BANK OF NOVA SCOTIA
Form FWP
December 21, 2017

Subject to Completion Preliminary Term Sheet dated December 21, 2017	Filed Pursuant to Rule 433 Registration Statement No. 333-215597 (To Prospectus dated February 1, 2017, Prospectus Supplement dated February 13, 2017 and Product Prospectus Supplement EQUITY INDICES SUN-1 dated February 23, 2017)

Units	Pricing Date*	January , 2018
$10 principal amount per unit	Settlement Date*	February , 2018
CUSIP No.	Maturity Date*	January , 2020
	*Subject to change based on the actual date the notes are priced for initial sale to the public (the "pricing date")	

Market-Linked Step Up Notes Linked to an Asian Equity Index Basket

§ Maturity of approximately two years

§ If the Basket is flat or increases up to the Step Up Value, a return of [21.50% to 27.50%]

§ If the Basket increases above the Step Up Value, a return equal to the percentage increase in the Basket

§ 1-to-1 downside exposure to decreases in the Basket, with up to 100.00% of your principal at risk

§ The Basket will be

comprised of the Hang Seng China Enterprises Index, the KOSPI 200 Index, and the Taiwan Stock Exchange Capitalization Weighted Stock Index. Each of the Hang Seng China Enterprises Index and the KOSPI 200 Index will be given an initial weight of 33.33%, and the Taiwan Stock Exchange Capitalization Weighted Stock Index will be given an initial weight of 33.34%

§ All payments occur at maturity and are subject to the credit risk of The Bank of Nova Scotia

§ No periodic interest payments

§ In addition to the underwriting discount set forth below, the notes include a hedging-related charge of $0.075 per unit. See "Structuring the Notes".

§ Limited secondary

market liquidity, with no exchange listing

§ The notes are unsecured debt securities and are not savings accounts or insured deposits of a bank. The notes are not insured or guaranteed by the Canada Deposit Insurance Corporation (the "CDIC"), the U.S. Federal Deposit Insurance Corporation (the "FDIC"), or any other governmental agency of Canada, the United States or any other jurisdiction

The notes are being issued by The Bank of Nova Scotia ("BNS"). There are important differences between the notes and a conventional debt security, including different investment risks and certain additional costs. See "Risk Factors" and "Additional Risk Factors" beginning on page TS-6 of this term sheet and "Risk Factors" beginning on page PS-7 of product prospectus supplement EQUITY INDICES SUN-1.
The initial estimated value of the notes as of the pricing date is expected to be between $9.38 and $9.77 per unit, which is less than the public offering price listed below. See "Summary" on the following page, "Risk Factors" beginning on page TS-6 of this term sheet and "Structuring the Notes" on page TS-19 of this term sheet for additional information. The actual value of your notes at any time will reflect many factors and cannot be predicted with accuracy.

None of the U.S. Securities and Exchange Commission (the "SEC"), any state securities commission, or any other regulatory body has approved or disapproved of these securities or determined if this Note Prospectus (as defined below) is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Unit	Total
Public offering price(1)	$10.00	$
Underwriting discount(1)	$ 0.20	$
Proceeds, before expenses, to BNS	$ 9.80	$

(1) For any purchase of 500,000 units or more in a single transaction by an individual investor or in combined transactions with the investor's household in this offering, the public offering price and the underwriting discount

will be $9.95 per unit and $0.15 per unit, respectively. See “Supplement to the Plan of Distribution” below.
The notes:

Are Not FDIC Insured	Are Not Bank Guaranteed	May Lose Value

Merrill Lynch & Co.
January , 2018

Market-Linked Step Up Notes
Linked to an Asian Equity Index Basket, due January , 2020

Summary

The Market-Linked Step Up Notes Linked to an Asian Equity Index Basket, due January , 2020 (the "notes") are our senior unsecured debt securities. The notes are not guaranteed or insured by the CDIC or the FDIC, and are not, either directly or indirectly, an obligation of any third party. The notes will rank equally with all of our other unsecured senior debt. Any payments due on the notes, including any repayment of principal, will be subject to the credit risk of BNS. The notes provide you with a Step Up Payment if the Ending Value of the Market Measure, which is the Asian equity index basket described below (the "Basket"), is equal to or greater than the Starting Value, but not greater than the Step Up Value. If the Ending Value is greater than the Step Up Value, you will participate on a 1-for-1 basis in the increase in the level of the Basket above the Starting Value. If the Ending Value is less than the Starting Value, you will lose all or a portion of the principal amount of your notes. Any payments on the notes will be calculated based on the $10 principal amount per unit and will depend on the performance of the Basket, subject to our credit risk. See "Terms of the Notes" below.

The Basket will be comprised of the Hang Seng China Enterprises Index, the KOSPI 200 Index, and the Taiwan Stock Exchange Capitalization Weighted Stock Index (each, a "Basket Component"). On the pricing date, each of the Hang Seng China Enterprises Index and the KOSPI 200 Index will be given an initial weight of 33.33%, and the Taiwan Stock Exchange Capitalization Weighted Stock Index will be given an initial weight of 33.34%.

The economic terms of the notes (including the Step Up Payment) are based on our internal funding rate, which is the rate we would pay to borrow funds through the issuance of market-linked notes, and the economic terms of certain related hedging arrangements. Our internal funding rate is typically lower than the rate we would pay when we issue conventional fixed rate debt securities. This difference in funding rate, as well as the underwriting discount and the hedging related charge described below, will reduce the economic terms of the notes to you and the initial estimated value of the notes on the pricing date. Due to these factors, the public offering price you pay to purchase the notes will be greater than the initial estimated value of the notes.

On the cover page of this term sheet, we have provided the initial estimated value range for the notes. This range of estimated values was determined by reference to our internal pricing models, which take into consideration certain factors, such as our internal funding rate on the pricing date and our assumptions about market parameters. For more information about the initial estimated value and the structuring of the notes, see "Structuring the Notes" on page TS-19.

Terms of the Notes

Issuer:	The Bank of Nova Scotia ("BNS")
Principal Amount:	$10.00 per unit
Term:	Approximately two years
Market Measure:	An approximately equally weighted Asian equity index basket comprised of the Hang Seng China Enterprises Index (Bloomberg symbol: "HSCEI"), the KOSPI 200 Index (Bloomberg symbol: "KOSPI2") and the Taiwan Stock Exchange Capitalization Weighted Stock Index (Bloomberg symbol: "TWSE"). Each Basket Component is a price return index.
Starting Value:	The Starting Value will be set to 100.00 on the pricing date.
Ending Value:	The value of the Market Measure on the scheduled calculation day, as described under "The Basket" on page TS-8. The calculation day is subject to postponement in the event of Market Disruption Events, as described on page PS-25 of product prospectus supplement EQUITY INDICES SUN-1.

Redemption Amount Determination

On the maturity date, you will receive a cash payment per unit determined as follows:

Step Up Value:	[121.50% to 127.50%] of the Starting Value. The actual Step Up Value will be determined on the pricing date.
Step Up Payment:	[$2.15 to $2.75] per unit, which represents a return of [21.50% to 27.50%] over the principal amount. The actual Step Up Payment will be determined on the pricing date.
Threshold Value:	100.00% of the Starting Value.
Calculation Day:	Approximately the fifth scheduled Market Measure Business Day immediately preceding the maturity date.
Fees and Charges:	The underwriting discount of $0.20 per unit listed on the cover page and the hedging related charge of $0.075 per unit described in "Structuring the Notes" on page TS-19.
Calculation Agent:	Merrill Lynch, Pierce, Fenner & Smith Incorporated ("MLPF&S").

Market-Linked Step Up Notes
Linked to an Asian Equity Index Basket, due January , 2020

The terms and risks of the notes are contained in this term sheet and in the following:

§ Product prospectus supplement EQUITY INDICES SUN-1 dated February 23, 2017: https://www.sec.gov/Archives/edgar/data/9631/000110465917011241/a17-4372_4424b5.htm

§ Prospectus supplement dated February 13, 2017: https://www.sec.gov/Archives/edgar/data/9631/000110465917008642/a17-4372_1424b3.htm

§ Prospectus dated February 1, 2017: https://www.sec.gov/Archives/edgar/data/9631/000119312517027656/d338678d424b3.htm

These documents (together, the "Note Prospectus") have been filed as part of a registration statement with the SEC, which may, without cost, be accessed on the SEC website as indicated above or obtained from MLPF&S by calling 1-800-294-1322. Before you invest, you should read the Note Prospectus, including this term sheet, for information about us and this offering. Any prior or contemporaneous oral statements and any other written materials you may have received are superseded by the Note Prospectus. Capitalized terms used but not defined in this term sheet have the meanings set forth in product prospectus supplement EQUITY INDICES SUN-1. Unless otherwise indicated or unless the context requires otherwise, all references in this document to "we," "us," "our," or similar references are to BNS.

Investor Considerations

You may wish to consider an investment in the notes if:

§ You anticipate that the value of the Basket will not decrease from the Starting Value to the Ending Value.
§ You are willing to risk a substantial or entire loss of principal if the value of the Basket decreases from the Starting Value to the Ending Value.
§ You are willing to forgo the interest payments that are paid on conventional interest bearing debt securities.
§ You are willing to forgo dividends or other benefits of owning the stocks included in the Basket Components.
§ You are willing to accept a limited or no market for sales prior to maturity, and understand that the market prices for the notes, if any, will be affected by various factors, including our actual and perceived creditworthiness, our internal funding rate and fees and charges on the notes.
§ You are willing to assume our credit risk, as issuer of the notes, for all payments under the notes, including the Redemption Amount.

The notes may not be an appropriate investment for you if:

§ You believe that the value of the Basket will decrease from the Starting Value to the Ending Value or that it will not increase sufficiently over the term of the notes to provide you with your desired return.
§ You seek principal repayment or preservation of capital.
§ You seek interest payments or other current income on your investment.
§ You want to receive dividends or other distributions paid on the stocks included in the Basket Components.
§ You seek an investment for which there will be a liquid secondary market.
§ You are unwilling or are unable to take market risk on the notes or to take our credit risk as issuer of the notes.

We urge you to consult your investment, legal, tax, accounting, and other advisors before you invest in the notes.

Market-Linked Step Up Notes
Linked to an Asian Equity Index Basket, due January , 2020

Hypothetical Payout Profile and Examples of Payments at Maturity

The graph below is based on hypothetical numbers and values.

Market-Linked Step Up Notes

This graph reflects the returns on the notes, based on the Threshold Value of 100.00% of the Starting Value, a hypothetical Step Up Payment of $2.45 per unit (the midpoint of the Step Up Payment range of [$2.15 to $2.75]) and a hypothetical Step Up Value of 124.50% of the Starting Value (the midpoint of the Step Up Value range of [121.50% to 127.50%]). The green line reflects the returns on the notes, while the dotted gray line reflects the returns of a direct investment in the stocks included in the Basket Components, excluding dividends.

This graph has been prepared for purposes of illustration only.

The following table and examples are for purposes of illustration only. They are based on hypothetical values and show hypothetical returns on the notes. They illustrate the calculation of the Redemption Amount and total rate of return based on the Starting Value of 100.00, the Threshold Value of 100.00, a hypothetical Step Up Value of 124.50, a hypothetical Step Up Payment of $2.45 per unit and a range of hypothetical Ending Values. The actual amount you receive and the resulting total rate of return will depend on the actual Ending Value, Step Up Value, Step Up Payment, and whether you hold the notes to maturity. The following examples do not take into account any tax consequences from investing in the notes.

For recent hypothetical values of the Basket, see “The Basket” section below. For recent actual levels of the Basket Components, see “The Basket Components” section below. Each Basket Component is a price return index and as such the Ending Value will not include any income generated by dividends paid on the stocks included in any of the Basket Components, which you would otherwise be entitled to receive if you invested in those stocks directly. In addition, all payments on the notes are subject to issuer credit risk.

Ending Value	Percentage Change from the Starting Value to the Ending Value	Redemption Amount per Unit	Total Rate of Return on the Notes
0.00	-100.00%	$0.00	-100.00%
50.00	-50.00%	$5.00	-50.00%
80.00	-20.00%	$8.00	-20.00%
90.00	-10.00%	$9.00	-10.00%
94.00	-6.00%	$9.40	-6.00%
97.00	-3.00%	$9.70	-3.00%
100.00(1)	0.00%	$12.45(2)	24.50%
102.00	2.00%	$12.45	24.50%
105.00	5.00%	$12.45	24.50%
110.00	10.00%	$12.45	24.50%
120.00	20.00%	$12.45	24.50%
124.50(3)	24.50%	$12.45	24.50%
130.00	30.00%	$13.00	30.00%
140.00	40.00%	$14.00	40.00%
143.00	43.00%	$14.30	43.00%
150.00	50.00%	$15.00	50.00%
160.00	60.00%	$16.00	60.00%

(1) The Starting Value and Threshold Value will be set to 100.00 on the pricing date.

(2) This amount represents the sum of the principal amount and the hypothetical Step Up Payment of $2.45.

(3) This is the hypothetical Step Up Value.

Market-Linked Step Up Notes
Linked to an Asian Equity Index Basket, due January , 2020

Redemption Amount Calculation Examples

Example 1
The Ending Value is 90.00, or 90.00% of the Starting Value:

Starting Value:	100.00
Threshold Value:	100.00
Ending Value:	90.00

Redemption Amount per unit

Example 2
The Ending Value is 110.00, or 110.00% of the Starting Value:

Starting Value:	100.00
Step Up Value:	124.50
Ending Value:	110.00

Redemption Amount per unit, the principal amount plus the Step Up Payment, since the Ending Value is equal to or greater than the Starting Value, but less than the Step Up Value.

Example 3
The Ending Value is 143.00, or 143.00% of the Starting Value:

Starting Value:	100.00
Step Up Value:	124.50
Ending Value:	143.00

Redemption Amount per unit

Market-Linked Step Up Notes
Linked to an Asian Equity Index Basket, due January , 2020

Risk Factors

There are important differences between the notes and a conventional debt security. An investment in the notes involves significant risks, including those listed below. You should carefully review the more detailed explanation of risks relating to the notes in the "Risk Factors" sections beginning on page PS-7 of product prospectus supplement EQUITY INDICES SUN-1, page S-2 of the prospectus supplement, and page 6 of the prospectus identified above. We also urge you to consult your investment, legal, tax, accounting, and other advisors before you invest in the notes.

§ Depending on the performance of the Basket as measured shortly before the maturity date, your investment may result in a loss; there is no guaranteed return of principal.

§ Your return on the notes may be less than the yield you could earn by owning a conventional fixed or floating rate debt security of comparable maturity.

§ Your investment return may be less than a comparable investment directly in the stocks included in the Basket Components.

§ Payments on the notes are subject to our credit risk, and actual or perceived changes in our creditworthiness are expected to affect the value of the notes. If we become insolvent or are unable to pay our obligations, you may lose your entire investment.

§ Our initial estimated value of the notes will be lower than the public offering price of the notes. Our initial estimated value of the notes is only an estimate. The public offering price of the notes will exceed our initial estimated value because it includes costs associated with selling and structuring the notes, as well as hedging our obligations under the notes with a third party, which may include MLPF&S or one of its affiliates. These costs include the underwriting discount and an expected hedging related charge, as further described in "Structuring the Notes" on page TS-19.

§ Our initial estimated value of the notes does not represent future values of the notes and may differ from others' estimates. Our initial estimated value of the notes is determined by reference to our internal pricing models when the terms of the notes are set. These pricing models consider certain factors, such as our internal funding rate on the pricing date, the expected term of the notes, market conditions and other relevant factors existing at that time, and our assumptions about market parameters, which can include volatility, dividend rates, interest rates and other factors. Different pricing models and assumptions could provide valuations for the notes that are different from our initial estimated value. In addition, market conditions and other relevant factors in the future may change, and any of our assumptions may prove to be incorrect. On future dates, the market value of the notes could change significantly based on, among other things, the performance of the Basket, changes in market conditions, our creditworthiness, interest rate movements and other relevant factors. These factors, together with various credit, market and economic factors over the term of the notes, are expected to reduce the price at which you may be able to sell the notes in any secondary market and will affect the value of the notes in complex and unpredictable ways. Our initial estimated value does not represent a minimum price at which we or any agents would be willing to buy your notes in any secondary market (if any exists) at any time.

§ Our initial estimated value is not determined by reference to credit spreads or the borrowing rate we would pay for our conventional fixed-rate debt securities. The internal funding rate used in the determination of our initial estimated value of the notes generally represents a discount from the credit spreads for our conventional fixed-rate debt securities and the borrowing rate we would pay for our conventional fixed-rate debt securities. If we were to use the interest rate implied by the credit spreads for our conventional fixed-rate debt securities, or the borrowing rate we would pay for our conventional fixed-rate debt securities, we would expect the economic terms of the notes to be more favorable to you. Consequently, our use of an internal funding rate for the notes would have an adverse effect on the economic terms of the notes, the initial estimated value of the notes on the pricing date, and the price at which you may be able to sell the notes in any secondary market.

§ A trading market is not expected to develop for the notes. Neither we nor MLPF&S is obligated to make a market for, or to repurchase, the notes. There is no assurance that any party will be willing to purchase your notes at any price in any secondary market.

§ Our business, hedging and trading activities, and those of MLPF&S and our respective affiliates (including trades in shares of companies included in the Basket Components), and any hedging and trading activities we, MLPF&S or our respective affiliates engage in for our clients' accounts, may affect the market value and return of the notes and may create conflicts of interest with you.

§ Changes in the level of one of the Basket Components may be offset by changes in the levels of the other Basket Components.

§ An index sponsor may adjust the relevant Basket Component in a way that may adversely affect its level and your interests, and has no obligation to consider your interests.

§ You will have no rights of a holder of the securities included in the Basket Components, and you will not be entitled to receive securities or dividends or other distributions by the issuers of those securities.

§ While we, MLPF&S or our respective affiliates may from time to time own securities of companies included in the Basket Components, we, MLPF&S and our respective affiliates do not control any company included in the Basket Components, and have not verified any disclosure made by any other company.

Market-Linked Step Up Notes
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§ Your return on the notes may be affected by factors affecting the international securities markets, specifically changes in the countries represented by the Basket Components. In addition, you will not obtain the benefit of any increase in the value of the currencies in which securities in the Basket Components trade against the U.S. dollar, which you would have received if you had owned the securities in the Basket Components during the term of your notes, although the value of the Basket may be adversely affected by general exchange rate movements in the market.

§ There may be potential conflicts of interest involving the calculation agent, which is MLPF&S. We have the right to appoint and remove the calculation agent.

§ The U.S. federal income tax consequences of the notes are uncertain, and may be adverse to a holder of the notes. See "Summary of U.S. Federal Income Tax Consequences" below.

§ The conclusion that no portion of the interest paid or credited or deemed to be paid or credited on a note will be "Participating Debt Interest" subject to Canadian withholding tax is based in part on the current published administrative position of the CRA. There cannot be any assurance that CRA's current published administrative practice will not be subject to change, including potential expansion in the current administrative interpretation of Participating Debt Interest subject to Canadian withholding tax. If, at any time, the interest paid or credited or deemed to be paid or credited on a note is subject to Canadian withholding tax, you will receive an amount that is less than the Redemption Amount. You should consult your own adviser as to the potential for such withholding and the potential for reduction or refund of part or all of such withholding, including under any bilateral Canadian tax treaty the benefits of which you may be entitled. For a discussion of the Canadian federal income tax consequences of investing in the notes, see "Summary of Canadian Federal Income Tax Consequences" below, "Canadian Taxation—Debt Securities" on page 50 of the prospectus dated February 1, 2017, and "Supplemental Discussion of Canadian Federal Income Tax Consequences" on page PS-29 of product prospectus supplement EQUITY INDICES SUN-1.

Additional Risk Factors

The stocks included in each Basket Component are concentrated in a limited number of companies.

As of December 15, 2017, the top 10 companies constituted approximately 65.80% of the Hang Seng China Enterprises Index, 50.40% of the KOSPI 200 Index, and 41.43% of the Taiwan Stock Exchange Capitalization Weighted Stock Index. In addition, as of December 15, 2017, Samsung Electronics Co., Ltd. constituted 27.48% of the KOSPI 200 Index, and Taiwan Semiconductor Manufacturing Company, Limited constituted 18.72% of the Taiwan Stock Exchange Capitalization Weighted Stock Index. The Hang Seng China Enterprises Index's index methodology permits one or more companies to have a weighting of up to 10% in the Hang Seng China Enterprises Index. Accordingly, any negative developments with respect to a relatively small number of companies may have a significant and adverse effect on the level of these indices, and consequently on the value of the notes.

Other Terms of the Notes

Market Measure Business Day

The following definition shall supersede and replace the definition of a "Market Measure Business Day" set forth in product prospectus supplement EQUITY INDICES SUN-1.

A "Market Measure Business Day" means a day on which:

(A) each of the Stock Exchange of Hong Kong (as to the Hang Seng China Enterprises Index), the KOSPI Market (as to the KOSPI 200 Index), and the Taiwan Stock Exchange (as to the Taiwan Stock Exchange Capitalization Weighted Stock Index) (or any successor to the foregoing exchanges) are open for trading; and

(B) the Basket Components or any successors thereto are calculated and published.

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The Basket

The Basket is designed to allow investors to participate in the percentage changes in the levels of the Basket Components from the Starting Value to the Ending Value of the Basket. The Basket Components are described in the section "The Basket Components" below. Each Basket Component will be assigned an initial weight on the pricing date, as set forth in the table below.

For more information on the calculation of the value of the Basket, please see the section entitled "Description of the Notes—Basket Market Measures" beginning on page PS-23 of product prospectus supplement EQUITY INDICES SUN-1.

If December 15, 2017 were the pricing date, for each Basket Component, the Initial Component Weight, the closing level, the hypothetical Component Ratio and the initial contribution to the Basket value would be as follows:

Basket Component	Bloomberg Symbol	Initial Component Weight	Closing Level(1)(2)	Hypothetical Component Ratio(1)(3)	Initial Basket Value Contribution
Hang Seng China Enterprises Index	HSCEI	33.33	11,365.92	0.00293245	33.33
KOSPI 200 Index	KOSPI2	33.33	326.23	0.10216718	33.33
Taiwan Stock Exchange Capitalization Weighted Stock Index	TWSE	33.34	10,491.44	0.00317783	33.34
				Starting Value	100.00

(1) The actual closing level of each Basket Component and the resulting actual Component Ratios will be determined on the pricing date, subject to adjustment as more fully described in the section entitled "Description of the Notes—Basket Market Measures—Determination of the Component Ratio for Each Basket Component" beginning on page PS-23 of product prospectus supplement EQUITY INDICES SUN-1 if a Market Disruption Event occurs on the pricing date as to any Basket Component.

(2) These were the closing levels of the Basket Components on December 15, 2017.

(3) Each hypothetical Component Ratio equals the Initial Component Weight of the relevant Basket Component (as a percentage) multiplied by 100, and then divided by the closing level of that Basket Component on December 15, 2017 and rounded to eight decimal places.

The calculation agent will calculate the Ending Value of the Basket on the calculation day by summing the products of the closing level for each Basket Component on that day and the Component Ratio applicable to such Basket Component. If a Market Disruption Event occurs as to any Basket Component on the scheduled calculation day, the closing level of that Basket Component will be determined as more fully described in the section entitled "Description of the Notes—Basket Market Measures—Observation Level or Ending Value of the Basket" beginning on page PS-24 of product prospectus supplement EQUITY INDICES SUN-1.

our ability to establish and maintain adequate infrastructure to support the commercial launch and sale of our diagnostic tests through our Adeona Clinical Laboratory subsidiary, including establishing adequate laboratory space, information technology infrastructure, sample collection and tracking systems and electronic ordering and reporting systems and other infrastructure and hiring adequate laboratory and other personnel;

- the availability of adequate study samples for validation studies for any diagnostic tests we develop, the success of such validation studies and our ability to publish study results in peer-reviewed journals;
- the availability of alternative and competing tests or products and technological innovations or other advances in medicine that cause our technologies to be less competitive;
- compliance with federal, state and foreign regulations governing laboratory testing and the sale and marketing of diagnostic or other tests, including copper and zinc; status tests;
- the accuracy rates of such tests, including rates of false-negatives and/or false-positives;
- concerns regarding the safety effectiveness or clinical utility of our tests;
- changes in the regulatory environment affecting health care and health care providers, including changes in laws regulating laboratory testing and/or device manufacturers and any laws regulating diagnostic testing;
- the extent and success of our sales and marketing efforts and ability to drive adoption of our diagnostic tests;
- coverage and reimbursement levels by government payers and private insurers;
- the level of physician and customer adoption of any diagnostic tests we develop;

- pricing pressures and changes in third-party payer reimbursement policies;
- general changes or developments in the market for Alzheimer’s disease diagnostics or diagnostics in general;
- ethical and legal issues concerning the appropriate use of the information resulting from Alzheimer’s disease diagnostic tests or other tests;
- our ability to promote and protect our products and technology; and
- intellectual property rights held by others or others infringing our intellectual property rights.

We have experienced several management changes.

We have had significant changes in management in the past two years. Effective July 1, 2008, Nicholas Stergis was appointed our Chief Executive Officer; however, effective March 29, 2009, Mr. Stergis resigned his position, but remained a director of the Company until August 20, 2009. The Board then appointed Steve H. Kanzer as our interim Chief Executive Officer and President. Effective June 26, 2009, Max Lyon was appointed our Chief Executive Officer and President, while Mr. Kanzer remained as Chairman of the Board of the Company. Effective February 6, 2010, James S. Kuo, M.D., M.B.A., was appointed our Chairman of the Board, Chief Executive Officer and President and Mr. Lyon resigned from his position as Chief Executive Officer, President and director. Changes in key positions in our Company, as well as additions of new personnel and departures of existing personnel, can be disruptive, might lead to additional departures of existing personnel and could have a material adverse effect on our business, operating results, financial results and internal controls over financial reporting.

We only acquired our CLIA-certified reference laboratory in July of 2009 and have limited experience operating a diagnostic and microbiology testing laboratory. Our ability to successfully develop and commercialize diagnostic and microbiology tests will depend on our ability to successfully operate our CLIA-certified reference laboratory and obtain and maintain required regulatory certifications.

We acquired Adeona Clinical Laboratory, our CLIA-licensed clinical reference laboratory located in Bolingbrook, IL, in July of 2009. Because there is substantial distance between Adeona Clinical Laboratory and our corporate headquarters in Ann Arbor, Michigan, we may have logistical and operational challenges in effectively managing and operating Adeona Clinical Laboratory. In November of 2009, we launched a panel of copper and zinc status tests through Adeona Clinical Laboratory. If we are unable to successfully commercialize our serum based copper and zinc diagnostic test panels through Adeona Clinical Laboratory, we may not be able to achieve significant revenues and profitability with respect to such activities. Our ability to successfully develop and commercialize diagnostic tests and microbiology testing will depend on our ability to successfully operate Adeona Clinical Laboratory and obtain and maintain required regulatory approvals.

As a clinical reference laboratory, Adeona Clinical Laboratory is subject to CLIA regulations, which are designed to ensure the quality and reliability of clinical laboratories by mandating specific standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory’s CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. Adeona Clinical Laboratory is also subject to regulation of laboratory operations under state clinical laboratory laws. State clinical laboratory laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. Certain states, including Maryland, New York, Pennsylvania and Rhode Island, each require that you obtain licenses to test specimens from patients residing in those states and additional states may require similar licenses in the future. If we are unable to obtain licenses from these states or there is delay in obtaining such licenses, we will not be able to process any samples from patients located in those states until we have obtained the requisite licenses. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could adversely affect our business and results of operations.

We may not obtain the necessary United States or worldwide regulatory approvals to commercialize our product candidate(s).

We will need FDA approval to commercialize some of our product candidates in the United States and approvals from equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval for any of our product candidates, we must submit to the FDA an NDA, demonstrating that the product candidate is safe for humans and effective for its intended use and that the product candidate can be consistently manufactured and is stable. This demonstration requires significant research and animal tests, which are referred to as “preclinical studies,” human tests, which are referred to as “clinical trials” as well as the ability to manufacture the product candidate, referred to as “chemistry manufacturing control” or “CMC.” We will also need to file additional investigative new drug applications and protocols in order to initiate clinical testing of our drug candidates in new therapeutic indications and delays in obtaining required FDA and institutional review board approvals to commence such studies may delay our initiation of such planned additional studies.

Satisfying the FDA’s regulatory requirements typically takes many years, depending on the type, complexity, and novelty of the product candidate, and requires substantial resources for research development, and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies.

The approval process may also be delayed by changes in government regulation, future legislation or administrative action, or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may do the following:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

The on-going and future development and commercialization of Effirma (oral flupirtine) for fibromyalgia is the responsibility of Meda AB and no assurance can be given that Meda will gain FDA approval of oral flupirtine for fibromyalgia.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by reducing our number of salable products and, therefore, corresponding product revenues.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize our product candidate for sale outside the United States.

Our diagnostic and microbiology tests are subject to changes in CLIA, FDA and other regulatory requirements.

We initially plan to develop assays and commercialize our tests in the form of laboratory developed tests (LDTs) through Adeona Clinical Laboratory, our CLIA-certified laboratory. Although LDT testing is currently solely under the purview of CMS and state agencies who provide oversight of the safe and effective use of LDTs, the FDA and the United States Department of Health and Human Services have been reviewing their approach to regulation in the area of LDTs, and the laws and regulations may undergo change in the near future. Although we have no current plans in our LDT strategy to utilize analyte specific reagents (ASRs) or In Vitro Diagnostic Multivariate Index Assay (IVDMIAs), which have been the focus of recent reforms and enforcement actions by the FDA, we cannot predict the extent of the FDA’s future regulation and policies with respect to LDTs. Concurrently with our LDT commercialization activities, we may conduct the development, validation, and other activities necessary to file submissions with the FDA seeking approval for selected diagnostic tests. If we are unable to successfully launch any diagnostic tests as LDTs or if we are otherwise required to obtain FDA premarket clearance or approval prior to commercializing any diagnostic tests or maintain Adeona Clinical Laboratory’s CLIA-certified laboratory status, our ability to generate revenue from the sale of such tests may be delayed and we may never be able to generate significant revenues from sales of diagnostic products.

If the medical relevance of copper and zinc in Alzheimer’s disease is not demonstrated or is not recognized by others, we may have less demand for our products and services and may have less opportunity to enter into diagnostic product development and commercialization collaborations with others.

Some of the products we have developed and additional products that we hope to develop involve new and unproven approaches or involve applications in markets that we are only beginning to explore. They are based on the assumption that information about the roles of copper and zinc in the progression and development of neurodegenerative diseases such as Alzheimer’s disease, dementia and mild cognitive impairment may help scientists and clinicians better understand and treat conditions or complex disease processes. We cannot be certain that this type of information will play a key role in the development of therapeutics, diagnostics or other products in the future, or that any of our findings would be accepted by clinicians, researchers or by any other potential market or industry partner or customer. If we are unable to generate additional valuable information and data about the usefulness of copper and zinc status testing, the demand for our products, applications, and services will be reduced and our business will be harmed.

We may not be able to retain rights licensed to us by others to commercialize key products and may not be able to establish or maintain the relationships we need to develop, manufacture, and market our products.

In addition to our own patent applications, we also currently rely on licensing agreements with third party patent holders/licensors for our products. Pipex, our wholly owned subsidiary, has an exclusive license agreement with the McLean Hospital relating to the use of oral flupirtine to treat fibromyalgia which was recently sublicensed to Meda AB; an exclusive license agreement with the Regents of the University of California relating to our Trimesta technology and an exclusive license agreement with the late Dr. Newsome and Mr. Tate relating to zinc-monocysteine. Each of these agreements requires us or our sublicensee to use our best efforts to commercialize each of the technologies as well as meet certain diligence requirements and timelines in order to keep the license agreement in effect. In the event we or our sublicensee are not able to meet our diligence requirements, we may not be able to retain the rights granted under our agreements or renegotiate our arrangement with these institutions on reasonable terms, or at all. Given the recent passing of Dr. Newsome, matters relating to our license agreements are expected to be handled by his estate and heirs.

Furthermore, we currently have very limited product development capabilities, and limited marketing or sales capabilities. For us to research, develop, and test our product candidates, we would need to contract with outside researchers, in most cases those parties that did the original research and from whom we have licensed the technologies.

We can give no assurances that any of our issued patents licensed to us or any of our other patent applications will provide us with significant proprietary protection or be of commercial benefit to us. Furthermore, the issuance of a patent is not conclusive as to its validity or enforceability, nor does the issuance of a patent provide the patent holder with freedom to operate without infringing the patent rights of others.

Developments by competitors may render our products or technologies obsolete or non-competitive.

Companies that currently sell or are developing both generic and proprietary pharmaceutical compounds to treat central nervous system diseases include: Pfizer, GlaxoSmithKline Pharmaceuticals, Merck & Co., Eli Lilly & Co., Biogen Idec, Forest Laboratories, Novartis, Teva Pharmaceuticals, Prana Biotechnology, Merz & Co., Alcon and Bausch and Lomb. Many of our competitors have significant financial and human resources. In addition, academic research centers may develop technologies that compete with our Trimesta, ZincMonoCysteine, reaZin gastroretentive sustained release oral high dose zinc preparations and oral flupirtine technologies. Should clinicians or regulatory authorities view these therapeutic regiments as more effective than our products, this might delay or prevent us from obtaining regulatory approval for our products, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid and private insurers. No assurance can be given that our current clinical trial of once daily reaZin for the dietary management of Alzheimer’s disease and mild cognitive impairment will prove to be safe and effective.

Competitors could develop and/or gain FDA approval of our products for a different indication.

Since we do not have composition of matter patent claims for oral flupirtine and oral estriol, others may obtain approvals for other uses of these products that are not covered by our issued or pending patents. For example, the active ingredients in both Effirma (oral flurpirtine) and Trimesta (oral estriol) have been approved for marketing in overseas countries for different uses. Other companies, including the original developers or licensees or affiliates may seek to develop Effirma or Trimesta or their respective active ingredient(s) for other uses in the United States or any country we are seeking approval for. We cannot provide any assurances that any other company may obtain FDA approval for products that contain oral flupirtine or oral estriol in various formulations or delivery systems that might adversely affect our ability or the ability of our sublicensee to develop and market these products in the United States. We are aware that other companies have intellectual property protection using the active ingredients and have conducted clinical trials of oral flupirtine and oral estriol for different applications than what we are developing. Many of these companies may have more resources than us. Should a competitor obtain FDA approval for their product for any indication prior to us, we might be precluded under the Waxman-Hatch Act to obtain approval for our product candidates for a period of five years. We cannot provide any assurances that our products will be FDA approved prior to our competitors.

If the FDA approves other products containing our active ingredients to treat indications other than those covered by our issued or pending patent applications, physicians may elect to prescribe a competitor’s products to treat the diseases for which we are developing—this is commonly referred to as “off-label” use. While under FDA regulations a competitor is not allowed to promote off-label uses of its product, the FDA does not regulate the practice of medicine and, as a result, cannot direct physicians as to which source it should use for these products they prescribe to their patients. Consequently, we might be limited in our ability to prevent off-label use of a competitor’s product to treat the diseases we are developing, even if we have issued patents for that indication. If we are not able to obtain and enforce these patents, a competitor could use our products for a treatment or use not covered by any of our patents. We cannot provide any assurances that a competitor will not obtain FDA approval for a product that contains the same active ingredients as our products.

Our oral reaZin product candidate does not contain the patented ingredient zinc-monocysteine and is instead the subject of pending United States and international patent applications in initially filed in January 2006 (see. U.S. Ser. No 11/621,962), which may not provide substantial protection from competitive products until, if and when, such pending patents issue, if at all. As a prescription medical food, no regulatory protection is afforded through FDA regulations to prevent others from marketing similar products. No assurance can be given that our current clinical trial of once daily reaZin for the dietary management of Alzheimer's disease and mild cognitive impairment will achieve superior or sufficient safety and efficacy in order to achieve significant sales. Similarly, the CopperProof Test Panel offered by our Adeona Clinical Labs subsidiary is the subject of pending patent applications that are expected to require a substantial amount of time to issue in order to provide protection from potential competitors.

We rely primarily on method patents and patent applications and various regulatory exclusivities to protect the development of our technologies, and our ability to compete may decrease or be eliminated if we are not able to protect our proprietary technology.

Our competitiveness may be adversely affected if we are unable to protect our proprietary technologies. Other than our ZincMonoCysteine program, we do not have composition of matter patents for Trimesta or Effirma, or their respective active ingredients oral estriol and oral flupirtine. We rely on issued patent and pending patent applications for use of Trimesta to treat multiple sclerosis (issued United States Patent No. 6,936,599) and various other therapeutic indications, which have been exclusively licensed to us. We have exclusively licensed an issued patent for the treatment of fibromyalgia with oral flupirtine, which we have sublicensed to Meda AB.

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Our ZincMonoCysteine product candidate is exclusively licensed from its inventors, the late David A. Newsome, M.D., and David Tate, Jr. ZincMonoCysteine is the subject of two issued United States patents, 7,164,035 and 6,586,611 and pending United States patent application ser. no. 11/621,380 which covers composition of matter claims. In our annual report on Form 10-KSB for the year ending December 31, 2007 that was filed March 31, 2008 (page 23), we described our receipt in March of 2008 (and potential impact on claim 1 of our exclusively licensed issued United States patent 7,164,035) of an English translation of a Russian disclosure, Zegzhda et. al. Chemical Abstracts Vol. 85 Abstract No. 186052 (1976) that was cited by the United States patent examiner during our prosecution of the pending divisional United States patent application Ser. No. 11/621,390. In April of 2008, we analyzed the zinccysteine complex described by Zegzhda and concluded that such complex describes an insoluble zinc salt and does not describe a non-zinc salt zinc-monocysteine complex and therefore believe that such disclosure should not affect the validity of any of our issued United States patent claims relating our zinc-monocysteine composition of matter claims. We have filed a response and declaration describing the results of our analysis with the United States Patent and Trademark Office with respect to the Zegzhda reference with respect to United States patent application ser. no. 11/621,380. In an office action dated August 20, 2008, the United States patent examiner did not accept our arguments filed May 23, 2008 in connection with the Zegzhda reference under pending divisional application ser. no. 11/621,390, the response to which we extended with the patent office and to which we intend to respond. Public copies of relevant and future communications can be obtained using the electronic PAIR system of the United States Patent and Trademark Office.

Our reaZin (gastroretentive sustained zinc and cysteine tablets) is the subject of United States and international pending patent applications, such as published United States patent application Ser. No. 11/621,962 and corresponding international applications that claim priority to January 10, 2006 as well as additional unpublished patent applications. No assurance can be given that such pending patent applications will issue or issue with claims satisfactorily broad enough to prevent others from developing and marketing competing products.

The patent positions of pharmaceutical companies are uncertain and may involve complex legal and factual questions. We may incur significant expense in protecting our intellectual property and defending or assessing claims with respect to intellectual property owned by others. Any patent or other infringement litigation by or against us could cause us to incur significant expense and divert the attention of our management.

We may also rely on the United States Drug Price Competition and Patent Term Restoration Act, commonly known as the “Hatch-Waxman Amendments,” to protect some of our current product candidates, specifically Trimesta and ZincMonoCysteine and other future product candidates we may develop. Once a drug containing a new molecule is approved by the FDA, the FDA cannot accept an abbreviated NDA for a generic drug containing that molecule for five years, although the FDA may accept and approve a drug containing the molecule pursuant to an NDA supported by independent clinical data. Recent amendments have been proposed that would narrow the scope of Hatch-Waxman exclusivity and permit generic drugs to compete with our drug.

Others may file patent applications or obtain patents on similar technologies or compounds that compete with our products. We cannot predict how broad the claims in any such patents or applications will be, and whether they will be allowed. Once claims have been issued, we cannot predict how they will be construed or enforced. We may infringe intellectual property rights of others without being aware of it. If another party claims we are infringing their technology, we could have to defend an expensive and time consuming lawsuit, pay a large sum if we are found to be infringing, or be prohibited from selling or licensing our products unless we obtain a license or redesign our product, which may not be possible.

We also rely on trade secrets and proprietary know-how to develop and maintain our competitive position. Some of our current or former employees, consultants, scientific advisors, current or prospective corporate collaborators, may unintentionally or willfully disclose our confidential information to competitors or use our proprietary technology for their own benefit. Furthermore, enforcing a claim alleging the infringement of our trade secrets would be expensive and difficult to prove, making the outcome uncertain. Our competitors may also independently develop similar knowledge, methods, and know-how or gain access to our proprietary information through some other means.

We may fail to retain or recruit necessary personnel, and we may be unable to secure the services of consultants.

As of December 31, 2010, we have 13 employees. We have also engaged regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. Our future performance will depend in part on our ability to successfully integrate newly hired officers into our management team and our ability to develop an effective working relationship among senior management.

Certain of our directors (Jeffrey Kraws, a director and former VP of Business Development, Jeffrey Wolf, a director, Steve Kanzer, a director and former Chairman and CEO, and Jeff Riley, a director), scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other biopharmaceutical or biotechnology companies that might be developing competitive products to ours. Other than corporate opportunities, none of our directors are obligated under any agreement or understanding with us to make any additional products or technologies available to us. Similarly, we can give no assurances, and we do not expect and stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by any of our directors or affiliates in the future would be made available to us other than corporate opportunities. We can give no assurances that any such other companies will not have interests that are in conflict with our interests.

Losing key personnel or failing to recruit necessary additional personnel would impede our ability to attain our development objectives. David A. Newsome, M.D., our former Senior Vice President of Research and Development recently passed away. There is intense competition for qualified personnel in the drug-development field, and we may not be able to attract and retain the qualified personnel we would need to develop our business.

We rely on independent organizations, advisors, and consultants to perform certain services for us, including handling substantially all aspects of regulatory approval, clinical management, manufacturing, marketing, and sales. We expect that this will continue to be the case. Such services may not always be available to us on a timely basis when we need them.

We may experience difficulties in obtaining sufficient quantities of our products or other compounds.

In order to successfully commercialize our product candidates, we and our sublicensees must be able to manufacture our products in commercial quantities, in compliance with regulatory requirements, at acceptable costs, and in a timely manner. Manufacture of the types of biopharmaceutical products that we propose to develop present various risks. For example, the manufacture of zinc-monocysteine is a complex process that can be difficult to scale up for purposes of producing large quantities at an acceptable cost. This process can also be subject to delays, inefficiencies, and poor or low yields of quality products. As such, we can give no assurances that we will be able to scale up the manufacturing of zinc-monocysteine.

For manufacturing and nonclinical information for Trimesta (oral estriol), we have relied upon an agreement with Organon, a division of Schering-Plough for access to clinical, nonclinical, stability and drug supply relating to oral estriol, the active ingredient in Trimesta, which is currently in clinical trial for multiple sclerosis. Should Organon terminate our agreement or be unable or unwilling to continue to supply Trimesta to us, this might delay enrollment and commercialization plans for our Trimesta clinical trial program. Organon has manufactured oral estriol the active ingredient of Trimesta for the European and Asian market for approximately 40 years but has never been approved in the United States. Organon has recently informed us of their decision to discontinue supply of estriol tablets beyond that required to satisfy the planned future needs of the ongoing clinical trial in relapsing-remitting multiple sclerosis. Accordingly, prior to initiation of additional clinical studies and/or commercial launch of oral estriol, we may need to identify and execute supply agreement(s) on terms suitable to us with an alternate supplier of estriol tablets.

Our plans to launch oral reaZin as a prescription medical food for the dietary management of zinc deficiency in Alzheimer’s disease and mild cognitive impairment will depend upon the successful cGMP manufacture, quality control and acceptable results of stability studies to be performed for reaZin for which we are utilizing and intend to engage third party contract manufacturers and analytic testing services, as well as the successful completion and results of Part 2 of our CopperProof-2 clinical trial being conducted at two centers in Florida.

Historically, our manufacturing has been handled by contract manufacturers and compounding pharmacies. We can give no assurances that we will be able to continue to use our current manufacturer or be able to establish another relationship with a manufacturer quickly enough so as not to disrupt commercialization of any of our products, or that commercial quantities of any of our products, if approved for marketing, will be available from contract manufacturers at acceptable costs.

In addition, any contract manufacturer that we select to manufacture our product candidates might fail to maintain a current “good manufacturing practices” (cGMP) manufacturing facility.

The cost of manufacturing certain product candidates may make them prohibitively expensive. In order to successfully commercialize our product candidates we may be required to reduce the costs of production, and we may find that we are unable to do so. We may be unable to obtain, or may be required to pay high prices for compounds manufactured or sold by others that we need for comparison purposes in clinical trials and studies for our product candidates.

The manufacture of our products is a highly exacting process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. We, or our materials suppliers, may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

If our laboratory facilities are damaged, our business would be seriously harmed.

Our only laboratory facility for copper and zinc testing products and general reference lab services is located in Bolingbrook, IL. Damage to our facility due to war, fire, natural disaster, power loss, communications failure, terrorism, unauthorized entry, or other events could prevent us from conducting our business for an indefinite period, could result in a loss of important data or cause us to cease development and production of our products. We cannot be certain that our limited insurance to protect against business interruption would be adequate or would continue to be available to us on commercially reasonable terms, or at all.

If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products.

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards and use in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

Clinical trials are very expensive, time-consuming, and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We estimate that clinical trials of our product candidates would take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Commencement and completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our submissions or conduct of our trials.

The results of our clinical trials may not support our product candidate claims and the results of preclinical studies and completed clinical trials are not necessarily predictive of future results.

To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our diagnostic product candidates. Favorable results in our early studies or trials may not be repeated in later studies or trials. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing and Phase II clinical trials does not ensure that later Phase II or Phase III clinical trials will be successful. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and preclinical testing. In particular, the limited results that we have obtained for our diagnostic tests may not predict results from studies in larger numbers of subjects drawn from more diverse populations over a longer period of time. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. Any such failure could cause us or our sublicensee to abandon a product candidate and might delay development of other product candidates. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Any delay in, or termination of, our clinical trials would delay our obtaining FDA approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate.

Physicians and patients may not accept and use our technologies.

Even if the FDA approves our product candidates, physicians and patients may not accept and use them. Acceptance and use of our product will depend upon a number of factors, including the following:

- the perception of members of the health care community, including physicians, regarding the safety and effectiveness of our product candidates;
- the cost-effectiveness of our product relative to competing products;
- availability of reimbursement for our products from government or other healthcare payers; and
- the effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

We depend on third parties, including researchers and sublicensees, who are not under our control.

Since we have in-licensed some of our product candidates and have sublicensed a product candidate, we depend upon our sublicensee and independent investigators and scientific collaborators, such as universities and medical institutions or private physician scientists, to conduct our preclinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs or the timing of their procurement of clinical-trial data or their compliance with applicable regulatory guidelines. Should any of these scientific inventors/advisors or those of our sublicensee become disabled or die unexpectedly, or should they fail to comply with applicable regulatory guidelines, we or our sublicensee may be forced to scale back or terminate development of that program. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking those programs ourselves. Failing to devote sufficient time and resources to our drug-development programs, or substandard performance and failure to comply with regulatory guidelines, could result in delay of any FDA applications and our commercialization of the drug candidate involved.

These collaborators may also have relationships with other commercial entities, some of which may compete with us. Our collaborators assisting our competitors at our expense could harm our competitive position. For example, we are highly dependent on scientific collaborators for our Trimesta and ZincMonoCysteine development programs. Specifically, all of the clinical trials have been conducted under physician-sponsored investigational new drug applications (INDs), not corporate-sponsored INDs. Generally, we have experienced difficulty in collecting data generated from these physician-sponsored clinical trials for our programs. We cannot provide any assurances that we will not experience any additional delays in the future. We have experienced similar difficulties with our zinc-monocysteine program.

We are also highly dependent on government and private grants to fund certain of our clinical trials for our product candidates. For example, Trimesta (oral estriol) has received a $5 million grant from the Southern California Chapter of the National Multiple Sclerosis Society and the National Institutes of Health which funds a majority of our ongoing 150 patient clinical trial in relapsing-remitting multiple sclerosis. If our scientific collaborator is unable to maintain these grants, we might be forced to scale back or terminate the development of this product candidate. We will also need to cross reference our IND with the inventor/IND holder for this program should we elect to file our own corporate IND for our Trimesta (oral estriol) program.

The on-going and future development and commercialization of Effirma (oral flupirtine) for fibromyalgia is the responsibility of Meda AB and no assurance can be given that Meda will gain FDA approval of oral flupirtine for fibromyalgia.

We have no experience selling, marketing, or distributing products and do not have the capability to do so.

We currently have no sales, marketing, or distribution capabilities. We do not anticipate having significant resources in the foreseeable future to allocate to selling and marketing our proposed products. Our success will depend, in part, on whether we are able to enter into and maintain collaborative relationships with a pharmaceutical or a biotechnology company charged with marketing one or more of our products. We may not be able to establish or maintain such collaborative arrangements or to commercialize our products in foreign territories, and even if we do, our collaborators may not have effective sales forces.

If we do not, or are unable to, enter into collaborative arrangements to sell and market our proposed products, we will need to devote significant capital, management resources, and time to establishing and developing an in-house marketing and sales force with technical expertise. We may be unsuccessful in doing so.

If we fail to maintain positive relationships with particular individuals, we may be unable to successfully develop our product candidates, conduct clinical trials, and obtain financing.

If we fail to maintain positive relationships with members of our management team or if these individuals decrease their contributions to our company, our business could be adversely impacted. We do not carry key employee insurance policies for any of our key employees.

We also rely greatly on employing and retaining other highly trained and experienced senior management and scientific personnel. The competition for these and other qualified personnel in the biotechnology field is intense. If we are not able to attract and retain qualified scientific, technical, and managerial personnel, we probably will be unable to achieve our business objectives.

We may not be able to compete successfully for market share against other drug companies.

The markets for our product candidates are characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval, they will compete with existing and future drugs and therapies developed, manufactured, and marketed by others. Competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies, or other public and private research organizations. Many of these competitors have therapies to treat central nervous system diseases already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs than we do, have substantially greater financial resources than we do, and have significantly greater experience in the following areas:

- developing drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, as well as costs associated with frivolous lawsuits.

If any other person files patent applications, or is issued patents, claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the United States Patent and Trademark Office to determine priority of invention. We, or our licensors, may also need to participate in interference proceedings involving our issued patents and pending applications of another entity.

We cannot guarantee that the practice of our technologies will not conflict with the rights of others. In some foreign jurisdictions, we could become involved in opposition proceedings, either by opposing the validity of another's foreign patent or by persons opposing the validity of our foreign patents.

We may also face frivolous litigation or lawsuits from various competitors or from litigious securities attorneys. The cost to us of any litigation or other proceeding relating to these areas, even if resolved in our favor, could be substantial and could distract management from our business. Uncertainties resulting from initiation and continuation of any litigation could have a material adverse effect on our ability to continue our operations.

If we infringe the rights of others we could be prevented from selling products or forced to pay damages.

If our products, methods, processes, and other technologies are found to infringe the proprietary rights of other parties, we could be required to pay damages, or we may be required to cease using the technology or to license rights from the prevailing party. Any prevailing party may be unwilling to offer us a license on commercially acceptable terms.

Our products, if approved, may not be commercially viable due to change in health care practice and third party reimbursement limitations

Recent initiatives to reduce the federal deficit and to change health care delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to successfully commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

We do not currently have product liability or malpractice insurance and may not be able to obtain adequate insurance coverage against product liability claims

Our business exposes us to potential product liability and other types of claims and our exposure will increase as we prepare to commercialize our copper and zinc status tests. We do not currently have any product liability or malpractice insurance that would cover us against any product liability, or malpractice claims. Any such claim would have to be paid out of our cash reserves, which would have a detrimental effect on our financial condition. Even if it is available, product liability insurance for the pharmaceutical and biotechnology industry generally is expensive. Adequate insurance coverage may not be available at a reasonable cost. We cannot assure you that we can or will be able to obtain product liability or malpractice insurance policies on commercially acceptable terms, or at all.

RISKS RELATING TO OUR STOCK

We will seek to raise additional funds in the future, which may be dilutive to stockholders or impose operational restrictions.

We expect to seek to raise additional capital in the future to help fund development of our proposed products. If we raise additional capital through the issuance of equity (as we recently have) or of debt securities, the percentage ownership of our current stockholders will be reduced. We may also enter into strategic transactions, issue equity as part of license issue fees to our licensors, compensate consultants or settle outstanding payables using equity that may be dilutive. Our stockholders may experience additional dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of the holders of our common stock. If we cannot raise additional funds, we will have to delay development activities of our products candidates.

We are substantially controlled by our current officers, directors, and principal stockholders.

Currently, our directors, executive officer, and principal stockholders beneficially own a substantial number of shares of our common stock. As a result, they will be able to exert substantial influence over the election of our board of directors and the vote on issues submitted to our stockholders. Our executive officer, directors and principal stockholders beneficially owned approximately 12.1 million shares of our common stock, including the stock options and warrants exercisable within 60 days of March 25, 2011. Because our common stock has from time to time been “thinly traded”, the sale of these shares by our executive officer, directors and principal stockholders could have an adverse effect on the market for our stock and our share price.

Our shares of common stock are from time to time thinly traded, so stockholders may be unable to sell at or near ask prices or at all if they need to sell shares to raise money or otherwise desire to liquidate their shares.

Our common stock has from time to time been “thinly-traded,” meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non−existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give stockholders any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

Our compliance with the Sarbanes-Oxley Act and SEC rules concerning internal controls may be time consuming, difficult and costly.

Although individual members of our management team have experience as officers of publicly traded companies, much of that experience came prior to the adoption of the Sarbanes-Oxley Act of 2002. It may be time consuming, difficult and costly for us to develop and implement the internal controls and reporting procedures required by Sarbanes-Oxley. We may need to hire additional financial reporting, internal controls and other finance staff in order to develop and implement appropriate internal controls and reporting procedures. If we are unable to comply with Sarbanes-Oxley's internal controls requirements, we may not be able to obtain the independent accountant certifications that Sarbanes-Oxley Act requires publicly traded companies to obtain.

We cannot assure you that the common stock will be liquid or that it will remain listed on a securities exchange.

We cannot assure you that we will be able to maintain the continued listing standards of the NYSE Amex (formerly the American Stock Exchange) or NYSE Alternext US. The NYSE Amex requires companies to meet certain continued listing criteria including certain minimum stockholders' equity and equity prices per share as outlined in the Exchange Company Guide. We may not be able to maintain such minimum stockholders' equity or prices per share or may be required to effect a reverse stock split to maintain such minimum prices and/or issue additional equity securities in exchange for cash or other assets, if available, to maintain certain minimum stockholders' equity required by the NYSE Amex. If we are delisted from the Exchange then our common stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board securities market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our common stock could further depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the Exchange could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities. In order to remain listed on NYSE Amex, we are required to maintain a minimum stockholders’ equity of $6 million, which exceeded our stockholders’ equity as of December 31, 2010, but at the present time does not exceed our stockholders’ equity due to the receipt of proceeds from our recent offering.

There may be issuances of shares of preferred stock in the future.

Although we currently do not have preferred shares outstanding, the board of directors could authorize the issuance of a series of preferred stock that would grant holders preferred rights to our assets upon liquidation, the right to receive dividends before dividends would be declared to common stockholders, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the common stock. To the extent that we do issue preferred stock, the rights of holders of common stock could be impaired thereby, including without limitation, with respect to liquidation.

We have never paid dividends.

We have never paid cash dividends on our common stock and do not anticipate paying any for the foreseeable future.

RISKS RELATED TO OUR INDUSTRY

We are subject to government regulation, compliance with which can be costly and difficult.

In the United States, the formulation, manufacturing, packaging, storing, labeling, promotion, advertising, distribution and sale of our products are subject to regulation by various governmental agencies, including (1) the Food and Drug Administration, or FDA, (2) the Federal Trade Commission, or FTC, (3) the Consumer Product Safety Commission, or CPSC, (4) the United States Department of Agriculture, or USDA. Our proposed activities may also be regulated by various agencies of the states, localities and foreign countries in which our proposed products may be manufactured, distributed and sold. The FDA, in particular, regulates the formulation, manufacture and labeling of over-the-counter, or OTC, drugs, conventional foods, dietary supplements, and cosmetics such as those that we intend to distribute. FDA regulations require us and our suppliers to meet relevant current good manufacturing practice, or cGMP, regulations for the preparation, packing and storage of foods and OTC drugs. As a result of inactivity and the removal and sale of certain equipment, our facility in Ann Arbor, Michigan is no longer currently cGMP compliant.

The United States Dietary Supplement Health and Education Act of 1994, or DSHEA, revised the provisions of the Federal Food, Drug and Cosmetic Act, or FFDCA, concerning the composition and labeling of dietary supplements and, we believe, the revisions are generally favorable to the dietary supplement industry. The legislation created a new statutory class of dietary supplements. This new class includes vitamins, minerals, herbs, amino acids and other dietary substances for human use to supplement the diet, and the legislation grandfathers, with some limitations, dietary ingredients that were on the market before October 15, 1994. A dietary supplement that contains a dietary ingredient that was not on the market before October 15, 1994 will require evidence of a history of use or other evidence of safety establishing that it is reasonably expected to be safe. Manufacturers or marketers of dietary supplements in the United States and certain other jurisdictions that make product performance claims, including structure or function claims, must have substantiation in their possession that the statements are truthful and not misleading. The majority of the products marketed by us in the United States are classified as conventional foods or dietary supplements under the FFDCA. Internationally, the majority of products marketed by us are classified as foods or food supplements.

In January 2000, the FDA issued a regulation that defines the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body pursuant to DSHEA. Under DSHEA, dietary supplement labeling may bear structure or function claims, which are claims that the products affect the structure or function of the body, without prior FDA approval, but with notification to the FDA. They may not bear a claim that they can prevent, treat, cure, mitigate or diagnose disease (a disease claim). The regulation describes how the FDA distinguishes disease claims from structure or function claims. During 2004, the FDA issued guidance, paralleling an earlier guidance from the FTC, defining a manufacturer's obligations to substantiate structure/function claims. The FDA also issued a Structure/Function Claims Small Entity Compliance Guide. In addition, the agency permits companies to use FDA-approved full and qualified health claims for products containing specific ingredients that meet stated requirements.

In order to make disease claims, we may seek to market some of our proposed products as medical foods for the dietary management of certain diseases. Medical foods are defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered internally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." We believe our products may qualify as medical foods provided we are able to generate, and have published, sufficient clinical data to support such claims. Medical foods are required to be utilized under a medical doctor’s supervision and as such, our distribution channels may be limited and/or complicated.

Should we seek to make disease claims beyond those permitted for medical foods, we may seek to conduct necessary clinical trials to support such claims and file one or more New Drug Applications with respect to such products which would be the subject of the time, expense and uncertainty associated with achieving approval of such NDA by the FDA.

On December 22, 2007, a new law went into effect in the United States mandating the reporting of all serious adverse events occurring within the United States which involve dietary supplements or OTC drugs. We believe that in order to be in compliance with this law we will be required to implement a worldwide procedure governing adverse event identification, investigation and reporting. As a result of our receipt of adverse event reports, we may from time to time elect, or be required, to remove a product from a market, either temporarily or permanently.

Some of the products marketed by us are considered conventional foods and are currently labeled as such. Within the United States, this category of products is subject to the Nutrition, Labeling and Education Act, or NLEA, and regulations promulgated under the NLEA. The NLEA regulates health claims, ingredient labeling and nutrient content claims characterizing the level of a nutrient in the product. The ingredients added to conventional foods must either be generally recognized as safe by experts, or GRAS, or be approved as food additives under FDA regulations. Our zinc-monocysteine complexes are comprised of zinc (a GRAS ingredient) and cysteine (an amino acid that also has GRAS status). While many chelated zinc products are currently on the market and are generally not considered new dietary ingredients, we cannot provide any assurance that zinc-monocysteine will be similarly considered by the FDA.

The FTC, which exercises jurisdiction over the advertising of all of our proposed products, has in the past several years instituted enforcement actions against several dietary supplement companies and against manufacturers of products generally for false and misleading advertising of some of their products. These enforcement actions have often resulted in consent decrees and monetary payments by the companies involved. In addition, the FTC has increased its scrutiny of the use of testimonials, which we also utilize, as well as the role of expert endorsers and product clinical studies. It is unclear whether the FTC will subject our advertisements to increased surveillance to ensure compliance with the principles set forth in its published advertising guidance. The copper industry has supported research studies that conclude that copper has no effect in Alzheimer’s disease. In February 2007, the State of California issued its public health goal for copper in drinking water and considered the research studies mentioned above as well as those of our scientific collaborators and concluded that at the present time, the data with respect to copper in drinking water’s role in Alzheimer’s disease were to be “equivocal”. We cannot provide assurance that the FTC will allow us to publically advertise or promote our products to the American public.

The FDA, comparable foreign regulators and state and local pharmacy regulators impose substantial requirements upon clinical development, manufacture and marketing of pharmaceutical products. These and other entities regulate research and development and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising, and promotion of our products. The drug approval process required by the FDA under the Food, Drug, and Cosmetic Act generally involves:

- preclinical laboratory and animal tests;
- submission of an IND, prior to commencing human clinical trials;
- adequate and well-controlled human clinical trials to establish safety and efficacy for intended use;
- submission to the FDA of a NDA; and
- FDA review and approval of a NDA.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all.

Preclinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, and animal studies to assess potential safety and efficacy. Certain preclinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring them to be replicated. In some cases, long-term preclinical studies are conducted concurrently with clinical studies.

We will submit the preclinical test results, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we begin human clinical trials. The IND automatically becomes effective 30 days after filing, unless the FDA raises questions about conduct of the trials outlined in the IND and imposes a clinical hold, in which case, the IND sponsor and FDA must resolve the matters before clinical trials can begin. It is possible that our submission may not result in FDA authorization to commence clinical trials.

Clinical trials must be supervised by a qualified investigator in accordance with good clinical practice regulations, which include informed consent requirements. An independent Institutional Review Board ("IRB") at each medical center reviews and approves and monitors the study, and is periodically informed of the study's progress, adverse events and changes in research. Progress reports are submitted annually to the FDA and more frequently if adverse events occur.

Human clinical trials typically have three sequential phases that may overlap:

Phase I: The drug is initially tested in healthy human subjects or patients for safety, dosage tolerance, absorption, metabolism, distribution, and excretion.

Phase II: The drug is studied in a limited patient population to identify possible adverse effects and safety risks, determine efficacy for specific diseases and establish dosage tolerance and optimal dosage.

Phase III: When phase II evaluations demonstrate that a dosage range is effective with an acceptable safety profile, Phase III trials to further evaluate dosage, clinical efficacy and safety, are undertaken in an expanded patient population, often at geographically dispersed sites.

We cannot be certain that we will successfully complete Phase I, Phase II, or Phase III testing of our product candidates within any specific time period, if at all. Furthermore, the FDA, an IRB or the IND sponsor may suspend clinical trials at any time on various grounds, including a finding that subjects or patients are exposed to unacceptable health risk. Concurrent with these trials and studies, we also develop chemistry and physical characteristics data and finalize a manufacturing process in accordance with good manufacturing practice ("GMP") requirements. The manufacturing process must conform to consistency and quality standards, and we must develop methods for testing the quality, purity, and potency of the final products. Appropriate packaging is selected and tested, and chemistry stability studies are conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life. Results of the foregoing are submitted to the FDA as part of a NDA for marketing and commercial shipment approval. The FDA reviews each NDA submitted and may request additional information.

Once the FDA accepts the NDA for filing, it begins its in-depth review. The FDA has substantial discretion in the approval process and may disagree with our interpretation of the data submitted. The process may be significantly extended by requests for additional information or clarification regarding information already provided. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians. Manufacturing establishments often are inspected prior to NDA approval to assure compliance with GMPs and with manufacturing commitments made in the application.

Submission of a NDA with clinical data requires payment of a fee. In return, the FDA assigns a goal of ten months for issuing its "complete response," in which the FDA may approve or deny the NDA, or require additional clinical data. Even if these data are submitted, the FDA may ultimately decide the NDA does not satisfy approval criteria. If the FDA approves the NDA, the product becomes available for physicians prescription. Product approval may be withdrawn if regulatory compliance is not maintained or safety problems occur. The FDA may require post-marketing studies, also known as phase IV studies, as a condition of approval, and requires surveillance programs to monitor approved products that have been commercialized. The agency has the power to require changes in labeling or prohibit further marketing based on the results of post-marketing surveillance.

Satisfaction of these and other regulatory requirements typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures on our activities. We cannot be certain that the FDA or other regulatory agencies will approve any of our products on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from preclinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications or uses.

Even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing FDA regulation, including record-keeping requirements, reporting of adverse experiences, submitting periodic reports, drug sampling and distribution requirements, manufacturing or labeling changes, record-keeping requirements, and compliance with FDA promotion and advertising requirements. Drug manufacturers and their subcontractors are required to register their facilities with the FDA and state agencies, and are subject to periodic unannounced inspections for GMP compliance, imposing procedural and documentation requirements upon us and third-party manufacturers. Failure to comply with these regulations could result, among other things, in suspension of regulatory approval, recalls, suspension of production or injunctions, seizures, or civil or criminal sanctions. We cannot be certain that we or our present or future subcontractors will be able to comply with these regulations.

The FDA regulates drug labeling and promotion activities. The FDA has actively enforced regulations prohibiting the marketing of products for unapproved uses. The FDA permits the promotion of drugs for unapproved uses in certain circumstances, subject to stringent requirements. We and our product candidates are subject to a variety of state laws and regulations which may hinder our ability to market our products. Whether or not FDA approval has been obtained, approval by foreign regulatory authorities must be obtained prior to commencing clinical trials, and sales and marketing efforts in those countries. These approval procedures vary in complexity from country to country, and the processes may be longer or shorter than that required for FDA approval. We may incur significant costs to comply with these laws and regulations now or in the future.

The FDA's policies may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. Increased attention to the containment of health care costs worldwide could result in new government regulations materially adverse to our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Failure to adhere to the quality control and other regulatory requirements could result in the suspension of such certification necessary to perform clinical testing and generate revenues.

The United States Federal Trade Commission and the Office of the Inspector General of the United States Department of Health and Human Services ("HHS") also regulate certain pharmaceutical marketing practices. Government reimbursement practices and policies with respect to our products are important to our success.

We are subject to numerous federal, state and local laws relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with these laws and regulations. The regulatory framework under which we operate will inevitably change in light of scientific, economic, demographic and policy developments, and such changes may have a material adverse effect on our business.

Clinical laboratories in the United States are subject to regulation under the Clinical Laboratory Improvements Act of 1988 ("CLIA") as well as corresponding state regulations. Failure to adhere to the quality control and other regulatory requirements of CLIA could result in the suspension of such certification necessary to perform clinical testing and generate revenues.

Failure to comply with requirements of the European Union can be costly and time consuming.

Prior regulatory approval for human healthy volunteer studies (Phase I studies) is required in member states of the European Union (E.U.). Summary data from successful Phase I studies are submitted to regulatory authorities in member states to support applications for Phase II studies. E.U. authorities typically have one to three months (which often may be extended in their discretion) to raise objections to the proposed study. One or more independent ethics committees (similar to United States IRBs) review relevant ethical issues.

For E.U. marketing approval, we submit to the relevant authority for review a dossier, or MAA (Market Authorization Application), providing information on the quality of the chemistry, manufacturing and pharmaceutical aspects of the product as well as non-clinical and clinical data.

Approval can take several months to several years, and can be denied, depending on whether additional studies or clinical trials are requested (which may delay marketing approval and involve unbudgeted costs) or regulatory authorities conduct facilities (including clinical investigation site) inspections and review manufacturing procedures, operating systems and personnel qualifications. In many cases, each drug manufacturing facility must be approved, and further inspections may occur over the product's life.

The regulatory agency may require post-marketing surveillance to monitor for adverse effects or other studies. Further clinical studies are usually necessary for approval of additional indications. The terms of any approval, including labeling content, may be more restrictive than expected and could affect the marketability of a product.

Failure to comply with these ongoing requirements can result in suspension of regulatory approval and civil and criminal sanctions. European renewals may require additional data, resulting in a license being withdrawn. E.U. regulators have the authority to revoke, suspend or withdraw approvals, prevent companies and individuals from participating in the drug approval process, request recalls, seize violative products, obtain injunctions to close non-compliant manufacturing plants and stop shipments of violative products.

We are subject to pricing controls that may not result in favorable arrangements for our products.

Pricing for products under approval applications is also subject to regulation. Requirements vary widely between countries and can be implemented disparately intra-nationally. The E.U. generally provides options for member states to control pricing of medicinal products for human use, ranging from specific price-setting to systems of direct or indirect controls on the producer's profitability. U.K. regulation, for example, generally provides controls on overall profits derived from sales to the U.K. National Health Service that are based on profitability targets or a function of capital employed in servicing the National Health Service market. Italy generally utilizes a price monitoring system based on the European average price over the reference markets of France, Spain, Germany and the U.K. Italy typically establishes price within a therapeutic class based on the lowest price for a medicine belonging to that category. Spain generally establishes selling price based on prime cost plus a profit margin within a range established yearly by the Spanish Commission for Economic Affairs.

There can be no assurance that price controls or reimbursement limitations will result in favorable arrangements for our products.

If we are not able to receive third-party reimbursements we may not be able to sell products at competitive prices.

In the United States, the E.U. and elsewhere, pharmaceutical sales are dependent in part on the availability and adequacy of reimbursement from third party payers such as governments and private insurance plans. Third party payers are increasingly challenging established prices, and new products that are more expensive than existing treatments may have difficulty finding ready acceptance unless there is a clear therapeutic benefit.

In the United States, consumer willingness to choose a self-administered outpatient prescription drug over a different drug or other form of treatment often depends on the manufacturer's success in placing the product on a health plan formulary or drug list, which results in lower out-of-pocket costs. Favorable formulary placement typically requires the product to be less expensive than what the health plan determines to be therapeutically equivalent products, and often requires manufacturers to offer rebates. Federal law also requires manufacturers to pay rebates to state Medicaid programs in order to have their products reimbursed by Medicaid. Medicare, which covers most Americans over age 65 and the disabled, adopted an insurance regime that offers eligible beneficiaries limited coverage for outpatient prescription drugs that became effective January 1, 2006. The prescription drugs that are covered under this insurance are specified on a formulary published by Medicare. As part of these changes, Medicare has adopted new payment formulas for prescription drugs administered by providers, such as hospitals or physicians that are generally expected to lower reimbursement.

The E.U. generally provides options for member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement. Member states can opt for a "positive" or "negative" list, with the former listing all covered medicinal products and the latter designating those excluded from coverage. The E.U., the U.K. and Spain have negative lists, while France uses a positive list. Canadian provinces establish their own reimbursement measures. In some countries, products may also be subject to clinical and cost effectiveness reviews by health technology assessment bodies. Negative determinations in relation to our products could affect prescribing practices. In the U.K., the National Institute for Clinical Excellence ("NICE") provides such guidance to the National Health Service, and doctors are expected to take it into account when choosing drugs to prescribe. Health authorities may withhold funding from drugs not given a positive recommendation by NICE. A negative determination by NICE may mean fewer prescriptions. Although NICE considers drugs with orphan status, there is a degree of tension on the application of standard cost assessment for orphan drugs, which are often priced higher to compensate for a limited market. It is unclear whether NICE will adopt a more relaxed approach toward the assessment of orphan drugs.

We cannot assure you that any of our products will be considered cost effective, or that reimbursement will be available or sufficient to allow us to sell them competitively and profitably.

We could be subject to challenges under fraud and abuse laws.

The United States federal Medicare/Medicaid anti-kickback law and similar state laws prohibit remuneration intended to induce physicians or others either to refer patients, or to acquire or arrange for or recommend the acquisition of health care products or services. While the federal law applies only to referrals, products or services receiving federal reimbursement, state laws often apply regardless of whether federal funds are involved. Other federal and state laws prohibit anyone from presenting or causing to be presented false or fraudulent payment claims. Recent federal and state enforcement actions under these statutes have targeted sales and marketing activities of prescription drug manufacturers. As we begin to market our products to health care providers, the relationships we form, such as compensating physicians for speaking or consulting services, providing financial support for continuing medical education or research programs, and assisting customers with third-party reimbursement claims, could be challenged under these laws and lead to civil or criminal penalties, including the exclusion of our products from federally-funded reimbursement. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition. We intend to consult counsel concerning the potential application of these and other laws to our business and to our sales, marketing and other activities to comply with them. Given their broad reach and the increasing attention given them by law enforcement authorities, however, we cannot assure you that some of our activities will not be challenged.

We do not have a guarantee of patent restoration and marketing exclusivity of the ingredients for our drugs even if we are granted FDA approval of our products.

The United States Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) permits the FDA to approve Abbreviated New Drug Applications (“ANDAs”) for generic versions of innovator drugs, as well as NDAs with less original clinical data, and provides patent restoration and exclusivity protections to innovator drug manufacturers. The ANDA process permits competitor companies to obtain marketing approval for drugs with the same active ingredient and for the same uses as innovator drugs, but does not require the conduct and submission of clinical studies demonstrating safety and efficacy. As a result, a competitor could copy any of our drugs and only need to submit data demonstrating that the copy is bioequivalent to gain marketing approval from the FDA. Hatch-Waxman requires a competitor that submits an ANDA, or otherwise relies on safety and efficacy data for one of our drugs, to notify us and/or our business partners of potential infringement of our patent rights. We and/or our business partners may sue the company for patent infringement, which would result in a 30-month stay of approval of the competitor’s application. The discovery, trial and appeals process in such suits can take several years. If the litigation is resolved in favor of the generic applicant or the challenged patent expires during the 30-month period, the stay is lifted and the FDA may approve the application. Hatch-Waxman also allows competitors to market copies of innovator products by submitting significantly less clinical data outside the ANDA context. Such applications, known as “505(b)(2) NDAs” or “paper NDAs,” may rely on clinical investigations not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use and are subject to the ANDA notification procedures described above.

The law also restores a portion of a product’s patent term that is lost during clinical development and NDA review, and provides statutory protection, known as exclusivity, against FDA approval or acceptance of certain competitor applications. Restoration can return up to five years of patent term for a patent covering a new product or its use to compensate for time lost during product development and regulatory review. The restoration period is generally one-half the time between the effective date of an IND and submission of an NDA, plus the time between NDA submission and its approval (subject to the five-year limit), and no extension can extend total patent life beyond 14 years after the drug approval date. Applications for patent term extension are subject to United States Patent and Trademark Office (“USPTO”) approval, in conjunction with FDA. Approval of these applications takes at least nine months, and there can be no guarantee that it will be given at all.

Hatch-Waxman also provides for differing periods of statutory protection for new drugs approved under an NDA. Among the types of exclusivity are those for a “new molecular entity” and those for a new formulation or indication for a previously-approved drug. If granted, marketing exclusivity for the types of products that we are developing, which include only drugs with innovative changes to previously-approved products using the same active ingredient, would prohibit the FDA from approving an ANDA or 505(b)(2) NDA relying on safety and efficacy data for three years. This three-year exclusivity, however, covers only the innovation associated with the original NDA. It does not prohibit the FDA from approving applications for drugs with the same active ingredient but without our new innovative change. These marketing exclusivity protections do not prohibit the FDA from approving a full NDA, even if it contains the innovative change.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our primary offices are located at 3985 Research Park Drive, Suite 200, Ann Arbor, MI 48108. We currently rent approximately 5,936 square feet of office and laboratory space in Ann Arbor, MI for monthly rent of $4,000. This is a month-to-month lease. Our Adeona Clinical Laboratory subsidiary leases approximately 3,000 square feet of clinical laboratory space in Bolingbrook, IL for $3,027 a month. This lease expires May 30, 2012, but is terminable at any time at our option for $250 times the number of months remaining. We believe our current offices will be adequate for the foreseeable future.

Item 3. Legal Proceedings

Not applicable.

Item 4. Removed and Reserved

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchase of Equity Securities

Our common stock has traded on the NYSE Amex (formerly the American Stock Exchange) under the symbol "AEN" since October 16, 2008. The following table states the range of the high and low sales prices of our common stock for each of the calendar quarters during the years ended December 31, 2010 and December 31, 2009. These quotations represent inter-dealer prices, without retail mark-up, markdown, or commission, and may not represent actual transactions. The last price of our common stock as reported on the NYSE Amex on March 25, 2011 was $1.80 per share. As of March 25, 2011, there were approximately 360 stockholders of record of our common stock. This number does not include beneficial owners from whom shares are held by nominees in street name.

	High		Low	
YEAR ENDED DECEMBER 31, 2010				
Fourth quarter	$	1.40	$	0.70
Third quarter	$	1.19	$	0.77
Second quarter	$	2.70	$	1.03
First quarter	$	2.58	$	0.57
YEAR ENDED DECEMBER 31, 2009				
Fourth quarter	$	0.92	$	0.41
Third quarter	$	1.70	$	0.30
Second quarter	$	1.10	$	0.16
First quarter	$	0.56	$	0.10

Dividend Policy

We have never paid any cash dividends on our common stock to date, and do not anticipate paying such cash dividends in the foreseeable future. Whether we declare and pay dividends is determined by our board of directors at their discretion, subject to certain limitations imposed under Nevada corporate law. The timing, amount and form of dividends, if any, will depend on, among other things, our results of operations, financial condition, cash requirements and other factors deemed relevant by our board of directors.

Equity Compensation Plan Information

See Item 11 – Executive compensation for equity compensation plan information.

Recent Sales of Unregistered Securities

In July of 2010, the Company issued warrants to purchase 60,606 shares of common stock to a placement agent. The warrants have an exercise price of $1.32 and are exercisable for a period of five years. In October of 2010, the Company issued 52,180 shares of common stock to Thomas Jefferson University having a fair value of $41,250 ($0.79 per share). and 28,855 shares of common stock to the University of Southern California having a fair value of $29,087 ($1.01 per share) in payment for licensing fees. The fair value of these issuances were based upon the quoted closing price. For the year ended December 31, 2009, the Company issued 50,000 shares of common stock for the acquisition of Adeona Clinical Laboratory, having a fair value of $19,000 ($0.38 per share), based on the quoted closing trading price. These issuances and sales of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuances did not involve a public offering. The issuances were not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the issuances. These issuances were done with no general solicitation or advertising by the Company. Based on an analysis of the above factors, the Company has met the requirements to quality for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

Item 6. Selected Financial Data

Not applicable because the Company is a smaller reporting company.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2010 found in this report. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward looking statements by using words such as "anticipate," "believe," "intends," or similar expressions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in Part I, Item 1A of this Report.

Overview

We are a pharmaceutical company developing innovative medicines for the treatment of serious central nervous system diseases. Our primary strategy is to license product candidates that have demonstrated a certain level of clinical efficacy and develop them to a stage that results in a significant commercial collaboration. Currently, we have the following product candidates in development: a prescription medical food for Alzheimer's disease, and drugs for multiple sclerosis, fibromyalgia and age-related macular degeneration.

- Alzheimer's disease and mild cognitive impairment: reaZin (zinc cysteine) is being developed as a prescription medical food for the dietary management of patients with Alzheimer's disease and mild cognitive impairment. A randomized, double-blind, placebo-controlled clinical study is underway at 2 centers in the United States. Sixty patients were enrolled in the study, and we recently completed the treatment phase of this clinical study. It is anticipated that top-line clinical study results should be presented on April 14, 2011 at the 63rd Annual Meeting of the American Academy of Neurology.
- Multiple sclerosis: Trimesta (oral estriol) is a drug candidate being developed for the treatment of relapsing-remitting multiple sclerosis in women. A randomized, double-blind, placebo-controlled clinical trial is currently underway at 15 centers in the United States. As of March 1, 2011 127 out of 150 patients have been enrolled.
- Fibromyalgia: Effirma (oral flupirtine) is a drug candidate being developed for the treatment of fibromyalgia. On May 6, 2010, we and Pipex, our wholly owned subsidiary, entered into a sublicense agreement with Meda AB, a multi-billion dollar international pharmaceutical company, covering all of our patents' rights on the use of oral flupirtine for fibromyalgia.
- Age-related macular degeneration: ZincMonoCysteine (zinc-monocysteine) is a drug candidate being developed for the treatment of age-related macular degeneration. An 80-patient, randomized, double-blind, placebo-controlled clinical trial has been completed.

As of March 31, 2011, we have discontinued our dnaJP1 (hsp peptide) clinical development program. While data from a Phase II clinical trial previously reported in November 2009 demonstrated safety and tolerability in patients with rheumatoid arthritis, the decision to discontinue was driven by economic factors, anticipated time to market and the perceived relative clinical and market potential. We will continue to focus our efforts on developing innovative medicines for the treatment of serious central nervous system diseases and to explore new opportunities.

Our secondary strategy is to market our core competency in measuring metabolic serum zinc and copper status. To further this effort, we purchased HartLab, LLC, on July 13, 2009. Renamed Adeona Clinical Laboratory, the wholly owned CLIA-certified clinical testing facility provides a broad array of chemistry and microbiology diagnostic tests in the Greater Chicago area. At Adeona Clinical Laboratory, we developed and offer the CopperProof panel, a series of diagnostic tests for accurately measuring the metabolic serum zinc and copper levels of patients with Alzheimer's disease and mild cognitive impairment. Adeona Clinical Laboratory is a licensed Medicare and Medicaid provider.

Since our inception in January 2001, our efforts and resources have been focused primarily on acquiring and developing our product candidates, our clinical trials, raising capital and recruiting personnel. As of June 30, 2010, we emerged from the development stage after entering into a sublicense agreement with Meda AB and receiving an up-front payment of $2.5 million. We consider this sublicense agreement to be an indication that we have commenced our principal operations.

To date, we have financed our operations primarily through public and private sales of our common stock, and we expect to continue to seek to obtain the required capital in a similar manner. We have incurred an accumulated deficit of $43.7 million through December 31, 2010. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

On October 16, 2008, we changed our name from Pipex Pharmaceuticals, Inc. to Adeona Pharmaceuticals, Inc. On October 15, 2009 we reincorporated in Nevada from Delaware pursuant to the discretionary reincorporation plan approved by our stockholders. The reincorporation was effected by our merger as a Delaware corporation, with and into a newly created, wholly owned, Nevada subsidiary corporation. In the reincorporation, each outstanding share of our common stock as a Delaware corporation was automatically converted into one share of common stock as a Nevada corporation, and all options and other rights to acquire our common stock as a Delaware corporation outstanding immediately prior to the reincorporation were automatically converted into options and rights to acquire the same number of shares of our common stock as a Nevada corporation. Stockholders were not required to exchange their existing stock certificates of the Delaware corporation which now represent the same number of shares of our common stock as a Nevada corporation. Outstanding shares of our common stock as a Nevada corporation retain the same CUSIP number as the corresponding shares prior to the reincorporation, and our common stock continues to be listed on the NYSE Amex stock exchange (formerly known as the American Stock Exchange and the NYSE Alternext US exchange) under the same symbol, "AEN". The reincorporation did not result in any material changes in our business, offices, assets, liabilities, obligations or net worth, or our directors, officers or employees, and the Delaware corporation ceased to exist as a separate legal entity. We continue to maintain our principal executive offices in Ann Arbor, MI, and are currently located at 3985 Research Park Drive, Suite 200, Ann Arbor, MI 48108.

As a result of the reincorporation and by operation of Rule 12g-3(a) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Company, as a Nevada corporation, is the successor issuer to Adeona Delaware and has succeeded to the attributes of Adeona Delaware as the registrant. The common stock of the Company, as a Nevada corporation, is deemed to be registered under Section 12(b) of the Exchange Act, and the Company is subject to the informational requirements of the Exchange Act, and the rules and regulations promulgated thereunder.

Critical Accounting Policies

The preparation of our consolidated financial statements in accordance with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, net revenues and expenses, and related disclosures. We believe our estimates and assumptions are reasonable; however, actual results and the timing of the recognition of such amounts could differ from these estimates.

There are accounting policies that we believe are significant to the presentation of our consolidated financial statements. The most significant accounting policies relate to stock-based compensation, revenue recognition and accounts receivable.

Stock-Based Compensation

Calculating stock-based compensation expense requires the input of highly subjective assumptions. We apply the Black-Scholes option-pricing model to determine the fair value of our stock options. Inherent in this model are assumptions related to expected stock-price volatility, option life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock at the date of grant based on historical volatility. We estimate the expected life of our option using the contractual term of the option. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected life of the options. The dividend rate is based on our historical rate, which we anticipate to remain at zero. The assumptions used in calculating the fair value of stock options represent our best estimates, however these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those stock options expected to vest over the service period.

Revenue Recognition

We record revenue when all of the following have occurred: (1) persuasive evidence of an arrangement exists, (2) the service is completed without further obligation, (3) the sales price to the customer is fixed or determinable, and (4) collectability is reasonably assured. We recognize milestone payments or upfront payments that have no contingencies as revenue when payment is received. Our primary streams of revenue are license revenue and laboratory revenue.

License Revenues

Our licensing agreements may contain multiple elements, such as non-refundable up-front fees, payments related to the achievement of particular milestones and royalties. Fees associated with substantive at risk performance-based milestones are recognized as revenue upon completion of the scientific or regulatory event specified in the agreement. When we have substantive continuing performance obligations under an arrangement, revenue is recognized over the performance period of the obligations using a time-based proportional performance approach. Under the time-based method, revenue is recognized over the arrangement's estimated performance period based on the elapsed time compared to the total estimated performance period. Revenue recognized at any point in time is limited to the amount of non-contingent payments received or due. When we have no substantive continuing performance obligations under an arrangement, we recognize revenue as the related fees become due.

Revenues from royalties on third-party sales of licensed technologies are generally recognized in accordance with the contract terms when the royalties can be reliably determined and collectibility is reasonably assured.

Laboratory Revenues

We primarily recognize revenue for services rendered upon completion of the testing process. Billing for services reimbursed by third-party payers, including Medicare and Medicaid, are recorded as revenues, net of allowances for differences between amounts billed and the estimated receipts from such payers.

We maintain a sales allowance to compensate for the difference inour clinical laboratory's billing practices and insurance company reimbursements. In determining this allowance, we look at several factors, the most significant of which is the average difference between the amount charged and the amount reimbursed by insurance carriers over the prior 18 months, otherwise known as the yearly average adjustment amount. The allowance taken is the averaged yearly average adjustment amount for these prior periods and multiplied by the period's actual gross sales to determine the actual sales allowance for each period.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are reported at realizable value, net of allowances for doubtful accounts, which is estimated and recorded in the period the related revenue is recorded. We estimate and review the collectability of our receivables based on a number of factors, including the period they have been outstanding. Historical collection and payer reimbursement experience is an integral part of the estimation process related to allowances for doubtful accounts. In addition, we regularly assess the state of our billing operations in order to identify issues, which may impact the collectability of these receivables or reserve estimates. Revisions to the allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within general and administrative expenses. Receivables deemed uncollectible are charged against the allowance for doubtful accounts at the time such receivables are written-off. Recoveries of receivables previously written-off are recorded as credits to the allowance for doubtful accounts.

Results of Operations

Year Ended December 31, 2010 and 2009

Revenues, net

Total net revenues for the year ended December 31, 2010 were $3,164,512. Total net revenues consisted of $2,125,000 from the oral flupirtine sublicense fee with Meda AB, which is net of the $375,000 payment to McLean Hospital, $550,553 of laboratory revenues from Adeona Clinical Laboratory and $488,959 of grant revenues from the Qualifying Therapeutic Discovery Project (QTDP) Program to support the our Alzheimer's disease and multiple sclerosis programs currently in clinical testing. Revenues for year ended December 31, 2009 consisted of $103,089 of laboratory revenues from Adeona Clinical Laboratory. Since purchasing Adeona Clinical Laboratory in July of 2009, the client base has increased and the in-house diagnostic testing services have been expanded to include a full array of microbiology testing.

General and Administrative Expenses

General and administrative expenses decreased slightly to $2,700,951 for the year ended December 31, 2010 from $2,708,778 for the year ended December 31, 2009. General and administrative costs in 2009 included acquisition costs relating to the purchase of Adeona Clinical Laboratory of $75,000. General and administrative expenses also include a non-cash charge relating to stock-based compensation expense of $310,098 for the year ended December 31, 2010, compared to $135,770 for the year ended December 31, 2009.

Research and Development Expenses

Research and development expenses increased to $1,579,891 for the year ended December 31, 2010, from $948,891 for the year ended December 31, 2009. This increase of 66% is primarily the result of increased costs associated with the continued development of our product candidates, including outside manufacturing costs, consultant fees, license fees and patent costs. Research and development expenses also include a non-cash charge relating to stock-based compensation expense of $90,290 for the year ended December 31, 2010, compared to $188,166 for the year ended December 31, 2009.

Costs of Laboratory Services

Costs of laboratory services increased to $467,632 for the year ended December 31, 2010, from $126,900 for the year ended December 31, 2009. This increase is primarily the result of the increased costs associated with the expansion of the client base at Adeona Clinical Laboratory, including salary and supply costs. The year ended December 31, 2010 include 12 months of costs compared to the year ended December 31, 2009, that included only 6 months (Adeona Clinical Laboratory was purchased in July of 2009).

Other Expense, net

Other expense was $127,206 compared to $49,925 for the years ended December 31, 2010 and 2009, respectively. Other expense for the year ended December 31, 2010, included an impairment loss of $120,747 relating to obsolete equipment and interest expense of $10,108, offset by a gain on the sale of equipment of $3,236 and interest income of $413. Other income for the year ended December 31, 2009, consisted of $2,965 in interest income. Other expense for the year ended December 31, 2009, included a loss on the sale of equipment of $34,399, interest expense of $9,879 and other expense of $8,612, offset by interest income of $2,965.

Net Loss

Our net loss for the year ended December 31, 2010, was $1,711,159, or $0.08 per common share compared to a $3,731,405, or $0.18 for the year ended December 31, 2009. The decrease in net loss is the result of increased revenues for the year ended December 31, 2010, that included license revenue, increased laboratory revenue and grant revenue.

Liquidity and Capital Resources

We have financed our operations since inception primarily through proceeds from equity financings and various private financings, primarily involving private sales of our common stock and other equity securities, corporate partnering license fees and to a lesser extent from the proceeds from the sale of our common stock under our registration statement on Form S-3, laboratory revenues, miscellaneous equipment sales.

Our cash totaled $2,648,853 at December 31, 2010, a decrease of $66,191 from December 31, 2009. During the year ended December 31, 2010, the primary sources of cash were $2,125,000 from the sublicense fee relating to the Meda Agreement and proceeds from the issuance of common stock to a single investor of $884,724 (net of offering costs of $115,276) and stock option exercises of $129,778. The primary uses of cash for the year ended December 31, 2010, included working capital requirements and $12,663 in capital equipment additions. Our cash at February 28, 2011, was approximately $6.0 million.

Our cash totaled $2,715,044 at December 31, 2009, the primary uses of cash were working capital requirements and the acquisition of Adeona Clinical Laboratory. The primary sources of cash were $25,200 from the sale of miscellaneous equipment and $10,734 from the exercise of stock options.

Our continued operations will primarily depend on whether we are able to generate revenues and profits through partnerships, joint ventures or sales of diagnostic clinical laboratory services and/or raise additional funds through various potential sources, such as license fees from a potential corporate partner, equity and debt financing. Such additional funds may not become available on acceptable terms and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term. We will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs.

Current and Future Financing Needs

We have incurred an accumulated deficit of approximately $43.7 million through December 31, 2010. With the exception of the quarter ended June 30, 2010, we have incurred negative cash flow from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts.

Based on our current plans, we believe that our cash will be sufficient to enable us to meet our planned operating needs for at least the next 12 months.

However, the actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our preclinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and

- the costs and timing of regulatory approvals; and
- profitability of our clinical laboratory diagnostic and microbiology services business.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our shares or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

License and Contractual Agreement Obligations

Below is a table of our contractual obligations for the years 2011 through 2015 as of December 31, 2010.

	Year ended December 31,					
	2011	2012	2013	2014	2015	Total
License Agreements	$ 90,000	$ 37,335	$ 5,000	$ 5,000	$ 5,000	$ 142,335
Lease Agreements	56,814	15,136	-	-	-	71,950
Total	$ 146,814	$ 52,471	$ 5,000	$ 5,000	$ 5,000	$ 214,285

Additional In-Licensed Programs

We may enter into additional license agreements relating to new product candidates.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable because the Company is a smaller reporting company.

Item 8. Financial Statements and Supplemental Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of:
Adeona Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Adeona Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2010 and 2009 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years ended December 31, 2010 and 2009. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included the consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly in all material respects, the consolidated financial position of Adeona Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2010 and 2009, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years ended December 31, 2010 and 2009, in conformity with accounting principles generally accepted in the United States of America.

Berman & Company, P.A.

Boca Raton, Florida
March 30, 2011

Adeona Pharmaceuticals, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31, 2010	December 31, 2009
Assets		
Current Assets		
Cash	$ 2,648,853	$ 2,715,044
Accounts receivable - net	338,510	30,572
Other	343,417	8,967
Total Current Assets	3,330,780	2,754,583
Property and equipment	511,142	1,051,958
Goodwill	178,229	178,229
Deposits and other assets	90,848	90,848
Total Assets	$ 4,110,999	$ 4,075,618
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 265,722	$ 400,475
Accrued liabilities	210,027	8,163
Current portion of capital lease	24,400	17,006
Total Current Liabilities	500,149	425,644
Long Term Liabilities:		
Accounts payable	32,335	93,000
Capital lease	-	12,788
Total Liabilities	532,484	531,432
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 23,420,189 issued and 23,338,707 outstanding and 21,530,834 issued and 21,449,352 outstanding	23,339	21,449
Additional paid-in capital	47,279,416	45,552,918
Accumulated deficit	(43,724,240)	(42,013,081)
Subscription receivable	-	(17,100)
Total Stockholders' Equity	3,578,515	3,544,186
Total Liabilities and Stockholders' Equity	$ 4,110,999	$ 4,075,618

See accompanying notes to consolidated financial statements

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Adeona Pharmaceuticals, Inc. and Subsidiaries
Consolidated Statements of Operations

	For the years ended December 31, 2010	2009
Revenues:		
License revenue, net	$2,125,000	$-
Laboratory revenues, net	550,553	103,089
Grant revenue	488,959	-
Total revenues, net	3,164,512	103,089
Operating Costs and Expenses:		
General and administrative	2,700,951	2,708,778
Research and development	1,579,891	948,891
Costs of laboratory services	467,623	126,900
Total Operating Costs and Expenses	4,748,465	3,784,569
Loss from Operations	(1,583,953)	(3,681,480)
Other Income (Expense):		
Interest income	413	2,965
Gain (loss) on sale of equipment	3,236	(34,399)
Interest expense	(10,108)	(9,879)
Other expense	-	(8,612)
Impairment loss on equipment	(120,747)	-
Total Other Expense, net	(127,206)	(49,925)
Net Loss	$(1,711,159)	$(3,731,405)
Net Loss Per Common Share – Basic and Dilutive	$(0.08)	$(0.18)
Weighted average number of common shares outstanding during the period – Basic and Dilutive	22,393,568	21,318,906

See accompanying notes to consolidated financial statements

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Adeona Pharmaceuticals, Inc. and Subsidiaries
Consolidated Statements of Changes in Stockholders' Equity

	Common Stock $0.001 Par Value					
	Shares	Amount	Additional Paid In Capital	Accumulated Deficit	Subscription Receivable	Total Stockholders' Equity
Balance, December 31, 2008	20,882,839	$ 20,883	$ 45,025,385	$ (38,281,676)	$ -	$ 6,764,592
Stock based compensation	-	-	323,936		-	323,936
Issuance of common stock for consulting fee	235,549	236	65,550	-	-	65,786
Issuance of common stock for license fee	257,813	257	40,992	-	-	41,249
Contributed services - related party	-	-	100,000	-	-	100,000
Issuance of common stock for acquisition of Hart Lab, LLC	50,000	50	18,950	-	-	19,000
Acquisition of treasury stock	(81,482)	(82)	(49,624)	-	-	(49,706)
Issuance of common stock for options exercised	104,633	105	27,729	-	(17,100)	10,734
Net loss for the year ended December 31, 2009	-	-	-	(3,731,405)		(3,731,405)
Balance, December 31, 2009	21,449,352	21,449	45,552,918	(42,013,081)	(17,100)	3,544,186
Stock based compensation	-	-	400,388	-	-	400,388
Issuance of common stock for consulting fees	279,724	280	213,369	-	-	213,649
Issuance of common stock for employee compensation	60,521	61	46,551	-	-	46,612
Issuance of common stock for license fees	81,035	81	70,256	-	-	70,337
Issuance of common stock for options exercised	255,954	256	112,422	-	17,100	129,778
Issuance of common stock, net of issuance costs of $115,276	1,212,121	1,212	883,512	-	-	884,724
Net loss for the year ended December 31, 2010	-	-	-	(1,711,159)	-	(1,711,159)
Balance, December 31, 2010	23,338,707	$ 23,339	$ 47,279,416	$ (43,724,240)	$ -	$ 3,578,515

See accompanying notes to consolidated financial statements

Adeona Pharmaceuticals, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	For the years ended December 31, 2010	2009
Cash Flows From Operating Activities:		
Net loss	$ (1,711,159)	$ (3,731,405)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	400,388	323,936
Stock issued for consulting fees	213,649	65,786
Stock issued as compensation	46,612	-
Stock issued for license fee	70,337	41,249
Contributed services - related party	-	100,000
Depreciation	358,708	382,089
Provision for uncollectible accounts receivable	130,403	97,377
(Gain) loss on sale of equipment	(3,236)	34,399
Impairment loss on equipment	120,747	-
Changes in operating assets and liabilities:		
Accounts receivable	(438,341)	(48,292)
Other current assets	(334,450)	61,562
Deposits and other assets	-	(78,859)
Accounts payable	(195,418)	(138,264)
Accrued liabilities	201,864	(28,442)
Net Cash Used In Operating Activities	(1,139,896)	(2,918,864)
Cash Flows From Investing Activities:		
Purchases of property and equipment	(12,663)	(1,850)
Proceeds from the sale of equipment	77,260	25,200
Cash paid to acquire Adeona Clinical Laboratory (formerly Hart Lab)	-	(201,141)
Cash received from the purchase of Adeona Clinical Laboratory (formerly Hart Lab)	-	5,624
Net Cash Provided By (Used In) Investing Activities	64,597	(172,167)
Cash Flows From Financing Activities:		
Repayments under capital lease	(5,394)	(11,337)
Proceeds from issuance of common stock for stock option exercises	129,778	10,734
Acquisition of treasury stock	-	(49,706)
Proceeds from the issuance of common stock	1,000,000	-
Cash paid as direct offering costs	(115,276)	-
Net Cash Provided By (Used In) Financing Activities	1,009,108	(50,309)
Net decrease in cash	(66,191)	(3,141,340)
Cash at beginning of year	2,715,044	5,856,384
Cash at end of year	$ 2,648,853	$ 2,715,044
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 10,108	$ 2,006

Cash paid for taxes	$ -	$ -
Supplemental disclosure of non-cash investing and financing activities:		
Exchange of equipment	$ 64,016	$ -
Loss on exchange of equipment to settle accounts payable	$ -	$ 5,925

See accompanying notes to consolidated financial statements

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Adeona Pharmaceuticals, Inc. and Subsidiaries
Notes to Consolidated Financial Statements
December 31, 2010 and 2009

1. Organization and Nature of Operations and Basis of Presentation

Description of Business

Adeona Pharmaceuticals, Inc. (the “Company” or Adeona”) is a pharmaceutical company developing innovative medicines for the treatment of serious central nervous system diseases. The Company’s primary strategy is to license product candidates that have demonstrated a certain level of clinical efficacy and develop them to a stage that results in a significant commercial collaboration. Currently, Adeona has the following product candidates in development: a prescription medical food for Alzheimer’s disease, and drugs for multiple sclerosis, fibromyalgia and age-related macular degeneration.

Medical Indication	Product Candidate	Status
Alzheimer’s disease and mild cognitive impairment	reaZin (zinc cysteine)	Pivotal clinical study underway
Multiple sclerosis	Trimesta (oral estriol)	Phase II clinical trial underway
Fibromyalgia	Effirma (oral flupirtine)	Partnered with Meda AB
Age-related macular degeneration	ZincMonoCysteine (zinc-monocysteine)	Phase II clinical trial complete

Adeona’s secondary strategy is to advance its core competency in measuring metabolic serum zinc and copper levels. To further this effort, Adeona purchased HartLab, LLC, on July 13, 2009 and renamed it Adeona Clinical Laboratory. This wholly owned, CLIA-certified clinical testing facility provides a broad array of chemistry and microbiology diagnostic tests in the Greater Chicago area. Adeona Clinical Laboratory developed and offers the CopperProof panel, a series of diagnostic tests for accurately measuring the metabolic serum zinc and copper levels of patients with Alzheimer's disease and mild cognitive impairment. Adeona Clinical Laboratory is a licensed Medicare and Medicaid provider.

Nevada Reincorporation

On October 15, 2009, Adeona Pharmaceuticals, Inc. reincorporated to Nevada. There was no financial statement impact associated with this reincorporation.

Basis of Presentation and Corporate Structure

The Company has eight active subsidiaries, Pipex Therapeutics, Inc. (“Pipex Therapeutics”), Adeona Clinical Laboratory (formerly Hart Lab, LLC), Effective Pharmaceuticals, Inc. (“EPI”), Solovax, Inc. (“Solovax”), CD4 Biosciences, Inc. (“CD4”), Epitope Pharmaceuticals, Inc. (“Epitope”), Healthmine, Inc. (“Healthmine”) and Putney Drug Corp. (“Putney”). As of December 31, 2010, EPI, Adeona Clinical Laboratory, Healthmine and Putney are wholly-owned and Pipex Therapeutics, Solovax, CD4 and Epitope are majority-owned.

For financial reporting purposes, the outstanding common stock of the Company is that of Adeona Pharmaceuticals, Inc. All statements of operations, stockholders' equity and cash flows for each of the entities are presented as consolidated. All subsidiaries were formed under the laws of the State of Delaware on January 8, 2001, except for EPI, which was incorporated in Delaware on December 12, 2000, Epitope which was incorporated in Delaware in January of 2002, Putney which was incorporated in Delaware in November of 2006, Healthmine which was formed in Delaware in December of 2007 and Adeona Clinical Laboratory which was incorporated in Illinois as a limited liability company on August 8, 2005.

2. Acquisition of Adeona Clinical Laboratory (formerly Hart Lab, LLC)

On July 10, 2009, the Company entered into a limited liability company purchase agreement to acquire Adeona Clinical Laboratory (formerly Hart Lab, LLC), an Illinois limited liability company and CLIA-certified clinical laboratory. The Company acquired Adeona Clinical Laboratory to develop and commercialize its diagnostic test panel for the detection of zinc and copper deficiencies in the mature population.

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In consideration for the purchase of Adeona Clinical Laboratory the Company paid $220,141, that consisted of $201,141 in cash and 50,000 unregistered shares of the Company's common stock, having a fair value of $19,000 ($0.36 per share), based upon the quoted closing trading price, in exchange for 100% of the issued and outstanding membership interests of Adeona Clinical Laboratory. The Company also agreed to guarantee and to release the seller from the seller's personal guarantee of the remaining balance of two outstanding clinical equipment leases, totaling $78,859. This balance is included in deposits and other assets. As of December 31, 2010 this amount remained in escrow, however all personal guarantee's of the seller have been removed. In January of 2011, this capital lease was paid in full and the funds were released from escrow (see Note 7).

The purchase price of Adeona Clinical Laboratory was allocated as follows:

Consideration transferred at fair value:		
Cash	$	201,141
Common stock		19,000
Total consideration	$	220,141
Net assets acquired:		
Current assets:		
Cash	$	5,624
Accounts receivable – net of allowance of $4,192		79,657
Equipment		39,465
Total	$	124,746
Current liabilities:		
Accounts payable	$	38,324
Accrued liabilities		12,593
Capital lease		31,917
Total	$	82,834
Net assets acquired	$	41,912
Goodwill	$	178,229

All assets acquired and liabilities assumed had a book value equivalent to fair value. The Company did not record any fair value adjustment for contingencies since there were none.

The Company believed that all assets were recoverable and that no impairment or write-down to net realizable value was required. As a result of this business combination, there was no allocation for a non-controlling interest since the Company acquired a 100% controlling interest in Adeona Clinical Laboratory. Direct costs associated with the acquisition were approximately $65,000.

3. Summary of Significant Accounting Policies

Principles of Consolidation

All inter-company transactions and accounts have been eliminated in consolidation.

Emerging from the Development Stage

During the second quarter of 2010, the Company emerged from the development stage. A development-stage enterprise is one in which planned principle operations have not commenced or if its operations have commenced, there has been no significant revenue. The Company's strategy is to license product candidates that have demonstrated a certain level of clinical efficacy and develop them to a stage that results in a significant commercial collaboration. On May 6, 2010, the Company entered into a Sublicense Agreement (the "Meda Agreement") with Meda AB of Sweden ("Meda") and received an up-front payment of $2.5 million. The execution of the Meda Agreement combined with increasing revenues from Adeona Clinical Laboratory are an indication of the commencement of principal operations, and therefore development-stage reporting is no longer required.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts reported in the consolidated financial statements and accompanying notes. Such estimates and assumptions impact, among others, the following: the amount allocated to goodwill, the estimated useful lives for property and equipment, fair value of warrants and stock options granted for services or compensation, respectively, estimates of the probability and potential magnitude of contingent liabilities, and the valuation allowance for deferred tax assets due to continuing and expected future operating losses.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the consolidated financial statements, which management considered in formulating its estimate could change in the near term due to one or more future confirming events. Accordingly, actual results could differ from those estimates.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are reported at realizable value, net of allowances for doubtful accounts, which is estimated and recorded in the period the related revenue is recorded. The Company estimates and reviews the collectability of its receivables based on a number of factors, including the period they have been outstanding. Historical collection and payer reimbursement experience is an integral part of the estimation process related to allowances for doubtful accounts associated with Adeona Clinical Laboratory. In addition, the Company regularly assesses the state of its billing operations in order to identify issues, which may impact the collectability of these receivables or reserve estimates. Revisions to the allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense. Receivables deemed uncollectible are charged against the allowance for doubtful accounts. Recoveries of receivables previously written-off are recorded as credits to the allowance for doubtful accounts. There were no recoveries during the years ended December 31, 2010 and 2009.

Revenue Recognition
The Company records revenue when all of the following have occurred: (1) persuasive evidence of an arrangement exists, (2) the service is completed without further obligation, (3) the sales price to the customer is fixed or determinable, and (4) collectability is reasonably assured. The Company recognizes milestone payments or upfront payments that have no contingencies as revenue when payment is received. During the year ended December 31, 2010, the Company's streams of revenue were license revenue, laboratory revenue and grant revenue. For the year ended December 31, 2009, the Company's only stream of revenue was laboratory revenue.

License Revenues

The Company's licensing agreements may contain multiple elements, such as non-refundable up-front fees, payments related to the achievement of particular milestones and royalties. Fees associated with substantive at risk performance-based milestones are recognized as revenue upon completion of the scientific or regulatory event specified in the agreement. When the Company has substantive continuing performance obligations under an arrangement, revenue is recognized over the performance period of the obligations using a time-based proportional performance approach. Under the time-based method, revenue is recognized over the arrangement's estimated performance period based on the elapsed time compared to the total estimated performance period. Revenue recognized at any point in time is limited to the amount of non-contingent payments received or due. When the Company has no substantive continuing performance obligations under an arrangement, it recognizes revenue as the related fees become due.

Revenues from royalties on third-party sales of licensed technologies are generally recognized in accordance with the contract terms when the royalties can be reliably determined and collectibility is reasonably assured. To date, the Company has not received any royalty revenues.

On May 6, 2010, the Company entered into a Sublicense Agreement (the “Meda Agreement”) with Meda AB of Sweden (“Meda”) for the development and commercialization of Effirma (oral flupirtine) for fibromyalgia. As consideration for the sublicense, the Company received an up-front payment of $2.5 million upon execution of the Meda Agreement. This payment was recorded as license revenue in June of 2010. Pursuant to the Company’s license agreement with McLean Hospital, the Company paid 15% of the $2.5 million payment ($375,000) to McLean Hospital. The payment to McLean Hospital was netted against the revenues received from Meda AB for financial statement purposes. The Company is also entitled to additional milestone payments of $5 million upon filing of a New Drug Application with the United States Food and Drug Administration for oral flupirtine for fibromyalgia and $10 million upon marketing approval. The Meda Agreement also provides that the Company is entitled to receive net royalties of 7% of net sales of oral flupirtine approved for the treatment of fibromyalgia covered by issued patent claims in the United States and Japan. The Meda Agreement provides that Meda AB will assume all future development costs for the commercialization of oral flupirtine for fibromyalgia. Pursuant to the terms of the Company’s agreement with McLean Hospital, the Company is obligated to pay them half of the royalties the Company receives. Future milestone payments will be recorded as revenue when payment is received as there are no future deliverables, and it is non-refundable. The Company will make similar disclosure for any future license agreements.

Laboratory Revenues

The Company primarily recognizes revenue for services rendered upon completion of the testing process. Billing for services reimbursed by third-party payers, including Medicare and Medicaid, are recorded as revenues, net of allowances for differences between amounts billed and the estimated receipts from such payers.

The Company maintains a sales allowance to compensate for the difference in its billing practices and insurance company reimbursements. In determining this allowance, the Company looks at several factors, the most significant of which is the average difference between the amount charged and the amount reimbursed by insurance carriers over the prior 18 months, otherwise known as the yearly average adjustment amount. The allowance taken is the averaged yearly average adjustment amount for these prior periods and multiplied by the period's actual gross sales to determine the actual sales allowance for each period.

The Company generated revenues from 3 significant insurance providers in 2010 and 2009.

Customer	2010		2009	
A	65	%	37	%
B	11	%	20	%
C	14	%	-	

Grant Revenues

On November 4, 2010, the Company was awarded two grants totaling $488,959 under the Qualifying Therapeutic Discovery Project (QTDP) Program to support the Company's Alzheimer's disease and multiple sclerosis programs currently in clinical testing. The Qualified Therapeutic Discovery Project Grants Program was included in the healthcare reform legislation and established a one-time pool of $1 billion for grants to small biotechnology companies developing novel therapeutics which show potential to: (a) result in new therapies that either treat areas of unmet medical need, or prevent, detect, or treat chronic or acute diseases and conditions; (b) reduce long-term health care costs in the United States; or (c) significantly advance the goal of curing cancer within a the 30-year period. All grant income was recognized in 2010 and there are no future obligations associated with these grants.

During 2010 and March 2011, all amounts awarded under these grants had been received.

See Note 9 regarding the taxability of grant revenues.

Revenues, net

	December 31,			
		2010		2009
License revenue	$	2,500,000	$	-
License fees		(375,000)		-
License revenue, net		2,125,000		-
Laboratory revenues, net		550,553		103,089
Grant revenue		488,959		-
Total revenues, net	$	3,164,512	$	103,089

Risks and Uncertainties

The Company's operations could be subject to significant risks and uncertainties including financial, operational and regulatory risks and the potential risk of business failure. The global economic crisis has caused a general tightening in the credit markets, lower levels of liquidity, increases in the rates of default and bankruptcy, and extreme volatility in credit, equity and fixed income markets. These conditions may not only limit our access to capital, but also make it difficult for our customers, our vendors and us to accurately forecast and plan future business activities.

Cash and Cash Equivalents

Cash and cash equivalents include cash and highly liquid short-term investments with original maturities of three months or less. At December 31, 2010 and 2009, respectively, the Company had no cash equivalents.

On December 31, 2010 and 2009, the Company had amounts in excess of FDIC insured limits totaling $2,111,554 and $0, respectively.

At December 31, 2010 and 2009, the Company had amounts in excess of FDIC insuredhe Company minimizes credit risk associated with cash by periodically evaluating the credit quality of its primary financial institution. The balance at times may exceed the federally insured limit of $250,000 per depositor, per bank.

Property and Equipment

Property and equipment is recorded at cost (greater than $1,000) and depreciated or amortized using the straight-line method over the estimated useful life of the asset or the underlying lease term for leasehold improvements, whichever is shorter. The estimated useful life by asset description is noted in the following table.

Asset Description	Estimated Useful Life
Office equipment and furniture	5 years
Laboratory equipment	7-10 years
Manufacturing equipment	10 years
Leasehold improvements and fixtures	Lesser of estimated useful or life of lease

Depreciation expense was $358,708 and $382,089 for the years ended December 31, 2010 and 2009, respectively. When assets are disposed of, the cost and accumulated depreciation are removed from the accounts. Repairs and maintenance are charged to expense as incurred.

During 2010, the Company reviewed property and equipment for impairment and determined that certain items had been impaired due to obsolescence. As a result of this review, the Company recorded an impairment loss of $120,747 that is recorded as impairment loss on equipment. For the year ended December 31, 2009, there were not significant events or changes in circumstances were identified by the Company that would indicate that the carrying value of an asset was not recoverable.

Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such an event or change in circumstances occurs and potential impairment is indicated because the carrying values exceed the estimated future undiscounted cash flows of the asset, the Company would measure the impairment loss as the amount by which the carrying value of the asset exceeds its fair value.

Goodwill

Goodwill is not amortized, and is tested for impairment at the reporting unit level annually and in interim periods if certain events occur indicating that the carrying value of goodwill may be impaired. A reporting unit is an operating segment for which discrete financial information is available and is regularly reviewed by management. The Company has one reporting unit, Adeona Clinical Laboratory, to which goodwill is assigned.

ASC No. 350 requires a two-step approach to test goodwill for impairment for each reporting unit. The first step tests for impairment by applying fair value-based tests to a reporting unit. The second step, if deemed necessary, measures the impairment by applying fair value-based tests to specific assets and liabilities within the reporting unit. Application of the goodwill impairment tests require judgment, including identification of reporting units, assignment of assets and liabilities to each reporting unit, assignment of goodwill to each reporting unit, and determination of the fair value of each reporting unit. The determination of fair value for a reporting unit could be materially affected by changes in these estimates and assumptions.

The Company will continue to evaluate goodwill for impairment annually. During the years ended December 31, 2010 and 2009, the Company did not identify any indication of goodwill impairment.

Beneficial Conversion Feature

For conventional convertible debt where the rate of conversion is below market value, the Company records a "beneficial conversion feature" ("BCF") and related debt discount.

When the Company records a BCF, the relative fair value of the BCF would be recorded as a debt discount against the face amount of the respective debt instrument. The discount would be amortized to interest expense over the life of the debt.

Derivative Liabilities

Fair value accounting requires bifurcation of embedded derivative instruments such as conversion features in convertible debt or equity instruments, and measurement of their fair value for accounting purposes. In determining the appropriate fair value, the Company uses the Black-Scholes option-pricing model. In assessing the convertible debt instruments, management determines if the convertible debt host instrument is conventional convertible debt and further if there is a beneficial conversion feature requiring measurement. If the instrument is not considered conventional convertible debt, the Company will continue its evaluation process of these instruments as derivative financial instruments.

Once determined, derivative liabilities are adjusted to reflect fair value at each reporting period end, with any increase or decrease in the fair value being recorded in results of operations as an adjustment to fair value of derivatives. In addition, the fair value of freestanding derivative instruments such as warrants, are also valued using the Black-Scholes option-pricing model.

Debt Issue Costs and Debt Discount

The Company may pay debt issue costs, and record debt discounts in connection with raising funds through the issuance of convertible debt. These costs are amortized over the life of the debt to interest expense. If a conversion of the underlying debt occurs, a proportionate share of the unamortized amounts is immediately expensed.

Original Issue Discount

For certain convertible debt issued, the Company may provide the debt holder with an original issue discount. The original issue discount was recorded to debt discount reducing the face amount of the note and is being amortized to interest expense over the life of the debt.

Net Loss per Share

Net earnings (loss) per share is computed by dividing net earnings (loss) less preferred dividends for the period by the weighted average number of common shares outstanding. Diluted earnings (loss) per share is computed by dividing net income (loss) less preferred dividends by the weighted average number of common shares outstanding including the effect of common share equivalents. Since the Company reported a net loss for the years ended December 31, 2010 and 2009, all common equivalent shares would be anti-dilutive; as such there is no separate computation for diluted loss per share. The number of options and warrants for the purchase of common stock, that were excluded from the computations of net loss per common share for the year ended December 31, 2010 were 1,990,444 and 1,070,472, respectively and for the year ended December 31, 2009 were 1,837,583 and 1,070,472, respectively.

Research and Development Costs

The Company expenses research and development costs as incurred. Research and development expenses consist primarily of license fees, manufacturing costs, salaries, stock-based compensation and related personnel costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and other expenses relating to the design, development, testing and enhancement of the Company's product candidates.

Fair Value of Financial Instruments

The fair value accounting standards define fair value as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. Fair value measurements are rated on a three-tier hierarchy as follows:

- Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2 inputs: Inputs, other than quoted prices included in Level 1 that are observable either directly or indirectly; and
- Level 3 inputs: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

In many cases, a valuation technique used to measure fair value includes inputs from multiple levels of the fair value hierarchy described above. The lowest level of significant input determines the placement of the entire fair value measurement in the hierarchy.

For the years ended December 31, 2010 and 2009, the Company had goodwill of $178,229. The Company considers its fair value measure of this goodwill to be based on Level 2 inputs.

The carrying amounts of the Company's short-term financial instruments, including accounts receivable, other current assets, accounts payable and accrued liabilities, approximate fair value due to the relatively short period to maturity for these instruments.

Stock-Based Payment Arrangements

Generally, all forms of stock-based payments, including stock option grants, warrants, restricted stock grants and stock appreciation rights are measured at their fair value on the awards' grant date, based on the estimated number of awards that are ultimately expected to vest. Stock-based compensation awards issued to non-employees for services rendered are recorded at either the fair value of the services rendered or the fair value of the stock-based payment, whichever is more readily determinable. The expense resulting from stock-based payments are recorded in research and development expense or general and administrative expense in the consolidated statement of operations, depending on the nature of the services provided.

Income Taxes

The Company accounts for income taxes in accordance with accounting guidance now codified as FASB ASC Topic 740, “Income Taxes,” which requires that the Company recognize deferred tax liabilities and assets based on the differences between the financial statement carrying amounts and the tax bases of assets and liabilities, using enacted tax rates in effect in the years the differences are expected to reverse. Deferred income tax benefit (expense) results from the change in net deferred tax assets or deferred tax liabilities. A valuation allowance is recorded when it is more likely than not that some or all deferred tax assets will not be realized.

Accounting guidance now codified as FASB ASC Topic 740-20, “Income Taxes – Intraperiod Tax Allocation,” clarifies the accounting for uncertainties in income taxes recognized in accordance with FASB ASC Topic 740-20 by prescribing guidance for the recognition, de-recognition and measurement in financial statements of income tax positions taken in previously filed tax returns or tax positions expected to be taken in tax returns, including a decision whether to file or not to file in a particular jurisdiction. FASB ASC Topic 740-20 requires that any liability created for unrecognized tax benefits is disclosed. The application of FASB ASC Topic 740-20 may also affect the tax bases of assets and liabilities and therefore may change or create deferred tax liabilities or assets. The Company would recognize interest and penalties related to unrecognized tax benefits in income tax expense. At December 31, 2010 and 2009, respectively, the Company did not record any liabilities for uncertain tax positions.

Reclassifications

To conform prior period amounts to current year classifications, the Company has reclassified costs of laboratory services of $126,900 at December 31, 2009, from research and development expenses, as well as, overhead costs of $128,139 from research and development expenses to general and administrative expenses. These reclassifications had no impact on the Company's previously reported results of operations or cash flows.

Recent Accounting Pronouncements

In January of 2010, FASB issued updated guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. This update requires new disclosures on significant transfers of assets and liabilities between Level 1 and Level 2 of the fair value hierarchy (including the reasons for these transfers) and the reasons for any transfers in or out of Level 3. This update also requires a reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In addition to these new disclosure requirements, this update clarifies certain existing disclosure requirements. For example, this update clarifies that reporting entities are required to provide fair value measurement disclosures for each class of assets and liabilities rather than each major category of assets and liabilities. This update also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. This update became effective for the interim and annual reporting period beginning January 1, 2010, except for the requirement to provide the Level 3 activity of purchases, sales, issuances, and settlements on a gross basis, which will become effective for the interim and annual reporting period beginning January 1, 2011. The Company will not be required to provide the amended disclosures for any previous periods presented for comparative purposes. Other than requiring additional disclosures, adoption of this update did not have a material effect on the Company's consolidated financial statements.

In April of 2010, FASB issued ASU No. 2010-17, Revenue Recognition — Milestone Method (Topic 605): Milestone Method of Revenue Recognition. ASU No. 2010-17 codifies the consensus reached in Emerging Issues Task Force Issue No. 08-9, "Milestone Method of Revenue Recognition." ASU No. 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Consideration that is contingent on achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone is judged to meet certain criteria to be considered substantive. Milestones should be considered substantive in their entirety and may not be bifurcated. An arrangement may contain both substantive and non-substantive milestones, and each milestone should be evaluated individually to determine if it is substantive. ASU No. 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted. The adoption of this ASU did not have a material impact on the Company's consolidated results of operations or financial condition.

In August of 2010, the FASB issued Accounting Standards Update ("ASU") No. 2010-05, Measuring Liabilities at Fair Value, or ASU 2010-05, which amends ASC 820 to provide clarification of a circumstance in which a quoted price in an active market for an identical liability is not available. A reporting entity is required to measure fair value using one or more of the following methods: 1) a valuation technique that uses a) the quoted price of the identical liability when traded as an asset or b) quoted prices for similar liabilities (or similar liabilities when traded as assets) and/or 2) a valuation technique that is consistent with the principles of ASC 820. ASU 2010-05 also clarifies that when estimating the fair value of a liability, a reporting entity is not required to adjust to include inputs relating to the existence of transfer restrictions on that liability. The adoption did not have a material impact on the Company's consolidated financial statements.

4. Selected Balance Sheet Information

Accounts receivable

	December 31,	
	2010	2009
Accounts receivable	$ 471,516	$ 33,175
Bad debt allowance - customer	(133,006)	(2,603)
Total	$ 338,510	$ 30,572

Other current assets

	December 31,	
	2010	2009
Grant receivable	$ 320,026	$ -
Prepaid expenses	23,391	8,967
Total	$ 343,417	$ 8,967

Property and equipment

	December 31, 2010	December 31, 2009
Leasehold improvements	$ 864,429	$ 862,359
Manufacturing equipment	410,997	697,854
Computer and office equipment	160,478	234,419
Laboratory equipment	213,908	243,289
	1,649,812	2,037,921
Less accumulated depreciation	(1,138,670)	(985,963)
Total	$ 511,142	$ 1,051,958

Accrued expenses

	December 31, 2010	December 31, 2009
Accrued vendor payments	$ 105,183	$ -
Bonus	100,000	-
Compensation	4,844	8,163
Total	$ 210,027	$ 8,163

5. Stock-Based Compensation

Stock Incentive Plan

During 2001, Pipex Therapeutics' board of directors and stockholders adopted the 2001 Stock Incentive Plan (the "2001 Stock Plan"). This plan was assumed by Pipex in the October of 2006 merger with Sheffield. As of the date of the merger, there were 1,489,353 options issued and outstanding under the 2001 plan. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2001 plan shall not exceed 250,000. All awards pursuant to the 2001 Stock Plan shall terminate upon the termination of the grantee's employment for any reason. Awards include options, restricted shares, stock appreciation rights, performance shares and cash-based awards (the "Awards"). The 2001 Stock Plan contains certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment, as defined in the plan. The 2001 Stock Plan provides for a Committee of the Board to grant awards and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the awards, including acceleration of the vesting of an award at any time. As of December 31, 2010, there were 1,320,354 options issued and outstanding under the 2001 Stock Plan.

On March 20, 2007, the Company's board of directors approved the Company's 2007 Stock Incentive Plan (the "2007 Stock Plan") for the issuance of up to 2,500,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. This plan was approved by stockholders on November 2, 2007. The exercise price of stock options under the 2007 Stock Plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2001 plan shall not exceed 250,000. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of December 31, 2010, there are 1,218,737 options issued and outstanding under the 2007 Stock Plan.

On November 2, 2010, the board of directors and stockholders adopted the 2010 Stock Incentive Plan (“2010 Stock Plan”) for the issuance of up to 3,000,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. The exercise price of stock options under the 2010 Stock Plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company’s common stock on the date the option is granted. Options become exercisable over various period from the date of grant, and generally expire ten years after the grant date. As of December 31, 2010, there are no options issued and outstanding under the 2010 Stock Plan.

In the event of an employee’s termination, the Company will cease to recognize compensation expense for that employee. There is no deferred compensation recorded upon initial grant date, instead, the fair value of the stock-based payment is recognized ratably over the stated vesting period.

The Company has applied fair value accounting for all share based payment awards since inception. The fair value of each option or warrant granted is estimated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes assumptions used in the years ended December 31, 2010 and 2009 are as follows:

	Year ended December 31, 2010	2009
Exercise price	\$0.56 - \$0.87	\$0.37 - \$0.80
Expected dividends	0%	0%
Expected volatility	187% - 207%	198% - 209%
Risk fee interest rate	2.54% - 3.63%	3.16% - 4.75%
Expected life of option	10 years	10 years
Expected forfeitures	0%	0%

The Company records stock based compensation based upon the stated vested provisions in the related agreements, with recognition of expense recorded on the straight line basis over the term of the related agreement. The vesting provisions for these agreements have various terms as follows:

- immediate vesting,
- half vesting immediately and the remainder over three years,
- quarterly over three years,
- annually over three years,
- one-third immediate vesting and remaining annually over two years,
- one half immediate vesting with remaining vesting over nine months,
- one quarter immediate vesting with the remaining over three years; and
- monthly over three years.

During 2010, the Company granted 743,332 options to employees and consultants having a fair value of \$596,816 based upon the Black-Scholes option pricing model. During 2009, the Company granted 979,999 options to employees and consultants having a fair value of \$485,799 based upon the Black-Scholes option pricing model.

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance – December 31, 2008	2,751,663	\$ 1.43	7.73 years	\$ 43,000
Granted	979,999	\$ 0.50		
Exercised	(104,633)	\$ 0.27		
Forfeited	(1,065,697)	\$ 1.09		
Balance – December 31, 2009	2,561,332	\$ 1.26	7.16 years	\$ 304,000
Granted	743,332	\$ 0.80		
Exercised	(255,954)	\$ 0.44		
Forfeited	(509,619)	\$ 0.69		
Balance – December 31, 2010 – outstanding	2,539,091	\$ 1.32	6.97 years	\$ 1,028,000
Balance – December 31, 2010 – exercisable	1,990,444	\$ 1.49	6.35 years	\$ 762,000
Grant date fair value of options granted – 2010		\$ 597,000		
Weighted average grant date fair value – 2010		\$ 0.80		
Grant date fair value of options granted – 2009		\$ 490,000		

Weighted average grant date fair value – 2009	$	0.50
Outstanding options held by related parties – 2010		1,083,160
Exercisable options held by related parties – 2010		858,160
Outstanding options held by related parties – 2009		1,099,828
Exercisable options held by related parties – 2009		766,495

The options outstanding and exercisable at December 31, 2010 are as follows:

	Options Outstanding			Options Exercisable		
Range of Exercise Price	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
$0.09 - $4.57	2,449,092	$ 1.16	7.09 years	1,900,445	$ 1.28	6.47 years
$4.58 - $9.05	89,999	$ 5.93	3.76 years	89,999	$ 5.93	3.76 years
$9.06 - $22.50	-	-	-	-	-	-
	2,539,091	$ 1.32	6.97 years	1,990,444	$ 1.48	6.35 years

The options outstanding and exercisable at December 31, 2009 are as follows:

	Options Outstanding			Options Exercisable		
Range of Exercise Price	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
$0.09 - $4.57	2,458,798	$ 1.05	7.25 years	1,747,132	$ 1.26	6.30 years
$4.58 - $9.05	100,312	$ 5.92	5.07 years	88,229	$ 5.92	5.22 years
$9.06 - $22.50	2,222	$ 22.50	7.02 years	2,222	$ 22.50	7.02 years
	2,561,332	$ 1.26	7.16 years	1,837,583	$ 1.51	6.25 years

The following is a summary of the Company’s non-vested stock options at December 31, 2010:

	Unvested Stock Options	Weighted Average Grant Date Fair Value
Non-vested – December 31, 2009	723,749	$ 1.14
Granted	743,332	$ 0.80
Vested/Exercised	(451,350)	$ 0.24
Forfeited/Cancelled	(467,084)	$ 0.12
Non-vested – December 31, 2010	548,647	$ 0.77
Weighted average remaining period for vesting	2.17 years	

Stock Warrants

On July 2, 2010, the Company issued warrants to purchase 60,606 shares of common stock to a placement agent (see Note 6). The warrants have an exercise price $1.32 and a life of 5 years. The warrants vest on January 1, 2011 and expire December 31, 2015. Since these warrants were granted as part of an equity raise, the Company has treated them as a direct offering cost. The result of the transaction has a $0 net effect to equity. The fair value of the warrants totaled $64,000 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 197%; risk free interest rate of 1.82% and an expected life of 5 years.

As part of the 2006 private placement, the Company issued additional warrants to purchase 958,277 shares of common stock to the placement agent. These warrants have an exercise price of $2.22 and are exercisable until November 27, 2016. On January 14, 2009, 381,020 of these warrants held by an affiliate of the Company's former

Chairman were cancelled for no consideration.

On October 31, 2006, the loans payable to the Company's founder and then Chairman were converted into 1,665,211 shares of common stock and 832,606 warrants to purchase common stock. The warrants had an exercise price of $2.22 and are exercisable until October 31, 2011. These warrants and an additional 7,651 that were also held by the Company's founder and then Chairman, were forfeited on January 14, 2009.

A summary of warrant activity for Adeona for the year ended December 31, 2010 and for the year ended December 31, 2009 is as follows:

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	Number of Warrants	Weighted Average Exercise Price
Balance at December 31, 2008	2,291,749	$ 2.87
Granted	-	-
Exercised	-	-
Forfeited	(1,221,277)	$ 2.23
Balance as December 31, 2009	1,070,472	$ 3.27
Granted	60,606	$ 1.32
Exercised	-	-
Forfeited	-	-
Balance as December 31, 2010	1,131,078	$ 3.49

A summary of all outstanding and exercisable warrants as of December 31, 2010 is as follows:

Exercise Price	Warrants Outstanding	Warrants Exercisable	Weighted Average Remaining Contractual Life
$ 0.41	5,000	5,000	0.38 years
$ 1.32	60,606	-	5.00 years
$ 2.22	49,552	49,552	0.79 years
$ 2.22	577,257	577,257	5.91 years
$ 3.30	61,207	61,207	4.41 years
$ 3.75	50,000	50,000	5.13 years
$ 6.36	327,456	327,456	1.86 years
	1,131,078	1,070,472	4.33 years

Options of Subsidiaries

As of December 31, 2010, CD4 Biosciences, Inc., a majority-owned subsidiary of Adeona, has a total of 20,000 stock options outstanding and exercisable. These stock options have an exercise price of $0.20 and a remaining contractual life of 1.37 years.

As of December 31, 2010, Epitope, a majority-owned subsidiary of Adeona, has 50,000 stock options outstanding and 20,000 stock options exercisable. These stock options have an exercise price of $0.001 and a remaining contractual life of 7.50 years.

6. Stockholders' Equity

Year Ended December 31, 2009

During the year ended December 31, 2009, the Company issued 104,633 shares of common stock, in connection with the exercise of stock options, for proceeds of $27,834. Of this amount $17,100 was not received until after December 31, 2009. The Company also issued 235,549 shares of common stock for consulting services, having a fair value of $65,786 ($0.28 per share) and 257,813 shares of common stock for license fees, having a fair value of $41,249 ($0.16 per share), based on the quoted closing trading prices.

During January of 2009, Steve Kanzer, the then current Chairman of the Board, agreed to forego his $100,000 guaranteed bonus due to him on January 1, 2009. As a result of this, the $100,000 was recorded as contributed services in 2009.

On July 10, 2009, the Company entered into a limited liability company purchase agreement to acquire Adeona Clinical Laboratory (formerly Hart Lab, LLC), an Illinois limited liability company and CLIA-certified clinical laboratory. In consideration for the purchase of Adeona Clinical Laboratory the Company issued 50,000 unregistered shares of the Company's common stock, having a fair value of $19,000 ($0.36 per share), based upon the quoted closing trading price.

Year Ended December 31, 2010

On July 2, 2010, the Company sold 1,212,121 shares of the Company's common stock at a closing price of $0.825 for gross proceeds of $1,000,000. The Company paid direct offering costs of $115,276. See Note 5 regarding warrants granted with this offering.

During the year ended December 31, 2010, the Company issued 255,954 shares of common stock, in connection with the exercise of stock options, for proceeds of $129,778. The Company also issued 279,724 shares of common stock for consulting services, having a fair value of $213,649 ($0.76 per share), 81,035 shares of common stock for license fees, having a fair value of $70,337 ($0.87 per share), and 60,521 shares of common stock for employment service, having a fair value of $46,612 ($0.77 per share). The fair value of these issuances were based upon the quoted closing trading prices.

7. License, Collaborative and Employment Agreements and Commitments

License Agreements

The Company has entered into various option and license agreements for the use of patents and their corresponding applications. These agreements have been entered into with various educational institutions and hospitals. These agreements contain payment schedules or stated amounts due for (a) option and license fees, (b) expense reimbursements, and (c) achievement of success milestones. All expenses related to these agreements have been recorded as research and development.

Research Agreement

In September of 2005, the Company entered into a three-year research agreement with the University of Michigan. Pursuant to that agreement, the Company sponsored research of approximately $460,000 per year. On March 20, 2008, the Company terminated the agreement. On March 24, 2009, the Company entered into a payment plan with the University of Michigan to pay the outstanding balance of $197,335. The Company agreed to pay $5,000 per month, until the balance is paid in full. At December 31, 2010, the balance is $92,335. The Company recorded $60,000 as a short term accounts payable, the remaining $32,335 is recorded as a long term accounts payable.

Employment Agreements

On February 6, 2010, the Company executed a three-year employment agreement with its Chairman, Chief Executive Officer and President. The agreement provides for an annual base salary of $199,000, discretionary performance and transactional bonus payments, and 400,000 stock options with an exercise price equal to the market price on the date of grant. Of these stock options, 100,000 vested immediately upon grant and the remainder will vest pro rata, on a monthly basis, over the following thirty-six months. The fair value of the options totaled $327,680 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 204.5%; risk free interest rate of 3.59% and an expected life of 10 years.

Other Commitments

As of December 31, 2010, amounts due for license agreements are as follows:

Year Ending December 31,		
2011	$	90,000
2012		37,355

2013		5,000
2014		5,000
2015		5,000
Total	$	142,335

Operating Lease

During 2007, the Company entered into a non-cancelable operating lease for office, laboratory and production space in Ann Arbor, Michigan. This lease expired on February 28, 2011. In March of 2011, the Company entered into a month-to-month lease, at a different location, for office and laboratory space in Ann Arbor, MI. The committed amount due in 2011 is $20,488.

During the years ended December 31, 2010 and 2009 the Company recognized rent expense of $214,315 and $207,160, respectively.

Capital Lease

In June of 2006, the Company acquired $65,000 of equipment (as discussed in Note 2) under a non-cancelable capital lease. The Company agreed to guarantee and to release the seller from the seller's personal guarantee of the remaining balance and the amount was placed in escrow. The effective interest rate of the lease was 8.51%. Related monthly payments of principal and interest were $1,417 over a period of sixty months. In September 2008, the lessor extended the term for repayment by eight months, with a final maturity date of January 2012. The remaining balance of this capital lease at December 31, 2010 is $24,400. In January of 2011, this capital lease was paid in full and the funds were released from escrow.

8. Stock Repurchase Program

On April 3, 2009, the Company's Board of Directors approved a Stock Repurchase Program authorizing the Company to repurchase, from time-to-time and through December 31, 2009, up to $1 million of its common stock, up to a maximum of four million shares at prices of up to $5 per share. As of December 31, 2009, the Company had repurchased 81,482 shares for approximately $50,000 ($0.61 per share), based upon the quoted closing trading price. These treasury shares are not included in the computation of earnings (loss) per share and are deemed to be canceled and retired.

9. Income Taxes

There was no income tax expense for the years ended December 31, 2010 and 2009 due to the Company's net losses.

The Company's tax expense differs from the "expected" tax expense for the years ended December 31, 2010 and 2009, (computed by applying the Federal Corporate tax rate of 34% to loss before taxes and 5.5% for Michigan State Corporate taxes, the blended rate used was 37.63%), as follows:

		2010		2009
Computed "expected" tax benefit - Federal	$	(550,000)	$	(1,199,000)
Computed "expected" tax benefit - State		(94,000)		(205,000)
Non-taxable federal grant		(184,000)		-
Meals, entertainment and other		5,000		54,000
Non-deductible stock based compensation		150,000		162,000
Contributed services related party		-		38,000
Change in valuation allowance	$	673,000	$	1,150,000

The effects of temporary differences that gave rise to significant portions of deferred tax assets at December 31, 2010 and 2009 are as follows:

Deferred tax assets:		2010		2009
Stock issued for services	$	(223,000)	$	-
Bad debt – change in allowance		(49,000)		-
Non-operating loss carry-forward		(8,644,000)		(8,243,000)
Total gross deferred tax assets		(8,916,000)		(8,243,000)
Less valuation allowance		8,916,000		8,243,000
Net deferred tax assets	$	-	$	-

At December 31, 2010, the Company has a net operating loss carry-forward of approximately $22,970,000 available to offset future taxable income expiring through 2030. Utilization of these net operating losses may be limited due to potential ownership changes under Section 382 of the Internal Revenue Code.

The valuation allowance at December 31, 2009 was approximately $8,243,000. The net change in valuation allowance during the year ended December 31, 2010 was an increase of approximately $673,000. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The ultimate realization of deferred income tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred income tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on consideration of these items, Management has determined that enough uncertainty exists relative to the realization of the deferred income tax asset balances to warrant the application of a full valuation allowance as of December 31, 2010.

During 2010, the Company received grant revenue of $488,959. Under the terms of the grant, this revenue is not taxable.

10. Subsequent Events

On January 28, 2011, the Company sold 2,857,144 shares of common stock and 1,428,572 warrants for $4,000,000. Direct offering costs were approximately $300,000. Each warrant is exercisable for thirteen months at $2.00 per share. The warrants have an anti-dilution price protection feature; if the Company issues securities at a price per share that is less than $2.00 per share, the warrant holders will be ratcheted down to the lower offering price. However, the Company has instituted a floor price of $1.40 per share in connection with the price protection.

The Company measured the fair value of the warrants at $785,857 using a Black-Scholes valuation model; these warrants were not indexed to the Company's own stock. The fair value at issuance was based upon the following management assumptions:

Expected dividends	0%
Expected volatility	118.7%
Expected term: warrants	1.08 years
Risk free interest rate	0.24%

The Company recorded the derivative liability and related derivative expense equal to the fair value of the warrants at the commitment date.

Item 9. Changes In and Discussions with Accountants on Accounting and Financial Disclosures

None.

Item 9A(T). Controls and Procedures

Disclosure Controls and Procedures

The Company has adopted and maintains disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Form 10-K, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the Securities and Exchange Commission. The Company's disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. As required under Exchange Act Rule 13a-15, the Company's management, including the Chief Executive Officer and Principal Financial Officer, has conducted an evaluation of the effectiveness of disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, the Company's CEO concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Company's CEO, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15. The Company's internal control over financial reporting is designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published financial statements. Management conducted an assessment of the Company's internal control over financial reporting based on the framework and criteria established by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on the assessment, management concluded that, as of December 31, 2010, the Company's internal control over financial reporting is effective based on those criteria.

The Company's management, including its Chief Executive Officer and Principal Financial Officer, does not expect that the Company's disclosure controls and procedures and its internal control processes will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of error or fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that the breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Changes in Internal Control

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during our fiscal quarter ended December 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Below is certain information regarding our directors and executive officers.

Name	Age	Position
James S. Kuo, M.D., M.B.A.	46	Chairman, Chief Executive Officer, Chief Financial Officer and President
Steve H. Kanzer, C.P.A., Esq.	47	Director
Jeffrey J. Kraws, M.B.A.	46	Director
Jeff Lucero Riley, M.B.A.	48	Director
Jeffrey Wolf, M.B.A., Esq.	48	Director

James S. Kuo, M.D., M.B.A. Dr. Kuo has been a director since February of 2007. Effective February 6, 2010, Dr. Kuo was appointed as our Chairman of the Board, Chief Executive Officer, Chief Financial Officer and President. Dr Kuo was the Chairman and Chief Executive Officer of Cordex Pharma, Inc., a public biopharmaceutical company, from September of 2007 until February 1, 2010 and remained as a director until March 13, 2010. From 2003 to 2006, he served as founder, Chairman and Chief Executive Officer of BioMicro Systems, Inc,. a private venture-backed, microfluidics company. Prior to that time, Dr. Kuo was a founder, President and Chief Executive Officer of Discovery Laboratories, Inc. where he raised over $22 million in initial private funding and was instrumental in the company going public. Dr. Kuo was also a founder and board member of Monarch Labs, LLC, a private medical device company. Dr. Kuo is the former Managing Director of Venture Analysis for Healthcare Ventures, LLC, which managed $378 million in venture funds. He has also been a senior licensing and business development executive at Pfizer, Inc., where he was directly responsible for cardiovascular licensing and development. After studying molecular biology and receiving his B.A. at Haverford College, Dr. Kuo simultaneously earned an M.D. from the University of Pennsylvania School of Medicine and an M.B.A. from the Wharton School of Business. He holds a B.A. in molecular biology from Haverford College. From 2004 until October of 2009 Dr. Kuo also served as a director of Soligenix, Inc.

Dr. Kuo brings to the Board significant executive leadership and operational experience. Dr. Kuo's prior business experience and board service, along with his tenure at Adeona, gives him a broad and extensive understanding of our operations and the proper role and function of the Board. His prior service on the board of other public companies has provided him with a strong corporate governance expertise. In addition, his medical background allows him to bring to the Board extensive knowledge about our industry. Due to his business background, he has a broad understanding of the operational, financial and strategic issues facing public companies.

Steve H. Kanzer, C.P.A., Esq. Mr. Kanzer is a co-founder and served as our President from our inception in February of 2001 until May of 2006. Mr. Kanzer previously served as our Chief Executive Officer from September of 2004 until November of 2008, Chairman of the Board until February 6, 2010 and currently serves as a director. Mr. Kanzer has also been a director and officer of our subsidiaries, including Solovax, Inc., Effective Pharmaceuticals, Inc., Putney Drug Corp. Epitope Pharmaceuticals, Inc. and CD4 Biosciences, Inc. Since December 2000, he has served as co-founder and Chairman of Accredited Ventures Inc. and Accredited Equities Inc., a venture capital firm and investment bank, respectively, which both specialize in the biotechnology industry. Prior to founding Accredited Ventures and Accredited Equities in December 2000, Mr. Kanzer served as Senior Managing Director-Head of Venture Capital at Paramount Capital from 1991 until December of 2000. While at Paramount Capital, Mr. Kanzer was involved in the formation and financing of a number of biotechnology companies and held various positions in these companies. Prior to joining Paramount Capital in 1992, Mr. Kanzer was an attorney at the law firm of Skadden, Arps, Slate, Meagher & Flom in New York where he specialized in mergers and acquisitions. Mr. Kanzer received a J.D. from New York University School of Law in 1988 and a B.B.A. in Accounting from Baruch College in 1985, where he was a Baruch Scholar. Mr. Kanzer is active in university-based pharmaceutical technology licensing and has served as Co-Chair of the New York Chapter of the Licensing Executives Society.

Mr. Kanzer has been associated with Adeona since inception and brings to the Board extensive knowledge about our business operations and in particular our licenses and products. Mr. Kanzer also brings to the Board significant executive leadership and operational experience. Mr. Kanzer's legal background provides him with a broad understanding of the legal issues facing Adeona, the financial markets and the financing opportunities available to Adeona.

Jeffrey J. Kraws, M.B.A. Mr. Kraws has been a director since January of 2006. Mr. Kraws is Chief Executive Officer and co-founder of Crystal Research Associates. Well known and respected on Wall Street, Mr. Kraws has received some of the most prestigious awards in the industry. Among other awards, he was given a 5-Star Rating" in 2001 by Zacks and was ranked the number one analyst among all pharmaceutical analysts for stock performance in 2001 by Starmine.com. Prior to founding Crystal Research Associates, Mr. Kraws served as co-president of The Investor Relations Group (IRG), a firm representing primarily under-followed, small-capitalization companies. Previously, Mr. Kraws served as a managing director of healthcare research for Ryan Beck & Co. and as director of research/senior pharmaceutical analyst and managing director at Gruntal & Co., LLC (prior to its merger with Ryan Beck & Company). Mr. Kraws served as managing director of the healthcare research group and senior pharmaceutical analyst at First Union Securities (formerly EVEREN Securities); as senior U.S. pharmaceutical analyst for the Swedish-Swiss conglomerate Asea Brown Boveri; and as managing director and president of the Brokerage/Investment Banking operation of ABB Aros Securities, Inc. He also served as senior pharmaceutical analyst at Nationsbanc Montgomery Securities, BT Alex Brown & Sons, and Buckingham Research. Mr. Kraws also has industry experience, having been responsible for competitive analysis within the treasury group at Bristol-Myers-Squibb Company. He holds an M.B.A. from Cornell University and a B.S. degree from State University of New York-Buffalo. During 2006 through February of 2007, Mr. Kraws served as our Vice President of Business Development, on a part-time basis.

Mr. Kraws brings a strong business background to Adeona, having worked as a pharmaceutical analyst for over 22 years. Mr. Kraws brings to the Board significant strategic, business and financial experience related to the business and financial issues facing pharmaceutical companies. Mr. Kraws has a broad understanding of the operational, financial and strategic issues facing pharmaceutical companies. Through his services as Adeona's Vice President of Business Development during 2006 and a part of 2007, he developed extensive knowledge of Adeona's business.
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Jeff Lucero Riley, M.B.A. Mr. Riley has been a director since March 16, 2010. Since November of 2009, Mr. Riley has served as the Managing Director of Black Crow Ventures, a life science-focused consulting firm with a commercial and transactional focus. He sits on the advisory boards of an Australia-based venture fund (Queensland Biocapital Fund) and Ruga Corporation, a Stanford University spin-out drug discovery company focused on endoplasmic reticulum stress targets. Mr. Riley has held senior corporate and commercial development positions with biotech companies Amphora Discovery, Ontogen Corporation, and AvMax. In these positions, he was responsible for raising equity and negotiating alliances including in-licensing, out-licensing, distribution agreements, technology acquisitions and research agreements with large pharmaceutical companies and government agencies. Mr. Riley's pharmaceutical experience includes commercial management and mergers and acquisition roles for Pfizer and SmithKline Beecham. Additionally, Mr. Riley served as CFO and VP Corporate Development for Nichols Institute Diagnostics, a CLIA-certified molecular diagnostics and reference lab, later acquired by Quest Diagnostics. Prior to attending university, Mr. Riley served in the U.S. Army. Mr. Riley's education includes: a B.S. in International Relations, a B.S. in Biology (Boise State), coursework at UCSF/Berkeley in drug discovery/development and participated in a dual-degree graduate program, an M.B.A./M.I.M. sponsored by Arizona State University and the American Graduate School of International Management (Thunderbird).

Mr. Riley brings to the Board extensive knowledge of the pharmaceutical industry. Having served in senior corporate positions in biotech and pharmaceutical companies he has a vast knowledge of the industry. His business experience provides him with a broad understanding of the operational, financial and strategic issues facing public companies.

Jeffrey Wolf, M.B.A., Esq. Mr. Wolf has substantial experience in creating, financing, nurturing and growing new ventures based upon breakthrough research and technology. Mr. Wolf is the founding partner of Seed-One Ventures, LLC, a venture capital group focused on seed-stage technology-based investments. Mr. Wolf has been a founder of Elusys Therapeutics, Inc., an antibody-based therapeutic company, Tyrx Pharma, Inc., a biopolymer-based company, Sensatex, Inc., a medical device company and Generation Mobile, Inc. a telecommunications company. Prior to founding Seed-One Ventures, Mr. Wolf served as the Managing Director of The Castle Group, Ltd., a biomedical venture capital firm. At both organizations, Mr. Wolf was responsible for supervising the formation and funding of new technology, biomedical, and service oriented ventures. Mr. Wolf currently sits on the board of Elusys Therapeutics and Netli, Inc. Mr. Wolf received an M.B.A. from Stanford Business School, a J.D. from New York University School of Law and a B.A. with honors in Economics from the University of Chicago.

Mr. Wolf also has extensive knowledge of the industry and in particular research and development. His legal and business background provide him with a broad understanding of the legal, operational, financial and strategic issues facing Adeona. Having served as a board member on other public company boards, Mr. Wolf has an extensive understanding of the operational, financial and strategic issues facing public companies.

Directors' Term of Office

Directors will hold office until the next annual meeting of stockholders and the election and qualification of their successors. Officers are elected annually by our board of directors and serve at the discretion of the board of directors.

Audit Committee

The Audit Committee is comprised of Mr. Wolf and Mr. Riley. The Audit Committee is responsible for recommending our independent public accounting firm and reviewing management's actions in matters relating to audit functions. The Committee reviews with our independent public accountants the scope and results of the audit engagement and the system of internal controls and procedures. The Committee also reviews the effectiveness of procedures intended to prevent violations of laws. The Committee also reviews, prior to publication, our reports on Form 10-K and Form 10-Q. Our board has determined that all audit committee members are independent under applicable SEC regulations. Our board of directors has determined that Mr. Riley qualifies as an "audit committee financial expert" as that term is used in Section 407 of the Sarbanes-Oxley Act of 2002. Our Audit Committee charter is located on our website www.adeonapharma.com.

Compensation Committee

Our Compensation Committee consists of Mr. Wolf and Mr. Kraws. This committee performs several functions, including reviewing all forms of compensation provided to our executive officers, directors, consultants and employees, including stock compensation. Our Compensation Committee charter is located on our website www.adeonapharma.com.

Nominations Committee

Our Nominations Committee consists of Mr. Wolf and Mr. Riley. This committee performs several functions, including identifying qualified individuals to become members of your board and recommending appointments to the board and appointment of executive officers. The committee seeks individuals who have an inquisitive and objective perspective, practical wisdom and mature judgment, and the talent and expertise to understand, and provide sound and prudent guidance with respect to, our activities, operations and interests. Candidates must also be individuals who have the highest personal and professional integrity, who have demonstrated exceptional ability and judgment, and who are likely to be the most effective, in conjunction with the other members of your board, in collectively serving the long-term interests of stockholders. Our Nominations Committee charter is located on our website www.adeonapharma.com.

The Nominations Committee will consider director nominees recommended by security holders. Recommendations should be submitted in writing and a reasonable time before we mail our proxy materials for the applicable meeting of stockholders. In order for a proposal to be considered for inclusion in the proxy statement for next year's annual meeting, the written proposals must be received by us June 2, 2011 and should be submitted to the Corporate Secretary, Adeona Pharmaceuticals, Inc., 3985 Research Park Drive, Suite 200, Ann Arbor, Michigan 48108.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our executive officers, directors and persons who beneficially own more than 10 percent of a registered class of the Adeona's equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. Such officers, directors and persons are required by SEC regulation to furnish us with copies of all Section 16(a) forms that they file with the SEC.

Based solely on a review of the copies of such forms that were received by us, or written representations from certain reporting persons that no Form 5s were required for those persons, we are not aware of any failures to file reports or report transactions in a timely manner during the year ended December 31, 2010.

Code of Ethics

We have long maintained a Code of Conduct which is applicable to all of our directors, officers and employees. In addition, we have adopted a Code of Ethics for Financial Management which applies to our Chief Executive Officer, Chief Financial Officer, Treasurer and Controller. Each of these codes is posted on our website at www.adeonapharma.com.

Item 11. Executive Compensation

Summary Compensation Table

The following table summarizes all compensation awarded to, earned by or paid to Max Lyon and James S. Kuo, M.D., M.B.A., who each served as the our chief executive officer and chief financial officer during the fiscal year ended December 31, 2010 or 2009.

Name and Principal Position	Year	Salary ($)		Bonus ($)	Options Awards($) (1)	All Other Compensation ($) (2)	Total ($)
Max Lyon, Former President,	2010	$ 42,723	(3)	$ -	$ -	$ -	$ 42,723
Former CEO and Former CFO	2009	$ 104,519		$ -	$ 152,000	$ -	$ 256,519
James S. Kuo, M.D., M.B.A., President, CEO and CFO	2010	$ 178,717	(4)	$ 20,406	$ 328,000	$ 9,947	$ 527,123

(1) Amount reflects the grant date fair value of the named executive officer’s stock options, calculated in accordance with FASB ASC Topic 718. For a discussion of the assumptions used in calculating these values, see Note 6 to our consolidated financial statements

(2) The all other compensation column includes the portion of medical and vision premiums paid by us on behalf of our named executive officer. These benefits are offered to all full-time Adeona employees.

(3) Mr. Lyon resigned as our President, Chief Executive Officer and Chief Financial Officer effective as of February 10, 2010. This amount represents the amount earned by Mr. Lyon prior to his resignation and severance in the amount of $22,613 paid in shares of Adeona common stock.
(4) Effective February 10, 2010, Dr. Kuo was appointed as our President, Chief Executive Officer and Chief Financial Officer. This amount represents the amount earned by Dr. Kuo during fiscal year 2010 after his employment commenced.

Outstanding Equity Awards at Fiscal Year End

The table below reflects all outstanding equity awards made to each of the named executive officers that are outstanding at December 31, 2010. We currently grant stock-based awards pursuant to our 2010 Stock Incentive Plan (the "2010 Stock Plan") and have outstanding awards under our 2001 Stock Incentive Plan (the "2001 Stock Plan") and 2007 Stock Incentive Plan (the "2007 Stock Plan").

Name	Grant Date (1)		Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable		Option Exercise Price ($)	Option Expiration Date
James S. Kuo	02/06/10	(2)	175,000	225,000	$	0.82	02/06/20
	12/22/09		-	8,333	$	0.53	12/22/19
	10/02/08		-	8,333	$	0.53	10/02/18
	11/02/07		-	8,333	$	5.85	11/02/17
	02/07/07		-	25,000	$	3.87	02/07/17

(1) Unless otherwise noted, options vest immediately on the date of grant.
(2) These options vest 100,000 shares immediately and the remainder in equal monthly installments over a three-year period beginning on the date of grant.

Employment Agreements

On February 6, 2010, Max Lyon resigned as President, Chief Executive Officer and Chief Financial Officer, and James S. Kuo, M.D., M.B.A., was thereby appointed Chairman, Chief Executive Officer, ,Chief Financial Officer and President. The following are summaries of the agreements that were executed in connection with these changes during fiscal year 2010.

Dr. Kuo's Agreement

In connection with his appointment, Dr. Kuo entered into a three-year employment agreement with us (the "Employment Agreement"). Pursuant to the Employment Agreement, Dr. Kuo is entitled to an annual base salary of $199,000 and is eligible for discretionary performance and transactional bonus payments. Additionally, Dr. Kuo was granted an initial stock option to purchase 400,000 shares of our common stock (with an exercise price of $0.82, the fair market value on February 6, 2010, which is the date of grant). Of this stock option grant, 100,000 shares vested immediately and the remainder vests in 36 equal monthly installments. Dr. Kuo will perform substantially all of his professional duties from our offices. The Employment Agreement also includes confidentiality obligations and invention assignments by Dr. Kuo.

Mr. Lyon's Agreement

In connection with his resignation, Mr. Lyon received $22,613 paid in shares of our common stock, as a severance payment. This payment was made pursuant to a Separation Agreement, dated February 6, 2010, between Mr. Lyon and us.

Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2010 regarding the compensation of our directors who at December 31, 2010 were not also named executive officers.

Name	Fees Earned or Paid in Cash	Option Awards(1)	Other Compensation	Total
Steve H. Kanzer	$ 2,000	$ 6,166	$ -	$ 8,166
Jeffrey J. Kraws	$ 5,000	$ 6,166	$ -	$ 11,166
Jeff Lucero Riley	$ 9,000	$ 27,916	$ -	$ 36,916
Jeffrey Wolf	$ 13,000	$ 6,166	$ -	$ 19,166

(1) The amounts in the "Option awards" column reflect the dollar amounts recognized as compensation expense for the financial statement reporting purposes for stock options for the fiscal year ended December 31, 2010 in accordance with SFAS 123(R). The fair value of the options was determined using the Black-Scholes model.

During 2007, director compensation for independent members was approved at $2,000 per board meeting that they attend in person, $1,000 per telephonic board meeting and $500 per committee meeting. In addition, We grant independent members of the board of directors upon appointment 25,000 stock options to purchase shares of our common stock at an exercise price equal to the fair market value of the our common stock on the date of grant, and an additional 8,333 stock options each year. We also reimburse directors for travel and other out-of-pocket expenses incurred in attending board of director and committee meetings.

Equity Compensation Plan Information

The following table sets forth information about the securities authorized for issuance under our equity compensation plans for the fiscal year ended December 31, 2010.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options	Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by stockholders:			
2001 Stock Incentive Plan	1,320,354	$ 1.15	22,690
2007 Stock Incentive Plan	1,218,737	$ 1.53	230,341
2010 Stock Incentive Plan	-	$ -	3,000,000
Equity compensation plans not approved by stockholder	N/A	N/A	N/A
Total	2,539,091	$ 1.33	3,253,031

Item 12. Security Ownership of Certain Beneficial Owners

The following table sets forth information, as of March 25, 2011, or as otherwise set forth below, with respect to the beneficial ownership of our common stock (i) all persons know to us to be the beneficial owners of more than 5% of the outstanding shares of our common stock, (ii) each of our directors and our executive officer named in the Summary Compensation Table, and (iii) all of our directors and our executive officer as a group.

Principal Stockholders Table

	Shares Owned(1)	
Name and Address of Beneficial Ownership(2)	Number of Shares	Percentage of Shares(3)
Accredited Venture Capital, LLC(4)	7,086,380	26.96 %
Firebird Capital(5)	1,496,550	5.69 %
Empery Asset Management, LP(6)	2,142,858	7.94 %
Steve H. Kanzer(7)	7,766,017	29.20 %
Jeffrey J. Kraws(8)	287,105	1.08 %
James S. Kuo(9)	274,999	1.04 %
Jeffrey Wolf(10)	83,332	*
Jeff Lucero Riley(11)	58,333	*

All officers and directors as a group (5 persons)	8,469,786	31.03	%

* represents less than 1% of our common stock

(1) Beneficial ownership is determined in accordance with SEC rules and generally includes voting or investment power with respect to securities. Except as indicated in the footnotes to the table, to the knowledge of the Company, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them, subject to community property laws, where applicable. Pursuant to the rules of the SEC, the number of shares of our common stock deemed outstanding includes shares issuable pursuant to options held by the respective person or group that are currently exercisable or may be exercised within 60 days of March 25, 2011.

(2) The address for each beneficial owner except Firebird Capital and Empery Asset Management, LP is 3985 Research Park Drive, Suite 200, Ann Arbor, Michigan 48108.
(3) As of March 25, 2011, we had 26,289,247 shares of common stock outstanding.
(4) Consists of 7,086,380 shares of common stock issued to Accredited Venture Capital, LLC. Pharmainvestors, LLC is the managing member of Accredited Venture Capital, LLC, and Mr. Kanzer is the managing member of Pharmainvestors, LLC. As such, Mr. Kanzer may be considered to have control over the voting and disposition of the shares registered in the name of Accredited Venture Capital, LLC, and therefore, such shares are also included in the shares listed as held by Mr. Kanzer. Mr. Kanzer disclaims beneficial ownership of those shares, except to the extent of his pecuniary interest.
(5) Consists of 743,275 shares of common stock issued to Firebird Global Master Fund, Ltd and 753,275 shares of common stock issued to Firebird Global Master Fund II, Ltd. The address for Firebird Capital is 152 West 57th Street, 24th Floor, New York, New York 10019.
(6) Consists of 1,428,572 shares of common stock and 714,286 warrants to purchase common stock currently exercisable issued to Empery Asset Management, LP. The address for Empery Asset Management, LP is 120 Broadway, Suite 1019, New York, New York 10271.
(7) Includes 7,086,380 shares of common stock issued to Accredited Venture Capital, LLC and 304,391 shares issuable upon exercise of options held by Mr. Kanzer that are exercisable within the 60-day period following March 25, 2011.
(8) Includes 287,105 shares issuable upon exercise of options held by Mr. Kraws that are exercisable within the 60-day period following March 25, 2011.
(9) Includes 274,999 shares issuable upon exercise of options held by Dr. Kuo that are exercisable within the 60-day period following March 25, 2011.
(10) Includes 83,332 shares issuable upon exercise of options held by Mr. Wolf that are exercisable within the 60-day period following March 25, 2011.
(11) Includes 58,333 shares issuable upon exercise of options held by Mr. Riley that are exercisable within the 60-day period following March 25, 2011.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Pursuant to our charter, our Audit Committee, shall review on on-going basis for potential conflicts of interest, and approve if appropriate, all our “Related Party Transactions” as required by Section 120 of the NYSE Amex Company Guide. For purposes of the Audit Committee Charter, “Related Party Transactions” shall mean those transactions required to be disclosed pursuant to SEC Regulation S-K, Item 404.

Item 14. Principal Accountant Fees and Services

Berman & Company, P.A. serves as our independent registered public accounting firm.

Independent Registered Public Accounting Firm Fees and Services

The following table sets forth the aggregate fees including expenses billed to us for the years ended December 31, 2010 and 2009 by Berman & Company, P.A.

	December 31, 2010	December 31, 2009
Audit Fees and Expenses(1)	$ 86,305	$ 63,500
Audit Related Fees(2)	2,000	54,140
All Other Fees	-	-
	$ 88,305	$ 117,640

(1) Audit fees and expenses were for professional services rendered for the audit and reviews of the consolidated financial statements of the Company, professional services rendered for issuance of consents and assistance with review of documents filed with the SEC.
(2) The audit related fees were for professional services rendered for additional filing and consents for registration statements and forms in connection with equity offerings filed with the SEC.

The Audit Committee has adopted procedures for pre-approving all audit and non-audit services provided by the independent registered public accounting firm, including the fees and terms of such services. These procedures include reviewing detailed back-up documentation for audit and permitted non-audit services. The documentation includes a description of, and a budgeted amount for, particular categories of non-audit services that are recurring in nature and therefore anticipated at the time that the budget is submitted. Audit Committee approval is required to exceed the pre-approved amount for a particular category of non-audit services and to engage the independent registered public accounting firm for any non-audit services not included in those pre-approved amounts. For both types of pre-approval, the Audit Committee considers whether such services are consistent with the rules on auditor independence promulgated by the SEC and the PCAOB. The Audit Committee also considers whether the independent registered public accounting firm is best positioned to provide the most effective and efficient service, based on such reasons as the auditor's familiarity with our business, people, culture, accounting systems, risk profile, and whether the services enhance our ability to manage or control risks and improve audit quality. The Audit Committee may form and delegate pre-approval authority to subcommittees consisting of one or more members of the Audit Committee, and such subcommittees must report any pre-approval decisions to the Audit Committee at its next scheduled meeting. All of the services provided by the independent registered public accounting firm were pre-approved by your Audit Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules and Reports on Form 8-K

(a)(1) The following financial statements are included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2010.

1. Independent Auditor's Report

2. Consolidated Balance Sheets as of December 31, 2010 and 2009

3. Consolidated Statements of Operations for the years ended December 31, 2010 and 2009

4. Consolidated Statements of changes in Stockholders' Equity for the years ended December 31, 2010 and 2009

5. Consolidated Statements of Cash Flows for the years ended December 31, 2010 and 2009

6. Notes to Consolidated Financial Statements

(a)(2) All financial statement schedules have been omitted as the required information is either inapplicable or included in the Consolidated Financial Statements or related notes.

(a)(3) The following exhibits are either filed as part of this report or are incorporated herein by reference:

3.1 Certificate of Incorporation, as amended (Incorporated by reference to (i) Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 16, 2008, (ii) Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2001 filed August 14, 2001 and (iii) Exhibits 3.1, 4.1 and 4.2 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1998 filed August 14, 1998.)

3.2 Articles of Merger (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009.)

3.3 Certificate of Merger filed with the Secretary of State of Delaware (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 19, 2009.)

3.4 Articles of Incorporation filed with the Nevada Secretary of State (Incorporated by reference to Exhibit 3.3 of the Registrant's Current Report on Form 8-K filed October 19, 2009.)

3.5 By-Laws (Incorporated by reference to (i) Exhibit 3.4 of the Registrant's Current Report on Form 8-K filed October 19, 2009 and (ii) Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed June 3, 2010.)

4.1 Form of Warrant Certificate (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed December 1, 2006.)

4.2 2001 Stock Incentive Plan (Incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-8 filed January 18, 2008.)*

4.3 2007 Stock Incentive Plan (Incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-8 filed January 18, 2008.) *

4.4 2010 Stock Incentive Plan (Incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-8 filed November 29, 2010.)

4.5 Form of Warrant Certificate issued to Enclave Capital LLC (Incorporated by reference to Exhibit 4.1 of the Registrant's Form 8-K filed July 6, 2010.)

4.6 Form of Warrant to Purchase Common Stock issued January 2011(Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed February 2, 2011.)

10.1 Unit Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed December 1, 2006.)

10.2 License Agreement between The Regents of the University of California and Epitope Pharmaceuticals, Inc. (Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2008 filed November 14, 2008.))

10.3 Form of Director/Officer Indemnification Agreement (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed January 6, 2009.)*

10.4 Warrant Cancellation and Registration Rights Agreement between Accredited Adventures Capital LLC and Adeona (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed January 20, 2009.)*

10.5 Stock Purchase Agreement with Neil O. Colwell and Connie Colwell (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed April 16, 2009.)

10.6 Escrow Agreement Nayaran Torke (Incorporated by reference to Exhibit 10.5 of the Registrant's Current Report on Form 8-K filed July 16, 2009.)

10.7 Consulting Agreement with Nayaran Torke (Incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed July 16, 2009.)

10.8 Purchase Agreement 1st Amendment HartLab LLC (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed July 16, 2009.)

10.9 Purchase Agreement 2nd Amendment Hartlab LLC (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed July 16, 2009.)

10.10 Agreement and Plan of Reincorporation Merger (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009.)

10.11 Employment Agreement with James S. Kuo, M.D., M.B.A. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed February 9, 2010.)

10.12 Separation Agreement with Max Lyons (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed February 9, 2010.)

10.13 Sublicense Agreement between Meda AB, Adeona Pharamaceuticals, Inc. and Pipex Therapeutics, Inc. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed May 11, 2010.)

10.14 Non-Disturbance Agreement among Pipex Therapeutics, Inc., Mclean Hospital Corp and Meda AB (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed May 11, 2010.)

10.15 Placement Agent Agreement with Enclave Capital LLC (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed July 6, 2010.)

10.16 Common Stock Purchase Agreement with Seaside 88,LP (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed July 6, 2010.)

10.17 Agreement with Chardan Capital Markets, LLC (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed February 2, 2011.)

10.18 Securities Purchase Agreement with investors (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed February 2, 2011.)

10.19 Amendment to Employment Agreement with Kanzer (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed January 6, 2009.)

10.20	License Agreement with David A. Newsome, M.D. and David J. Tate, Jr. (Incorporated by reference to Exhibit 10.19 of the Registrant's Current Report on Form 8-K filed July 10, 2007.)
10.21	McLean Hospital Corporation Exclusive License Agreement (1)
31.1	Certification pursuant to Rule 13a-14(a)/15d-14(a) (1)
31.2	Certification pursuant to Rule 13a-14(a)/15d-14(a) (1)
32.1	Certification pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002(1)

(1) Filed herewith.
* Management compensation agreement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned.

ADEONA PHARMACEUTICALS, INC.
By: /s/ James S. Kuo
James S. Kuo
Chief Executive Officer and Chairman
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)
Date: March 31, 2011

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

	By:	/s/ James S. Kuo
Date: March 31, 2011	James S. Kuo Chief Executive Officer and Chairman (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	
Date: March 31, 2011	By: Steve H. Kanzer Director	/s/ Steve H. Kanzer
Date: March 31, 2011	By: Jeffrey J. Kraws Director	
Date: March 31, 2011	By: Jeffrey Wolf Director	/s/ Jeffrey Wolf
Date: March 31, 2011	By: Jeff Lucero Riley Director	/s/ Jeff Lucero Riley

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GLOSSARY

Term	Definition
Adverse Event	Any adverse change in health or "side-effect" that occurs in a person participating in a clinical trial, from the time they consent to joining the trial until a pre-specified period of time after their treatment has been completed.
Bioavailability	The quantity or fraction of the ingested dose that is absorbed by the body.
Clinical Study/Trial	A research study that is conducted to find out if a treatment or procedure is safe and/or effective in humans.
Controlled Clinical Trial	A clinical study that compares patients receiving a specific treatment to patients receiving an alternate treatment for the condition of interest. The alternate treatment may be another active treatment, standard of care for the condition and/or a placebo (inactive) treatment.
Double-blinded Study/Trial	Both the participant and the researcher are unaware of who is receiving the active treatment or the placebo.
Effirma (oral flupirtine)	Adeona's centrally-acting investigational oral drug for the treatment of fibromyalgia syndrome
FDA - Food & Drug Administration	The U.S. government agency that ensures that medicines, medical devices, prescription medical foods and radiation-emitting consumer products are safe and effective. Authorized by Congress to enforce the Federal Food, Drug, and Cosmetic Act and several other public health laws, the agency monitors the manufacture, import, transport, storage, and sale of $1 trillion worth of goods annually.
Gastroretentive	Medications designed to be retained in the upper gastrointestinal system.
GMP - Good Manufacturing Practice	Regulations that require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are consistently produced, pure, and stable. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors.
GRAS - Generally Regarded As Safe	A Food and Drug Administration (FDA) designation that a chemical or substance added to food is considered safe by experts, and so is exempted from the usual Federal Food, Drug, and Cosmetic Act (FFDCA) food additive tolerance requirements.
IND - Investigational New Drug	An application in the United States submitted to the FDA for a new drug or biologic that, if allowed, will be used in a clinical trial.
IRB - Institutional Review Board	A committee designated to formally approve, monitor, and review biomedical research at an institution involving human studies. Institutional Review Boards aim to protect the rights and welfare of the research subjects.
NDA - New Drug Application	An application in the United States through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing.
Open-label Clinical Study/Trial	A trial in which both the treating physician and the patient know they are receiving the experimental treatment.
Phase I Clinical Trial	

	A Phase I trial represents an initial study in a small group of patients to primarily test for safety.
Phase II Clinical Trial	A Phase II trial represents a study in a larger number of patients to assess the safety and efficacy of a product.
Phase III Clinical Trial	Phase III trials are initiated to establish safety and efficacy in an expanded patient population and at multiple clinical trial sites and are generally larger than trials in earlier phases of development.
Placebo	An inactive pill or liquid. Many studies compare an active drug to a placebo to determine whether any changes seen during the study can be attributed to the active drug.
Principal Investigator	This is the study director who is ultimately responsible for the conduct of the study.
Prospective Clinical Study/Trial	A clinical study/trial in which participants are identified and then followed throughout the study going forward in time.
Protocol	A clinical study/trial's plan — includes the schedule of tests, requirements for participation, procedures, and medications.
Randomized Study/Trial	Participants in a study are assigned by chance to either one or more of the active treatment group(s) or the placebo group.
reaZinTM (zinc cysteine)	Adeona's oral prescription medical food product candidate for the dietary management of Alzheimer's disease and mild cognitive impairment. reaZin was formerly known as Zinthionein.
Single-blinded Study/Trial	One party, either the participant or the researcher, does not know if the participant is taking the active treatment or the placebo.
Study/Trial Coordinator	Staff member who is often the primary contact for research participants and coordinates their care and evaluations throughout the study.
Trimesta (oral estriol)	Adeona's investigational oral drug for the treatment of relapsing-remitting multiple sclerosis.
ZincMonoCysteine (zinc-monocysteine)	Adeona's investigational drug formulated for the potential treatment of dry age-related macular degeneration.