UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2014

OR

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

Commission File Number: 000-15006

MATINAS BIOPHARMA HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**No. 46-3011414**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1545 Route 206 South, Suite 302
Bedminster, New Jersey 07921
(Address of principal executive offices) (Zip Code)

908-443-1860
(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☒

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

As of May 14, 2014, 32,000,000 shares of common stock, $0.0001 par value per share, were outstanding.

MATINAS BIOPHARMA HOLDINGS, INC.

FORM 10-Q

Quarter Ended March 31, 2014

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. UNAUDITED FINANCIAL STATEMENTS

MATINAS BIOPHARMA HOLDINGS, INC.
(Formerly Matinas BioPharma, Inc.)
(A Development Stage Entity)
Unaudited Condensed Consolidated Balance Sheets

	March 31, 2014	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	$ 8,558,105	$ 10,840,428
Prepaid expenses and other current assets	87,630	84,493
Total current assets	8,645,736	10,924,921
Property, plant and equipment, net	364,854	93,057
Other long term assets	315,986	315,778
Total assets	$ 9,326,576	$ 11,333,756
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 242,326	$ 396,768
Accrued expenses	386,481	462,200
Lease liability - current	44,543	—
Total current liabilities	673,350	858,968
Lease liability – long term	43,636	—
Total liabilities	716,986	858,968
Stockholders' equity		
Preferred stock - $0.001 par value, 10,000,000 shares authorized, 0 shares issued and outstanding at March 31,2014 and December 31, 2013	—	—
Common stock - $0.001 par value, 150,000,000 shares authorized, 32,000,000 shares issued and outstanding at March 31, 2014 and December 31, 2013	3,200	3,200
Additional paid-in capital	14,576,131	14,302,307
Deficit accumulated during development stage	(5,969,742)	(3,830,719)
Total stockholders' equity	8,609,590	10,474,788
Total liabilities and stockholders' equity	$ 9,326,576	$ 11,333,756

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

MATINAS BIOPHARMA HOLDINGS, INC.
(Formerly Matinas BioPharma, Inc.)
(A Development Stage Entity)
Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended March 31,		Period from August 11, 2011 (Inception) to March 31,
	2014	2013	2014
Costs and expenses:			
Research and development	$ 1,073,781	$ 49,586	$ 2,915,296
General and administrative	1,055,247	62,547	3,043,762
Total costs and expenses	2,129,027	112,133	5,959,058
Loss from operations	(2,129,027)	(112,133)	(5,959,058)
Other expense, net	9,996	—	10,684
Net loss	$ (2,139,024)	$ (112,133)	$ (5,969,742)
Net loss per share - basic and diluted	$ (0.07)	$ (0.01)	
Weighted average common shares outstanding:			
Basic and diluted	32,000,000	10,000,000	

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

Matinas BIOPHARMA HOLDINGS, INC.
(Formerly Matinas BioPharma, Inc.)
(A Development Stage Company)
Unaudited Condensed Consolidated Statements of Cash Flows

	Three months ended March 31,		Period from August 11, 2011 (Inception) to March 31,
	2014	2013	2014
Operating Activities			
Net loss	$ (2,139,024)	$ (112,133)	$ (5,969,742)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	9,452	—	10,583
Share-based compensation	273,824	—	491,248
Issuance of equity instruments below fair value	—	—	108,316
Changes in operating assets and liabilities:			
Other Assets	(41,117)	—	(356,895)
Prepaid expense	37,980	(33,126)	(46,513)
Other liabilities	(75,720)	—	386,530
Accounts payable	(154,441)	(4,864)	242,329
Net cash used in operating activities	(2,089,046)	(150,123)	(5,134,144)
Investing Activities			
Purchase of property, equipment	(193,277)	—	(287,467)
Net cash used in investing activities	(193,277)	—	(287,467)
Financing Activities			
Return of membership capital in Matinas BioPharma LLC	—	—	(2,000)
Loans provided by founders	—	—	24,100
Payment of loans provided by founders	—	(12,850)	(24,100)
Proceeds from membership units issued for cash	—	—	2,000
Proceeds from redeemable convertible preferred stock issued for cash	—	400,001	1,000,001
Preferred Stock issuance costs	—	(1,716)	(47,613)
Proceeds from common stock issued for cash	—	—	15,001,000
Common stock issuance costs	—	—	(2,378,672)
Proceeds from formation of holding's common stock	—	—	375,000
Proceeds from formation warrants	—	—	10,000
Proceeds from private placement warrants	—	—	20,000
Net cash provided by financing activities	—	385,435	13,979,716
Net change in cash and cash equivalents	(2,282,323)	235,312	8,558,105
Cash and cash equivalents			
Beginning of period	10,840,428	424,364	—
End of period	$ 8,558,105	$ 659,676	$ 8,558,105
Supplemental disclosures of cash flow information			
Issuance of shares	$ —	$ —	$ 953,389
Issuance of private placement warrants as consideration for equity issuance costs	$ —	$ —	$ 1,252,111
Issuance of restricted stock for services	$ —	$ —	$ 470,000

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

MATINAS BIOPHARMA HOLDINGS, INC.
(Formerly Matinas BioPharma, Inc.)
(A Development Stage Company)
Notes to Unaudited Financial Statements
(tabular dollars and shares in thousands, except per share data)

Note A - Company Information And History

[1] Corporate History

Matinas BioPharma Holdings Inc. ("Holdings") is a development stage enterprise and a Delaware corporation formed in 2013 and is the parent company of Matinas BioPharma, Inc., its operating subsidiary ("BioPharma" or "the Company" or "we" or "our" or "us"). Nereus BioPharma LLC, a Delaware limited liability company (and Matinas BioPharma's predecessor) ("Nereus") was formed on August 12, 2011. On February 29, 2012, Nereus converted from a limited liability company to a corporation and changed its name to Matinas BioPharma, Inc.

On July 11, 2013, and contemporaneously with the initial closing of a private placement in July and August 2013 described below, Matinas BioPharma Inc. entered into a Merger agreement whereby it become a wholly owned subsidiary of Holdings (the "Merger") to effect its recapitalization plan. In connection with the Merger, the stockholders of Matinas BioPharma Inc. become the stockholders of the Holdings and received an aggregate of 9,000,000 shares of Holdings common stock and warrants to purchase 1,000,000 shares of Holdings common stock. See Note D for further discussion. For financial reporting purposes the accounting acquirer is Matinas BioPharma Inc., and accordingly, the historical financial statements of Matinas BioPharma Inc. are the continuing financial statements of the entity. In July and August of 2013, the Company completed the private placement, under which the Company sold an aggregate of 15,000,000 shares of common stock and warrants to purchase an aggregate of 7,500,000 shares of common stock (the "2013 Private Placement"). See Note D for further discussion. On February 12, 2014, the Company's S-1 covering the resale of certain shares of our common stock was declared effective by the Securities and Exchange Commission (the "SEC").

[2] Proprietary Products and Technology Portfolios

Matinas is a development stage biopharmaceutical company with a focus on identifying and developing novel pharmaceutical products for the treatment of abnormalities in blood lipids, referred to as dyslipidemia, and the treatment of cardiovascular and metabolic diseases.

The Company is primarily focused on developing its lead product candidate, MAT9001, through approval with the United States Food and Drug Administration ("FDA"), with a primary indication for the treatment of severe hypertriglyceridemia. Severe hypertriglyceridemia refers to a condition in which patients have high blood levels of triglycerides (>500 mg/dl) and is recognized as an independent risk factor for pancreatitis and cardiovascular disease.

The Company's MAT9001 development approach for the severe hypertriglyceridemia indication is similar to the clinical trial programs used by other pharmaceutical companies for FDA approval of other omega-3 fatty acid based products in this indication. By designing the MAT9001 development program for this indication in a manner consistent with the established FDA guidance, the Company believes the required clinical development program and regulatory approval pathway for MAT9001 for severe hypertriglyceridemia is more predictable and may be relatively lower in risk compared to other typical clinical development programs in the cardiovascular field.

In addition to MAT9001, the Company has established a discovery program called MAT8800 to identify and develop product candidates derived from omega-3 fatty acids for the treatment of prevalent liver diseases for which there are currently only limited therapeutic solutions. Our development work has indicated that certain omega-3 fatty acids may yield improvement in liver enzyme levels and liver histology. Accordingly, the Company has identified potential omega-3 fatty acid compositions to study in preclinical settings. This discovery program is focused on identifying and optimizing candidates comprising omega-3 fatty acids as potential treatments for nonalcoholic fatty liver disease, or NAFLD, nonalcoholic steatohepatitis, or NASH, or other hepatic conditions.

[3] Business Risks

The Company's operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company's products, any changes in the regulatory environment and FDA requirements for approval within the dyslipidemia field, the Company's ability to obtain regulatory approval to market its products, competition from products manufactured and sold or being developed by other companies, the price of, and demand for, Company products, the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products, the Company's ability to raise capital and other factors listed under the heading "Risk Factors" elsewhere in this report.

Note B - Going Concern And Plan Of Operation

The accompanying financial statements have been prepared in conformity with generally accepted accounting principles, which contemplate continuation of the Company as a going concern.

The Company has experienced net losses and negative cash flows from operations each period since its inception. Through March 31, 2014, the Company had an accumulated deficit of approximately $6.0 million. The Company's operations have been financed through the sale of equity securities and advances from officers and directors. The Company's net loss for the three months ended March 31, 2014 was approximately $2.1 million.

The Company has been engaged in developing MAT9001 since 2011. To date, the Company has not generated any revenue from MAT9001 and the Company expects to incur significant expenses to complete clinical work and to prepare MAT9001 for Phase III trials in the United States. The Company may never be able to obtain regulatory approval for the marketing of MAT9001 in any indication in the United States or internationally and even if the Company is able to commercialize MAT9001 or any other product candidate, there can be no assurance that the Company will generate significant revenues or ever achieve profitability.

Assuming the Company obtains FDA approval for MAT9001, which the Company does not expect to receive until 2017 at the earliest, the Company expects that its expenses will increase if the Company reaches commercial launch of MAT9001. The Company also expects that its research and development expenses will continue to increase as it moves forward for other indications for MAT9001 and diversifies its R&D portfolio. Furthermore, the Company expects that its research and development expenses will significantly increase as its MAT8800 discovery program progresses and advances to preclinical and clinical trials with one or more product candidates. As a result, the Company expects to continue to incur substantial losses for the foreseeable future, and that these losses will be increasing.

The Company will need to secure additional capital in order to initiate and complete its planned clinical and operational activities related to MAT9001 and we can provide no assurances that such additional financing will be available on favorable terms, or at all. Without such additional funding, the Company is anticipating that the existing cash balance on hand at March 31, 2014 would be sufficient to meet operating activities until approximately January 2015. The Company's recurring losses from operations, and need for additional funding, raise substantial doubt about its ability to continue as a going concern, and as a result, the Company's independent registered public accounting firm included an explanatory paragraph in its report on the Company's financial statements as of and for the year ended December 31, 2013 with respect to this uncertainty.

Note C - Summary Of Significant Accounting Policies

[1] Basis of Presentation

The accompanying consolidated financial statements include the consolidated accounts of Matinas BioPharma Holdings Inc. (Holdings) and its wholly owned subsidiary, Matinas BioPharma Inc. Matinas BioPharma Inc. is the operational subsidiary of Holdings. The accompanying unaudited condensed consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and reflect the operations of the Company and its wholly-owned subsidiary. All intercompany transactions have been eliminated in consolidation.

These interim financial statements do not include all the information and footnotes required by U.S. GAAP for annual financial statements and should be read in conjunction with the audited financial statements for the year ended December 31, 2013, which are included in the Company's Special Financial Report on Form 10-K filed with the SEC on April 11, 2014. In the opinion of management, the interim financial statements reflect all normal recurring adjustments necessary to fairly state the Company's financial position and results of operations for the interim periods presented. The year-end consolidated balance sheet data presented for comparative purposes was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP.

The condensed consolidated balance sheet at December 31, 2013 was derived from the audited consolidated financial statements as of that date. Operating results for the three months ended March 31, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014. For further information, refer to the consolidated financial statements and notes thereto included in the Company's Special Financial Report on Form 15d2 for the year ended December 31, 2013.

[2] Use of Estimates

The preparation of 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 of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

[3] Cash and Cash Equivalents

For purposes of financial statement presentation the Company considers all highly liquid instruments purchased with a maturity of three months or less to be cash equivalents to the extent the funds are not being held for investment purposes.

[4] Concentration of Credit Risk

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents. Cash balances are maintained principally at one major U.S. financial institution and are insured by the Federal Deposit Insurance Corporation ("FDIC") up to regulatory limits. At various times throughout the period ended March 31, 2014, the Company's cash balances exceeded the FDIC insurance limit. The Company has not experienced any losses in such accounts.

[5] Property, Plant and Equipment

Property, plant and equipment is stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. The estimated useful lives of the Company property, plant, and equipment range from three to ten years. Capitalized costs associated with leasehold improvements are depreciated over the lesser of the useful life of the asset or the remaining life of the lease.

[6] Income Taxes

Deferred taxes are provided on a liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates.

The Company adopted the provisions of ASC 740-10 and has analyzed its filing positions in 2013 and 2012 in jurisdictions where it may be obligated to file returns. The Company believes that its income tax filing position and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties as of March 31, 2014. In addition, future changes in unrecognized tax benefits will have no impact on the effective tax rate due to the existence of the valuation.

Since the Company incurred net operating losses in every tax year since inception, 2012 and 2013 income tax returns are subject to examination and adjustments by the IRS for at least three years following the year in which the tax attributes are utilized.

[7] Stock-Based Compensation

The Company accounts for stock-based compensation to employees in conformity with the provisions of ASC Topic 718, "Stock *Based Compensation"*. Stock-based compensation to employees consist of stock options grants and restricted shares that are recognized in the statement of operations based on their fair values at the date of grant.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of ASC Topic 505, subtopic 50, *Equity-Based Payments to Non-Employees* based upon the fair-value of the underlying instrument. The equity instruments, consisting of stock options granted to consultants, are valued using the Black-Scholes valuation model. The measurement of stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the period which services are received.

The Company calculates the fair value of option grants utilizing the Black-Scholes pricing model, and estimates the fair value of the restricted stock based upon the estimated fair value or the common stock. The amount of stock-based compensation recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. The authoritative guidance requires forfeitures to be estimated at the time stock options are granted and warrants are issued and revised. If necessary in subsequent periods, an adjustment will be booked if actual forfeitures differ from those estimated. The term “forfeitures” is distinct from “cancellations” or “expirations” and represents only the unvested portion of the surrendered stock option or warrant. The Company estimates forfeiture rates for all unvested awards when calculating the expense for the period. In estimating the forfeiture rate, the Company monitors both stock option and warrant exercises as well as employee and non-employee termination patterns.

The resulting stock-based compensation expense for both employee and non-employee awards is generally recognized on a straight-line basis over the requisite service period of the award.

[8] Financial Instruments

Accounting considerations

The Company evaluates the terms of the equity instruments to determine whether any embedded derivatives or other features required liability classification. The Company’s instruments did not contain any features that would require liability or derivative accounting treatment in 2011 through March 31, 2014.

July and August 2013 issuance pursuant to Private Placement

The Company allocated the aggregate proceeds of the units sold between the warrants and the common stock based on their relative fair values.

The fair value of the warrants issued to unit holders is calculated utilizing the Black-Scholes option-pricing model and similar assumptions as described in Note G. Since these warrant instruments were considered equity instruments, the allocation did not change the total amount of additional paid in capital.

As discussed in Note F, the placement agent was issued warrants as part of their cost of raising the funds in the private placement. The fair value of the warrants issued to the placement agent was calculated utilizing the Black-Scholes option-pricing model and similar assumptions as described in Note F, and is considered a component of equity (no net effect on Additional Paid In Capital), and amounted to $1,252,111 at the date of issuance.

Matinas BioPharma Inc. Series A Convertible Redeemable Preferred Stock issuance

Prior to the merger transaction described in Note D, Matinas BioPharma Inc. had issued shares of Series A Convertible Redeemable Preferred Stock ("Preferred Stock") to investors in four separate tranches occurring from December 2012 to April 2013. The Preferred shares were converted to common shares of Holdings as part of the Merger transaction. The Preferred Stock entitled the holder to voting rights, and it did not accrue a dividend at a stated rate. The term of the Preferred Stock also had included options for conversion into common stock and potential redemption by the Company if certain conditions were met.

[9] Fair Value Measurements

ASC 820 “Fair Value Measurements” defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity’s own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under ASC 820 are described below:

- Level 1 - Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

- Level 2 - Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.

- Level 3 - Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

The carrying amounts of cash and cash equivalents, other current assets, accounts payable and accrued expenses approximate fair value due to the short-term nature of these instruments.

[10] Basic Net Loss per Common Share

Basic net loss per common share is computed as net loss divided by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share because the Company incurred a net loss during each period presented, and the potentially dilutive securities from the assumed exercise of all outstanding stock options, warrants would have an antidilutive effect. As of March, 31, 2014 and 2013 the number of shares issuable upon the exercise of stock options, warrants, and shares held in escrow was 18,410,000 and 0, respectively.

[11] Revenue Recognition

The Company will develop an appropriate revenue recognition policy when planned anticipated future commercial operations commence.

[12] Research and Development

Research and development costs are charged to operations as they are incurred. Legal fees and other direct costs incurred in obtaining and protecting patents are also expensed as incurred, due to the uncertainty with respect to future cash flows resulting from the patents and our included as part of General and Administrative expenses.

Note D – Formation And Reverse Acquisition of Matinas Biopharma Holdings

Formation

In May 2013, Holdings was formed solely to prepare the Company for the capital raising transaction described below under "2013 Private Placement". As part of the formation of Holdings, Holdings sold an aggregate of 7,500,000 shares of Holdings' common stock and 3,750,000 warrants to purchase 3,750,000 shares of its common stock at an exercise price of $2.00 per share, for an aggregate of $375,000 (at a purchase price of $0.10 for two shares and one warrant), including 2,000,000 shares and warrants to purchase 1,000,000 shares of its common stock to Adam Stern and entities owned by Mr. Stern. Mr. Stern is an affiliate of Aegis Capital Corp., the placement agent in Holdings' private placement in 2013 described below under 2013 Private Placement and a member of the board of directors of Holdings. The net cash proceeds of $375,000 has been reflected in the total equity for Holdings. The remaining 5,500,000 shares of its common stock and 2,250,000 warrants to purchase 2,250,000 shares of its common stock were sold to third parties, including certain representatives of Aegis Capital Corp., the placement agent for the 2013 Private Placement.

The aggregate proceeds of the units sold ($375,000 gross proceeds) were allocated between the warrants and the common stock based on their relative fair values which amounted to approximately $300,000 allocated to the common stock and $75,000 allocated to the warrants.

In addition, Holdings also offered and sold to Mr. Stern 250,000 warrants to purchase an additional 250,000 shares of its common stock at an exercise price of $2.00 per share, for which he paid $10,000 (at a purchase price of $0.04 per warrant) (the "Formation Warrants") for his effort in connection with the transaction. These additional Formation Warrants offered to Mr. Stern are compensatory for his services in connection with structuring the formation transaction and were sold at a lower price than the fair value of $0.47 per warrant. The difference of the fair value of the warrants and the cash proceeds in the amount of $108,316 was recorded as acquisition costs incurred in connection with this transaction, and included in general and administrative expenses. Mr. Stern is an affiliate of Aegis Capital Corp., the placement agent in the 2013 Private Placement (the "Placement Agent"), and became a director of Holdings in connection with the transactions described below.

Merger

In July 2013, Matinas BioPharma entered into the Merger Agreement with Merger Sub, a wholly owned subsidiary of Holdings. Pursuant to the terms of the Merger Agreement, as a condition of and contemporaneously with the initial closing of the 2013 Private Placement, Merger Sub merged with and into Matinas BioPharma and Matinas BioPharma became a wholly owned subsidiary of Holdings.

In connection with the Merger, all shares of common stock and preferred stock of Matinas BioPharma were cancelled, and the stockholders of Matinas BioPharma received an aggregate of 9,000,000 shares (approximately 28.5% of the issued common shares) of Holdings' common stock and warrants to purchase 1,000,000 shares of Holdings' common stock at an exercise price of $2.00 per share (the "Merger Warrants"). As a result of this Merger, the shareholders of Matinas BioPharma became shareholders of Holdings, and the respective holdings of management are as follows: Herbert Conrad, Chairman of the Board, who received 351,563 shares of Holdings' common stock and 250,000 Merger Warrants; Roelof Rongen, President and Chief Executive Officer, who received 3,417,186 shares of Holdings' common stock, Abdel A. Fawzy, Executive Vice President, Pharmaceutical Development and Supply Chain Development, who received 1,708,593 shares of Holdings' common stock; George Bobotas, executive vice president and chief scientific officer, and his spouse, who received an aggregate of 1,366,875 shares of Holdings' common stock; Jerome Jabbour, Executive Vice President, Chief Business Officer and General Counsel, who received 759,374 shares of Holdings' common stock and Stefano Ferrari, a member of the board of directors, through an entity controlled by him, received 351,563 shares of Holdings' common stock and 250,000 Merger Warrants.

After consummation of the Merger transaction, the management of Matinas BioPharma became the management of Holdings and the board representatives consisted of four former Board members of Matinas BioPharma and Mr. Adam Stern as the Aegis Capital Corp. nominee. Because Holdings was formed solely to effect the Merger and the 2013 Private Placement, with no operations, and assets consisting solely of cash and cash equivalents, the Company accounted for the Merger as a reverse acquisition. The legal acquiree Matinas BioPharma becomes the successor entity, and its historical results became the historical results for Holdings (the legal acquirer and the registrant). The Statement of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) reflects the recapitalization of Matinas BioPharma equity as a result of this reverse acquisition.

2013 Private Placement

In July and August 2013, Holdings completed the 2013 Private Placement, under which it sold an aggregate of 15,000,000 shares of its common stock and warrants to purchase an aggregate of 7,500,000 shares of Holdings' common stock with an exercise price of $2.00 per share, which warrants are exercisable for a period of five years from the initial closing date (the "Investor Warrants"). The aggregate gross proceeds of the units sold ($15.0 million gross proceeds) were allocated between the warrants and the common stock based on their relative fair values which amounted to approximately $11,983,000 allocated to the common stock and $3,017,000 allocated to the warrants. One of the units was sold to Mr. Herb Conrad for the full offering price of $250,000, and consisted of 250,000 shares of common stock and 125,000 warrants.

Aegis Capital Corp. acted as the Placement Agent for the 2013 Private Placement. The gross proceeds to Holdings from the 2013 Private Placement were $15.0 million. In connection with the 2013 Private Placement, the Placement Agent received a cash placement agent fee of $1.5 million and a non-accountable expense allowance of $450,000. In addition, as part of its compensation for acting as placement agent for the 2013 Private Placement, Holdings issued (x) warrants to the Placement Agent to purchase 750,000 shares of its common stock with an exercise price of $2.00 per share and (y) warrants to the Placement Agent to purchase 1,500,000 shares of its common stock with an exercise price of $1.00 per share. These warrants contain a "cashless exercise" feature and are exercisable at any time prior to July 30, 2018. The fair value of such warrants at the date of issuance was approximately $1.3 million using assumptions similar to those described in Note G and was recorded as part of equity, together with the other sales of common stock and warrants and not as a separate entry in the statement of stockholders equity for this stock issuance cost.

In connection with the closing of the 2013 Private Placement, the Placement Agent had a right to appoint one out of five members of Board of Directors of Holdings for a two-year term from the initial closing (the "Aegis Nominee"). Adam Stern was appointed to the Board of Directors at the initial closing and his successor, if any, will be chosen by the Placement Agent, subject to the reasonable approval of Holdings and the Voting Agreement described below. Holdings agreed to engage the Placement Agent as its warrant solicitation agent in the event the warrants, other than the Placement Agent Warrants, are called for redemption and shall pay a warrant solicitation fee to the Placement Agent equal to five (5%) percent of the amount of funds solicited by the Placement Agent upon the exercise of the warrants following such redemption.

After the consummation of the Merger and the 2013 Private Placement, the former shareholders of Matinas BioPharma held 28.5% of the common stock of Holdings by category of these transactions and approximately 30% when the additional shares purchased by Mr. Conrad in the 2013 Private Placement are included.

The private placement issuance cost totaled approximately $2.4 million of which $1.95 million was related to Placement Agent cash fees and expenses, $425,000 related to external legal costs and the remaining balance in other costs directly and incrementally attributable to the private placement funds raised. These costs are reflected as an offset to additional paid in capital.

Warrant Private Placement

Contemporaneously with the initial closing of the 2013 Private Placement, Holdings offered to all former preferred stockholders of Matinas BioPharma the right to purchase additional warrants with an exercise price of $2.00 per share of its common stock at a purchase price of $0.04 per warrant. Only Mr. Conrad exercised such right. As a result, Holdings sold 500,000 Private Placement Warrants to Herbert Conrad, the Chairman of the Board, for net cash proceeds of $20,000.

Summary of Changes in Capitalization

The following summarizes the capital structure before and after the Merger.

Investor Group	Matinas BioPharma Inc. (Accounting Acquirer)	Holdings (Accounting Acquiree)
Former preferred and common shareholders	10,000,000 shares of common and 1,851,852 shares of preferred stock	9,000,000 shares of commons stock (28.6% of aggregate common stock holdings) and 1,500,000 warrants (1)
$0.10 unit purchasers, including Mr. Adam Stern and certain representatives of Aegis Capital	none	7,500,000 shares of commons stock (23.8% of aggregate common stock holdings) and 4,000,000 warrants (2)
2013 Private Placement Investors	none	15,000,000 shares of common stock (47.7% of the aggregate common stock holdings) and 7,500,000 warrants (3)
Aegis Capital Corporation	none	2,250,000 warrants

1. Includes 500,000 warrants purchased my Mr. Conrad - see Warrant Private Placement section.
2. Includes 2,250,000 warrants issued in connection with the placement agent fees, 3,750,000 issued in connection with the sale of units at the Formation and 250,000 warrants purchased by Mr. Stern - see section entitled "Formation"
3. From the 2013 Private Placement, and includes 1 unit purchased by Mr. Conrad for $ 250,000 at the full price paid by all third party investors.

Registration Rights and Other

In connection with the 2013 Private Placement, Holdings entered into a registration rights agreement with the private placement investors, the Placement Agent and the holders of its outstanding warrants. Holdings was required to file with the SEC no later than October 7, 2013 (the "Filing Deadline"), a registration statement covering the resale of the shares of common stock and the shares of common stock underlying the warrants, issued in the 2013 Private Placement, as well as the shares of common stock underlying the Formation Warrants, the Merger Warrants, and the Private Placement Warrants. The Company was also required to use commercially reasonable efforts to have the registration statement declared effective within one hundred and fifty (150) days after the registration statement was filed (the "Effectiveness Deadline"), and to keep the registration statement continuously effective under the Securities Act of 1933, as amended (the "Securities Act"), until the earlier of the date when all the registrable securities covered by the registration statement have been sold or such time as all of the registrable securities covered by the registration statement can be sold under Rule 144 without any volume limitations. If this registration statement was not declared effective on or before the Effectiveness Deadline, Holdings would have been required to pay to each holder of registrable securities purchased in the 2013 Private Placement an amount in cash equal to one half of one percent (0.5%) of such holder's investment amount on every thirty (30) day anniversary of such Effectiveness Deadline until such failure was cured. The Company's registration statement was declared effective by the Securities and Exchange Commission on February 12, 2014, therefore no liability for the above provision has been recognized. However, assessments will be made on a quarterly basis, until all the securities can be sold without restriction under Rule 144.

Through March 31, 2014, approximately $350,000 in professional fees related to this registration statement have been incurred, and are included in general and administrative expenses, since they are not directly related to the fund raising.

At the closing of the 2013 Private Placement (July 30, 2013), Holdings entered into a consulting agreement with the Placement Agent. The consulting agreement has a term of 12 months pursuant to which the Placement Agent receives $20,000 per month.

Note E - Prepaid Assets

In March 2013, the Company entered into a rights agreement with a manufacturer to insure the use of a dedicated Good Manufacturing Process (GMP) suite to produce Active Pharmaceutical Ingredient (API) for MAT 9001 during the development phase. These right costs of approximately $34,000, which were paid during the nine months ended September 30, 2013 are included in prepaid expenses and will be amortized over 20 months on a straight line basis.

Note F - Stock Holders Equity

Preferred Stock – Matinas BioPharma Inc.

Prior to July 11, 2013, the Company was authorized to issue up to 6,481,481 shares of redeemable convertible preferred stock, par value $0.0001 per share, with such designations, rights, and preferences as may be determined from time to time by the Company Board of Directors.. Among other features, shares of Series A Convertible Redeemable Preferred Stock were redeemed by the Company at a price equal to the Series A Original Issue Price per share, plus all declared but unpaid dividends thereon in two annual installments commencing not more than 90 days after receipt by the Company at any time on or after October 2017 (fifth anniversary of initial public offering closing), from the holders of at least a majority of the then outstanding shares of Series A Convertible Redeemable Preferred Stock, of written notice requesting redemption of all shares of Series A Convertible Redeemable Preferred Stock. The Company was required to redeem, on a pro-rata basis in accordance with the number of shares of Series A Convertible Redeemable Preferred Stock owned by each holder. This instrument was classified outside of permanent equity in the accompanying consolidated balance sheet.

As part of the formation and reverse acquisition of Matinas BioPharma Holdings discussed in Note D all authorized Preferred Shares of Matinas BioPharma Inc. were canceled and exchanged for Holdings' common shares. There were no shares of the redeemable convertible preferred stock outstanding at March 31, 2014, and this instrument is no longer authorized by the Company articles of incorporation.

Warrants

As of March 31, 2014, the Company had outstanding warrants to purchase an aggregate of 15,250,000 shares of common stock at exercise prices ranging from $1.00 to $2.00 per share.

The Warrants are exercisable immediately upon issuance and have a five-year term. The Warrants may be exercised at any time in whole or in part upon payment of the applicable exercise price until expiration of the Warrants. No fractional shares will be issued upon the exercise of the Warrants. All of the Warrants may be exercised on a "cashless" basis in certain circumstances. However, since all such cashless exercises are settled on a net share basis, the exercise price and the number of warrant shares purchasable upon the exercise of the Investor Warrants are subject to adjustment upon the occurrence of certain events, which include stock dividends, stock splits, combinations and reclassifications of the Company capital stock or similar "organic changes" to the equity structure of the Company. Accordingly, pursuant to ASC 815, the warrants are classified as equity in the accompanying statement of stockholder's Equity.

The Company may call the Warrants, other than the Placement Agent Warrants, at any time the common stock trades above $5.00 for twenty (20) consecutive days following the effectiveness of the registration statement covering the resale of the shares of common stock underlying the Warrants, provided that the Warrants can only be called if such registration statement is current and remains effective at the time of the call and provided further that the Company can only call the Investor Warrants for redemption, if it also calls all other Warrants for redemption on the terms described above. The Placement Agent Warrants do not have a redemption feature. Such term is a contingent feature and within the control of the Company, therefore does not require liability classification.

A summary of equity warrants outstanding as of March 31, 2014 is presented below, all of which are fully vested.

	Shares
July 11, 2013 formation of Holdings, 4,000,0000 warrants issued, terms 5 years, exercisable at $ 2.00, including 250,000 warrants sold to Mr. Adam Stern	4,000,000
July 11, 2013 recapitalization of Matinas BioPharma Inc. 1,000,000 warrants issued, terms 5 years, exercisable at $ 2.00	1,000,000
July and August,2013 completion of Private Placement, 7,500,000 warrants issued, terms 5 years, exercisable at $ 2.00	7,500,000
July 30, 2013 Placement Agent warrants issued as part of compensation for Private Placement. Terms 5 years, exercisable at $ 2.00	750,000
July 30. 2013 Placement Agent warrant issued as part of compensation for Private Placement. Terms 5 years exercisable at $ 1.00	1,500,000
July 30, 2013 500,000 warrants sold to Chairman of Board Mr. Herb Conrad for $ 20,000. Terms 5 years, exercisable at $ 2.00 per share	500,000
Total Warrants Outstanding at March 31, 2014	15,250,000

Note G - Share Based Compensation

Valuation of common stock

The Company was privately held with no active public market for its common stock. Therefore, management has for financial reporting purposes determined the estimated per share fair value of the Company's common stock and redeemable convertible preferred stock using valuation consistent with the American Institute of Certified Public Accountants Practice Aid, "Valuation of Privately-Held Company Equity Securities Issued as Compensation," also known as the Practice Aid. This valuation was performed with the assistance of a third-party valuation specialist. The Company performed its valuation as of September 1, 2013. In conducting its valuation, management considered all objective and subjective factors that it believed to be relevant, including management's best estimate of the Company's business condition, prospects and operating performance at the valuation date. Within the valuation performed, a range of factors, assumptions and methodologies were used. The significant factors included external market conditions affecting the biotechnology industry, trends within the biotechnology industry, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of the preferred stock relative to common stock at the time of each grant, the results of operations, financial position, status of research and development efforts, stage of development and business strategy, the lack of an active public market for the common and preferred stock, and the likelihood of achieving a liquidity event such as an initial public offering (IPO) or sale of the Company in light of prevailing market conditions. Such analysis resulted in an estimated fair value of common stock to be $0.94 per share. Management does not believe there is a significant change in the value of the common stock between September 1, 2013 and March 31, 2014, since the Company had not raised any additional capital or completed any major clinical activities in that period.

Stock Options

In August 2013, the Company adopted the 2013 Equity Compensation Plan (the "Plan"), which provides for the granting of incentive stock options, nonqualified stock options, restricted, stock units, performance units, and stock purchase rights. Options under the Plan may be granted at prices not less than 100% of the fair value of the shares on the date of grant as determined by the Board Committee. The Board Committee determines the period over which the options become exercisable subject to certain restrictions as defined in the Plan, with the current outstanding options generally vesting over three years. The term of the options is no longer than ten years. The Company currently has reserved 8,250,000 shares of common stock for issuance under the plan.

During the twelve months ended December 31, 2013, the Company granted stock options to certain employees and non-employees. Stock-based compensation expense recognized during the three months ended March 31, 2014, includes compensation expense for stock-based awards granted to employees and non-employees based on the grant date fair value estimated in accordance with the provisions of ASC 718 and amounted to approximately $158,000. The unrecognized compensation expense related to stock option grants as of March 31, 2014 was approximately $1,580,000 which will be recognized over approximately the next 2.5 years. During 2013, options granted to employees and directors had a vesting period of 3 years and a term of 10 years. Options granted to non-employees (e.g. consultants/contractors) had a vesting period of 4 years combined with performance targets for vesting a percentage of the grant, with a term of 10 years.

The Plan is the only active plan pursuant to which options to acquire common stock or restricted stock awards can be granted and are currently outstanding. As of March 31, 2014, there were approximately 5,090,000 shares of the Company common stock available for issuance under the Plan.

As of March 31, 2014, the Company had outstanding options to purchase an aggregate of 3,160,000 shares of the Company common stock with an exercise price of $0.94 price. At March 31, 2014, 565,055 options vested at a weighted average exercise price of $0.94 per share. The computation of the aggregate intrinsic value is based upon the difference between the original exercise price of the options and the Company's estimate of the deemed fair value of the Company's common stock at March 31, 2014. The total intrinsic value of options outstanding and vested at March 31, 2014 was deminimus. No options were granted prior to 2013 and none were granted during the three months ended March 31, 2014.

The Company recognizes compensation expense for stock option awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period, with the exception of options granted subject to a consulting agreement, whereby the option vesting period and the service period defined pursuant to the terms of the consulting agreement may be different. Stock options issued to consultants are revalued quarterly until fully vested, with any change in fair value expensed. The following weighted-average assumptions were used to calculate share based compensation for the three months ended March 31, 2014 and 2013:

	For the three months ended March 31,	
	2014	**2013**
Volatility	69.12%	N/A
Risk-free interest rate	1.93%	N/A
Dividend yield	0.00	N/A
Expected life	5.54	N/A

The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding and is based on the options vesting term, contractual terms, and industry peers as the Company did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.

The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have any trading history for the Company’s common stock. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company’s common stock becomes available.

The risk-free interest rate assumption is based on the U.S treasury instruments whose term was consistent with the expected term of the Company’s stock options

The expected dividend assumption is based on the Company’s history and expectation of dividend payouts. The Company has never paid dividends on its common stock and does not anticipate paying dividends on its common stock in the foreseeable future. Accordingly, the Company has assumed no dividend yield for purposes of estimating the fair value of the Company share-based compensation.

The Company estimates the forfeiture rate at the time of grant and revises, if necessary, were estimated based on management’s expectation through industry knowledge and historical data.

Restricted Stock

The Company granted 500,000 shares of restricted common stock to a third party consultant for services. These shares were fully vested and non-forfeitable at the time of grant, but are restricted to resale over varying periods in 2014. The Company recognized the fair value of the entire grant as a service receivable (disclosed as contra equity) and will recognize expenses as services are rendered over a 12 month period. The value of the restricted stock grant is estimated using the assumed fair market value of the common stock as of date of grant, which was $0.94 a share.

Note I - Commitments and officer loans

Security Deposit

The Company was obligated to provide a security deposit of $300,000 to obtain lease space. Starting May 1, 2015, this deposit can be reduced by $100,000 on an annual basis, down to $50,000, as long as the Company makes timely rental payments.

Lease Space

On November 1, 2013, the Company entered into 7 year lease for office space in Bedminster, New Jersey to start approximately June, 2014 at a monthly rent of $12,723, increasing to approximately $14,200 per month toward the end of the term. The Company will be required to record rent expense on a straight-line basis.

In December of 2013, the Company has entered into an agreement to lease laboratory space for one year starting January 1, 2014 in Monmouth Junction, New Jersey at a monthly rent of $2,072.

Listed below is a summary of future lease rental payments as of March 31, 2014:

	Lease Commitments
2014	$ 101,200
2015	154,140
2016	157,076
2017	160,014
2018 & Beyond	582,797
Total future minimum lease payments	$ 1,155,227

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the related notes and the other financial information included elsewhere in this Quarterly Report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Quarterly Report, particularly those under "Risk Factors" Dollars in tabular format are presented in thousands, except per share data, or otherwise indicated.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 10-Q contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our limited operating history;
- our history of operating losses in each year since inception and the expectation that we will continue to incur operating losses for the foreseeable future;
- our current and future capital requirements to support our development and commercialization efforts for MAT9001 and any product candidates under our MAT8800 discovery program and our ability to satisfy our capital needs;
- our dependence on MAT9001, our lead product candidate, which is still in an early development stage;
- our ability to manufacture GMP batches of MAT9001 as required for pre-clinical and clinical trials and, subsequently, our ability to manufacture commercial quantities of MAT9001;
- our ability to complete required clinical trials for MAT9001 and obtain approval from the FDA or other regulatory agents in different jurisdictions;
- our lack of a sales and marketing organization and our ability to commercialize MAT9001, if we obtain regulatory approval;
- our dependence on third-parties, including third-parties to manufacture MAT9001 and third-party CROs to conduct our clinical trials for MAT9001;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- our ability to retain key executive members;
- our ability to internally develop new inventions and intellectual property;
- interpretations of current laws and the passages of future laws;

- acceptance of our business model by investors;
- the accuracy of our estimates regarding expenses and capital requirements;
- our ability to adequately support growth; and
- the factors listed under the headings "Risk Factors" elsewhere in this report and other reports that we file with the Securities and Exchange Commission.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

Overview

We are a development stage biopharmaceutical company, founded in 2011, with a focus on identifying and developing novel pharmaceutical products for the treatment of abnormalities in blood lipids, referred to as dyslipidemia, and the treatment of cardiovascular and metabolic diseases. By capitalizing on our management's experience working on pharmacological formulation, evaluation and clinical development in the field of lipid science and the therapeutic benefits of omega-3 fatty acids in treating lipid disorders, we have designed a program to develop our lead product candidate MAT9001, with a focus on cardiovascular disease. Specifically, our Chief Executive Officer, Chief Scientific Officer and Executive Vice President for Pharmaceutical and Supply Chain Development were all colleagues at Reliant Pharmaceuticals, Inc., where they were directly responsible for the in-licensing, development, manufacturing optimization and commercialization of various dyslipidemia therapies, including Lovaza ® , the first prescription omega-3 drug approved in the United States, Antara ® , a fenofibrate, and Lescol ® , more commonly known by its generic name fluvastatin. With respect to our lead product candidate, MAT9001, our goal is to establish significant differentiation over existing available therapies by demonstrating significant reductions in triglyceride levels, lowering of cholesterol levels, and improving other important physiological parameters, thereby addressing what we believe is currently a significant unmet medical need. In addition, our MAT8800 discovery program is seeking to identify and develop product candidates derived from omega-3 fatty acids for the treatment of prevalent liver diseases for which there are currently only limited therapeutic solutions available. We believe that our unique ability to produce and isolate highly concentrated omega-3 fatty acids which have demonstrated effects on liver enzyme levels and histology could yield product candidates which are particularly well suited to treat these diseases.

Our lead product candidate, MAT9001, is a proprietary prescription-grade omega-3 fatty acid composition, comprised of a complex mixture of omega-3 fatty acids, including eicosapentaenoic acid, or EPA, docosapentaenoic acid, or DPA, a potent but less prevalent omega-3 fatty acid, several other omega-3 fatty acids, and only nominal amounts of docosahexaenoic acid, or DHA, and non-omega-3 fatty acids. We have initiated the good manufacturing practice, or GMP, manufacturing process for our complex composition and have also initiated preclinical studies. To date, we have been optimizing the manufacturing process for the MAT9001 active pharmaceutical ingredient and are working toward our Investigational New Drug, or IND, filing with the United States Food and Drug Administration, or FDA.

In addition to MAT9001, we have established a discovery program called MAT8800 to identify and develop product candidates derived from omega-3 fatty acids for the treatment of prevalent liver diseases for which there are currently only limited therapeutic solutions. Our development work indicated that certain omega-3 fatty acids may yield improvement in liver enzyme levels and liver histology. Accordingly, we have identified potential omega-3 fatty acid compositions to study in preclinical settings. This discovery program is focused on identifying and optimizing product candidates comprising omega-3 fatty acids as potential treatments for nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH) or other hepatic conditions.

We are primarily focused on developing and commercializing MAT9001 through approval by the FDA, with an initial indication for the treatment of severe hypertriglyceridemia. Severe hypertriglyceridemia refers to a condition in which patients have high blood levels of triglycerides (TG ≥500 mg/dl) and is recognized as an independent risk factor for pancreatitis and cardiovascular disease. Based on information provided by the National Heart, Lung and Blood Institute and National Cholesterol Education Program, or NCEP, ATP III Guidelines (collectively, the "NCEP Guidelines"), we estimate that more than four million people in the United States have severe hypertriglyceridemia. If we receive FDA approval for severe hypertriglyceridemia, we may seek approval for use of MAT9001 in additional indications, including the treatment of patients with mixed dyslipidemia who may already be undergoing treatment with a statin, a commonly used class of cholesterol lowering medication. Mixed dyslipidemia refers to a condition in which patients have a combination of both elevated triglycerides (≥200mg/dl), and elevated cholesterol levels. Based on the NCEP Guidelines, we estimate that approximately 30 to 35 million Americans have mixed dyslipidemia.

We are a development stage company and have not generated any revenues. We have never been profitable and, from inception through March 31, 2014, our losses from operations have been approximately $6.0 million. Our net loss was approximately $2.1 million and $0.1 million for the three months ended March 31, 2014 and 2013, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase significantly in connection with our ongoing activities to develop, seek regulatory approval and commercialization of MAT9001. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

Financial Operations Overview

Revenue

To date, we have not generated any revenue. Our ability to generate product revenue, which we do not expect will occur before 2017, if ever, will depend significantly on the successful development and eventual commercialization of our lead product candidate, MAT9001.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of MAT9001 and identification of product candidates under our MAT8800 discovery program, which include:

- the cost of conducting pre-clinical work;
- the cost of acquiring, developing and manufacturing pre-clinical trial materials;
- costs for consultants and contractors associated with Chemistry and Manufacturing Controls (CMC), pre-clinical activities and regulatory operations;
- expenses incurred under agreements with contract research organizations, or CROs, that conduct our pre-clinical trials; and
- employee-related expenses, including salaries and stock-based compensation expense for those employees involved in the research and development process.

The table below summarizes our direct research and development expenses for MAT9001 for the periods indicated. Our direct research and development expenses consist principally of external costs, such as fees paid to contractors, consultants, analytical laboratories and CROs, in connection with our development work. We typically use our employee and infrastructure resources for developing MAT9001.

	Three months Ended March 31,		From August 11, 2011 (date of inception) to March 31,
	2014	2013	2014
	($ in thousands)		
Direct research and development expenses:			
Manufacturing process development	$ 312	$ 50	$ 1,039
Preclinical trails	12		248
Regulatory	96		209
Internal staffing, Overhead and Other	654		1,419
Total research & development	$ 1,074	$ 50	$ 2,915

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage human trials.

We believe we have optimized the manufacturing process for the active pharmaceutical ingredient of MAT9001 and have initiated preclinical studies with the MAT9001 active ingredient. We completed the first preclinical studies of MAT9001 during the fourth quarter of 2013. We commenced manufacturing of GMP batches of MAT9001 late in the first quarter of 2014 and expect to file our IND with the U.S. FDA and commence a human study of MAT9001 during the middle of 2014. Thereafter we are considering initiating a Special Protocol Assessment Review with the FDA during the second half of 2014 and expect to commence the first pivotal Phase III study of MAT9001 in patients with severe hypertriglyceridemia in late 2014, complete our Phase III program and plan to submit an NDA with the FDA during late 2016, and to commercialize MAT9001 in the United States for the treatment of patients with triglyceride levels greater than or equal to 500 mg/dl, or severe hypertriglyceridemia, during 2017.

The continued development of MAT9001 is subject to a number of risks including, but not limited to:

- the uncertainty of the outcome of preclinical studies with MAT9001;
- the uncertainty of the timing and outcome of regulatory IND submissions for MAT9001 and subsequent FDA review thereof;
- the uncertainty of the timing and outcome of the manufacturing of GMP batches of MAT9001;
- the uncertainty of the timing and outcome of initial human studies with MAT9001;
- the possibility of changes to existing treatment guidelines for dyslipidemia and cardiovascular disease;
- the uncertainty of the timing and outcome of regulatory review of the potential Special Protocol Assessment for the pivotal Phase III program for MAT9001;
- the uncertainty of the timing and outcome of our Phase III program for MAT9001;
- the uncertainty of the timing and outcome of an NDA submission for MAT9001 and subsequent FDA review thereof;
- the uncertainty of the timing and outcome of the prosecution of patents covering MAT9001, within the U.S. or abroad;
- the possibility that the emergence of competing technologies and products and other adverse market developments could impede our fund raising and commercial efforts; and
- the requirement that the facilities used by our contract manufacturers to manufacture MAT9001 must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA.

The estimated costs expected to be incurred for the research and development activities prior to the initiation of Phase III pivotal studies of MAT9001 are between $5.0 million and $7.0 million, which we expect to fund from the proceeds of the 2013 Private Placement. The estimated additional costs expected to be incurred for research and development activities thereafter through the filing of our first NDA with the U.S. FDA are between $20.0 million and $60.0 million, which we expect to fund through future capital raising activities.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive and finance functions. Other general and administrative expenses include facility costs, communication expenses, and professional fees for legal, patent review, consulting and accounting services.

We anticipate that our general and administrative expenses will increase in 2014 and 2015 due to many factors, the most significant of which include:

- increased personnel as we expand our operations to prepare for and execute upon our Phase III pivotal studies of MAT9001, which we expect to commence late in 2014;
- increased expenses related to becoming a publicly-traded company, including increased legal and accounting services, stock registration and printing fees, expenses in support of compliance and communication needs, and increased insurance premiums;
- increased compensation costs since 2013 is only a partial year (approximately 5 months vs. full year compensation costs of existing staff moving forward in 2014 and 2015; and
- increased infrastructure costs related to rent expense, office infrastructure expenses, and Information Technology/Communication costs.

Other Expense, net

Other Expense, net for the three months ended March 31, 2014 is comprised of miscellaneous tax payments partially offset by interest income earned on cash balances.

Application of Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Quarterly Report. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses, particularly for product development costs. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments as necessary. Examples of estimated accrued research and development expenses include:

- fees paid to contractors in connection with the development of manufacturing processes for MAT9001;
- fees paid to CROs in connection with preclinical development activities;
- fees paid to contractors in connection with preparation of regulatory submissions; and

- fees paid to vendors related to product manufacturing, development and distribution of clinical study supplies.

We base our expenses related to pre-clinical and human studies on our estimates of the services received and efforts expended pursuant to contracts with multiple development contractors that conduct and manage development work and studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts may depend on factors such as the successful enrollment of subjects and the completion of specific study milestones. In accruing service fees, we will estimate the time period over which services will be performed, the completion of certain tasks, enrollment of subjects, study center activation and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual or prepayment accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. Based on limited historical experience, actual results have not been materially different from our estimates.

Research and Development expenses

Research and development expenses are charged to operations as they are incurred.

Stock-Based Compensation

Option Grants

We account for all share-based compensation payments issued to employees, directors, and non-employees using an option pricing model for estimating fair value. Accordingly, share-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of forfeitures. We recognize compensation expense for the portion of the award that is ultimately expected to vest over the period during which the recipient renders the required services to us using the straight-line single option method. In accordance with authoritative guidance, we remeasure the fair value of non-employee share-based awards as the awards vest, and recognize the resulting value, if any, as expense during the period the related services are rendered.

Significant Factors, Assumptions and Methodologies Used in Determining Fair Value

We apply the fair value recognition provisions of ASC Topic 718, Compensation-Stock Compensation, which we refer to as ASC 718. Determining the amount of share-based compensation to be recorded required us to develop estimates of the fair value of stock options as of their grant date before operating as a public company. We recognize share-based compensation expense ratably over the requisite service period, which in most cases is the vesting period of the award. Calculating the fair value of share-based awards requires that we make highly subjective assumptions.

We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the volatility of our common stock, the expected term of our stock options, the risk free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. As a privately-held company with a limited operating history, we utilized data from a representative group of companies to estimate expected stock price volatility. We selected companies from the biopharmaceutical industry with similar characteristics to us, including those in the early stage of product development and with a therapeutic focus.

We use the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term of stock option grants to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. The risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

We recognize compensation expense for stock option awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period, with the exception of options granted subject to a consulting agreement, whereby the option vesting period and the service period defined pursuant to the terms of the consulting agreement may be different. Stock options issued to consultants are revalued quarterly until fully vested, with any change in fair value expensed. We did riot issue any options or warrants in the three month periods ended March 31, 2014 or 2013, however the following assumptions were used to re-measure stock options issued to consultants at March 31, 2014.

	Three months Ended March 31,	
	2013	2014
Weighted-average exercise price of options granted	—	$ 0.94
Expected volatility	—	69.12
Risk-free interest rate	—	1.93%
Expected life of options (years)	—	5.54 years
Expected annual dividend per share	—	$ 0.00

The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding and is based on the options vesting term, contractual terms, and industry peers as we did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.

The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as we did not have any trading history for our common stock. We will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for our common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of our stock options. The expected dividend assumption is based on our history and expectation of dividend payouts.

We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. Accordingly, we have assumed no dividend yield for purposes of estimating the fair value of our share-based compensation.

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. We use historical data to estimate pre-vesting option forfeitures and record share-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised.

Share-based compensation expense associated with stock options and restricted stock granted to employees and non-employees was $0 for the three months ended March 31, 2013 and $274,000 for the three months ended March 31, 2014. As of March 31, 2014, we had $1.9 million of total unrecognized share-based compensation expense, which we expect to recognize over a weighted-average remaining vesting period of approximately 2.5 years. While our share-based compensation for stock options granted to employees and non-employees to date has not been material to our financial results, in future periods, our share-based compensation expense is expected to increase as a result of recognizing our existing unrecognized share-based compensation for awards that will vest and as we issue additional share-based awards to attract and retain our employees.

We have included stock based compensation as part of our operating expenses in our statement of operation for the three months ended March 31, 2014 and 2013 as follows:

	Three months ended March 31,	
	2014	2013
General and administrative	$ 219,211	-
Research and development	$ 54,613	-
Total	$ 273,824	-

Described below is the methodology we utilized in measuring stock-based compensation. Management had for financial reporting purposes determined the estimated per share fair value of our common stock and redeemable convertible preferred stock using valuation consistent with the American Institute of Certified Public Accountants Practice Aid, “Valuation of Privately-Held Company Equity Securities Issued as Compensation,” also known as the Practice Aid. This valuation was performed as of September 1, 2013 with the assistance of a third-party valuation specialist. In conducting the valuation, management considered all objective and subjective factors that it believed to be relevant, including management’s best estimate of our business condition, prospects and operating performance at the valuation date. Within the valuation performed, a range of factors, assumptions and methodologies were used as previously described in this section.

The significant factors included;

- external market conditions affecting the biotechnology industry;
- trends within the biotechnology industry;
- the prices at which we sold shares of preferred stock;
- the superior rights and preferences of the preferred stock relative to common stock at the time of each grant;
- the prices at which we sold units of common stock and warrants;
- the results of operations and financial position;
- status of research and development efforts;
- stage of development and business strategy;
- the lack of an active public market for the common stock; and
- the likelihood of achieving a liquidity event such as a sale of the company in light of prevailing market conditions.

We estimated the forfeiture rate at the time of grant and, if necessary, revised in subsequent periods if actual forfeitures differed from those estimates. Forfeitures were estimated based on management's expectation through industry knowledge and historical data.

The 2013 Equity Compensation Plan, or the Plan, is the only active plan pursuant to which options to acquire common stock or restricted stock awards can be granted and are currently outstanding. As of March 31, 2014, there were approximately 5,090,000 shares of our common stock available for issuance under the Plan.

As of March 31, 2014, we had outstanding options to purchase an aggregate of 3,160,000 shares of our common stock with an exercise price of $0.94. At March 31, 2014, 565,055 options vested at a weighted average exercise price of $0.94 per share. The computation of the aggregate intrinsic value is based upon the difference between the original exercise price of the options and our estimate of the deemed fair value of our common stock at March 31, 2014. The total intrinsic value of options outstanding and vested at March 31, 2014 was de-minimis.

The per share estimated fair market value of common stock in the table below represents the determination by our board of directors of the fair market value of our common stock as of the date of grant, taking into consideration the various objective and subjective factors described above, including the conclusions, if applicable, of contemporaneous valuations of our common stock as discussed below. We computed the per share weighted average estimated fair value for stock option grants based on the Black-Scholes option pricing model. The following table sets forth information about our stock option grants since August 2013 on a monthly basis for each month during which we granted stock options:

A summary of the Company stock option grants for 2013 and the three months ended March 31, 2014 is as follows:

Date of Grant/Termination	# of options granted	# options vested as of 03/31/2014	Exercise Price Per Share	Common Stock Fair Value on Date Per Share of Grant
Third Quarter				
8/1/2013	1,835,000	N/A	$ 0.79	$ 0.94
Fourth Quarter				
October 3, 2013 (cancellation)	(1,835,000)	N/A	$ 0.79	$ 0.94
October 3, 2013 (reissuance) *	1,835,000	407,778	$ 0.94	$ 0.94
10/4/2013	200,000	33,333	$ 0.94	$ 0.94
10/15/2013	375,000	23,250	$ 0.94	$ 0.94
11/1/2013	475,000	65,972	$ 0.94	$ 0.94
11/15/2013	150,000	20,833	$ 0.94	$ 0.94
12/2/2013	125,000	13,889	$ 0.94	$ 0.94
Total as of March 31, 2014 **	3,160,000	565,055		

*All grants outstanding as of September 30, 2013 (1,835,000 shares) were terminated and reissued at an exercise price of $ 0.94 on October 3, 2013, to reflect the independent valuation contracted by the Company on September 1, 2013. The $0.79 exercise price initially set was based upon management's estimate of the fair value of the underlying shares in July 2013. We received a subsequent valuation report from a third party valuation firm, whose valuation report was finalized as of September 16, 2013. Pursuant to that report and consistent with the value of the Company's shares sold in transactions in the time period around the issuance of the stock options, the fair value of the securities was determined to be $0.94 per share. Given that the exercise price was below the previously estimated fair value for the underlying shares, we obtained Board approval on October 3, 2013 to cancel the existing stock options and reissue them with a strike price of $0.94 per share. The cancellation and reissuance of the shares did not result in additional total compensation cost to be amortized over the options requisite service period because the strike price increased from $0.79 to $0.94.

** All options expire ten years from the date of grant. Except for options granted on October 15, 2013, all remaining options vest entirely and evenly over three years. The October 15, 2013 options had been granted to non-employee consultants. A portion of each of these consultant options vests over four years, with the remaining vesting being based upon the achievement of performance milestones, which are tied to either financing or drug development initiatives. No new options have been granted in 2014.

Basic and Diluted Net Loss Per Share of Common Stock

We compute basic net loss per share of common stock by dividing net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects stock options. We compute diluted net loss per share of common stock by dividing the net loss applicable to common stockholders by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects stock options outstanding during the period calculated in accordance with the treasury stock method, but such items are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between our basic and diluted net loss per share of common stock for the three months ended March 31, 2014 and 2013.

Emerging Growth Company Status

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Results of Operations

Comparison of three months ended March 31, 2014 and 2013

	Three months ended March 31,		Increase
	2014	2013	(Decrease)
	(In thousands)		
Expenses:			
Research and development	$ 1,073	$ 50	$ 1,023
General and administrative	1,055	62	993
Net loss	$ (2,139)	$ (112)	$ 2,027

Research and Development expenses. Research and development expense for the three months ended March 31, 2014 was $1.1 million , compared to $50,000 for the three months ended March 31, 2013, an increase of $1.0 million. The increase in research and development expense was primarily due to an increase in activities for the development of the manufacturing process for MAT9001, preclinical studies and build out of our corporate infrastructure.

General and Administrative expenses. General and administrative expense for the three months ended March 31, 2014 was $1.1 million compared to $62,000 for the three months ended March 31, 2013, an increase of $993,000. The increase in general and administrative expense was primarily due to compensation expenses, particularly associated with new employee compensation, ongoing accounting and legal services, including those legal services those associated with the registration statement for resale of common stock for our private placement investors, compliance and intellectual property filings.

As noted previously, in terms of operating expenses (particularly compensation expenses), 2013 represents a partial year (i.e. start-up year), hence 2014 will show increased expenses due to a full year of operations in both Research and Development, and General and Administrative expenses.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations since inception through private placements of preferred stock and our common stock and common stock warrants. As of March 31, 2014, we raised a total of $14.0 million in net proceeds from sales of our equity securities.

As of March 31, 2014, we had cash and cash equivalents totaling $8.6 million.

2013 Private Placement

In July and August 2013, we completed the 2013 Private Placement, under which we sold an aggregate of 15,000,000 shares of our common stock and warrants to purchase an aggregate of 7,500,000 shares of our common stock with an exercise price of $2.00 per share, which warrants are exercisable for a period of five years from the initial closing date. Aegis Capital Corp. acted as the Placement Agent for the 2013 Private Placement (the "Placement Agent"). The gross proceeds to us from the 2013 Private Placement were $15.0 million.

Warrant Private Placement

Contemporaneously with the initial closing of the 2013 Private Placement, we sold 500,000 Private Placement Warrants to Herbert Conrad, our chairman of the board, for a purchase price of $0.04 per warrant. The Private Placement Warrants have an exercise price of $2.00 per share. The Private Placement Warrants were offered to all preferred stockholders of Matinas BioPharma prior to the Merger, and only Mr. Conrad exercised the offer.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Three months ended March 31,		From August 11, 2011 (date of inception) to March 31,
	2014	**2013**	**2014**
Cash used in operating activities	$ (2,089)	$ (150)	$ (5,134)
Cash used in investing activities	(193)	-	(287)
Cash provided by financing activities	-	385	13,980
Net increase in cash and cash equivalents	$ (2,282)	$ 235	$ 8,558

Operating Activities

We have incurred significant costs in the area of research and development, including manufacturing, analytical, regulatory and other development costs, as the manufacturing process for our product was being developed. However, we will have significantly increased development costs in conducting preclinical and human studies, regulatory filing activities, preparation of the IND and NDA for MAT9001 as well as costs for continued development and validation of the manufacturing process for MAT9001. We also expect significantly increased development costs associated with our MAT8800 discovery program. We also expect our general and administrative expenses to increase as we expand our administrative, compliance, legal and investor relations activities, increase our activities in developing and maintaining our intellectual property and establish our company as a publicly traded company. Net cash used in operating activities was approximately $2.1 million for the three months ended March 31, 2014 and $150,000 for the three months ended March 31, 2013. The increase in cash used in operating activities for the three months ended March 31, 2014 compared to the three months ended March 31, 2013 was primarily due to higher development costs in connection with development of the manufacturing process and the costs in connection with fund raising activities and compliance. We expect that there will be a significant increase in cash used in our operating activities during 2014, as we move MAT9001 forward as well as incur full year costs associated with our compensation expenses and corporate infrastructure.

Investing Activities

Net cash used in investing activities was $193,000 for the three months ended March 31, 2014 and $0 for the three months ended March 31, 2013. The cash used in investing activities for the three months ended March 31, 2014 was primarily the purchase of scientific laboratory equipment.

Financing Activities

Net cash provided by financing activities was $0 for the three months ended March 31, 2014 and net cash provided by financing activities was $385,000 for the three months ended March 31, 2013. The cash provided by financing activities for the three months ended March 31, 2013 was primarily due to proceeds received from issuance of redeemable convertible preferred stock.

Funding Requirements and Other Liquidity Matters

MAT9001 is still in a development stage and our MAT8800 discovery program is in a very early stage. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- receive acceptance by the FDA of our IND for MAT9001 in patients with severe hypertriglyceridemia;
- initiate human trials of MAT9001;
- commence non-clinical studies of MAT9001;
- initiate our Phase III clinical program for MAT9001;
- enter into manufacturing and supply agreements for MAT9001;
- seek to identify additional indications for MAT9001;
- seek to identify product candidates under our MAT8800 discovery program;
- maintain, leverage and expand our intellectual property portfolio for MAT9001 and MAT8800;
- acquire or in-license other products and technologies;
- add operational, financial and management information systems and personnel, including personnel to support our product development and future compliance and/or commercialization efforts;
- seek marketing approval for MAT9001for the currently planned or any additional indication;
- commence non-clinical and preclinical studies of product candidates in our MAT8800 discovery program; and
- establish a sales and marketing infrastructure to commercialize MAT9001 in the United States.

We expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditures requirements through January 2015 and will allow us to file our IND for MAT9001 and potentially initiate a special protocol assessment with the FDA for our MAT9001 Phase III clinical program for MAT9001. We will need additional financing to initiate and conduct our intended Phase III clinical program for MAT9001, file additional patent applications and enhance our intellectual property position for MAT9001 and MAT8800, validate the manufacturing processes at our various suppliers and prepare for submission of an NDA for MAT9001, and conduct preclinical work in order to identify product candidates under our MAT8800 discovery program. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Significant additional funds may be required to initiate and complete our Phase III clinical program for MAT9001 if the FDA does not agree with our intended regulatory pathway under Section 505(b)(2) of the Act and to initiate and complete those preclinical and human trials deemed necessary or advisable for product candidates selected pursuant to our MAT8800 discovery program. If the FDA does not agree with our streamlined regulatory and clinical approach for our intended Phase III trial to support a NDA filing for MAT9001 under Section 505(b)(2) of the Act, we believe that we will need at least $20.0 to $60.0 million of additional capital following to complete our Phase III clinical program and submit a NDA under Section 505(b)(1) of the Act if so required by the FDA.

Until the time we can generate substantial product revenues from commercializing MAT9001, if ever, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and could increase our expenses and require that our assets secure such debt. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, MAT9001, product candidates emerging from MAT8800 or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market MAT9001 and any product candidates under MAT8800 that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

On November 1, 2013, we entered into a seven year lease for office space in Bedminster, New Jersey. The commencement date and first obligation to pay rent is June 2014, with annual rent beginning at approximately $152,000 per year, increasing to $174,000 in the final year.

In December 2013, the Company entered into an agreement to lease laboratory space for one year commencing January 1, 2014 in Monmouth Junction, New Jersey. Base rent for the year ended December 31, 2014 will be approximately $25,000.

We may enter into contracts in the normal course of business with clinical research organizations for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore we believe that our non-cancelable obligations under these agreements are not material. As of March 31, 2014, we had no material Contractual Obligations or Commitments that will affect our future liquidity.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is limited to our cash and cash equivalents, all of which have maturities of one year or less. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. We do not have any foreign currency or other derivative financial instruments.

RECENT ACCOUNTING PRONOUNCEMENTS

Refer to Note 2, “Significant Accounting Policies,” in the accompanying notes to the condensed consolidated financial statements for a discussion of recent accounting pronouncements.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures.

As of March 31, 2014, we evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of March 31, 2014 due to material weaknesses identified in connection with the preparation and audit of our consolidated financial statements for the years ended December 31, 2013 and 2012. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within time periods specified by the SEC's rules and forms, and that such information is accumulated and communicated to our management, including principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In connection with the preparation and audit of our consolidated financial statements for the years ended December 31, 2013 and 2012, we and our independent registered public accounting firm identified material weaknesses in internal control over financial reporting related to (i) financial closing procedures and lack of sufficient resources to maintain financial records and account for significant accounting transactions, particularly related to equity transactions and restricted stock and stock options for employees and non-employees and (ii) lack of proper segregation of duties. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a Company's annual or interim financial statements will not be prevented or detected on a timely basis by the Company's internal control over financial reporting.

We have implemented and are continuing to implement procedures and controls designed to remediate these material weaknesses and underlying deficiencies. Amongst other actions, we have recently added a senior accountant to our finance team; commenced implementation of enhanced review procedures; and begun a comprehensive documentation of our accounting policies and our internal controls and procedures. We have also hired an accounting firm to provide technical accounting support and an additional level of review. Although we believe these controls will be effective, we have not yet determined if we have successfully remediated the material weaknesses identified in connection with the preparation and audit of our consolidated financial statements for the years ended December 31, 2013 and 2012.

Notwithstanding the identified material weaknesses in internal control over financial reporting, management believes the consolidated financial statements included in this Quarterly Report on Form 10-Q fairly represent in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with U.S. GAAP.

Changes in Internal Control Over Financial Reporting.

Other than the remediation efforts discussed above, there were no changes in our internal control over financial reporting during the three months ended March 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

None.

Item 1A. Risk Factors

Owning our common stock involves a high degree of risk, including the risk of a loss of your entire investment. You should carefully consider the risks and uncertainties described below and the other information contained in this Quarterly Report. The risks set forth below are not the only ones facing us. Additional risks and uncertainties, including those of which the Company is not aware or that it deems immaterial, may exist that could also adversely affect our business, operations and prospects. If any of the following risks actually materialize, our business, financial condition, prospects and/or operations could suffer and be materially harmed. In such event, the value of our common stock could decline.

Risks Related to Our Financial Position and Need for Capital

We are a development stage biopharmaceutical company with a limited operating history.

We are a development stage biopharmaceutical company with a limited operating history. We have not commenced human trials and anticipate meeting with the FDA prior to commencing such clinical trials to discuss our proposed clinical pathway. The likelihood of success of our business plan must be considered in light of the problems, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Biopharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially development stage biopharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors

should consider that we cannot assure you that we will be able to:

- receive FDA acceptance of our proposed regulatory pathway for MAT9001;
- successfully implement or execute our current business plan, or that our business plan is sound;
- successfully complete pre-clinical and clinical trials for MAT9001 and obtain regulatory approval for the marketing of MAT9001;
- successfully identify product candidates under our MAT8800 discovery program;

- successfully manufacture clinical product and establish commercial drug supply for MAT9001;
- secure market exclusivity and/or adequate intellectual property protection for MAT9001 or a product candidate under our MAT8800 discovery program;
- attract and retain an experienced management and advisory team; and
- raise sufficient funds in the capital markets to effectuate our business plan, including the preparation and completion of our Phase III clinical program for MAT9001.

If we cannot successfully execute any one of the foregoing, our business may not succeed.

We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.

We expect to incur substantial expenses without corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize MAT9001. We have been engaged in developing MAT9001 since 2011. To date, we have not generated any revenue from MAT9001 and we expect to incur significant expense to complete our Phase III clinical program for MAT9001 in the United States. We may never be able to obtain regulatory approval for the marketing of MAT9001 in any indication in the United States or internationally. Even if we are able to commercialize MAT9001 or any other product candidate, there can be no assurance that we will generate significant revenues or ever achieve profitability. Our net loss for the year ended December 31, 2012 and 2013 was $0.1 million and $3.7 million, respectively. As of December 31, 2013, we had an accumulated deficit of $3.8 million.

Assuming we obtain FDA approval for MAT9001, which we do not expect until 2017 at the earliest, we expect that our expenses will increase if we reach commercial launch of MAT9001. We also expect that our research and development expenses will continue to increase as we advance to human trials for an indication for the treatment of severe hypertriglyceridemia and we may pursue FDA approval for MAT9001 in other indications, which will result in significant additional research and development expense. Furthermore, we expect that our research and development expenses will significantly increase as our MAT8800 discovery program progresses and we advance to pre-clinical and clinical trials with one or more product candidates. As a result, we expect to continue to incur substantial losses for the foreseeable future, and we expect these losses will be increasing. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital.

We will need to raise significant additional capital to support our development and commercialization efforts for MAT9001 if the FDA does not accept our proposed regulatory pathway.

We believe that our cash and cash equivalents will be sufficient to fund our operations and capital expenditure requirements through 2014 and will allow us to conduct our currently planned pre-clinical studies, file additional patent applications in order to potentially enhance our intellectual property position, file our investigational new drug application, or IND, initiate a special protocol assessment with the FDA for our MAT9001 Phase III clinical program for patients with severe hypertriglyceridemia. However, we will need to seek additional equity or debt financing to initiate and conduct our intended Phase III clinical program for MAT9001, file additional patent applications and enhance our intellectual property position for MAT9001 and MAT8800, validate the manufacturing processes at our various suppliers and prepare for submission of an NDA for MAT9001, and conduct preclinical work in order to identify product candidates under our MAT8800 discovery program. We believe we will need at least $20 to $60 million of additional capital to complete our Phase III clinical program and submit a New Drug Application, or NDA. See “Matinas’ Business – MAT9001 Development Program”. In addition, we will need to raise additional funding to complete clinical development of any product candidate that emerges from MAT 8800.

We do not currently have any arrangements or credit facilities in place as a source of funds, and there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all. We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic collaborations and/or licensing arrangements. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, could increase our expenses and require that our assets secure such debt. Moreover, any debt we incur must be repaid regardless of our operating results. Equity financing, if obtained, could result in dilution to our then existing stockholders and/or require such stockholders to waive certain rights and preferences or otherwise adversely affect their rights. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected. In addition, if we are unable to secure sufficient capital to fund our operations, we might have to enter into strategic collaborations that could require us to share commercial rights to MAT9001 with third parties in ways that we currently do not intend or on terms that may not be favorable to us. If we choose to pursue additional indications and/or geographies for MAT9001 or otherwise expand more rapidly than we presently anticipate we may also need to raise additional capital sooner than expected.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2013 with respect to this uncertainty. This going concern opinion, and any future going concern opinion, could materially limit our ability to raise additional capital. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. We have devoted our resources to developing MAT9001, but this product candidate cannot be marketed for any indication until regulatory approvals have been obtained. Meaningful revenues will likely not be available until, and unless, MAT9001 or any future product candidate is approved by the FDA or comparable regulatory agencies in other countries and successfully marketed, either by us or a partner. The perception that we may not be able to continue as a going concern may cause potential partners or investors to choose not to deal with us due to concerns about our ability to meet our contractual and financial obligations.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

We currently depend entirely on the success of MAT9001, which is still in clinical development. If we are unable to generate revenues from MAT9001, our ability to create stockholder value will be limited.

Our lead product candidate is MAT9001, which is at the clinical development stage. We do not commercialize any FDA-approved drug products and our drug discovery program, MAT8800, has yet to identify any specific product candidate. Other than MAT9001 and our MAT8800 discovery program, we currently have no other product candidates in development. We intend to follow the regulatory pathway described in this registration statement for the approval of MAT9001 with an indication to treat severe hypertriglyceridemia. We have commenced pre-clinical studies with MAT9001 and intend to submit an IND to the FDA seeking to initiate our first clinical trial in humans in the United States. We must complete these efforts before we will be able to commence our Phase III clinical program for MAT9001. We may not be successful in obtaining acceptance from the FDA for our proposed regulatory pathway under Section 505(b)(2) of the Food and Drug Act, including acceptance of the IND for MAT9001. If we do not obtain such acceptance, the time in which we expect to commence our Phase III clinical program will be extended and such extension will significantly increase our expenses, reduce our capital and we will likely need to seek additional equity or debt financing. Moreover, there is no guarantee that our Phase III clinical program will be successful or that it will ultimately be adequate to support an approval from the FDA for any indication. We note that most drug candidates never reach the clinical development stage and even those that do reach clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends entirely on the successful development, regulatory approval and commercialization of MAT9001, which may never occur.

If we are not able to obtain any required regulatory approvals for MAT9001, we will not be able to commercialize our only current product candidate and our ability to generate revenue will be limited.

We must successfully complete pre-clinical and clinical trials for our lead product candidate, MAT9001, before we can apply for its marketing approval. We have limited experience in managing clinical trials, particularly late-stage clinical trials. Even if we complete our clinical trials, it does not assure FDA approval. We have commenced pre-clinical testing of MAT9001. Our pre-clinical trials may be unsuccessful, which would materially harm our business. Even if these trials are successful, we are required to conduct clinical trials and manufacturing quality assessments to establish MAT9001's safety and efficacy, and extensive pharmaceutical development to ensure its quality before a New Drug Application, or NDA, can be filed with the FDA for marketing approval of MAT9001.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize MAT9001. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market MAT9001 as a prescription pharmaceutical product in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of pre-clinical testing and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are eventually approved for commercialization. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities. If our development efforts for MAT9001, including regulatory approval, are not successful for its planned indications, or if adequate demand for MAT9001 is not generated, our business will be materially adversely affected.

Our success depends on the receipt of regulatory approval and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following:

- the FDA or comparable foreign regulatory authorities or institutional review boards, or IRBs, may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of MAT9001's safety and efficacy;
- the results of our pre-clinical or clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, European Medicines Agency, or EMA, or other regulatory agencies for marketing approval;
- the FDA may not agree with a portion or any of our planned streamlined approach for approval of MAT9001;
- the dosing of MAT9001 in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to MAT9001;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain regulatory approval for MAT9001 for the foregoing or any other reasons will prevent us from commercializing this product candidate as a prescription product, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we intend to conduct in the future or that such trials will be successful. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

We are a development stage biopharmaceutical company and we have not submitted an NDA or received regulatory approval to market MAT9001 in any jurisdiction. We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission of pre-clinical, clinical, and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. MAT9001 may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for MAT9001 in any indication will prevent us from commercializing the product candidate, and our ability to generate revenue will be materially impaired.

MAT9001 is currently our only product candidate in development. If we fail to successfully commercialize MAT9001, we may need to acquire additional product candidates and our business may be adversely affected.

We have never commercialized any product candidates and do not have any other compounds in pre-clinical testing, lead optimization or lead identification stages beyond MAT9001 and MAT8800. We cannot be certain that our lead product candidate, MAT9001, will prove to be sufficiently effective and safe to meet applicable regulatory standards for any indication. If we fail to successfully commercialize MAT9001 as a treatment for severe hypertriglyceridemia or any other indication, whether as a stand-alone therapy or in combination with other treatments, our business would be adversely affected. If this occurs, we may seek out opportunities to discover, develop, acquire or license additional promising product candidates or drug compounds to expand our product candidate pipeline beyond MAT9001 and our MAT8800 discovery program. This would constitute a significant change in our strategy and would likely require substantial additional capital. We would also be exposed to numerous additional risks related to our ability to identify, select and acquire the right product candidates and products on terms that are acceptable to us, and there is no guarantee that we would be successful in these efforts.

Even if we receive regulatory approval for MAT9001, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, may be limited.

If approved for marketing, the commercial success of MAT9001 will depend upon its acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of MAT9001 will depend on a number of factors, including:

- demonstration of clinical safety and efficacy of prescription omega-3 products generally;
- relative convenience, pill burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe MAT9001 and of the target patient population to try new therapies;
- the efficacy of MAT9001 compared to competing products, including Lovaza, Vascepa and omega-3 dietary supplements;
- the introduction of any new products, including generic prescription omega-3 products and dietary supplements, that may in the future become available to treat indications for which MAT9001 may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications in which MAT9001 may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of prescription omega-3 products in applicable treatment guidelines;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-approved labeling;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

If MAT9001 is approved, but does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of MAT9001 may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize MAT9001 successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render MAT9001 not commercially viable. For example, regulatory authorities may approve MAT9001 for fewer or more limited indications than we request, may not approve the price we intend to charge for MAT9001, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve MAT9001 with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA may place conditions on approvals including potential requirements or risk management plans and the requirement for a Risk Evaluation and Mitigation Strategy ("REMS") to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of MAT9001. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of MAT9001.

We currently have no sales and marketing organization. If we are unable to establish satisfactory sales and marketing capabilities, we may not successfully commercialize MAT9001.

At present, we have no sales or marketing personnel. In order to commercialize products that are approved for commercial sales, we must either develop a sales and marketing infrastructure or collaborate with third parties that have such commercial infrastructure. If we elect to develop our own sales and marketing organization, we do not intend to begin to hire sales and marketing personnel until the time of NDA submission to the FDA at the earliest, and we do not intend to establish our own sales organization in the United States until shortly prior to FDA approval of MAT9001. Therefore, at the time of our anticipated commercial launch of MAT9001, assuming regulatory approval of the drug by the FDA, our sales and marketing team will have worked together for only a limited period of time. Accordingly, we may not be successful in marketing MAT9001 in the United States.

We may not be able to establish a direct sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize MAT9001 in the United States without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe MAT9001;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty successfully commercializing MAT9001, which would adversely affect our business, operating results and financial condition. Outside the United States, we intend to commercialize MAT9001 by entering into collaboration agreements with pharmaceutical partners. We may not be able to enter into such agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Established competitors may invest heavily to quickly discover and develop novel compounds that could make MAT9001 or any product candidate resulting from our MAT8800 discovery program obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to MAT9001 or to a product developed under our MAT8800 discovery program. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Our potential competitors both in the United States and Europe include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies and specialized cardiovascular treatment companies. These companies include GlaxoSmithKline plc, which currently markets Lovaza, a prescription omega-3 fatty acid indicated for patients with severe hypertriglyceridemia, and Abbvie, Inc. (previously Abbott Laboratories), which currently markets Tricor® and Trilipix® (both fibrates) and Niaspan® (niacin) for the treatment of high triglycerides and severe hypertriglyceridemia in the United States and Omacor (the equivalent of Lovaza) in Europe and Asia. In March 2011, Pronova BioPharma Norge AS, now owned by BASF, which owns the patents for Lovaza, entered into an agreement with Apotex Corp. and Apotex Inc., or Apotex, to settle their patent litigation in the United States related to Lovaza. Pursuant to the terms of the settlement agreement, Pronova granted Apotex a license to enter the U.S. market with a generic version of Lovaza in the first quarter of 2015, or earlier depending on circumstances. In addition, Pronova recently lost an appeal in its patent infringement lawsuit against Teva Pharmaceuticals USA, Inc., or Teva, and Par Pharmaceutical Inc., or Par, which would have prevented Teva and Par from launching generic versions of Lovaza. Apotex, Teva and Par must obtain FDA approval of generic versions of Lovaza before they are permitted to sell such products in the United States. On April 8, 2014, Teva announced that it had received FDA approval of its abbreviated new drug application, or ANDA, to sell a generic equivalent of Lovaza and was immediately launching its product into the market. Other companies are also seeking to introduce generic versions of Lovaza. Each of these competitors has greater resources than we do, including financial, product development, marketing, personnel and other resources.

Amarin currently markets Vascepa®, an ethyl-ester form of EPA, for the treatment of patients with severe hypertriglyceridemia. In February 2013, Amarin submitted a supplemental NDA (sNDA) to the FDA seeking approval of Vascepa for the treatment of patients with high triglyceride levels (TG ≥200 mg/dL and <500 mg/dL) who are also on statin therapy for elevated LDL-C levels, which has been referred to as Amarin's ANCHOR indication. This indication is also referred to as mixed dyslipidemia. On October 16, 2013, the FDA convened an advisory committee to review Amarin's sNDA for mixed dyslipidemia and the advisory committee voted 9 to 2 against recommending approval of Amarin's sNDA based on the information presented at that meeting. In its decision whether to approve Amarin's sNDA, the FDA will consider the recommendation of the advisory committee, but the final decision will be made by the FDA. Amarin's sNDA for mixed dyslipidemia is subject to a standard review and was assigned a Prescription Drug User Fee Act, or PDUFA, date of December 20, 2013. The PDUFA date is the target date for the FDA to complete its review of the sNDA. On October 29, 2013, the FDA notified Amarin that it rescinded the Special Protocol Assessment, or SPA, agreement entered into between the FDA and Amarin for the ANCHOR indication. On November 7, 2013, Amarin submitted a formal appeal of the FDA's decision to rescind the ANCHOR SPA. On January 17, 2014, the Division of Metabolism and Endocrinology Products, or DMEP, within the FDA notified Amarin in connection with Amarin's request for reconsideration of the October 2013 decision to rescind the ANCHOR SPA that the DMEP did not plan to reinstate the ANCHOR SPA agreement. Amarin has stated that it plans to continue to appeal the decision to higher levels within the FDA. Amarin has still not received a decision from FDA with respect to its sNDA filing for the ANCHOR indication. We also understand that on February 21, 2014, in connection with Amarin's July 26, 2012 approval of Vascepa to treat severe hypertriglyceridemia, the FDA denied a grant of NCE marketing exclusivity to Vascepa and granted three-year marketing exclusivity. Such three-year exclusivity extends through July 25, 2015 and could possibly be supplemented by a 30-month stay triggered after patent infringement litigation initiated by Amarin following a valid notice to Amarin of the filing of an ANDA with the FDA seeking approval of a generic version of Vascepa. Thereafter, on February 27, 2014, Amarin filed a lawsuit against the FDA challenging FDA's denial of its request for five-year exclusivity based on Amarin's interpretation of the relevant statute and that FDA's decision was inconsistent with past FDA actions. On March 14, 2014, Amarin announced that it had received paragraph IV certifications from Apotex and Roxane Laboratories, Inc., or Roxane, on March 10 and 12, 2014, respectively, advising Amarin that such companies have filed ANDAs with the FDA for generic versions of Vascepa.

In addition, we are aware of other companies that are developing products that, if approved and marketed, will compete directly with MAT9001. These companies that are in various stages of clinical development with omega-3 prescription therapies for the treatment of very high triglycerides include a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA) developed by Omthera Pharmaceuticals, now owned by AstraZeneca PLC. In July 2013, Omthera submitted an NDA to the FDA seeking approval of this drug candidate for the treatment of severe hypertriglyceridemia. On May 5, 2014, Omthera received approval from the FDA for its NDA. We are also aware that in January 2014, Acasti Pharma Inc., a subsidiary of Neptune Technologies and Bioresources Inc., announced that the FDA had accepted its IND submission to conduct a pharmacokinetic, or PK, study of its krill-oil based omega-3 phospholipid product. In addition, we believe Catabasis Pharmaceuticals, or Catabasis, Resolvyx Pharmaceuticals, or Resolvyx, and Sancilio & Company are developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids and, to our knowledge, Catabasis initiated a Phase II clinical trial of its product in December 2013; Resolvyx's compound remains in Phase I clinical testing and Sancilio is preparing to commence Phase III clinical testing. We also understand that another company, Trygg Pharma AS, received FDA approval on April 23, 2014 for its NDA for an omega-3 based drug used as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia.

MAT9001 is designed to be a prescription-only omega-3 fatty acid based medication. Omega-3 fatty acid based products are also marketed by other companies as dietary supplements, which, unlike drugs, are not subject to FDA approval and therefore do not require a prescription and are not subject to pharmaceutical manufacturing standards. As a result, MAT9001, if approved, would be subject to competition from products for which no prescription is required.

If approved by the regulatory authorities, MAT9001 will be a prescription-only omega-3 fatty acid based medication. Mixtures of omega-3 fatty acids are naturally occurring substances in various foods, including fatty fish. Omega-3 fatty acids are also marketed as dietary supplements, which may generally be marketed without a lengthy FDA premarket review and approval process and are not subject to prescription. However, unlike prescription drug products, manufacturers of dietary supplements may not make therapeutic claims for their products; dietary supplements may be marketed with claims describing how the product affects the structure or function of the body without premarket approval, but may not expressly or implicitly represent that the dietary supplement will diagnose, cure, mitigate, treat, or prevent disease. We believe the exact omega-3 fatty acid composition and pharmaceutical-grade purity of MAT9001 has a superior therapeutic profile to the omega-3 compositions in commercially available dietary supplements. However, we cannot be sure that physicians or consumers will view MAT9001 as superior. To the extent the price of MAT9001 is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements, physicians may recommend these commercial alternatives instead of MAT9001 or patients may elect on their own to take commercially available non-prescription omega-3 fatty acids. Either of these outcomes may adversely impact our results of operations by limiting product sales and how we price our product, thereby limiting the revenue we receive from sales of MAT9001.

Even if we obtain marketing approval for MAT9001, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, MAT9001 could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with MAT9001.

Even if we obtain United States regulatory approval of MAT9001, the FDA may still impose significant restrictions on its indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase IV clinical trials, and post-market surveillance to monitor safety and efficacy. MAT9001 will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continuous review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

The FDA has the authority to require a REMS, as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for MAT9001, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions, including revocation of its marketing approval. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize MAT9001 and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize MAT9001 and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for MAT9001, restrict or regulate post-approval activities and affect our ability to profitably sell MAT9001.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of MAT9001, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for MAT9001 and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or, collectively, the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners, and incur substantial costs to ensure compliance.

Despite initiatives to invalidate the Health Care Reform Law, the United States Supreme Court has upheld certain key aspects of the legislation, including the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the individual mandate. Although there are legal challenges to the Health Care Reform Law in lower courts on other grounds, at this time it appears the implementation of the Health Care Reform Law will continue. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize MAT9001 in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize MAT9001 in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for MAT9001 in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;

- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of MAT9001 could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

If we market MAT9001 in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

The FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off label" use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct can subject that company to significant liability. Similarly, industry codes in the EU and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

The import of our fish oils containing omega-3 fatty acids and concentrates thereof is subject to supervision and licensing by the United States Department of Agriculture.

The import of our fish oils containing Omega-3 fatty acids and concentrates thereof is subject to supervision and licensing by the United States Department of Agriculture ("USDA"). If the USDA were to halt the import of such materials or issuance of licenses for the import of such materials, the development, production, or sale of MAT9001 could be delayed.

We are, and will be, completely dependent on third parties to manufacture MAT9001, and our commercialization of MAT9001 could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of MAT9001 or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredient, or API, in MAT9001 for use in our clinical trials or for commercial product, if any. In addition, we do not have the capability to encapsulate MAT9001 as a finished drug product for commercial distribution. As a result, we will rely on contract manufacturers throughout the development process and then if and when MAT9001 is approved for commercialization. We have not entered into any agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of MAT9001 on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture MAT9001 must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to MAT9001. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of MAT9001 or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market MAT9001, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We do not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market MAT9001, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market MAT9001.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished MAT9001 product or should cease doing business with us, we could experience significant interruptions in the supply of MAT9001 or may not be able to create a supply of MAT9001 at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of MAT9001 might be negatively affected. Our inability to coordinate the efforts of our third party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply MAT9001 at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of MAT9001 if we decided to transfer the manufacture of MAT9001 to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of MAT9001, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of MAT9001 over time. If the commercial-scale manufacturing costs of MAT9001 are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of MAT9001 for any additional indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

We will review our strategy with respect to additional indications for MAT9001. In the event we initiate an outcomes study or another type of study, delays in the commencement or completion of such study could significantly affect our product development costs. We do not know whether such study will begin or will be completed on schedule, if at all. The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA failing to grant permission to proceed or placing a clinical study on hold;
- subjects failing to enroll or remain in our trials at the rate we expect;
- subjects choosing an alternative treatment for the indications for which we are developing MAT9001, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports from clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, good laboratory practices, good clinical practices,, or third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;
- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or withdrawal from a trial;
- the addition of new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason; and
- government or regulatory delays or “clinical holds” requiring suspension or termination of a trial.

Product development costs for MAT9001 in a future indication will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of MAT9001, its commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of MAT9001. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of MAT9001 could be significantly reduced.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Since we may be required by the FDA to pursue an outcomes study for an indication for MAT9001 for the reduction of the risk of cardiovascular events and may pursue other clinical studies for other indications, we will continue to be subject to risks related to clinical trials. Pre-clinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the pre-clinical or clinical trial process. The results of pre-clinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. We cannot assure you that the FDA will view the results as we do or that any future trials of MAT9001 for other indications will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Likewise, any future clinical trial results for MAT9001 may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for MAT9001 for other indications. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and varying patient characteristics including demographic factors and health status.

We expect that we will rely on third parties to conduct clinical trials for MAT9001. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize MAT9001 and our business could be substantially harmed.

We expect to enter into agreements with third-party CROs to conduct and manage our clinical programs. We would rely heavily on these parties for execution of clinical studies for MAT9001 and would control only certain aspects of their activities. Nevertheless, we would be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs would not relieve us of our regulatory responsibilities. We and our CROs would be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we intend to design the clinical trials for MAT9001, we expect that the CROs would actually conduct all of the clinical trials. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs may not perform all of their obligations under their arrangements with us or in compliance with regulatory requirements. If the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of MAT9001 for the subject indication may be delayed or our development program may be materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs would devote to our program or MAT9001. If we are unable to rely on the clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. As a result of the foregoing, our financial results and the commercial prospects for MAT9001 would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues.

Our ability to successfully market MAT9001 will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our products and related treatments. Countries in which MAT9001 is sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell MAT9001 profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope. Increasingly, third-party payors attempt to contain health care costs in ways that are likely to impact our development of products including:

- failing to approve or challenging the prices charged for health care products;
- introducing reimportation schemes from lower priced jurisdictions;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

Risks Relating to Our Intellectual Property Rights and Regulatory Exclusivity

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our commercial success will depend, in part, on obtaining and maintaining patent protection for our technologies, products and processes, successfully defending these patents against third-party challenges and successfully enforcing these patents against third party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in our patents (including patents owned by us). We currently have no issued patents and the pending patent applications for MAT9001 and for the MAT8800 discovery program may never be approved by the United States or foreign patent offices. Furthermore, any patents, which may eventually be issued from existing patent applications relating to MAT9001, MAT8800 or any other technologies, may be challenged, invalidated or circumvented. MAT8800 and related technologies may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. For example, others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to MAT9001, or otherwise important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before the United States or foreign patent offices.

We also rely on trade secrets to protect technology, especially in cases where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we fail to obtain or maintain patent protection or trade secret protection for MAT9001 or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

We may also develop trademarks to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us or our business partners will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks.

MAT9001 may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of MAT9001 or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize MAT9001, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties against us would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent MAT9001 from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to MAT9001 or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market MAT9001 or any future product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign MAT9001 or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing MAT9001 or a future product candidate, which could harm our business, financial condition and operating results.

We anticipate that competitors may from time to time oppose our efforts to obtain patent protection for new technologies or to submit patented technologies for regulatory approval. Competitors may seek to oppose our patent applications to delay the approval process or to challenge our granted patents, for example, by requesting a reexamination of our patent at the United States Patent and Trademark Office, or the USPTO, or by filing an opposition in a foreign patent office, even if the opposition or challenge has little or no merit. Such proceedings are generally highly technical, expensive and time consuming, and there can be no assurance that such a challenge would not result in the narrowing or complete revocation of any patent of ours that was so challenged.

A number of companies, including several major pharmaceutical companies, have conducted research on pharmaceutical uses of omega-3 fatty acids, which has resulted in the filing of many patent applications related to this research. We are aware of third-party United States patents/applications, and corresponding foreign counterparts, that contain broad claims related to methods of using these general types of compounds, which may be construed to include potential uses of MAT9001 or any future product candidates. If we were to challenge the validity of these or any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we were to challenge the validity of these or any issued United States patent in an administrative trial before the Patent Trial and Appeal Board in the United States Patent and Trademark Office, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity or enforceability.

Our intended path for FDA approval of MAT9001 with an indication to treat severe hypertriglyceridemia involves the filing of a Section 505(b)(2) NDA. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit us to rely upon certain preclinical or clinical studies conducted by third parties for their approved product. As a result, we are allowed under Section 505(b)(2) to file an NDA utilizing information from these studies even though we have not obtained a right of reference The FDA may require us to perform additional studies or measurements to support any changes in our product as compared to the approved product. Pursuant to an NDA filed under Section 505(b)(2), the FDA may approve our new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by us.

If a Paragraph I or II certification is filed, FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the 505(b)(2) application. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the Referenced Listed Drug has expired.

A certification that the new product will not infringe the Reference Listed Drug's listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders for the Reference Listed Drug once the applicant's NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA by imposing a 30 month automatic statutory injunction. The court may shorten or lengthen the 30 month stay period in a pending patent case if either party fails to reasonably cooperate in expediting the case. The 30 month stay terminates if a court issues a final order determining that the patent is invalid unenforceable or not infringed. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

If MAT9001 is not granted any exclusivity protection from the FDA our business may be materially harmed.

Under Sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the Food Drug and Cosmetic Act, or FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Amendments, a drug that is granted regulatory approval may be eligible for five years of marketing exclusivity in the United States following regulatory approval if that drug is classified as a new chemical entity, or NCE. A drug can be classified as a NCE if the FDA has not previously approved any other drug containing the same active moiety.

The FDA typically publishes a determination on the marketing exclusivity of recently approved products in a cumulative supplement to its Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, mid-month in the month following the drug's approval. NCE marketing exclusivity, if granted, would preclude approval during the five-year exclusivity period of certain 505(b)(2) applications or certain abbreviated new drug applications submitted by another company for another version of the drug. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. If we are not able to gain or exploit the period of marketing exclusivity, we may face significant competitive threats to our commercialization of these compounds from other manufacturers, including the manufacturers of generic alternatives. Further, even if MAT9001 is considered to be a NCE and we are able to gain five-year marketing exclusivity, another company could challenge that decision to seek to overturn the FDA's determination. Another company could also gain such marketing exclusivity under the provisions of the FDCA, as amended by the Hatch-Waxman Amendments, if such company can, under certain circumstances, complete a human clinical trial process and obtain regulatory approval of its product.

If MAT9001 is not granted NCE marketing exclusivity, we expect it will be granted three years of new product exclusivity under the Hatch-Waxman Amendments. Such exclusivity protection would preclude the FDA from approving a marketing application for a duplicate of MAT9001, a product candidate that the FDA views as having the same conditions of approval as MAT9001 (for example, the same indication and/or other conditions of use), or a 505(b)(2) NDA submitted to the FDA with MAT9001 as the reference product, for a period of three years from the date of FDA approval, although the FDA may accept and commence review of such applications during the exclusivity period. Such three-year exclusivity grant would not prevent a company from challenging the validity of our patents at any time. In this case, we may be afforded the benefit of a 30-month stay against the launch of such a competitive product that would extend from the period that we respond to a pending patent challenge. This three-year form of exclusivity may also not prevent the FDA from approving an NDA that relies only on its own data to support the change or innovation.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we employ individuals who were previously employed at or retained by other pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

General Company-Related Risks

In order to establish our sales and marketing infrastructure, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

We currently have only ten employees. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize MAT9001 and any other future product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees, including Roelof Rongen, our President and CEO, Jerome D. Jabbour, our Chief Business Officer and General Counsel, George Bobotas, our Chief Scientific Officer, and Abdel A. Fawzy, our Executive Vice President for Pharmaceutical and Supply Chain Development would adversely impact our business prospects.

Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract highly qualified managerial, scientific and medical personnel. In order to induce valuable employees to remain with us, we intend to provide employees with stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that we will not be able to control and may at any time be insufficient to counteract more lucrative offers from other companies.

Our management team has expertise in many different aspects of drug development and commercialization. However, we will need to hire additional personnel as we further develop MAT9001 and any product candidates identified in our MAT8800 discovery program. Competition for skilled personnel in our market is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. We have employment agreements with certain of our executive officers. However, these employment arrangements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results or financial condition. In particular, we believe that the loss of the services of Roelof Rongen, our President and Chief Executive Officer, Jerome D. Jabbour, our Chief Business Officer and General Counsel, George Bobotas, our Chief Scientific Officer, or Abdel A. Fawzy, our Executive Vice President for Pharmaceutical and Supply Chain Development, would have a material adverse effect on our business. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of MAT9001.

We face a potential risk of product liability as a result of the clinical testing of MAT9001 and will face an even greater risk if we commercialize MAT9001 or any other future product. For example, we may be sued if any product we develop, including MAT9001, or any material that we use in our products allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of MAT9001. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for MAT9001 or any future products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize MAT9001; and
- a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We intend to obtain product liability insurance covering our clinical trials in the amount of greater than or equal to $1 million in the aggregate. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Risks Related to Our Common Stock

Our directors and executive officers will continue to have substantial influence over us for the foreseeable future could delay or prevent a change in corporate control.

Our officers and directors, and their affiliates, collectively, beneficially own approximately 40% of our outstanding shares of common stock, based on the number of shares outstanding on March 31, 2014. These stockholders, acting together, have significant influence over the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, will continue to have significant influence over our management and affairs. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

No public market for our common stock currently exists, and an active trading market may not develop or be sustained.

As we are in our early stages, an investment in our company will likely require a long-term commitment, with no certainty of return. There is no public market for our common stock, and even if we become a publicly-listed company, of which no assurances can be given, we cannot predict whether an active market for our common stock will ever develop in the future. In the absence of an active trading market:

- investors may have difficulty buying and selling or obtaining market quotations;
- market visibility for shares of our common stock may be limited; and
- a lack of visibility for shares of our common stock may have a depressive effect on the market price for shares of our common stock.

Assuming we can find market makers to establish quotations for our common stock, we expect that our common stock will be quoted on the OTC Bulletin Board (known as the OTCBB) or OTCQB market operated by OTC Markets Group, Inc. These markets are relatively unorganized, inter-dealer, over-the-counter markets that provide significantly less liquidity than NASDAQ or the NYSE MKT (formerly known as the NYSE AMEX). No assurances can be given that our common stock, even if quoted on such markets, will ever trade on such markets, much less a senior market like NASDAQ or NYSE MKT. In this event, there would be a highly illiquid market for our common stock and you may be unable to dispose of your common stock at desirable prices or at all. Moreover, there is a risk that our common stock could be delisted from the OTCBB/OTCQB, in which case it might be listed on the so called “Pink Sheets”, which is even more illiquid than the OTC Bulletin Board.

The lack of an active market impairs your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

We may not qualify for OTC Bulletin Board inclusion, and therefore you may be unable to sell your shares.

We believe that our common stock will become eligible for quotation on the OTC Bulletin Board and/or OTCQB Market, which we refer to herein as the OTCBB/OTCQB. No assurances can be given, however, that this eligibility will be granted. OTCBB/OTCQB eligible securities include securities not listed on a registered national securities exchange in the U.S. and that are also required to file reports pursuant to Section 13 or 15(d) of the Securities Act of 1933, as amended (which we refer to herein as the Securities Act), and require that we be current in its periodic securities reporting obligations.

Among other matters, in order for our common stock to become OTCBB/OTCQB eligible, a broker/dealer member of FINRA, must file a Form 211 with FINRA and commit to make a market in our securities once the Form 211 is approved by FINRA. As of the date of this Quarterly Report, a Form 211 has been filed with FINRA by a broker/dealer which will act as our market maker. If for any reason our common stock does not become eligible for quotation on the OTCBB/OTCQB or a public trading market does not develop, purchasers of shares of our common stock may have difficulty selling their shares should they desire to do so. If we are unable to satisfy the requirements for quotation on the OTCBB/OTCQB, any quotation of in our common stock would be conducted in the "pink" sheets market. As a result, a purchaser of our common stock may find it more difficult to dispose of, or to obtain accurate quotations as to the price of their shares. The above-described rules may materially adversely affect the liquidity of our securities. See "Plan of Distribution."

Even if our common stock becomes publicly-traded and an active trading market develops, the market price our common stock may be significantly volatile.

Even if our securities become publicly-traded and even if an active market for our common stock develops, of which no assurances can be given, the market price for our common stock may be volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;
- changes in the economic performance or market valuations of companies similar to ours; and
- general economic or political conditions in the United States or elsewhere.

In particular, the market prices of biotechnology companies like ours have been highly volatile due to factors, including, but not limited to:

- any delay or failure to conduct a clinical trial for our product or receive approval from the FDA and other regulatory agents;
- developments or disputes concerning our product's intellectual property rights;
- our or our competitors' technological innovations;
- changes in market valuations of similar companies;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents; and
- failure to complete significant transactions or collaborate with vendors in manufacturing our product.

The securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of shares of our common stock.

If our shares become subject to the penny stock rules, this may make it more difficult to sell our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTCBB does not meet such requirements and if the price of our common stock is less than $5.00, our common stock will be deemed penny stocks. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stock holders may have difficulty selling their shares.

FINRA sales practice requirements may also limit your ability to buy and sell our common stock, which could depress the price of our shares.

FINRA rules require broker-dealers to have reasonable grounds for believing that an investment is suitable for a customer before recommending that investment to the customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status and investment objectives, among other things. Under interpretations of these rules, FINRA believes that there is a high probability such speculative low-priced securities will not be suitable for at least some customers. Thus, FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our shares, have an adverse effect on the market for our shares, and thereby depress our share price.

You may face significant restrictions on the resale of your shares due to state "blue sky" laws.

Each state has its own securities laws, often called "blue sky" laws, which (1) limit sales of securities to a state's residents unless the securities are registered in that state or qualify for an exemption from registration, and (2) govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or it must be exempt from registration. The applicable broker-dealer must also be registered in that state.

We do not know whether our securities will be registered or exempt from registration under the laws of any state. A determination regarding registration will be made by those broker-dealers, if any, who agree to serve as market makers for our common stock. There may be significant state blue sky law restrictions on the ability of investors to sell, and on purchasers to buy, our securities. You should therefore consider the resale market for our common stock to be limited, as you may be unable to resell your shares without the significant expense of state registration or qualification.

You may experience substantial dilution by exercises of outstanding warrants and options.

As of March 31, 2014, we had outstanding warrants to purchase an aggregate of 15,250,000 shares of our common stock at a weighted average exercise price of $1.90 and options to purchase an aggregate of 3,160,000 shares of our common stock at an exercise price of $0.94 per share. The exercise of such outstanding options and warrants will result in substantial dilution of your investment. In addition, you may experience additional dilution if we issue common stock in the future. As a result of this dilution, the value of our common stock may decline.

We are an "emerging growth company," and will be able take advantage of reduced disclosure requirements applicable to "emerging growth companies," which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and, for as long as we continue to be an "emerging growth company," we intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an "emerging growth company" for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will incur significantly increased costs and devote substantial management time as a result of operating as a public company particularly after we are no longer an "emerging growth company."

As a public company, we will incur significant legal, accounting and other expenses. For example, we are required to comply with certain of the requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the Securities and Exchange Commission, or the SEC, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. We are just beginning the process of compiling the system and processing documentation needed to comply with such requirements. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. In that regard, we currently do not have an internal audit function, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

However, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We intend to take advantage of these reporting exemptions until we are no longer an "emerging growth company."

Under the JOBS Act, "emerging growth companies" can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

After we are no longer an "emerging growth company," we expect to incur additional management time and cost to comply with the more stringent reporting requirements applicable to companies that are deemed accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs

We have had material weaknesses in our internal control over financial reporting.

Prior to February 2014, we had not been a public reporting company and have had limited accounting personnel and systems to adequately execute accounting processes and limited other supervisory resources with which to address internal control over financial reporting. We and our independent registered public accounting firm identified material weaknesses in internal control over financial reporting for the years ended December 31, 2013 and 2012. Under standards established by the Public Company Accounting Oversight Board, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. We are in the process of remediating the material weaknesses identified by us and our independent registered public accounting firm; however, we cannot assure that there will not be additional material weaknesses and significant deficiencies that our independent registered public accounting firm or we will identify. If we identify such issues or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected and we may be unable to maintain compliance with applicable securities laws and listing requirements.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal control requirements for publicly traded companies.

As a public company, we will operate in an increasingly demanding regulatory environment, which requires us to comply with applicable provisions of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, and the related rules and regulations of the Securities and Exchange Commission, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

We rely on consultants to perform certain of our accounting and financial reporting functions. We will need to hire additional finance personnel and build our financial infrastructure as we transition to operating as a public company, including complying with the applicable requirements of Section 404 of the Sarbanes-Oxley Act. We may be unable to do so on a timely basis.

Moreover, we do not expect that disclosure controls or internal control over financial reporting, even if established, will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be 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 fraud, if any, have been detected. Failure of our control systems

to prevent error or fraud could materially adversely impact us.

We may be unable to complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting for our annual report for the fiscal ended December 31, 2015. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting.

We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

If we are unable to assert that our internal control over financial reporting is effective, or, if applicable, our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC. We will also be required to disclose changes made in our internal controls and procedures on a quarterly basis.

However, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an "emerging growth company" as defined in the recently enacted JOBS Act, if we take advantage (as we expect to do) of the exemptions contained in the JOBS Act. We could be an "emerging growth company" for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, amended, or the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three-year period..

At such time that we no longer qualify as an emerging growth company, our independent registered public accounting firm may issue a report that is adverse to us in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in our internal control over financial reporting in the future. Any of the foregoing occurrences, should they come to pass, could negatively impact the public perception of our company, which could have a negative impact on our stock price.

We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

In the event of a liquidation, dissolution or winding-up of our company, whether voluntary or involuntary, the proceeds and/or assets of our company remaining after giving effect to such transaction, and the payment of all of our debts and liabilities will be distributed to the stockholders of common stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of common stock, or any amounts, upon such a liquidation, dissolution or winding-up of our Company. In this event, you could lose some or all of your investment.

Our certificate of incorporation allows for our board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our board of directors has the authority to fix and determine the relative rights and preferences of preferred stock. We anticipate that our board of directors will have the authority to issue up to 10,000,000 shares of our preferred stock without further stockholder approval. As a result, our board of directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our board of directors could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

Anti-takeover provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our amended and restated certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors. These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions, among other things:

- allow the authorized number of directors to be changed only be resolution of our board of directors;
- authorize our board of directors to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition of which our board of directors does not approve;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call a stockholder meeting.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As a result of the Merger, our ability to utilize our federal net operating loss, carryforwards and federal tax credit may be limited under Sections 382 of the Internal Revenue Code of 1986, as amended. The limitations apply if an "ownership change," as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). In addition, future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change" and, consequently, Section 382 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

Item 3. DEFAULTS UNDER SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None.

Item 6. EXHIBITS

See the Exhibit Index following the signature page to this Quarterly Report on Form 10-Q for a list of exhibits filed or furnished with this report, which Exhibit Index is incorporated herein by reference.

SIGNATURES

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

MATINAS BIOPHARMA HOLDINGS, INC.

BY:

/s/ Roelof Rongen

Dated: May 14, 2014

Roelof Rongen
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Gary Gaglione

Dated: May 14, 2014

Gary Gaglione
Interim Chief Financial Officer

(Principal Financial and Accounting Officer)

EXHIBIT INDEX

3.1	Certificate of Incorporation of the Company, incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-1 (Reg. No. 333-193455), filed February 7, 2014 with the Securities and Exchange Commission.
3.2	Bylaws of the Company, incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-1 (Reg. No. 333-193455), filed February 7, 2014 with the Securities and Exchange Commission.
*31.1	Certification of President and Chief Executive Officer
*31.2	Certification of Interim Chief Financial Officer
**32.1	Section 1350 Certifications
101.1+	XBRL Instance Document.
101.2+	XBRL Taxonomy Extension Schema Document.
101.3+	XBRL Taxonomy Extension Calculation Linkbase Document.
101.4+	XBRL Taxonomy Extension Definition Linkbase Document.
101.5+	XBRL Taxonomy Extension Label Linkbase Document.
101.6+	XBRL Taxonomy Extension Presentation Linkbase Document.

*	Filed herewith.
**	Furnished herewith.
+	XBRL Interactive Data File will be filed by amendment to this Form 10-Q within 30 days of the filing date of this Form 10-Q, as permitted by Rule 405(a)(2)(ii) of Regulation S-T. The XBRL information will be furnished and not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any registration statement under the Securities Act of 1933, as amended.

Exhibit 31.1

CERTIFICATION

I, Roelof Rongen, certify that:

1. I have reviewed this report on Form 10-Q of Matinas BioPharma Holdings, Inc.;

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

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

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

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

   (b) [omitted]

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

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

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

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

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

Date: May 14, 2014

By /s/ Roelof Rongen
Name: Roelof Rongen
Title: President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Gary Gaglione, certify that:

1. I have reviewed this report on Form 10-Q of Matinas BioPharma Holdings, Inc.;

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

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

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

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

   (b) [omitted]

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

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

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

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

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

Date: May 14, 2014

By: /s/ Gary Gaglione
Name: Gary Gaglione
Title: Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

SECTION 1350 CERTIFICATIONS

Pursuant to 18 U.S.C. §1350 as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of Matinas BioPharma Holdings, Inc. (the "Company") hereby certify that to their knowledge and in their respective capacities that the Company's quarterly report on Form 10-Q to which this certification is attached (the "Report"), fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2014

By: /s/ Roelof Rongen
Name: Roelof Rongen
Title: President and Chief Executive Officer

Date: May 14, 2014

By: /s/ Gary Gaglione
Name: Gary Gaglione
Title: Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification shall not be deemed "filed" for any purpose, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Matinas BioPharma Holdings, Inc. and will be retained by Matinas BioPharma Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.