no related revenues in the other comparable periods. $4,122 of revenue recognized relates to sales made related to a beta version of the tablets. The revenue was deferred and recognized during the three and nine months ended September 30, 2018 as the Company rolled out the ReminX product and will not be continuing the service related to these sales.

Cost of revenue

Cost of revenue

Cost of revenues totaled $95,885 for the three and nine months ended September 30, 2018, with no related costs in the other comparable periods. $56,440 of cost of revenue recognized relates to sales made related to a beta version of the tablets. The cost of revenue was deferred and recognized during the three and nine months ended September 30, 2018, as the Company rolled out the ReminX product and will not be continuing the service related to these sales.

Impairment of inventory

Impairment of inventory totaled $16,019 for the three and nine months ended September 30, 2018, with no related costs in the other comparable periods. The impairment was due to the obsolescence upon the ReminX rollout of certain beta version hardware purchased prior to the completion of the manufacturing of the proprietary ReminX tablet.

Operating Expenses

General and Administrative Expenses

General and administrative expenses for the three and nine months ended September 30, 2018, totaled $912,161 and $1,994,319, respectively, an 838% and 26% increase, respectively, compared to general and administrative expenses of $97,259 and $1,584,466 for the three and nine months ended September 30, 2017, respectively. The increase is due to an increase in stock compensation expense and the increase in the size and complexity of the Company as it prepared for the rollout of ReminX and uplisting.

Sales and Marketing Expenses

Sales and marketing expenses for the three and nine months ended September 30, 2018, totaled $273,545 and $609,692, respectively, a 193% and 224% increase, respectively, compared to sales and marketing expenses of $93,240 and $188,415 for the three and nine months ended September 30, 2017, respectively. The increase is primarily due to an increase in advertising spending as the Company prepared for the rollout of ReminX.

Research and Development Expenses

Research and development expenses for the three and nine months ended September 30, 2018, totaled $64,377 and $142,565, a 4% and 10% decrease, respectively, compared to research and development expenses of $66,940 and $158,274 for the three and nine months ended September 30, 2017. The decrease is due to capitalization of software development costs as technological feasibility was achieved in January 2018.

Other Expenses

Interest Expense

Interest expense for the three and nine months ended September 30, 2018, totaled $49,323 and $51,440, a 100% increase and 72% decrease, respectively, compared to interest expenses of $0 and $185,847 for the three and nine months ended September 30, 2017. The increase is due to notes accruing interest and the decrease due to full amortization of debt discounts due to payment of all convertible notes in the prior year.

Gain on Derivative Liability

Gain on derivative liability for the three and nine months ended September 30, 2018, was $75,309, a 100% increase and 47% decrease, respectively, compared with gains of $0 and $142,835 in the three and nine months ended September 30, 2017. The gain is from revaluing the derivative instruments before the instruments settled during the prior year.

Loss on Settlement of Debt

Loss on settlement of debt for the nine months ended September 30, 2017, was $91,593 with no related gains in the other comparable periods. The loss resulted from settling convertible notes and accrued interest for stock and cash during the prior year.

Loss on disposal of assets

For the three and nine months ended September 30, 2018, the Company recognized $0 and $6,170, respectively, as a loss on disposal of its fixed assets, with no related expense in the three and nine months ended September 30,2017. The increase is due to the Company disposing damaged equipment in the current period.

Derivative Expense

For the three and nine months ended September 30, 2018, the Company recognized $305,398 in derivative expense, with no related expense in the three and nine months ended September 30,2017. The increase is due to the excess fair value of the conversion feature related to the convertible note at initial measurement and is recorded in the Statement of Operations.

Net Loss

For the reasons stated above, the Company's net loss for the three and nine months ended September 30, 2018, was $1,634,914 and $3,139,694, compared to net loss of $257,439 and $2,065,760 during the three and nine months ended September 30, 2017.

Liquidity and Capital Resources

As of the September 30, 2018, the Company had cash and restricted cash of $1,587,877, inventory of $70,945, prepaid expenses of $608,483 and deposits of $4,270, compared to cash and restricted cash of $323,483, inventory of $0, prepaid expenses of $95,176, and deposits of $2,500 for the year ended December 31, 2017. The increase in cash is due to the Company issuing debt, and equity, offset by prepaying for ReminX tablets rolled out in the current quarter. The increase in prepaid expenses are related to prepayment on 5,000 tablets ordered offset by prepayments for insurance and marketing services in the fourth quarter of 2017, which were amortized during the three and nine months ended September 30, 2018. The Company had current liabilities of $2,663,005 as of September 30, 2018 consisting of accounts payable, accrued expenses, deferred revenue, notes payable, convertible notes payable, and derivative liabilities as compared to current liabilities totaling $438,272 for the year ended December 31, 2017. The increase in current liabilities is directly related to the Company taking on debt in the form of notes payable and convertible notes payable along with the associated derivative liabilities. As of the nine months ended September 30, 2018, the Company had working capital of $381,775 which increased when compared to a working deficit of $17,113 for the year ended December 31, 2017.

The Company incurred operating losses and had negative operating cash flows and may continue to generate negative cash flows as the Company implements its business plan for the future. There can be no assurance that the Company's continuing efforts to execute its business plan will be successful and that the Company will be able to continue as a going concern as the report of our independent registered public accounting firm with respect to our financial statements for the years ended December 31, 2017 and 2016, indicates that the Company's recurring losses and negative cash flows from operations and the need for additional capital raise substantial doubt about the Company's ability to continue as a going concern. During the three and nine months ended September 30, 2018, the Company had a net loss of $1,634,914 and $3,139,694, respectively, and a net loss of $257,439 and $2,065,760 for the three and nine months ended September 30, 2017, respectively. The Company had net cash used in operations of $2,270,924 and $1,599,535 in the nine months ended September 30, 2018 and 2017, respectively. The consolidated financial statements have been prepared assuming that the Company will continue as a going concern; however, the above conditions raise substantial doubt about the Company's ability to do so. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern.

In July 2018, the Company closed a private securities offering launched in the fourth quarter of 2017, raising $2,551,350 in exchange for 196,264 shares. The Company intends to raise additional financing to support the sales of the ReminX product in the fourth quarter of the 2018. As of September 30, 2018, the Company had current liabilities of approximately $1,556,294, excluding derivative liabilities. If the Company is not able to raise additional capital that may be needed, it is probable that the Company will be unable to meet its obligations as they become due within one year from the issuance date of this filing and could have a material adverse effect on the Company's future business plans. Management believes that if the Company is not able to consummate a public or private offering of its securities, the Company would have to find other sources of financing to complete and implement its business plans for the future. There can be no guarantee that the Company would obtain financing with terms that are acceptable to the Company, in which case, the Company may have to limit its expansion of new products or limit its working capital.

Recent Developments

Pre-Launch Offering

The Company commenced a private placement offering of shares of its common stock (the "Pre-launch Offering") in the fourth quarter of 2017. As of year-end the Company had sold a total of 59,770 shares of the Company's Common Stock for net proceeds of $777,000 in the Pre-launch Offering.

As of July 20, 2018, the Company closed the Pre-launch Offering. As of the date of the closing of the Offering, the Company had sold a total of 196,264 shares of the Company's common stock in the Offering and had raised an aggregate of approximately $2,551,350.

The Pre-launch offering was made to accredited investors only. No warrants or other securities were offered in the offering.

Promissory Notes

On May 11, 2018, the Company issued a short-term promissory note to an unrelated party for $50,000 due 30 days from the date of issuance. The note bore an interest rate of 14.4% per annum, and the Company had the right to pre-pay with no penalty or premium. The Company's obligation to repay the note was secured by the grant of a security interest in the assets of the Company. On June 10, 2018, the Company extended the term of the above short-term promissory note of $50,000 to October 31, 2018. All other terms remained the same. This note was subsequently repaid. See Subsequent Events Footnote 13 in the Consolidated Statements for the period ending September 30, 2018 for additional details.

On June 28, 2018, the Company issued a short-term promissory note to an unrelated party for $50,000 due 90 days from the date of issuance. The note bore interest at a rate of 12% per annum, and the Company had the right to pre-pay with no penalty or premium. The Company's obligation to repay the note was secured by the grant of a security interest in the assets of the Company. This note was subsequently repaid. See Subsequent Events Footnote 13 in the Consolidated Statements for the period ending September 30, 2018 for additional details. On July 2, 2018, the Company received $50,000 for a short-term promissory note to an unrelated party due 60 days from the date of issuance. The note bore interest at a rate of 12% per annum, and the Company had the right to pre-pay with no penalty or premium. The Company's obligation to repay the note was secured by the grant of a security interest in the assets of the Company. This note was subsequently modified. See Subsequent Events Footnote 13 in the Consolidated Statements for the period ending September 30, 2018 for additional details.

On July 2, 2018, the Company issued a short-term note to a related party for $100,000 due 60 days from the date of issuance. The note bore an interest rate of 12% per annum, and the Company had the right to pre-pay with no penalty or premium. The Company's obligation to repay the note was secured by the grant of a security interest in the assets of the Company. This note was extinguished as a part of the following note.

On September 17, 2018, the Company issued a short-term 10% original issue discount ("OID") note to a related party with a face amount of $550,000 and a purchase price of $500,000, $400,000 of which was received in cash and $100,000 was paid through the extinguishment of an existing promissory note, referenced above. The note is due and payable January 17, 2019. In connection with the note, the Company issued 25,000 shares of common stock and warrants to purchase 50,000 additional shares.

On September 14, 2018, the Company issued a short-term 10% OID note to a related party with a face amount of $275,000 and a purchase price of $250,000. The note is due and payable January 14, 2019. In connection with the note, the Company issued 12,500 shares of common stock and warrants to purchase 25,000 additional shares.

On September 21, 2018, the Company issued a short term 10% OID convertible note to an unrelated party with a face amount of $1.1 million and a purchase price of $1.0 million. $550,000 automatically converts to common shares upon uplisting and $550,000 is convertible into common shares at a conversion price of $10.00 per share at any time after uplisting or certain other events. In connection with the note, the Company issued 50,000 shares of common stock and warrants to purchase 100,000 additional shares.

Initial Commercialization of ReminX Product

On August 1, 2018, the Company announced that it had commenced sales of ReminX™. ReminX is a consumer health product and general wellness device exempt from FDA regulations that is designed for seniors suffering from social isolation and living with dementia. Using elements of Reminiscence Therapy, the product is designed to provide individuals with the opportunity to reconnect with life's memories and to remotely engage with their loved ones by receiving recent stories of family members and events

FDA Breakthrough Device designation

On August 20, 2018, the FDA granted Breakthrough Device designation to our early development-stage product, DTHR-ALZ. The Breakthrough Device designation applies only to DTHR-ALZ, and does not apply to our ReminX product.

Under the Breakthrough Devices program, a provision of the 21st Century Cures Act, the FDA works with medical device developers to expedite regulatory review in order to give patients more timely access to a Breakthrough Device. A "Breakthrough Device" is a medical device that may be more effective at treating or diagnosing a life-threatening or irreversibly debilitating disease or condition compared to the current standard of care and represents a breakthrough technology (1) for which no approved or cleared alternatives exist, (2) offers significant advantages over existing approved or cleared alternatives, or (3) the availability of the device is in the best interest of patients.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As a smaller reporting company, the Company is not required to provide the disclosure required by this item.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer who is also our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 15(d)-15(e) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**") as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were not effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and (ii) is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. As of the end of the period covered by the Report, we did not have a formal audit committee and there was a lack of segregation of duties.

The Company is continuing to work to remediate the issues relating to segregation of duties and to strengthen its disclosure controls and procedures.

Changes in internal control over financial reporting

Other than as discussed above, there has been no change in our internal control over financial reporting, as defined in Rules 13a-15(f) of the Exchange Act, during quarter ended September 30, 2018, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHE R INFORMATION

Item 1A. Ri sk Factors

See “Item 1A – Risk Factors” as disclosed in Form 10-K as filed with the Commission on April 2, 2018.

Additional risk factors:

We are a development-stage company and will need to make additions to senior management in order to successfully execute our business plan.

We will need to identify and recruit additional prospective executives and other employees with experience in the digital therapeutic and neurocognitive disorder industries, specifically candidates who have managed and completed FDA-required regulatory affairs and clinical studies concerning new products. Edward Cox, our Chief Executive Officer, is one of our founders and has agreed to serve in that capacity in the interim. Although his primary background involves biosciences, healthcare, life sciences, and technology, he has experience in development-stage companies and venture-level investments and early stage capital formation for emerging growth companies. Our inability to recruit and retain executives with proven experience in these fields could delay or negatively affect our ability to execute on our business plan, which would have a material adverse effect on our financial condition and results of operation.

Our business is subject to government regulation, which may have a negative impact on our ability to develop and implement our business strategy and bring new products to market, and our ability to continue operations.

The digital health sector is relatively new and untested, and impacts of regulations and general market conditions could have a negative impact on our business. The digital health sector may be impacted by economic volatility, consumer spending patterns and market share gains of competitors’ branded products. Overall the digital health market is largely new and untested; the uptake of products may not meet uptake projections as there is little to no prior data. In addition, the United States healthcare industry is highly regulated and subject to frequent and substantial changes. Digital health is an evolving industry within the United States healthcare industry, and is particularly susceptible to these changes. The impacts of these regulations and the general market conditions could have a negative impact on our business and operations.

Research, development, and commercialization of medical devices are inherently risky. The cost and time needed to obtain regulatory clearance or approval are uncertain. We cannot give any assurance that we will receive or maintain regulatory clearance or approval of DTHR-ALZ or potentially other products.

DTHR-ALZ is a medical device that will be subject to FDA regulation. Therefore, FDA clearance or approval will be required before marketing DTHR-ALZ. As a company, we have no experience in obtaining regulatory clearance or approval of a medical device. Likewise, we have no experience in the commercialization or marketing of a medical device. Although DTHR-ALZ has been granted Breakthrough Device designation, such a designation does not guarantee that a device will be approved by the FDA. In addition, Breakthrough Device designation does not guarantee faster development, regulatory review or approval. The FDA has acknowledged that review times may take longer for some Breakthrough Devices than for other devices because of the novel scientific issues Breakthrough Devices may raise. The FDA may also withdraw Breakthrough Device designation after it is granted if the device is no longer eligible or if the request for Breakthrough Designation contained untrue statements of material fact or omitted material information. To receive FDA clearance or approval, we must provide reasonable assurance of the safety and effectiveness of DTHR-ALZ. To provide such assurance, we may be required to conduct clinical studies or other analyses. The cost and length of time needed to complete such studies or analyses are uncertain. As a company, we have no experience in conducting the types of clinical studies or analyses required to receive FDA clearance or approval of a medical device. If we are unable to successfully complete required clinical studies or other analyses, we will not receive FDA clearance or approval. Following FDA clearance or approval, if received, we will be subject to ongoing regulatory requirements around the continued development, commercialization, and marketing of DTHR-ALZ. If we do not comply with such requirements, FDA may withdraw its clearance or approval and may direct us to remove DTHR-ALZ from the market.

Our management plans to seek Medicare, Medicaid and/or private payor reimbursement for this and potential other products, but there is no guarantee that we will be successful in these efforts. If FDA disagrees with our analysis that ReminX is a general wellness device exempt from FDA regulations and decides to exercise regulatory authority over ReminX, if we are unable to obtain FDA clearance or approval for our DTHR-ALZ product and potential other products, or if we are unsuccessful in obtaining Medicare, Medicaid or private payor reimbursement for DTHR-ALZ and potential other products, our ability to develop and implement our business strategy could be delayed, limited, or unsuccessful. Even if we are successful in obtaining Medicare, Medicaid, or private payor reimbursement for this and potentially other products, such products may become subject to unfavorable pricing regulations, third party reimbursement practices, or healthcare reform initiatives, which would harm our business.

If our efforts to sell to Direct-Response Consumer Health (DRCH) companies and other sales channels are not successful, our revenues may be materially affected.

We intend to generate substantially all of our revenues initially through sales of the ReminX Product to the Direct-Response Consumer Health (DRCH) channel. We also plan to initiate sales through a number of channels. We must develop these sales channels, which we seek to do in part by investing in our product platform and new services and technologies. If our efforts to grow these sales channels are not successful, our revenues would be adversely affected. We intend to rely on our marketing and advertising efforts to attract new clients and subscribers. If we are unable to effectively attract new clients and subscribers, our business, financial condition and results of operations would be materially adversely affected.

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

Our future arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products. Federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights will be applicable to our business. Restrictions under applicable federal, state and foreign healthcare laws and regulations may affect our ability to operate and expose us to areas of risk, including:

- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;

- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, 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 under the Open Payments Program, 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, as well as other state and foreign laws regulating marketing activities;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. 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 may 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 healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Digital Therapeutics, and particularly Digital Therapeutics based on Reminiscence Therapy, is relatively new and unproven in the healthcare market, and our products may experience slow or limited growth, which would adversely affect our ability to fully realize the potential of our products.

Our products combine elements of Reminiscence Therapy and Digital Therapeutics to improve the lives of seniors and individuals suffering from social isolation and dementia, as well as those who care for them. This approach is relatively new, and evaluating the size and scope of the market is subject to a number of risks and uncertainties. We believe that our future success will depend in large part on the growth of this market. Our management anticipates that DTHR-ALZ will be the first non-pharmacological prescription treatment for the symptoms of agitation and depression associated with major neurocognitive disorder of the Alzheimer's type, and it is expected be used primarily in the senior living, skilled nursing, and/or home care/home health sectors. These markets and market participants may not recognize the need for, or benefits of, our products. Even if this market does grow, our ability to expand our business and extend our market position depends upon a number of factors, including the cost, performance and perceived value of our products and the applications we develop for them. The perceived value of our products and the applications we develop for them may be a function of estimated cost savings by healthcare providers using our products, which may be difficult to accurately predict. Market opportunity and cost saving estimates are subject to significant uncertainty and are based on assumptions and estimates, including our internal analysis and industry experience. Assessing the market for our solutions in each of the markets we are planning to compete in is particularly difficult due to a number of factors, including limited available information and rapid evolution of the market. The market for our products may fail to grow significantly or be unable to meet the level of growth we expect. As a result of these and other factors, we may experience lower-than-expected demand for our products and services due to lack of channel partner, hospital and/or physician acceptance, technological challenges, competing products and services, decreases in spending by current and prospective customers, weakening economic conditions and other causes. If our market does not experience significant growth, or if demand for our products does not increase in line with our projections, then our business, results of operations and financial condition will be adversely affected.

To the extent our business model depends on government payors, and those payors fail to provide coverage or adequate reimbursement for the services in which our products are used, our revenue and prospects for profitability would be harmed.

Our current go-to-market strategy for our ReminX product does not contemplate or rely upon governmental or third party payor reimbursement. As noted, DTHR-ALZ is a development-stage medical device that has been granted Breakthrough Device designation by the FDA for the mitigation of the symptoms of agitation and depression associated with major neurocognitive disorder of the Alzheimer's type. Our management plans to seek Medicare, Medicaid and/or private payor reimbursement for this and potentially other products, but there is no guarantee that we will be successful in these efforts. To the extent that we adopt a market strategy which is in whole or in part reliant on third party reimbursement, commercial sales of our DTHR-ALZ product will depend in part on the availability of reimbursement from such third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Each third-party payor may have its own policy regarding what products it will cover, the conditions under which it will cover such products, and how much it will pay for such products. Third-party payors are increasingly examining the medical necessity and cost effectiveness of medical products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved devices.

Risks Related to Regulatory Matters

Breakthrough Device designation by the FDA does not guarantee clearance or approval and may not actually lead to a faster development or regulatory review or approval process.

DTHR-ALZ was granted Breakthrough Device designation by the FDA on August 20, 2018, for the mitigation of the symptoms of agitation and depression associated with major neurocognitive disorder of the Alzheimer's type. Under the Breakthrough Devices program, a provision of the 21st Century Cures Act, the FDA works with medical device developers to expedite development assessment and review in order to give patients more timely access to diagnostic and therapeutic medical devices. According to the FDA, a “Breakthrough Device” is a medical device that may be more effective at treating or diagnosing a life-threatening or irreversibly debilitating disease or condition compared to the current standard of care and represents a breakthrough technology (1) for which no approved or cleared alternatives exist, (2) offers significant advantages over existing approved or cleared alternatives, or (3) the availability of the device is in the best interests of patients.

There is no assurance we will receive similar designations for any of our future products. Further, even though we have received Breakthrough Device designation for DTHR-ALZ, we may not experience a faster development process, review or clearance/approval compared to conventional FDA procedures, or may not receive clearance or approval at all. The FDA may withdraw Breakthrough Device designation for DTHR-ALZ or any other device designated as a Breakthrough Device if it believes that such designation is no longer supported by data from our clinical development program.

As we develop our DTHR-ALZ product and other potential products that are regulated by the FDA, we will be subject to costly and complex laws and governmental regulations and any adverse regulatory action may materially adversely affect our financial condition and business operations.

As noted, DTHR-ALZ is a development-stage medical device that has been granted Breakthrough Device designation by the FDA for the mitigation of the symptoms of agitation and depression associated with major neurocognitive disorder of the Alzheimer's type. As we develop DTHR-ALZ and other potential products that are regulated by the FDA, we will be subject to regulation by numerous government agencies, including the FDA and comparable agencies outside the United States. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our products.

We cannot guarantee that we will be able to obtain or maintain marketing clearance or approval for our medical device products or enhancements or modifications to existing products. We have no FDA cleared or approved products, and we may not receive further clearances or approvals on a timely basis, if at all. The failure to maintain or obtain approval or clearance for new products or functions could have a material adverse effect on our business, results of operations, financial conditions and cash flows. Even if we are able to obtain such approval or clearance, it may:

- take a significant amount of time;
- require the expenditure of substantial resources;
- involve stringent clinical and pre-clinical testing, as well as increased post-market compliance requirements and surveillance;
- involve modifications, repairs, or replacements of our products; and
- result in limitations on the proposed uses and marketing of our products.

Further, if the FDA or other applicable regulatory authorities approve or clear a similar product that competes with our product or products, it could decrease our expected sales. Both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. Many of our facilities and procedures and those of our suppliers are also subject to periodic inspections by the FDA to determine compliance with the FDA’s requirements, including primarily the quality system regulations and medical device reporting regulations. The results of these inspections can include inspectional observations on FDA’s Form-483, warning letters, or other forms of enforcement. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our products are ineffective or pose an unreasonable health risk, the FDA could prohibit us from marketing such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of such devices, refuse to grant pending pre-market clearance or approval applications or require certificates of non-U.S. governments for exports, or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA may also assess civil or criminal penalties against us, our officers or employees and impose restrictions on a company-wide basis, or enjoin or restrain certain conduct resulting in violations of applicable law. The FDA may also recommend prosecution to the U.S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future pre-market clearances or approvals, and could result in a substantial modification to our business practices and operations.

Our ability to generate product revenue from DTHR-ALZ is dependent on the success of our development of DTHR-ALZ, for human therapeutic use, specifically for the mitigation of the symptoms of agitation and depression associated with major neurocognitive disorder of the Alzheimer's type . We are in the early stage of developing DTHR-ALZ. FDA clearance may require significant additional development efforts, preclinical testing and studies, as well as applicable regulatory guidance for preclinical and clinical studies from the FDA and other regulatory authorities before we can seek regulatory clearance and begin commercial sales of any potential products. The design and execution of clinical studies to support FDA clearance of DTHR-ALZ is subject to substantial risk and uncertainty. Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development. We likely will rely on third parties to conduct our clinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if they terminate their agreement with us, we may not be able to obtain regulatory clearance for or commercialize our products.

The regulatory clearance processes of the FDA are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory clearance for our products, our business will be substantially harmed.

In addition, the marketing license for any product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated. The FDA has taken the position that device manufacturers are prohibited from promoting their products other than for the uses and indications set forth in the approved product labeling. The U.S. government has initiated a number of enforcement actions against manufacturers that promote products for "off-label" uses, including actions alleging that federal health care program reimbursement of products promoted for "off-label" uses (or services in which such products are utilized) constitute false and fraudulent claims to the government. The failure to comply with "off-label" promotion restrictions can result in significant civil or criminal exposure, administrative obligations and costs, or other potential penalties from, or agreements with, the federal government.

FDA may disagree with our assessment that ReminX is a general wellness device, or may decide in the future to exercise regulatory authority over some or all general wellness devices.

We have assessed the regulatory status of ReminX under the law and FDA regulations and guidance documents. We have concluded that for certain of its intended uses, broadly summarized as alleviating social isolation in people who may or may not have a particular disease state, ReminX is a consumer health product that does not make medical claims. Under the 21st Century Cures Act of 2016, "a software function that is intended … for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition" is not a device under the Federal Food, Drug, and Cosmetic Act and thus is not subject to FDA regulation. For its other intended uses, to help people live well with Alzheimer's and other forms of dementia, we have concluded that ReminX is a device under Federal Food, Drug, and Cosmetic Act but meets the definition of a "general wellness" device under an FDA guidance document published in 2016. In that guidance, FDA states that it will not exercise regulatory authority over general wellness devices, and therefore such devices are not required to comply with otherwise applicable FDA requirements for premarket review and approval or clearance and post-market regulatory requirements for devices, including, but not limited to: registration and listing and premarket notification requirements, labeling requirements, good manufacturing practice requirements, and Medical Device Reporting.

There is no guarantee that the FDA will agree with our assessment that ReminX is not a device for some of its intended uses and a general wellness device for other intended uses. In the event that the FDA were to disagree with our assessment we may be subject to FDA enforcement actions, including but not limited to seizure and recall of our products, injunctions and civil and criminal penalties. We may also be forced to alter some of the claims that we make for ReminX.

There is also no guarantee that the FDA will continue to decline to exercise its regulatory authority over general wellness devices. If FDA alters its approach to these products, we may have to alter the intended uses of ReminX and/or seek regulatory clearance or approval for some of its intended uses.

We make our FDA regulated products under extensive FDA and foreign regulatory quality and manufacturing requirements and may face future regulatory difficulties under these requirements.

The FDA and other regulatory authorities require that our FDA-regulated devices be manufactured in compliance with Quality System Regulations, or QSR, and similar standards in foreign markets where we intend to sell our products. Any failure by us or our third-party manufacturers to comply with QSR or failure to scale up manufacturing processes as needed, including any failure to deliver sufficient quantities of products in a timely manner, could have a material adverse effect on our business, financial condition, operating results and cash flows. In addition, such failure could be the basis for action by the FDA to withdraw clearance for products previously granted to us and for other regulatory action. Compliance with quality standards is further complicated by the fact that the FDA's guidance and expectations for software quality systems is evolving. Thus, changes to current product quality and manufacturing standards, guidance and regulations may impact the timeline and resources required to develop and make our products.

Our industry is experiencing greater scrutiny and regulation by governmental authorities, which may lead to greater regulation in the future.

Our medical devices and technologies and our business activities are subject to a complex regime of regulations and enforcement environment, including regulations promulgated by the FDA, the U.S. Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Federal Trade Commission (FTC), and numerous other federal, state, and non-U.S. governmental authorities. In addition, certain state governments and the federal government have enacted legislation aimed at increasing transparency of our interactions with health care providers. As a result, if our devices and solutions (or the procedures in which they are used) are reimbursed by Federal Healthcare programs such as Medicare or Medicaid, we are required by law to disclose payments and other transfers of value to health care providers licensed by certain states and to all U.S. physicians and U.S. teaching hospitals at the federal level. Any failure to comply with these legal and regulatory requirements could impact our business. In addition, we will continue to devote substantial additional time and financial resources to further develop and implement policies, systems, and processes to comply with enhanced legal and regulatory requirements, which may also impact our business. We anticipate that governmental authorities will continue to scrutinize our industry closely, and that additional regulation may increase compliance and legal costs, exposure to litigation, and other adverse effects to our operations.

If we fail to comply with applicable health information privacy and security laws and other state and federal privacy and security laws, we may be subject to significant liabilities, reputational harm and other negative consequences, including decreasing the willingness of current and potential customers to work with us.

DTHR-ALZ may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, established uniform federal standards for “covered entities,” which include certain healthcare providers, healthcare clearinghouses, and health plans, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information, or PHI. The Health Information Technology for Economic and Clinical Health Act, or HITECH Act, which became effective on February 17, 2010, makes HIPAA’s security standards directly applicable to “business associates,” which are independent contractors or agents of covered entities that create, receive, maintain, or transmit PHI in connection with providing a service for or on behalf of a covered entity. The HITECH Act also increased the civil and criminal penalties that may be imposed against covered entities, business associates and certain other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA’s requirements and seek attorney’s fees and costs associated with pursuing federal civil actions.

A portion of the data that we obtain and handle for or on behalf of certain of our clients may be considered PHI, subject to HIPAA. If so, we would also be required to maintain similar business associate agreements with our subcontractors that have access to PHI of our customers in rendering services to us or on our behalf. Under HIPAA and our contractual agreements with our HIPAA-covered entity health plan customers, we would be considered a “business associate” to those customers, and would be required to maintain the privacy and security of PHI in accordance with HIPAA and the terms of our business associate agreements with our clients, including by implementing HIPAA-required administrative, technical and physical safeguards. We would incur significant costs to establish and maintain these safeguards and, if additional safeguards are required to comply with HIPAA regulations or our clients’ requirements, our costs could increase further, which would negatively affect our operating results. Furthermore, we cannot guarantee that such safeguards have been and will continue to be adequate. If we fail to maintain adequate safeguards, or we or our agents or subcontractors use or disclose PHI in a manner prohibited or not permitted by HIPAA, our subcontractor business associate agreements, or our business associate agreements with our customers, or if the privacy or security of PHI that we obtain and handle is otherwise compromised, we could be subject to significant liabilities and consequences, including, without limitation:

- breach of our contractual obligations to clients, which may cause our clients to terminate their relationship with us and may result in potentially significant financial obligations to our clients;
- investigation by the federal and state regulatory authorities empowered to enforce HIPAA and other data privacy and security laws, which include the U.S. Department of Health and Human Services the Federal Trade Commission and state attorneys general, and the possible imposition of civil and criminal penalties;
- private litigation by individuals adversely affected by any misuse of their personal health information for which we are responsible and/or breach notification related costs; and
- negative publicity, which may decrease the willingness of potential future customers to work with us and negatively affect our sales and operating results.

Further, we publish statements to end users of our services that describe how we handle and protect personal information. If federal or state regulatory authorities or private litigants consider any portion of these statements to be untrue, we may be subject to claims of deceptive practices, which could lead to significant liabilities and consequences, including, without limitation, damage to our reputation and costs of responding to investigations, defending against litigation, settling claims and complying with regulatory or court orders.

Recent legal developments in Europe have created compliance uncertainty regarding certain transfers of personal data from Europe to the United States. For example, the General Data Protection Regulation (GDPR), which came into application in the European Union (EU) on May 25, 2018, applies to all of our activities conducted from an establishment in the EU or related to products and services that we offer to EU users. The GDPR created a range of new compliance obligations which may cause us to change our business practices, and significantly increased financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher) for the most serious infringements).

Federal or state governmental authorities may impose additional data security standards or additional privacy or other restrictions on the collection, use, maintenance, transmission and other disclosures of health information. Legislation has been proposed at various times at both the federal and the state level that would limit, forbid or regulate the use or transmission of medical information outside of the United States. Such legislation, if adopted, may render our use of off-shore partners for work related to such data impracticable or substantially more expensive. Alternative processing of such information within the United States may involve substantial delay in implementation and increased cost.

If we fail to comply with federal and state healthcare laws and regulations, including those governing submission of false or fraudulent claims to government healthcare programs and financial relationships among healthcare providers, we may be subject to civil and criminal penalties or loss of eligibility to participate in government healthcare programs.

We may be subject to certain federal and state laws and regulations designed to protect patients, governmental healthcare programs, and private health plans from fraudulent and abusive activities. These laws include anti-kickback restrictions and laws prohibiting the submission of false or fraudulent claims. These laws are complex and their application to our specific products, services and relationships may not be clear and may be applied to our business in ways that we do not anticipate. Federal and state regulatory and law enforcement authorities have recently increased enforcement activities with respect to Medicare and Medicaid fraud and abuse regulations and other reimbursement laws and rules. From time to time in the future, we may receive inquiries or subpoenas to produce documents in connection with such activities. We could be required to expend significant time and resources to comply with these requests, and the attention of our management team could be diverted to these efforts. If we are found to be in violation of any federal or state fraud and abuse laws, we could be subject to civil and criminal penalties, and we could be excluded from participating in federal and state healthcare programs such as Medicare and Medicaid. The occurrence of any of these events could significantly harm our business and financial condition.

Provisions in Title XI of the Social Security Act, commonly referred to as the federal Anti-Kickback Statute, prohibit the knowing and willful offer, payment, solicitation or receipt of remuneration, directly or indirectly, in cash or in kind, in return for or to induce either the referral of an individual or arranging for the referral of an individual for items or services for which payment may be made in whole or in part by a federal health care program, or the purchasing, leasing, ordering, or arranging for or recommending the purchasing, leasing, or ordering of items, services, goods, or facilities for which payment may be made, in whole or in part, by a federal healthcare program, including but not limited to Medicare or Medicaid. The definition of “remuneration” has been broadly interpreted to include anything of value such as gifts, discounts, rebates, waiver of payments or providing anything at less than its fair market value. Many states have adopted similar prohibitions against kickbacks and other practices that are intended to induce referrals which are applicable to all patients regardless of whether the patient is covered under a governmental health program or private health plan. We attempt to scrutinize our business relationships and activities to comply with the federal Anti-Kickback Statute and similar laws and we generally attempt to structure our sales and group purchasing arrangements in a manner that is consistent with the requirements of applicable safe harbors to these laws. We cannot assure you, however, that our arrangements will be protected by such safe harbors or that such increased enforcement activities will not directly or indirectly have an adverse effect on our business, financial condition or results of operations. Any determination by a state or federal agency that any of our activities or those of our vendors or customers violate any of these laws could subject us to civil or criminal penalties, monetary fines, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, could require us to change or terminate some portions of operations or business, could disqualify us from providing services to healthcare providers doing business with government programs and, thus, could have an adverse effect on our business.

Our business may also be subject to numerous federal and state laws regarding submission of false or fraudulent claims, including without limitation the civil False Claims Act, which forbids knowingly presenting or "causing to be presented" false or fraudulent claims for payment to a federal health care program. Analogous state laws and regulations may apply to our arrangements and our customers' claims involving healthcare items or services reimbursed by non-governmental third-party payors. Additionally, HIPAA also imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters.

These laws and regulations may change rapidly, and it is frequently unclear how they apply to our business. Errors created by our products that relate to entry, formatting, preparation or transmission of claim or cost report information may be determined or alleged to be in violation of these laws and regulations. Any failure of our products or services to comply with these laws and regulations could result in substantial civil or criminal liability, monetary fines, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, could adversely affect demand for our one or more of our offerings, could invalidate all or portions of some of our customer contracts, could require us to change or terminate some portions of our business, could require us to refund certain amounts collected, could cause us to be disqualified from serving clients doing business with government payors and could have an adverse effect on our business.

Our activities are also subject to state and federal self-referral laws, including the federal Physician Self-referral Law, commonly known as the Stark Law, which prohibits physicians from referring patients to an entity for Medicare-covered "designated health services" if the physician, or a member of the physician's immediate family, has a financial relationship with the entity, unless a statutory or regulatory exception applies. Many states have similar laws that may apply regardless of payor. In addition, our activities may also implicate state laboratory licensure laws, as well as the corporate practice of medicine prohibition in certain states that maintain such laws or regulations. Our failure to abide by these state and federal laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations and financial conditions.

We may encounter substantial delays in completing our clinical studies which in turn will require additional costs, or we may fail to demonstrate adequate safety and efficacy to the satisfaction of applicable regulatory authorities.

It is impossible to predict if or when DTHR-ALZ will be deemed to be effective for the mitigation of the symptoms of agitation and depression associated with major neurocognitive disorder of the Alzheimer's type . Before obtaining marketing clearance or approval from regulatory authorities for the sale and marketing of DTHR-ALZ or future FDA regulated products, we may be required to conduct clinical studies to demonstrate their safety and efficacy. Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching, or failing to reach, a consensus with regulatory agencies on study design;
- delays in reaching, or failing to reach, agreement on acceptable terms with a sufficient number of prospective contract research organizations ("CROs") or clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in obtaining required Institutional Review Board ("IRB") or Ethics Committee ("EC") approval at each clinical study site;
- delays in recruiting a sufficient number of suitable patients to participate in our clinical studies;
- imposition of a clinical hold by regulatory agencies, after an inspection of our clinical study operations or study sites;
- failure by our CROs, other third parties or us to adhere to clinical study, regulatory or legal requirements;
- failure to perform in accordance with the FDA's good clinical practices ("GCP") or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery of sufficient quantities of our product candidates to the clinical sites;
- delays in having patients complete participation in a study or return for post-treatment follow-up;

- clinical study sites or patients dropping out of a study;
- delay or failure to address any patient safety concerns that arise during the course of a trial;
- unanticipated costs or increases in costs of clinical studies of our product candidates;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

We could also encounter delays if a clinical study is suspended or terminated by us, by the IRBs or ECs of the institutions or partners with which such trials are being conducted, by an independent Safety Review Board ("SRB") for such study or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical study due to a number of factors, including failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols, inspection of the clinical study operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a device, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical study.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if we make manufacturing or software changes to our product candidates, we may need to conduct additional studies to prove the efficacy of DTHR-ALZ or our future FDA regulated products.

Clinical study delays could also shorten any periods during which we are able to commercialize DTHR-ALZ or allow our competitors to bring a competing product to market before we do, which could impair our ability to successfully commercialize DTHR-ALZ. In addition, any delays in completing our clinical studies will increase our costs, slow down the development and approval or clearance process for DTHR-ALZ and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval or clearance of DTHR-ALZ or our future FDA regulated products.

The outcome of preclinical studies and early clinical studies may not be predictive of the success of later clinical studies, and interim results of a clinical study do not necessarily predict final results. Further, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical studies have nonetheless failed to obtain marketing approval or clearance. If the results of our clinical studies are inconclusive or if there are concerns or adverse events associated with DTHR-ALZ or our future FDA regulated products, we may:

- be delayed in obtaining marketing approval for DTHR-ALZ and other products, if approved at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be required to change the way the product is used;
- be required to perform additional clinical studies to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of a product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be sued; or
- experience damage to our reputation.

Additionally, use of DTHR-ALZ could potentially cause other adverse events that have not yet been predicted. As described above, any of these events could prevent us from achieving or maintaining market acceptance of DTHR-ALZ and impair our ability to commercialize DTHR-ALZ and other products.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.

Patient enrollment in clinical studies and completion of patient participation and follow-up depends on many factors, including the size of the patient population; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical study investigators; support staff; and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical study and patient compliance. For example, patients may be discouraged from enrolling in our clinical studies if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the effectiveness of our products or if they determine that the uses and results of DTHR-ALZ under the trial protocols are not attractive. Patients may also not participate in our clinical studies if they choose to participate in contemporaneous clinical studies of competitive products.

If the third parties on which we rely to conduct our clinical studies and to assist us with preclinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

We do not have the ability to independently conduct our pre-clinical and clinical studies for our products and we must rely on third parties, such as contract research organizations, pharmaceutical companies, medical institutions, clinical investigators and contract laboratories to conduct such studies. If these third parties do not successfully carry out their contractual duties or regulatory obligations, meet expected deadlines or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval or clearance for, or successfully commercialize, our products on a timely basis, if at all. Furthermore, our third-party clinical study investigators may be delayed in conducting our clinical studies for reasons outside of their control. The occurrence of any of the foregoing may adversely affect our business, operating results and prospects.

The future results of our current or future clinical studies may not support our product candidate claims or may result in the discovery of unexpected adverse side effects.

Even if our clinical studies are completed as planned, we cannot be certain that their results will support the claims for which DTHR-ALZ has received Breakthrough Device Designation, or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in preclinical studies and early clinical studies does not ensure that later clinical studies will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and preclinical studies. The clinical study process may fail to demonstrate that DTHR-ALZ is safe and effective for the proposed indicated uses. If the FDA concludes that the clinical studies for DTHR-ALZ, or any other product for which we might seek clearance in the future, has failed to demonstrate safety and effectiveness, we would not receive FDA clearance to market that product in the United States for the indications sought.

In addition, such an outcome could cause us to abandon DTHR-ALZ and might delay development of others. Any delay or termination of our clinical studies will delay the filing of any product submissions with the FDA and, ultimately, our ability to commercialize DTHR-ALZ and our future products and generate revenues.

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

Pre-Launch Offering

The Company commenced a private placement offering of shares of its common stock (the “Pre-launch Offering”) in the fourth quarter of 2017. As of December 31, 2017, the Company had sold a total of 59,770 shares of the Company's Common Stock for net proceeds of $777,000 in the Pre-launch Offering.

As of August 14, 2018, the Company closed the private placement offering, selling a total of 196,264 shares of the Company’s common stock and had raised an aggregate of $2,551,350.

The Offering was made to accredited investors only. No warrants or other securities were offered in the offering.

The above issuances were completed in reliance on exemptions from registration under Section 4(a)(2) of the Securities Act of 1933 (the "Securities Act"). These transactions qualified for exemption from registration because (i) the Company did not engage in any general solicitation or advertising to market the securities; (ii) each purchaser was provided the opportunity to ask questions and receive answers from the Company regarding the Company and the issuance; (iii) the securities were issued to persons with knowledge and experience in financial and business matters so that he or she is capable of evaluating the merits and risks of an investment in the Company; and (iv) the recipients received "restricted securities" that include a restrictive legend on the certificate, which restricts the shares from being transferred except pursuant to a registration statement that is effective with the SEC or pursuant to an exemption from registration.

Options Granted to Employees and Consultants

On June 28, 2018, the Company's Board of Directors approved the grant of an aggregate of 30,000 options to purchase shares of the Company's common stock, consisting of grants of 1,250 options to 24 employees and consultants to the Company who had been instrumental in helping the Company get to the point of the initial launch. The options granted had an exercise price of $8.40 per share, which was the market price of the common stock on the date of grant, and vest one-third on each of the first, second, and third anniversaries of the date of grant, and expire on the eighth anniversary of the date of grant.

On June 29, 2018, the Company's Board of Directors approved the grant of an aggregate of 12,500 options to purchase shares of the Company's common stock, consisting of grants of 6,250 options to the two board members of the Company. The options granted had an exercise price of $8.40 per share, and vest one-third on each of the first, second, and third anniversaries of the date of grant, and expire on the eighth anniversary of the date of grant.

The option grants were completed in reliance on exemptions from registration pursuant to Section 4(a)(2) and Rule 701 and other rules. The grants of options qualified for exemption from registration because the Company is not subject to the reporting requirements of the Securities Exchange Act of 1934 (the "Exchange Act"), and the other requirements of Rule 701 were met.

RSJ and Wade Capital Bridge Transaction

On September 14, 2018, the Company entered into a Promissory Note Purchase Agreement (collectively, the "Wade Note Purchase Agreements") with Wade Capital Corporation ("Wade"), pursuant to which the Company issued a 10% Original Issue Discount Promissory Note with a face amount of $275,000, with a purchase price of $250,000 (the "Wade Note").

On September 17, 2018, the Company entered into another Promissory Note Purchase Agreement (the "RSJ Note Purchase Agreement," and with the Wade Note Purchase Agreement, the "Bridge Note Purchase Agreements") with RSJ INVESTMENTS SICAV A.S. pursuant to which the Company issued a 10% Original Issue Discount Promissory Note (the "RSJ Note," and with the Wade Note, the "Bridge Notes") with a face amount of $550,000, with a purchase price of $500,000, $100,000 of which was paid through the exchange of an existing promissory note, and the other $400,000 of which was paid in cash.

In addition, the Company issued warrants (the "Bridge Warrants") to acquire an aggregate of 75,000 shares (the "Warrant Shares") of the Company's Common Stock pursuant to the terms of the Note Purchase Agreement, covering 25,000 shares of Common Stock to Wade and 50,000 shares of Common stock to RSJ. As an added inducement to the Purchasers to enter into its respective Bridge Note Purchase Agreement, the Company also issued an aggregate of 37,500 shares of our restricted common stock, consisting of 12,500 shares to Wade and 25,000 shares to RSJ (collectively, the "Commitment Shares," and collectively with the Warrants and the Bridge Notes, the "Bridge Securities").

Pursuant to the Note Purchase Agreements, each of the Purchasers agreed that the face amounts of the Bridge Notes would convert automatically into or be exchanged for securities to be issued in certain potential future financings, as specified in the Bridge Notes and the Bridge Purchase Agreements. The Company agreed that until the Bridge Notes are so converted, with limited exceptions, the Company would not incur any debt that is senior to or pari passu with the Bridge Notes without the approval of the Purchasers.

The proceeds from the sale of the Bridge Securities are intended to be used for general corporate proceeds.

The sale of the Bridge Securities is exempt from the registration requirements of the Securities Act of 1933, as amended (the "Act"), pursuant to Section 4(a)(2) of the Act (in that the Bridge Notes, the Commitment Shares, the Bridge Warrants, and the Bridge Warrant Shares were sold by us in a transaction not involving any public offering) and pursuant to Rule 506 of Regulation D promulgated thereunder. The Bridge Notes, the Commitment Shares, the Bridge Warrants, and the Bridge Warrant Shares are restricted securities that have not been registered under the Act, and will not be registered under the Act, and may not be offered or sold absent registration or applicable exemption from the registration requirements.

Ionic Bridge Transaction

On September 21, 2018, the Company entered into a Securities Purchase Agreement (the “Ionic Purchase Agreement”) with Ionic Ventures, LLC (“Ionic”) for the issuance and sale of (i) an Original Issue Discount Senior Convertible Promissory Note (the “Ionic Note”) in the aggregate principal amount of $1,100,000 with a six-month term, that is convertible into shares (the “Ionic Conversion Shares”) of the Company’s common stock, par value $0.001 per share (the “Common Stock”) under certain conditions set forth in the Ionic Note, and (ii) 100,000 warrants (the “Ionic Warrants”) to acquire shares (the “Ionic Warrant Shares”) of our Common Stock pursuant to the terms of the Ionic Purchase Agreement. As an added inducement to Ionic to enter into the Ionic Purchase Agreement, the Company also issued 50,000 shares of our restricted common stock (the “Ionic Commitment Shares,” and collectively with the Ionic Note and the Ionic Warrants, the “Ionic Securities”). The purchase price for the Ionic Securities was $1,000,000.

Pursuant to the Ionic Purchase Agreement, as long as the Ionic Note is outstanding (including any extension or modification thereto), if the Company effects a future financing that is permitted under the Ionic Purchase Agreement, Ionic may elect, in its sole discretion, to exchange up to $550,000 of the Note then held by Ionic for any securities issued in such permitted future financing, all on terms as specified in the Ionic Purchase Agreement. In addition, at any time prior to the listing of the Common Stock on a national securities exchange, Ionic benefits from a “most favored nation” provision requiring the Company to amend the terms of the Ionic Securities to reflect any more favorable terms in any subsequent sales of securities of like tenor, structure or kind as the Ionic Securities.

The Company incurred certain fees in connection with the Ionic Purchase Agreement, all of which were paid on or about September 21, 2018: (i) the Company reimbursed Ionic for their legal fees; and (ii) the Company paid an advisory fee to Alliance Global Partners (“AGP”), which served as the placement agent in connection with the sale of the Ionic Securities.

The Ionic Purchase Agreement contains certain customary representations, warranties, and covenants by, among, and for the benefit of the parties, which were made solely for the benefit of the parties thereto and are intended as a way of allocating the risk among such parties. Accordingly, stockholders should not rely on such representations, warranties and covenants as characterizations of the actual state of facts or condition of the Company.

The Company intends to use the proceeds from the sale of the Ionic Securities for general corporate purposes.

The sale of the Ionic Securities is exempt from the registration requirements of the Securities Act of 1933, as amended (the "Act"), pursuant to Section 4(a)(2) of the Act (in that the Ionic Securities were sold by us in a transaction not involving any public offering) and pursuant to Rule 506 of Regulation D promulgated thereunder. The Ionic Securities are restricted securities that have not been registered under the Act, and will not be registered under the Act, and may not be offered or sold absent registration or applicable exemption from the registration requirements.

Option Grants to New Director

On October 29, 2018, the Company’s Board of Directors approved the grant of 20,000 options to purchase shares of the Company’s common stock. The options granted had an exercise price of $4.10 per share, and vest one-third on each of the first, second, and third anniversaries of the date of grant, and expire on the eighth anniversary of the date of grant.

The option grants were completed in reliance on exemptions from registration pursuant to Section 4(a)(2) and Rule 701 and other rules. The grants of options qualified for exemption from registration because we were not subject to the reporting requirements of the Securities Exchange Act of 1934 (the "Exchange Act") as of the dates of grant, and the other requirements of Rule 701 were met.

Promissory Notes; Extensions; Repayments

On July 2, 2018, we issued a short-term note to an unrelated party for $100,000 due 60 days from the date of issuance, which was subsequently extended through October 31, 2018. This holder of this note participated in the Bridge Financing and exchanged the face value of the note for the same amount in the Bridge Financing.

On June 28, 2018, we received $50,000 for a short-term promissory note to an unrelated party due 60 days from the date of issuance. The note bore interest at a rate of 12% per annum. The face value of this note was exchanged into a subsequent financing round.

On May 11, 2018, we issued a short-term promissory note to an unrelated party for $50,000 due 30 days from the date of issuance, which was subsequently extended through October 31, 2018. The note bore an interest rate of 14.4% per annum, and we had the right to pre-pay with no penalty or premium. Our obligation to repay the note was secured by the grant of a security interest in all of our assets except for our intellectual property assets. This note was repaid in full on October 2, 2018.

On July 2, 2018, we issued a short-term promissory note to an unrelated party for $50,000 due 60 days from the date of issuance, which was subsequently extended through October 31, 2018. The note bore interest at a rate of 12% per annum, and we had the right to pre-pay with no penalty or premium. Our obligation to repay the note was secured by the grant of a security interest in all of the assets of the Company except for our intellectual property assets. This note was repaid in full on October 2, 2018.

The above issuances were completed in reliance on exemptions from registration under Section 4(a)(2) of the Securities Act. These transactions qualified for exemption from registration because (i) we did not engage in any general solicitation or advertising to market the securities; (ii) each purchaser was provided the opportunity to ask questions and receive answers from us regarding our business and the issuance; (iii) the securities were issued to persons with knowledge and experience in financial and business matters so that he or she is capable of evaluating the merits and risks of an investment in us; and (iv) the recipients received "restricted securities" that include a restrictive legend on the note, which restricts the note from being transferred except pursuant to a registration statement that is effective with the SEC or pursuant to an exemption from registration.

Item 5. Other Information

We have filed as Exhibit 99.1 certain additional information about the FDA approval process and certain healthcare-related laws and regulations applicable to our DTHR-ALZ product.

Item 6. Exhibits

Exhibit Number	Title of Document
3.1	Certificate of Amendment (1)
4.1	Form of Bridge Note (2)
4.2	Form of Bridge Warrant (2)
4.3	Ionic Note (1)
4.4	Ionic Warrant (1)
10.8	Standard Services Agreement with Hatch International Limited (portion redacted pursuant to request for confidential treatment and filed separately with SEC) (previously filed as an exhibit to the Company's Annual Report on Form 10-K)
10.9	Wade Note Purchase Agreement (2)
10.10	RSJ Note Purchase Agreement (2)
10.11	Ionic Purchase Agreement (1)
10.12	Subsidiary Guarantee (1)
10.13	Security Agreement (1)
31.1	Certification by Principal Executive and Financial Officer
32.1	Certification of Principal Executive and Financial Officer
99	Regulatory Overview Rider
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Previously filed as an exhibit to a Current Report on Form 8-K filed on September 27, 2018.
(2) Previously filed as an exhibit to a Current Report on Form 8-K filed on September 20, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dthera Sciences

Date:November 14, 2018

By: /s/ Edward Cox
Edward Cox
Chief Executive Officer, Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 31.1

Certification

I, Edward Cox, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Dthera Sciences for the quarter ended June 30, 2018;

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:November 14, 2018

/s/ Edward Cox
Edward Cox
Chief Executive Officer, Chief Financial Officer
(Principal Executive Officer and Principal 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 Dthera Sciences (the "Company") on Form 10-Q for the quarter ended September 30, 2018, as filed with the Securities and Exchange Commission (the "Report"), the undersigned principal executive and financial officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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.

Date: November 14, 2018

/s/ Edward Cox
Edward Cox
Chief Executive Officer, Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 99

REGULATORY OVERVIEW

The following is information relating to the Company's business and related government regulation of the Company's current and in-development products, ReminX and DTHR-ALZ.

Government Regulation

In the United States, medical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDCA, the FTC, the Public Health Service Act, or the PHSA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of medical products. Prior to marketing certain medical products, manufacturers are required to obtain permission from the FDA via a product approval or clearance. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to file submissions, refusal to approve or clear products, warning or untitled letters, product recalls, field actions, product seizures, total or partial suspension of production or distribution, refusal to permit the importation of product, injunctions, fines, civil penalties, and criminal prosecution. Additionally, costs of complying with applicable regulations and requirements, which are difficult to determine in advance, may be significant.

The following is a summary of regulatory requirements and procedures to which we may be subject.

FDA Regulatory and Market Pathway Process

Class II Devices

The FDA regulates the development, testing, manufacturing, labeling, storage, recordkeeping, promotion, marketing, distribution, and service of medical devices in the U.S. to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the U.S. to markets outside of the U.S. and the importation of medical devices manufactured abroad.

Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. DTHR-ALZ is expected to be classified as a Class II medical device.

Class II devices are those which are subject to general controls and most require premarket demonstration of adherence to certain performance standards or other special controls, as specified by the FDA, and clearance by the FDA. Premarket review and clearance by the FDA for these devices is accomplished through the 510(k) premarket notification process. Unless a Class II device is exempt from premarket review, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" in intended use and technology to a "predicate device" that is either:

(i) a device that has grandfather marketing status because it was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or

(ii) a device that has previously been cleared through the 510(k) process.

If the FDA agrees that the device is substantially equivalent to a predicate device, it will grant clearance to commercially market the device in the U.S. The FDA has a statutory 90-day period to respond to a 510(k) submission, or a guidance-based 30-day period for "special" 510(k) submissions which have a more restrictive scope and generally involve more specific or very limited changes to a legally marketed device. As a practical matter, clearance often takes longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not "substantially equivalent," the FDA may deny the request for clearance.

For products that would otherwise be automatically classified as Class III because the technology employed is sufficiently novel or there is no available predicate device enabling it to be classified as a Class I or Class II device, the *de novo* 510(k) classification process may be available. We would have to be able to describe why the device is low to moderate risk and would more appropriately be classified as Class I or II to be eligible for this regulatory pathway.

If the *de novo* process is not available for a product, the FDA may classify the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill more rigorous pre-market approval, or PMA, requirements. A PMA application, which is intended to demonstrate that a device is safe and effective, must be supported by extensive data, including data from preclinical studies and human clinical trials. The FDA, by statute and regulation, has 180 days to review a PMA application, though the review more often occurs over a significantly longer period of time, and can take up to several years. In approving a PMA application or clearing a 510(k) submission, the FDA may also require some form of post-market surveillance when necessary to protect the public health or to provide additional safety and effectiveness data for the device. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients.

After a device receives FDA 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA application approval. The FDA requires each manufacturer to make the determination of whether a modification requires a new 510(k) notification or PMA application in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance or PMA approval for a particular change, the FDA may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease U.S. marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

Based on an internal analysis of predicate devices, including other Digital Therapeutics products, we expect DTHR-ALZ to be regulated as a Class II device and to be cleared as Class II under the *de novo* pathway. We believe that the Class II designation for DTHR-ALZ creates a precedent for devices of this type which will be a significant regulatory barrier to entry for competitor products. We have not yet met with the FDA to discuss the regulatory path for DTHR-ALZ, but we did suggest a *de novo* path in our Breakthrough Devices application.

Inspection of Foreign-produced Products

Products manufactured outside the U.S. by or for us are subject to U.S. Customs and Border Protection inspection upon entry into the U.S. We must demonstrate compliance of such products to U.S. regulations and carefully document the eventual distribution or re-exportation of such products. Failure to comply with all applicable regulations could prevent us from having access to products or components critical to the manufacture of finished products and lead to shortages and delays.

Breakthrough Device Program

The FDA's Breakthrough Device Program is designed to expedite development, assessment and review of devices that "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and that represent breakthrough technologies; for which no approved or cleared alternatives exist; that offer significant advantages over existing approved or cleared alternatives, or the availability of which is in the best interest of patients."

This status confers a number of benefits on the development path of medical devices. These include:

- a dedicated FDA team, including senior management engagement, to facilitate development of the device;
- a defined process for resolving disputes that may arise between the sponsor and the FDA;
- a commitment to interactive and timely communication between the FDA and the sponsor;
- increased flexibility in clinical study design;
- options for data collection in the post-market setting, in place of a full clinical study prior to approval;
- priority review status, meaning that a sponsor's submissions will be placed at the top of the relevant review queue and receive additional FDA resources as needed;
- expedited review and potential deferral of manufacturing and quality systems compliance audits;
- advance disclosure to the sponsor of the topics of any consultation between the FDA and external experts or an advisory committee;
- an opportunity for the sponsor to recommend external experts for such consultations;
- assignment of the FDA staff to address questions by institutional review committees concerning investigational use of the medical device; and
- any additional steps the FDA deems appropriate to expedite the development and review of the medical device.

Post-Market Compliance

In addition, after a device is placed on the market, numerous FDA and other regulatory requirements continue to apply. These include establishment registration and device listing with the FDA; compliance with medical device reporting regulations, which require that manufacturers report to the FDA if their device 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 it were to recur; and compliance with corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health. 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 is scientific data to substantiate the claims and that our advertising is neither false nor misleading. In general, we may not promote or advertise our products for uses not within the scope of our intended use statement in our clearances or make unsupported safety and effectiveness claims. Many regulatory jurisdictions outside of the U.S. have similar regulations to which we may be subject.

Clinical Trials

We may seek to conduct clinical studies or trials in the U.S. or other countries on DTHR-ALZ and other potential future products that have not yet been cleared or approved for a particular indication. Additional regulations govern the approval, initiation, conduct, documentation and reporting of clinical studies to regulatory agencies in the countries or regions in which they are conducted. Such investigational use is generally also regulated by local and institutional requirements and policies which usually include review by an ethics committee or institutional review board, or IRB. Failure to comply with all regulations governing such studies could subject the company to significant enforcement actions and sanctions, including halting of the study, seizure of investigational devices or data, sanctions against investigators, civil or criminal penalties, and other actions. Without the data from one or more clinical studies, it may not be possible for us to secure the data necessary to support certain regulatory submissions, to secure reimbursement or demonstrate other requirements for DTHR-ALZ and other potential future products. We cannot assure that access to clinical investigators, sites and subjects, documentation and data will be available on the terms and timeframes necessary.

Reimbursement

Our current go-to-market strategy for DTHR-ALZ contemplates or relies upon governmental or third party payor reimbursement. (Our current go-to-market strategy for our ReminX product does not contemplate or rely upon governmental or third party payor reimbursement.) To the extent that we adopt a market strategy which is in whole or in part reliant on third party reimbursement, commercial sales of our products will depend in part on the availability of reimbursement from such third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Each third-party payor may have its own policy regarding what products it will cover, the conditions under which it will cover such products, and how much it will pay for such products. Third-party payors are increasingly examining the medical necessity and cost effectiveness of medical products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved devices. Further, healthcare policy and payment reform models and medical cost containment models are being considered and/or adopted in the United States and other countries. Legislative and/or administrative reforms to applicable reimbursement systems may significantly reduce reimbursement for the services in which our products are used or result in the denial of coverage for such services outright. As a result, third-party reimbursement adequate to enable us to realize an appropriate return on our investment in research and product development may not be available for our products.

The Patient Protection and Affordable Care Act

In March 2010, President Obama signed into legislation the Patient Protection and Affordable Care Act, or the ACA, which resulted in sweeping changes across the health care industry. The ACA contained measures designed to promote quality and cost efficiency in health care delivery and to generate budgetary savings in the Medicare and Medicaid programs. The ACA includes significant provisions that encourage state and federal law enforcement agencies to increase activities related to preventing, detecting and prosecuting those who commit fraud, waste and abuse in federal healthcare programs, including Medicare, Medicaid and Tricare. The ACA continues to be implemented through regulation and government activity but is subject to possible repeal, amendment, additional implementing regulations and interpretive guidelines. The manner in which the ACA continues to evolve could materially affect the extent to which and the amount at which reimbursements are made by government programs such as Medicare, Medicaid and Tricare.

Anti-Kickback Statutes in the United States

The U.S. federal anti-kickback statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending of a good or service, for which payment may be made in whole or in part under a U.S. federal healthcare program such as the Medicare and Medicaid programs. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, the furnishing of supplies or equipment, payments of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that, if any one purpose of an arrangement involving remuneration is to induce referrals or otherwise generate business involving goods or services reimbursed in whole or in part under U.S. federal healthcare programs, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other U.S. federal healthcare programs. The reach of the federal anti-kickback statute was broadened by the ACA, which, among other things, amends the intent requirement of the federal anti-kickback statute. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. The ACA further 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 U.S. False Claims Act or the Civil Monetary Penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The U.S. federal anti-kickback statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the statute is broad and may technically prohibit many innocuous or beneficial arrangements, the Office of Inspector General of the Department of Health and Human Services, or OIG, has issued a series of regulations, known as the "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the anti-kickback statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG or the U.S. Department of Justice.

Many states have adopted laws similar to the U.S. federal anti-kickback statute. Some of these state prohibitions are broader than the U.S. federal statute, and apply to the referral of patients and recommendations for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs. Government officials have focused certain enforcement efforts on marketing of healthcare items and services, among other activities, and have brought cases against individuals or entities with sales personnel who allegedly offered unlawful inducements to potential or existing physician users in an attempt to procure their business.

U.S. Health Insurance Portability and Accountability Act of 1996

HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, including private payors, or making false statements relating to healthcare matters. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information and which can impose civil or criminal liability for violations of its provisions.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates" — independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business.