AtheroNova Inc.
Form 424B4
October 29, 2014

Filed Pursuant to Rule 424(b)(4)

Registration Nos. 333-194645 and 333-199628

4,000,000 Shares of Common Stock

Warrants to Purchase 5,000,000 Shares of Common Stock

We are offering 4,000,000 shares of our common stock and warrants to purchase up to an aggregate of 5,000,000 shares of our common stock pursuant to this prospectus. Each share of common stock is being sold together with 1.25 warrants to purchase one share of our common stock. The warrants will have an exercise price of \$4.00 per share. The warrants are exercisable immediately, will be issued separately from the shares of common stock and will expire five years from the date of issuance.

Our common stock is presently quoted on the OTCQB under the symbol "AHRO." The warrants will not be listed or quoted on any trading market. On October 27, 2014, the last reported sale price of our common stock on the OTCQB was \$1.62 per share.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 7 of this prospectus for a discussion of information that should be considered in connection with an investment in our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share of Common	Per Warrant	Total
	Stock		
Public offering price	\$0.75	\$ 0.00001	\$ 3,000,050
Underwriting discount and commissions <sup>(1)</sup>	\$.0525	\$ 0.0000007	\$ 210,004
Proceeds, before expenses, to us	\$ 0.6975	\$ 0.0000093	\$ 2,790,046

<sup>(1)</sup> The underwriters will receive compensation in addition to the underwriting discount described above. See "Underwriting" for a description of compensation payable to the underwriters.

We have granted the underwriters an option to purchase up to 600,000 additional shares of our common stock and/or warrants to purchase up to an aggregate of 750,000 shares of our common stock at the public offering price, less the underwriting discounts and commissions, 45 days from the date of this prospectus, to cover over-allotments, if any. The underwriters expect to deliver the shares of common stock and warrants to purchasers in the offering against payment therefor on or about October 31, 2014.

Sole Book-Running Manager

#### **Aegis Capital Corp**

Co-Manager

### Merriman Capital Inc.

October 28, 2014

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#### ABOUT THIS PROSPECTUS

Please read this prospectus carefully. It describes our business, our financial condition and results of operations. We have prepared this prospectus so that you will have the information necessary to make an informed investment decision.

The registration statement we filed with the Securities and Exchange Commission (the "SEC") includes exhibits that provide more detail of the matters discussed in this prospectus. You should read this prospectus and the related exhibits filed with the SEC, together with the additional information described under the heading "Where You Can Find More Information," before making your investment decision.

You should rely only on the information provided in this prospectus or in a prospectus supplement or amendment thereto. We have not, and the underwriters have not, authorized anyone else to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any state where the offer or sale is not permitted. You should assume that the information in this prospectus is accurate only as of the date hereof. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: Neither we nor the underwriters has done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus outside of the United States.

#### PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus. Because this is only a summary, it does not contain all the information that may be important to you. You should read the entire prospectus carefully before making an investment decision, including the section entitled "Risk Factors" and the consolidated financial statements and the related notes and the information set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations." Unless the context otherwise requires, all references in this prospectus to "we," "us," "our" and the "Company" refer to AtheroNova Inc. and its wholly-owned subsidiary AtheroNova Operations, Inc.

#### **Our Business**

We have developed intellectual property ("IP"), covered by our issued and pending patent applications, which uses certain pharmacological compounds for the treatment of atherosclerosis, which is the primary cause of various cardiovascular diseases. Atherosclerosis occurs when cholesterol or fats are deposited and harden as plaques in the walls of arteries. This hardening reduces the space within the arteries through which blood can flow. The plaque can also rupture and greatly restrict or block altogether blood flow. Through a process called delipidization, such compounds dissolve the plaques so they can be eliminated through normal body processes and avoid such rupturing. Such compounds may be used both to treat and prevent atherosclerosis.

In the near future, we plan to continue studies and trials to demonstrate the safety and efficacy our IP. Ultimately, we plan to license our technology to various licensees throughout the world who may use it in treating or preventing atherosclerosis and other medical conditions or sublicense the IP to other such users.

Our first license agreement, entered into in November 2011, grants an exclusive distribution territory to CardioNova, a wholly-owned subsidiary of the Maxwell Biotech Group, for the Russian Federation, Belarus, Ukraine, Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan, Moldova, Azerbaijan and Armenia (the "Territory"). CardioNova has agreed to fund Phase 1 and 2 clinical trials for our lead atherosclerotic plaque regression candidate, AHRO-001in the Territory in exchange for shares of our common stock issued at milestone achievements in the clinical trials. To date, we have issued a total of 199,716 shares of our common stock representing 30% of the research budget for the clinical trials. If CardioNova is successful in receiving marketing approval of AHRO-001 from the Russian Ministry of Healthcare, they will be obligated to a royalty based on annual net sales of the product in the Territory for as long as intellectual property rights are in full force and effect.

Our licensees may also produce, market or distribute products which utilize or add our compounds and technology in such treatment or prevention.

## **Our Strategy**

Our goal is to develop a complete line of products based on our IP involving bile salts to address a number of medical conditions with the goal of introducing naturally occurring compounds to improve the medical conditions of those suffering from the effects of atherosclerosis caused by diabetes, heredity, poor diet and other plaque inducing states. Mortality and morbidity from the effects of atherosclerosis is believed to total in the billions of dollars each year for the United States healthcare system alone, with many times that for the worldwide market.

Our primary product goal is to develop our initial product candidate to address the disease of atherosclerosis. We have manufactured a significant quantity of our Active Pharmaceutical Ingredient ("API") necessary for use in clinical trials plus any requirements needed for toxicology testing. We have formulated and refined the oral administration tablet necessary to deliver our API to the ideal site in the digestive tract and are continuing to work on improvement and refinements to the formula. Frontage Laboratories, Inc., our contract manufacturer, produced sufficient supplies of our drug tablets to be used in our Phase 1b clinical trials being conducted by our Russian development partner. The shipment of the tablets being used in this additional clinical trial conducted there were shipped in June 2014 with the commencement of enrollment of patients having commenced in July 2014. The active treatment phase is planned to be for a period of twelve weeks and data should be available in approximately 6-8 months after commencement. A successful completion of that trial will allow CardioNova to move forward with a clinical study intended to enable the possible drug registration application for commercial sale in its distribution territory.

#### **Our Industry**

We compete against well-capitalized, established pharmacological companies and smaller companies, as well as from academic institutions, government agencies, and private and public research institutions in the U.S. and abroad. The market for our product candidates is highly competitive. The pharmacological sector is evolving and growing rapidly, and companies are continually introducing new products and services.

#### **Recent Developments**

On September 12, 2014, the Company issued \$500,000 aggregate principal amount of 8% Secured Convertible Notes for gross aggregate proceeds of \$500,000. These notes have a maturity of one year from the date of issuance, are secured by the assets of the Company and are convertible at any time into common stock at a conversion price of \$1.11 per share. Upon consummation of an underwritten offering of common stock the notes will mandatorily convert into common stock with a value of 115% of the amount of principal purchased. The notes also included a warrant to purchase 50% of the principal value purchased at a purchase price of \$2.00 per share for up to five years from the date of closing of the offering.

On October 14, 2014, the Company and the holder of a 2.5% Senior Secured Convertible Note in the principal amount of \$427,500 agreed to amend such holder's note to provide the Company with the option to trigger conversion of all amounts due under such note into common stock upon the consummation of a private placement or registered offering generating gross proceeds to the Company of at least \$4,000,000. The note would convert to common stock at a per share price of \$2.90.

On October 14, 2014, the Company and the holders of a majority of the outstanding principal amount under the Company's 6% Senior Secured Convertible Notes agreed to amend such notes to provide the Company with the option to trigger conversion of all amounts due under such notes into common stock upon the consummation of a private placement or registered offering generating gross proceeds to the Company of at least \$4,000,000. The notes would convert to common stock at a per share price of \$1.11.

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#### **Our Corporate Information**

We were incorporated in Delaware in 1997 and from December 31, 2007 through May 13, 2010, we were a public "shell" company with nominal assets. On March 26, 2010, we entered into an Agreement and Plan of Merger with Z&Z Merger Corporation, a Delaware corporation and our wholly-owned subsidiary ("MergerCo"), and AtheroNova Operations, Inc., a Delaware corporation then known as Z&Z Medical Holdings, Inc. ("Z&Z Delaware"). At the closing of the merger on May 13, 2010, (i) MergerCo was merged with and into Z&Z Delaware (the "Merger"), whose name was concurrently changed to AtheroNova Operations, Inc. ("AtheroNova Operations"); (ii) Z&Z Delaware, as AtheroNova Operations, become our wholly-owned subsidiary; (iii) all of AtheroNova Operations' shares, warrants and options outstanding prior to the Merger were exchanged (or assumed, in the case of warrants and options) for comparable securities of our company; and (iv) approximately 98% of our fully-diluted shares (excluding shares issuable in certain note and warrant issuances described elsewhere in this prospectus) were owned by AtheroNova Operations' former stockholders, warrant holders and option holders.

As a result of the Merger we are solely engaged in AtheroNova Operations' business, AtheroNova Operations' officers became our officers and three of AtheroNova Operations' directors became members of our seven-member board of directors.

The address of our principal executive office is 2301 Dupont Drive, Suite 525, Irvine, California 92612, and our telephone number is (949) 476-1100. Our website address is www.atheronova.com. The information contained in, and that can be accessed through, our website is not incorporated into and is not part of this prospectus.

#### The Offering

Common stock offered by us

4,000,000 shares of common stock.

Common stock

presently outstanding<sup>(1)</sup>

4,809,139 shares of common stock

Common stock outstanding after

this offering

8,809,139 shares of common stock.

Warrants offered by us

Each share of our common stock is being sold together with 1.25 warrants to purchase one share of our common stock. The warrants will have a per share exercise price equal to \$4.00. The warrants are exercisable immediately and expire five years from the date of issuance. The securities issuable upon exercise of the warrants will be adjusted in certain circumstances. See "Description of Securities" beginning on page 77 of this prospectus. The warrants will not be listed or quoted on any trading market.

Over-allotment option

We have granted the underwriters the right to purchase up to 600,000 additional shares of common stock and/or warrants to purchase up to an aggregate of 750,000 shares of our common stock within 45 days from the date of this prospectus solely to cover over-allotments, if any.

We estimate that the net proceeds of this offering will be approximately \$2,349,319 million, or approximately \$2,767,826 million if the underwriters exercise their over-allotment option in full, after deducting the underwriting discount and estimated offering expenses payable by us.

Use of proceeds

The principal purposes of this offering are to increase our capitalization and financial flexibility in order to continue development of our potential products. We intend to use the net proceeds from this offering for general corporate purposes, including working capital, operating expenses and capital expenditures. See the section entitled "Use of Proceeds" on page 30 of this prospectus for additional information.

Representative's Warrants

We have agreed to issue to the representative of the underwriters, at the closing of this offering, warrants to purchase that number of shares of our common stock equal to 5% of the aggregate number of shares sold in this offering. The representative's warrants will be exercisable at any time and from time to time, in whole or in part, during the four year period commencing on October 28, 2015, at a price per share of \$0.9375.

Dividend policy	Our board of directors does not intend to declare cash dividends on our common stock for the foreseeable future.
OTCQB Symbol	Our common stock is currently quoted on the OTCQB under the symbol "AHRO". The warrants will not be listed or quoted on any trading market.
Risk Factors	See the section entitled "Risk Factors" beginning on page 7 of this prospectus for a discussion of factors that you should consider carefully before deciding to invest in our common stock.
Transfer Agent and Registrar	Securities Transfer Corporation

<sup>(1)</sup> Unless we indicate otherwise, all information in this prospectus is based on 4,809,139 shares of our common stock outstanding as of September 12, 2014, assumes no exercise of the over-allotment option and excludes the following:

1,352,990 shares of our common stock issuable upon the exercise of common stock purchase warrants with a weighted average exercise price of approximately \$3.83 per share;

548,950 shares of our common stock issuable upon the exercise of stock options with an exercise price of approximately \$8.42 per share;

2,998,785 shares of our common stock (including 391,937 shares accounting for accrued interest through maturity) issuable upon conversion of convertible promissory notes at a weighted average conversion price of approximately \$1.31;

292,297 additional shares of common stock reserved for issuance under our 2010 Stock Incentive Plan;

5,000,000 shares of common stock initially issuable upon excercise of the warrants to be sold in this offering, subject to adjustment as described herein;

200,000 shares of common stock underlying the warrants that will be issued to the representative in connection with this offering. See "Underwriting – Representative's Warrant"; and

84,000 shares of common stock are estimated to be issuable to an investor and research provider based on current progress if the final milestone of our collaborative research plan is achieved. See "Business-Strategic Alliances and Collaboration Agreements".

#### **Summary Financial Data**

As of June 30, 2014, we had a stockholders' deficit of \$4,678,829. We incurred net losses of \$5,602,647 and \$4,189,827 for the six months ended June 30, 2014 and 2013, respectively. We have recorded net income of \$530,664 for the three months ended June 30, 2014 compared to incurring a net loss of \$2,565,927 for the three months ended June 30, 2013. We have not yet achieved profitability from operations and anticipate that we will continue to incur net losses for at least the next year. We anticipate that a substantial portion of our capital resources and efforts will be focused on research and development and other general corporate purposes. Research and development projects include the initiation of an additional clinical study by our Russian licensing partner, CardioNova, in the second half of 2014, additional ICH compliant toxicology work to be done to support filing of our IND application with the FDA as well as commencement of human clinical trials in additional sites outside of Russia. We plan to develop multiple applications for our compounds, to be used in pharmaceutical grade products, for the treatment of lipid modulation, atherosclerosis and other lipid-related diseases. As of June 30, 2014, we had \$319,779 in cash and cash equivalents and a working capital deficit of approximately \$1,612,326, when excluding the derivative liability of \$2,348,484, compared to \$1,173,747 in cash and cash equivalents and working capital of approximately \$359,034 at June 30, 2013.

As of December 31, 2013, we had a stockholders' deficit of \$2,503,004. We incurred net losses of \$7,814,722 and \$2,635,561 for the fiscal years ended December 31, 2013 and 2012, respectively. We have not yet achieved profitability and anticipate that we will continue to incur net losses for at least the next year. We anticipate that a substantial portion of our capital resources and efforts will be focused on research and development and other general corporate purposes. Research and development projects include the initiation of an additional clinical study by our Russian licensing partner, CardioNova, in the second half of 2014, additional ICH compliant toxicology work to be done to support filing of our investigational new drug ("IND") application with the U.S. Food and Drug Administration ("FDA") as well as commencement of human clinical trials in additional sites outside of Russia. We plan to develop multiple applications for our compounds, to be used in pharmaceutical grade products, for the treatment of lipid modulation, atherosclerosis and other lipid-related diseases. As of December 31, 2013 we had \$266,210 in cash and cash equivalents and a working capital deficit of approximately \$989,341 as compared to \$2,774,046 in cash and cash equivalents and working capital of approximately \$2,121,023 at December 31, 2012.

#### RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this prospectus before purchasing shares of our common stock. If any of the following risks occur, our business, financial condition, results of operations or prospects could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you could lose all or part of your investment.

#### **Risks Related to Our Business**

We will need additional funding to support our operations and capital expenditures. Such funds may not be available to us, which lack of availability could reduce our operating income, research and development activities and future business prospects.

While we have historically funded our working capital needs through the sale of equity and debt interests and through capital contributions from related parties, we will need to obtain significant additional funding to continue our planned operations, pursue business opportunities, react to unforeseen difficulties and/or respond to competitive pressures. Our financing activities in 2013, compose of exercise of common stock warrants issued in previous financings as well as a private placement of our common stock, which together raised about \$787,000 during the year ended December 31, 2013, which will allow us to continue ongoing clinical trial work as well as meeting corporate obligations. We also concluded a private placement of convertible promissory notes in the principal amount of \$1,906,500 in February 2014 and a private placement of convertible promissory notes in the principal amount of \$500,000 in September 2014, which we estimate will be sufficient to fund our planned activities through October 2014.

While we will need to raise significant additional funds, we currently have no committed sources of additional capital, and there can be no assurance that any financing arrangements will be available in amounts or on terms acceptable to us, if at all. Furthermore, the sale of additional equity or convertible debt securities may result in additional dilution to existing stockholders. If adequate additional funds are not available, we may be required to delay, reduce the scope of or eliminate material parts of the implementation of our business strategy. This limitation would impede our growth and could result in a contraction of our operations, which would reduce our operating income, research and development activities and future business prospects.

A variety of factors could impact the timing and amount of any required financings, including, without limitation:

•	unforeseen developments during our clinical trials;
•	delays in our receipt of required regulatory approvals;
•	delayed market acceptance of our product candidates;
• rig	unanticipated expenditures in our acquisition and defense of intellectual property rights, and/or the loss of those hts;
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•	the failure to develop strategic alliances for the marketing of some of our product candidates;
•	unforeseen changes in healthcare reimbursement for any of our product candidates;
•	lack of financial resources to adequately support our operations;
•	difficulties in maintaining commercial scale manufacturing capacity and capability;
•	unanticipated difficulties in operating in international markets;
•	unanticipated financial resources needed to respond to technological changes and increased competition;
•	unforeseen problems in attracting and retaining qualified personnel;
•	enactment of new legislation or administrative regulations;
•	the application to our business of new regulatory interpretations;
•	claims that might be brought in excess of our insurance coverage;
•	the failure to comply with regulatory guidelines; and
•	the uncertainty in industry demand.

In addition, although we have no present commitments or understandings to do so, we may seek to expand our operations and product candidates through acquisitions or joint ventures. Any acquisition or joint venture would likely increase our capital requirements.

We may be unable to continue as a going concern if we do not successfully raise additional capital.

If we are unable to successfully raise the capital we need we may need to reduce the scope of our business to fully satisfy our future short-term liquidity requirements. If we cannot raise additional capital or reduce the scope of our business, we may be otherwise unable to achieve our goals or continue our operations. As discussed in Note 2 in the Notes to the accompanying December 31, 2013 and 2012 and June 30, 2014 Consolidated Financial Statements, we have incurred losses from operations in the prior two years and have a lack of liquidity. These factors raise substantial doubt about our ability to continue as a going concern. In addition, our independent registered public accounting firm has included in their report on our audited financial statements at December 31, 2013 and 2012 an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. While we believe that we will be able to raise the capital we need to continue our operations, there can be no assurances that we will be successful in these efforts or will be able to resolve our liquidity issues or eliminate our operating losses.

We have a history of operating losses and there can be no assurance that we can achieve or maintain profitability.

We have a history of operating losses and may not achieve or sustain profitability. Even if we achieve profitability, given the competitive and evolving nature of the industry in which we operate, we may not be able to sustain or increase profitability and our failure to do so would adversely affect our business, including our ability to raise additional funds.

Our	product	candidates	may not	be de	veloped o	or commerci	alized	successfully.

Our product candidates are based on a technology that has not been used previously in the manner we propose and
must compete with more established treatments currently accepted as the standards of care. Market acceptance of our
products will largely depend on our ability to demonstrate their relative safety, efficacy, cost-effectiveness and ease of
use.

We are subject to the risks that:

- the U.S. Food and Drug Administration or a foreign regulatory authority finds our product candidates ineffective or unsafe;
- we do not receive necessary regulatory approvals;
- the regulatory review and approval process may take much longer than anticipated, requiring additional time, effort and expense to respond to regulatory comments and/or directives;
- we are unable to get our product candidates in commercial quantities at reasonable costs; and
- the patient and physician community does not accept our product candidates

In addition, our product development program may be curtailed, redirected, eliminated or delayed at any time for many reasons, including;

- adverse or ambiguous results;
- undesirable side effects that delay or extend the trials;

•	the inability to locate, recruit, qualify and retain a sufficient number of clinical investigators or patients for our
tria	als; and

• regulatory delays or other regulatory actions.

We cannot predict whether we will successfully develop and commercialize our product candidates. If we fail to do so, we will not be able to generate substantial revenues, if any.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us or our licensees from marketing our products abroad. International sales of our product candidates that we commercialize are subject to the regulatory requirements of each country in which the products are sold. Accordingly, the introduction of our product candidates in markets outside the U.S. will be subject to regulatory approvals in those jurisdictions. The regulatory review process varies from country to country. Many countries impose product standards, packaging and labeling requirements, and import restrictions. In addition, each country has its own tariff regulations, duties and tax requirements, as well as reimbursement and healthcare payment systems. The approval by foreign government authorities is unpredictable and uncertain, and can be expensive. We may be required to perform additional pre-clinical, clinical or post-approval studies even if FDA clearance/approval has been obtained. Our ability to market our product candidates could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances.

We are uncertain regarding the success of our clinical trials for our products in development.

We believe that all of our products in development will require clinical trials to determine their safety and efficacy by regulatory bodies in their target markets, including the U.S. Food and Drug Administration and various foreign regulators. There can be no assurance that we will be able to successfully complete the U.S. and foreign regulatory approval processes for products in development. In addition, there can be no assurance that we will not encounter additional problems that will cause us to delay, suspend or terminate our clinical trials. In addition, we cannot make any assurance that clinical trials will be deemed sufficient in size and scope to satisfy regulatory approval requirements, or, if completed, will ultimately demonstrate our products to be safe and efficacious.

We and our licensees will be subject to federal and state regulation. Our inability to comply with these regulations would cause us to curtail or cease our operating activities, which would result in a reduction in revenue and harm our business, operating results and financial condition.

We and our potential licensing partners are subject to many laws and regulations, and any adverse regulatory action may affect our ability to exploit our IP. Developing, manufacturing, and marketing regulated medical products and pharmaceuticals are subject to extensive and rigorous regulation by numerous government and regulatory agencies, including the FDA and comparable foreign agencies. Under the Federal Food, Drug, and Cosmetic Act, regulated medical devices must receive FDA clearance and approval before they can be commercially marketed in the U.S. Markets outside the U.S. require similar clearance and approval before a medical product or pharmaceutical can be commercially marketed. We cannot guarantee that the FDA or other regulatory authorities will accept any IND (or similar foreign) applications we may file or that such authorities will not delay consideration of accepted applications. We also cannot guarantee that we will be able to agree on matters raised during the regulatory review process or obtain, directly or through our licensees, marketing clearance/approval from the FDA and other governing agencies for any new products, or modifications or enhancements to existing products, which we depend on for royalty revenues. Furthermore, if FDA clearance/approval is obtained, such clearance/approval could (i) take a significant amount of time; (ii) require the expenditure of substantial resources; (iii) involve rigorous pre-clinical and clinical testing; (iv) require significant modifications to, or replacements of, products; and/or (v) result in limitations on the proposed uses of products.

Even after regulated medical products or pharmaceuticals have received marketing clearance/approval, such clearance/approval by the FDA can be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen issues following initial clearance/approval. Failure to comply with regulatory standards or subsequent discovery of unknown problems with a regulated medical product could result in fines, suspensions of regulatory approvals, seizures or recalls of devices, operating restrictions, and/or criminal prosecution. There can be no assurance that any FDA clearance/approval will not be subsequently withdrawn. Any adverse regulatory action by the FDA or another regulatory agency may restrict us and our licensees from effectively marketing and selling our IP applications in medical products, resulting in a reduction in revenue and harm to our business, operating results and financial condition. In addition, foreign laws and regulations have become more stringent and regulated medical products may become subject to increased regulation by foreign agencies in the future. Penalties for our licensees for any of their

noncompliance with foreign governmental regulations could be severe, including revocation or suspension of their business licenses and criminal sanctions. Any foreign law or regulation imposed on our IP applications may materially affect our projected operations and revenues, by adversely impacting the distribution and sale of regulated medical products in foreign jurisdictions through our intended licensees.

We depend on third parties for testing the product candidates we intend to develop. Any failure of those parties to perform as expected or required could adversely affect our product development and commercialization plans.

We have used and intend to continue to use various types of collaborative arrangements with commercial and academic entities as vehicles for testing compounds and molecules for our future product candidates. Our research arrangements and any other similar relationships we may establish may not proceed on the expected timetable, or our collaborators may not perform as expected or required under their agreements with us. The research performed under such collaborations and arrangements may not provide results that are satisfactory for regulatory approval of products containing our compounds or molecules. If our research and commercial relationships fail to yield product candidates that we can take into development, such failure will delay or prevent our ability to commercialize products.

In addition, we rely on third parties such as contract laboratories and clinical research organizations to conduct, supervise or monitor, some or all aspects of the preclinical studies and clinical trials for our product candidates, and we have limited ability to control many aspects of their activities. Accordingly, we have less control over the timing and other aspects of those clinical trials than if we conducted them on our own. Third-party contractors may not complete activities on schedule, or may not conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our trial design. The failure of these third parties to perform their obligations could delay or prevent the development, approval and commercialization of our product candidates.

Our inability to effectively manage our growth could harm our business and materially and adversely affect our operating results and financial condition.

Our strategy envisions growing our business. We plan to expand our technology, sales, administrative and marketing organizations. Any growth in or expansion of our business is likely to continue to place a strain on our management and administrative resources, infrastructure and systems. As with other growing businesses, we expect that we will need to further refine and expand our business development capabilities, our systems and processes and our access to financing sources. We also will need to hire, train, supervise and manage new employees. These processes are time consuming and expensive, will increase management responsibilities and will divert management attention. We cannot assure you that we will be able to:

expand our systems effectively or efficiently or in a timely manner;

allocate our human resources optimally;

meet our capital needs;

identify and hire qualified employees or retain valued employees; or

incorporate effectively the components of any business or product line that we may acquire in our effort to achieve growth.

Our inability or failure to manage our growth and expansion effectively could harm our business and materially and adversely affect our operating results and financial condition.

Future developments in technology or future pharmacological compounds may make the products we are planning to bring to market obsolete, with a consequent negative impact on our profitability.

We believe that the methods for treating and preventing atherosclerosis of the pharmacological compounds we intend to bring to market enjoy certain competitive advantages, including superior performance and cost-effectiveness. Although we are not aware of any other treatments or methods currently being developed that would directly compete with the compounds and methods we intend to employ, there can be no assurance that future developments in technology or pharmacological compounds will not make our technology non-competitive or obsolete, or significantly reduce our operating margins or the demand for our offerings, or otherwise negatively impact our profitability.

Our inability to effectively protect our intellectual property would adversely affect our ability to compete effectively, our revenue, our financial condition and our results of operations.

We regard the protection of our intellectual property, which includes patents and patent applications, trade secrets, trademarks and domain names, as critical to our success. We strive to protect our intellectual property rights by relying on federal, state and common law rights, as well as contractual restrictions. We enter into confidentiality and non-disclosure agreements with most of our employees, consultants and contractors, and confidentiality agreements with parties with whom we conduct business in order to limit access to, and disclosure and use of, our proprietary information. However, these contractual arrangements and the other steps we have taken to protect our intellectual property may not prevent the misappropriation of our proprietary information or deter independent development of similar technologies by others. Further, premature disclosure of our intellectual property could adversely affect or nullify our ability to obtain patent protection in the U.S. or foreign jurisdictions.

Although all of our current employees and consultants have signed confidentiality/non-disclosure agreements with us concerning our confidential and/or proprietary information relating to our technology, know-how, discoveries, data, inventions, development plans, business practices and the like, pre-mature or unauthorized disclosure of such information may jeopardize our ability to obtain patent protection for our technology. Further, such disclosure may violate agreements we have with our licensees, other collaborators or third parties.

We do not currently require all of our employees and/or consultants to assign to us any right, title or interest the employee or consultant may have as a result of inventions, ideas, processes, techniques, formulas, discoveries, know-how, or improvements that were made by the employee/consultant, either alone or jointly with others, in direct performance of their employment/consultation for us. Failure of any aforementioned employee/consultant to assign

such rights may jeopardize our ability to obtain patent protection for our technology and may require us to obtain licenses for future use of the aforementioned inventions, ideas, processes, techniques, formulas, discoveries, know-how, or improvements made by the employee/consultant. Further, the aforementioned employee/consultant may also sell or license the aforementioned inventions, ideas, processes, techniques, formulas, discoveries, know-how, or improvements made by the employee/consultant to a competitor.

We have obtained patents and we have patent applications pending in both the U.S. and foreign jurisdictions. There can be no assurance that our patent applications will be approved, that any patents issued will adequately protect our intellectual property, or that these patents will not be challenged by third parties or found to be invalid or unenforceable. We have also obtained trademark registration in the U.S. Effective trade secret, trademark and patent protection is expensive to develop and maintain, both in terms of initial and ongoing registration requirements and the costs of defending our rights. We may be required to protect our intellectual property in an increasing number of jurisdictions, a process that is expensive and may not be successful or which we may not pursue in every location. We may, over time, increase our investment in protecting our intellectual property through additional patent and/or trademark filings that could be expensive and time-consuming.

Monitoring unauthorized use of our intellectual property is difficult and costly. Our efforts to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Further, our competitors may develop technologies that are similar to ours but which avoid the scope of our intellectual property rights. Further, the laws in the U.S. and elsewhere change rapidly, and any future changes could adversely affect us and our intellectual property. Our failure to meaningfully protect our intellectual property could result in competitors offering solutions that incorporate our most technologically advanced features, which could seriously reduce demand for our product candidates. In addition, we may in the future need to initiate infringement claims or litigation. Litigation, whether we are a plaintiff or a defendant, can be expensive, time-consuming and may divert the efforts of our technical staff and managerial personnel, which could harm our business, whether or not the litigation results in a determination that is unfavorable to us. In addition, litigation is inherently uncertain, and thus we may not be able to stop our competitors from infringing our intellectual property rights.

We and our licensees may be unable to obtain IP rights to effectively protect our technology. Patents and other proprietary rights are an important part of our business plans. Our ability to compete effectively may be affected by the nature and breadth of our IP rights. We intend to rely on a combination of patents, trade secrets and licensing arrangements to protect our technology. While we intend to defend against any threats to our IP rights, there can be no assurance that any of our patents, patent applications, trade secrets, licenses or other arrangements will adequately protect our interests.

At this time, we have two granted U.S. patents, specifically U.S. Patent Number 8,304,383 that was issued on November 6, 2012, claiming a method of treating atherosclerosis plaque by administering a hyodeoxycholic acid pharmaceutical formulation, and U.S. Patent Number 8,697,633 that was issued on April 15, 2014, claiming a method of treating atherosclerosis plaque by administering a ursodeoxycholic acid pharmaceutical formulation. We also have an allowed U.S. application, no. 13/528,772, titled Subcutaneous Fat Reduction. There can also be no assurance that this or any additional patent issued to or licensed by us in the future will not be challenged or circumvented by competitors, or that any patent issued to or licensed by us will be found to be valid or be sufficiently broad to protect us and our technology. A third party could also obtain a patent that may require us to negotiate a license to conduct our business, and there can be no assurance that the required license would be available on reasonable terms or at all.

Additionally, we have pending patent applications in the United States and under the international Patent Cooperation Treaty covering other uses of our technology, for which we have not received, and may never receive, any additional patent protection for that technology. We cannot guarantee any particular result or decision by the U.S. Patent and Trademark Office or a U.S. court of law, or by any patent office or court of any country in which we have sought patent protection. If we are unable to secure patent protection for our technology, our revenue and earnings, financial condition, or results of operations would be adversely affected.

We do not warrant any opinion as to patentability or validity of any pending patent application. We do not warrant any opinion as to non-infringement of any patent, trademark, or copyright by us or any of our affiliates, providers, or distributors. Nor do we warrant any opinion as to invalidity of any third-party patent or unpatentability of any third-party pending patent application.

We may also rely on nondisclosure and non-competition agreements to protect portions of our technology. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that third parties will not otherwise gain access to our trade secrets or proprietary knowledge, or that third parties will not independently develop the technology.

We could incur substantial costs and disruption to our business as a result of any claim of infringement of another party's intellectual property rights, which could harm our business and operating results.

In recent years, there has been significant litigation in the U.S. over patents and other intellectual property rights. From time to time, we may face allegations that we or customers who use our products have infringed the trademarks, copyrights, patents and other intellectual property rights of third parties, including allegations made by our competitors or by non-practicing entities. We cannot predict whether assertions of third party intellectual property rights or claims arising from these assertions will substantially harm our business and operating results. If we are forced to defend any infringement claims, whether they are with or without merit or are ultimately determined in our favor, we may face costly litigation and diversion of technical and management personnel. Most of our competitors have substantially greater resources than we do and are able to sustain the cost of complex intellectual property litigation to a greater extent and for longer periods of time than we could. Furthermore, an adverse outcome of a dispute may require us, among other things: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party's patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate or make use of the intellectual property of others; to expend additional development resources to redesign our products; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies. Royalty or licensing agreements, if required, may be unavailable on terms acceptable to us, or at all. In any event, we may need to license intellectual property which would require us to pay royalties or make one-time payments. Even if these matters do not result in litigation or are resolved in our favor or without significant cash settlements, the time and resources necessary to resolve them could harm our business, operating results, financial condition and reputation.

### IP litigation would be costly and could adversely impact our business operations.

We may have to take legal action in the future to protect some or all of our technology or to assert our IP rights against others. Any legal action could be costly and time consuming to us and no assurances can be made that any action will be successful. The invalidation of any patent or IP right that we own, or an unsuccessful outcome in lawsuits to protect our technology, could have a material adverse effect on our business, financial position, or results of operations.

We operate and compete in an industry that is characterized by extensive IP litigation. In recent years, it has been common for companies in the medical product and pharmaceutical businesses to aggressively file patent-infringement and other intellectual-property litigation in order to prevent the marketing of new or improved medical products, treatments, or pharmaceuticals. IP litigation can be expensive, complex, and protracted. Because of such complexity, and the vagaries of the jury system, IP litigation may result in significant damage awards and/or injunctions that could prevent the manufacture, use, distribution, importation, exportation, and sale of products or require us and/or any of our licensing partners to pay significant royalties in order to continue to manufacture, use, distribute, import, export, or sell products. Furthermore, in the event that our right to license or to market our technology is successfully challenged, and if we and/or our licensing partners fail to obtain a required license or are unable to design around a patent held by a third party, our business, financial condition, or results of operations could be materially adversely affected. We believe that the patents we have applied for, if granted, would provide valuable protection for our intellectual property, but there nevertheless could be no assurances that they would be respected or not subject to infringement by others.

Product safety and product liability claims and litigation would be costly and adversely impact our financial condition.

Our pharmaceutical compounds will have known side effects and could have significant side effects that are not identified during the research and approval phases. If patients are adversely affected by known or unknown side effects, related claims may exceed insurance coverage and materially and adversely impact our financial condition.

Our business exposes us to the risk of product liability claims that are inherent in the development of medical products. If the use of one or more of our products harms people, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, pharmaceutical companies or others selling our products. However, we cannot predict all of the possible harms or side effects that may result and, therefore, the amount of insurance coverage we hold may not be adequate to cover all liabilities we might incur. In addition, our failure to maintain such coverage may violate certain of our development agreements. We intend to expand our insurance coverage to include the sale of commercial products as we obtain marketing approval for our product candidates and as our sales expand, but we may be unable to obtain commercially reasonable product liability insurance for such products. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, or if our coverage turns out to be insufficient, we may be exposed to significant liabilities, including liabilities under certain of our development agreements, which may materially and adversely affect our business and financial position. A product liability claim or series of claims brought against us would decrease our cash and could reduce our value or marketability.

Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete.

We are engaged in highly competitive fields of pharmaceutical research and development. Competition from numerous existing companies and others entering the fields in which we operate is intense and expected to increase. We face competition from established pharmaceutical companies, as well as from academic institutions, government agencies, and private and public research institutions in the U.S. and abroad. Most, if not all, of our competitors have significantly greater financial resources and expertise than we do in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, marketing approved products, protecting and defending their intellectual property rights and designing around the intellectual property rights of others. Other small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements, or mergers with, or acquisitions by, large and established companies, or through the development of novel products and technologies. Moreover, competitors that are able to complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before we do may enjoy a significant competitive advantage over us. There are also existing therapies that may compete with the products we are developing. There can be no assurance that we will be able to successfully compete against these other entities.

If we do not establish strategic partnerships to commercialize our products under development, we will have to undertake commercialization efforts on our own, which could be costly and may ultimately be unsuccessful.

We may selectively partner with other companies to obtain assistance for the commercialization of certain of our products. We may enter into strategic partnerships with third parties to develop and commercialize some of our products that are intended for larger markets or that otherwise require a large, specialized sales and marketing organization, and we may enter into strategic partnerships for products that are targeted beyond our selected target markets. We face competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. If we are unable to negotiate strategic partnerships for our products under development, we may be forced to reduce the scope of our anticipated sales or marketing activities or undertake commercialization activities at our own expense. In addition, we will bear the entire risk related to the commercialization of these products. If we elect to increase our expenditures to fund commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all.

Furthermore, if we enter into commercialization arrangements with third parties, we may have limited or no control over the sales, marketing and distribution activities of these third parties, and these third parties may not be successful or effective in commercializing, selling and marketing our products. If we fail to create successful and effective marketing and distribution channels, our ability to generate revenue and achieve our anticipated growth could be adversely affected. If these distributors experience financial or other difficulties, sales of our products could be

reduced, and our business, financial condition and results of operations could be harmed.

We cannot predict whether we will successfully develop and commercialize our product candidates. If we fail to do so, we will not be able to generate substantial revenues, if any.

If our licensees fail to sustain compliance with regulatory standards and laws applicable to medical products production, manufacturing and quality processes, the marketing of our products could be suspended, and such suspension could, for our licensees, lead to fines, withdrawal of regulatory clearances, product recalls, or other consequences, any of which could in turn adversely affect our projected business operations, financial condition, or results of operations.

Both before and after clearance/approval of our product candidates, we, our product candidates, our suppliers and our contract manufacturers are subject to extensive regulation by governmental authorities in the U.S. and other countries. Failure to comply with applicable requirements could result in, among other things, any of the following actions:

warning letters;
fines and other monetary penalties;
unanticipated expenditures;
delays in FDA clearance/approval, or FDA refusal to approve or clear a product candidate;
product recall or seizure;
interruption of manufacturing or clinical trials;
operating restrictions;
injunctions; and
criminal prosecutions.

The FDA's requirements may change and additional government regulations may be promulgated that could affect us, our product candidates, and our suppliers and contract manufacturers. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations in the future, or that such laws or regulations will not have a material adverse effect upon our business.

Our licensees, which will be manufacturers of medical products or pharmaceuticals, will be subject to periodic inspection by the FDA for compliance with regulations that require manufacturers to comply with certain practices and standards, including testing, manufacturing, quality control, labeling, advertising, promotion, distribution and documentation procedures. In addition, federal medical device reporting regulations will require them to provide information to the FDA whenever there is evidence that reasonably suggests that a medical product may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with these requirements is subject to continual review and is rigorously monitored through periodic FDA inspections. We cannot be sure that the FDA will not identify compliance issues that may disrupt production or distribution, or require substantial resources to correct. In foreign markets, our licensing partners will be required to obtain certain certifications in order to sell medical products and will have to undergo periodic inspections by regulatory bodies to maintain these certifications. If our licensees fail to adhere to any laws and standards applicable to medical product manufacturers, the marketing of products could be suspended, and such failure could, for our licensees, lead to fines and withdrawal of regulatory clearances, product recalls, or other consequences, any of which could in turn adversely affect our projected business operations, financial condition, or results of operations. Our licensees will also be subject to certain environmental laws and regulations. Our licensing partners' manufacturing operations may involve the use of substances and materials regulated by various environmental protection agencies and regulatory bodies. We cannot guarantee that any licensee will sustain compliance with environmental laws, and that regulations will not have a material impact on our earnings, financial condition, or business operations.

Failure of our licensees to comply with laws and regulations relating to reimbursement of health care products may adversely impact our business operations.

Medical products are subject to regulation regarding quality and cost by the United States Department of Health and Human Services, Centers for Medicare & Medicaid services and comparable state and foreign agencies that are responsible for payment and reimbursement of healthcare goods and services. In the U.S., healthcare laws apply to our licensing partners' business operations when a reimbursement claim is submitted under a federal government funded healthcare program. Federal laws and regulations prohibit the filing of false or improper claims for federal payment and unlawful inducements for the referral of business reimbursable under federally-funded healthcare programs (known as the anti-kickback laws). If a governmental agency or regulatory body were to conclude that our licensees were not in compliance with applicable laws and regulations regarding payment or reimbursement of medical products, they could be subject to criminal and civil penalties, including exclusion from participation as a supplier of products to beneficiaries covered by government healthcare programs. Such exclusions could negatively affect our distribution channels, financial condition or results of operations.

Quality problems with a licensee's manufacturing processes could harm our reputation and affect demand for medical products using our technology.

Ensuring the quality of products and manufacturing processes is critical for medical product companies due to the high cost and seriousness of product failures or malfunctions. If any of our licensees failed to meet adequate quality standards, its and our reputations could be damaged and our revenues would decline. In addition, production of medical products which utilize our technology may depend on our licensees' abilities to engineer and manufacture precision components and assemble such components into intricate medical products. We cannot guarantee that our licensees or third-party suppliers will not encounter problems or delays in timely manufacturing or assembling our products and other materials related to the manufacture or assembly of our products, or in manufacturing our products in amounts sufficient to support our development and commercialization efforts. If our licensees fail to meet these requirements or fail to adapt to changing requirements, their and our reputations may suffer and demand for products implementing our technology would decline significantly.

#### Uncertainties regarding healthcare reimbursements may adversely affect our business.

Healthcare cost containment pressures decrease the prices end-users are willing to pay for medical products, which could have an adverse effect on our royalty revenue. Products that may implement our technology may be purchased by hospitals or physicians, which typically bill governmental programs, private insurance plans and managed care plans for the healthcare devices and services provided to their patients. The ability of these customers to obtain reimbursement from private and governmental third-party payors for the products and services they provide to patients is critical to commercial success. The availability of reimbursement affects which products customers purchase and the prices they are willing to pay. Reimbursement varies from country to country and can significantly impact the acceptance of new products and services. Although we and our licensees may have a promising new product, we and our licensees may find limited demand for the medical product unless reimbursement approval is obtained from private and governmental third-party payors. Even if reimbursement approval is obtained from private and governmental third-party payors, we may still find limited demand for the product for other reasons. In addition, legislative or administrative reforms to the U.S., or to international reimbursement systems, in a manner that significantly reduces reimbursement for products or procedures using our technology, or denial of coverage for those products or procedures, could have a material adverse effect on our business, financial condition or results of operations.

Major third-party payors for hospital services in the U.S. and abroad continue to work to contain healthcare costs. The introduction of cost containment incentives, combined with closer scrutiny of healthcare expenditures by both private health insurers and employers, has resulted in increased discounts and a contractual adjustment to hospital charges for services performed and has shifted services between inpatient and outpatient settings. Initiatives to limit the increase of healthcare costs, including price regulation, are also ongoing in markets in which our licensees may do business. Hospitals or physicians may respond to these cost-containment pressures by insisting that our licensees lower prices, which may adversely affect our royalties.

In response to increasing healthcare costs, there has been and may continue to be proposals by legislators, regulators, and third-party payors to reduce these costs. If these proposals are passed, limitations and/or reductions may be placed on the net or allowable price of products implementing our technology or the amounts of reimbursement available for these products from customers, governmental bodies, and third-party payors. These limitations and reductions on prices may have a material adverse effect on our financial position and results of operations.

To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our approved products to other available therapies. We may not obtain reimbursement or pricing approvals in markets we seek to enter in a timely manner, if at all. Our failure to receive reimbursement or pricing approvals in target markets would negatively impact market acceptance of our product candidates in these jurisdictions, placing us at a material cost disadvantage to our competitors.

Even if we obtain reimbursement approvals for our product candidates, we believe that, in the future, reimbursement for any of our product candidates may be subject to increased restrictions both in the U.S. and in international markets. Future legislation, regulation or policies of third party payers that limit reimbursement may adversely affect the demand for our product candidates and our ability to sell our product candidates on a profitable basis. In addition, third party payers continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services.

In the U.S., specifically, health care providers, such as hospitals and clinics, generally rely on third-party payers. Third-party reimbursement is dependent upon decisions by the Centers for Medicare and Medicaid Services, contracted Medicare carriers or intermediaries, individual managed care organizations, private insurers, foreign governmental health programs and other payers of health care costs. Failure to receive or maintain favorable coding, coverage and reimbursement determinations for our product candidates by these organizations could discourage medical practitioners from using our product candidates due to their costs. In addition, with recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform including the reform of the Medicare and Medicaid entitlement programs, and on the cost of medical products and services, which could limit reimbursement. Additionally, third-party payers are increasingly challenging the prices charged for medical products and services. We may be unable to sell our product candidates on a profitable basis if third-party payers deny coverage, provide low reimbursement rates or reduce their current levels of reimbursement.

We and our licensees will be required to attract and retain top quality talent to compete in the marketplace.

We believe our future growth and success will depend in part on our and our licensees' abilities to attract and retain highly skilled managerial, product development, sales and marketing, and finance personnel. There can be no assurance of success in attracting and retaining such personnel. Shortages in qualified personnel could limit our ability to increase sales of existing products and services and launch new product and service offerings.

Our forecasts are highly speculative in nature and we cannot predict results in a development stage company with a high degree of accuracy.

Any financial projections, especially those based on ventures with minimal operating history, are inherently subject to a high degree of uncertainty, and their ultimate achievement depends on the timing and occurrence of a complex series of future events, both internal and external to the enterprise. There can be no assurance that potential revenues or expenses we project will, in fact, be received or incurred.

We are subject to evolving and expensive corporate governance regulations and requirements. Our failure to adequately adhere to these requirements or the failure or circumvention of our controls and procedures could seriously harm our business.

As a publicly traded company, we are subject to various federal, state and other rules and regulations, including applicable requirements of the Sarbanes-Oxley Act of 2002. Compliance with these regulations is costly and requires a significant diversion of management time and attention, particularly with regard to our disclosure controls and procedures and our internal control over financial reporting. Our internal controls and procedures may not be able to

prevent errors or fraud in the future. Faulty judgments, simple errors or mistakes, or the failure of our personnel to adhere to established controls and procedures may make it difficult for us to ensure that the objectives of the control system are met. A failure of our controls and procedures to detect other than inconsequential errors or fraud could seriously harm our business and results of operations.

Our limited senior management team size may hamper our ability to effectively manage a publicly traded company while developing our products and harm our business.

Our management team has experience in the management of publicly traded companies and complying with federal securities laws, including compliance with recently adopted disclosure requirements on a timely basis. They realize it will take significant resources to meet these requirements while simultaneously working on licensing, developing and protecting our IP. Our management will be required to design and implement appropriate programs and policies in responding to increased legal, regulatory compliance and reporting requirements, and any failure to do so could lead to the imposition of fines and penalties and harm our business.

The issuance of convertible promissory notes has subjected us to possible remedies of a secured creditor and has limited our financing alternatives.

Our obligations under our outstanding convertible promissory notes are debt obligations secured by security interests in all of our and all of the assets of our subsidiaries, including intellectual property. If we default on our obligations under our convertible promissory notes and related agreements, the holders of such notes will be entitled to all the remedies available to secured creditors under the applicable Uniform Commercial Code, including (without limitation) the ability to accelerate the due date for the entire principal amount, charge default interest and penalties and foreclose on our assets. In addition, we are required to comply with certain covenants under such notes, including covenants relating to incurring additional indebtedness without consent of the holders of such notes. These covenants, in the absence of waiver by the holders of such notes, limit our ability to fund our operations through additional debt financing. Additionally, financial penalties in such notes and the accompanying warrants may make it difficult to us to obtain funding from, or be acquired by, a third party.

Our Chief Executive Officer's departure could be an event of default under our convertible promissory notes.

While we believe that Thomas Gardner's services will be available to us, there can be no assurances that the financial arrangements that we have made for Mr. Gardner, or the provisions of the management consulting agreement we entered into with him will be effective and adequate at this stage in our development to retain his services. If Mr. Gardner ceases to be a contractor of our Company (other than due to a termination without good cause), that will be an event of default under our outstanding convertible promissory notes unless we obtain a reasonably acceptable full-time replacement for Mr. Gardner within 90 days after such termination.

#### Risks Related to Our Common Stock and this Offering

The limited trading market for our common stock results in limited liquidity for shares of our common stock and significant volatility in our stock price.

Although prices for our shares of common stock are quoted on the OTCQB, there is little current trading and no assurance can be given that an active public trading market will develop or, if developed, that it will be sustained. The OTCQB is generally regarded as a less efficient and less prestigious trading market than other national markets. There is no assurance if or when our common stock will be quoted on another more prestigious exchange or market. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders. The absence of an active trading market reduces the liquidity of our common stock.

The market price of our stock is likely to be highly volatile because for some time there will likely be a thin trading market for the stock, which causes trades of small blocks of stock to have a significant impact on our stock price. As a result of the lack of trading activity, the quoted price for our common stock on the OTCQB is not necessarily a reliable indicator of its fair market value. Further, if we cease to be quoted, holders of our common stock would find it more difficult to dispose of, or to obtain accurate quotations as to the market value of, our common stock, and the market value of our common stock would likely decline.

An active trading market may not develop for our common stock, and you may not be able to sell your stock at or above the public offering price per share.

There is a very limited trading market for our common stock, and the market for our common stock may be highly volatile or may decline regardless of our operating performance. An active public market for our common stock may not develop or be sustained after this offering. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market in our common stock or how liquid that market might become. If an active market does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at the time you wish to sell them, at a price that is attractive to you, or at all.

The public offering price per share has been determined based on the bid price on our common stock on the OTCQB and through negotiation between us and representatives of the underwriters, and may not be indicative of the market price for our common stock after this offering. You may not be able to sell your shares at or above the public offering price per share.

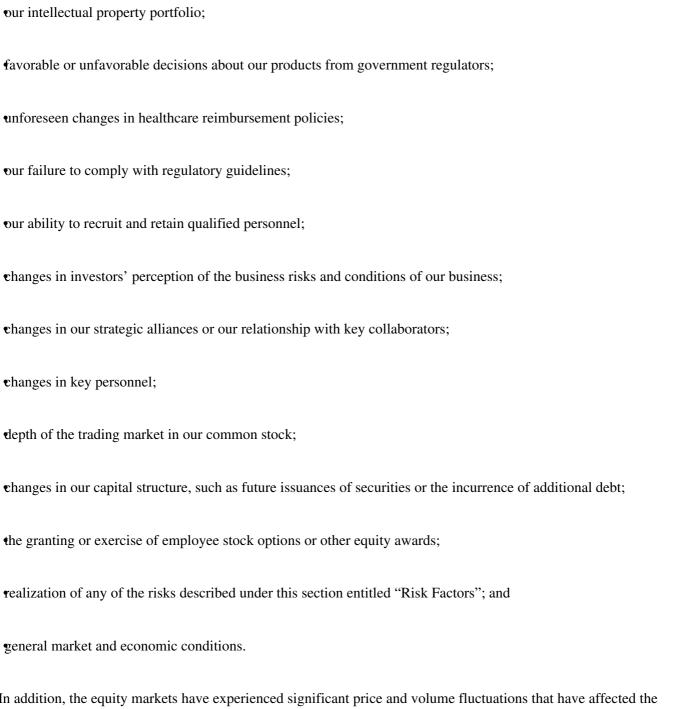
Trading in our common stock will be subject to regulatory restrictions since our common stock is considered a "penny stock."

Our common stock is currently, and in the near future will likely continue to be, considered a "penny stock." The Securities and Exchange Commission ("SEC") has adopted rules that regulate broker-dealer practices in connection with transactions in "penny stocks." Penny stocks generally are 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 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 prepared by the SEC, which specifies information about penny stocks and the nature and significance of risks of the penny stock market. The broker-dealer also must provide the customer with bid and offer quotations for the penny stock, the compensation of the broker-dealer and any salesperson in the transaction, and monthly account statements indicating the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that, prior to a transaction in a penny stock not otherwise exempt from those rules; the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure and other requirements may adversely affect the trading activity in the secondary market for our common stock.

The price of our common stock may be volatile, and the market price of our common stock after this offering may drop below the price you pay.

Our public offering price per share may vary from the market price of our common stock after the offering. If an active market for our stock develops and continues, our stock price nevertheless may be volatile. Market prices for securities of development-stage life sciences companies have historically been particularly volatile. As a result of this volatility, you may not be able to sell your common stock at or above the public offering price per share. The factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

progress, or lack of progress, in developing and commercializing our products;



In addition, the equity markets have experienced significant price and volume fluctuations that have affected the market prices for the securities of newly public companies for a number of reasons, including reasons that may be unrelated to our business or operating performance. These broad market fluctuations may result in a material decline in the market price of our common stock and you may not be able to sell your shares at prices you deem acceptable. In the past, following periods of volatility in the equity markets, securities class action lawsuits have been instituted against public companies. Such litigation, if instituted against us, could result in substantial cost and the diversion of management attention.

The shares you purchase in this offering will experience immediate and substantial dilution.

The public offering price per share of our common stock will be substantially higher than the net tangible book value per share of our common stock immediately after the offering. At the public offering price of \$0.75 per share, purchasers of our common stock will incur immediate dilution of \$1.01 per share in the net tangible book value of their purchased shares. Conversely, the shares of our common stock that our existing stockholders currently own will receive an increase in net tangible book value per share. See the section entitled "Dilution" elsewhere in this prospectus.

You may be diluted by exercises of outstanding options and warrants and conversions of outstanding convertible promissory notes.

As of September 12, 2014, we had outstanding options to purchase an aggregate of 548,950 shares of our common stock at a weighted average exercise price of \$8.42 per share, warrants to purchase an aggregate of 1,352,990 shares of our common stock at a weighted average exercise price of \$3.83 per share and convertible promissory notes convertible into an aggregate of 2,998,785 shares of our common stock (including 391,937 shares accounting for accrued interest through maturity) at a weighted average conversion price of \$1.31 per share. The exercise of such outstanding options and warrants and the conversion of such outstanding convertible promissory notes will result in further dilution of your investment. In addition, you may experience additional dilution if we issue common stock in the future, including the issuance of common stock upon the exercise of the warrants offered hereby. As a result of this dilution, you may receive significantly less in net tangible book value than the full purchase price you paid for the shares in the event of liquidation.

Substantial future sales of our common stock in the public market could cause our stock price to fall.

Sales of a significant number of shares of our common stock in the open market could cause additional harm to the market price of our common stock. Further reduction in the market price for our shares could make it more difficult to raise funds through future equity offerings.

Some of our shares may also be offered from time-to-time in the open market pursuant to Rule 144, and these sales may have a depressive effect on the market for our shares. In general, a non-affiliate who has held restricted shares for a period of six months may sell an unrestricted number of shares of our common stock into the market.

Our management will have broad discretion over the use of the proceeds we receive in this offering, and may not apply the proceeds in ways that increase the value of your investment.

We estimate that net proceeds of the sale of the securities that we are offering will be approximately \$2,349,319, or \$2,767,826, if the underwriters exercise their over-allotment option in full. We currently intend to use the net proceeds from this offering for general corporate purposes, including working capital, operating expenses and capital expenditures. We anticipate making capital expenditures during the fourth quarter of 2014 of approximately \$20,000 to \$30,000, and we may use a portion of the net proceeds to fund our anticipated capital expenditures. We also may use a portion of the net proceeds to acquire businesses, products, services or technologies. However, we will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the proceeds of this offering. The actual amounts and timing of our expenditures depends on numerous factors, including the success of our efforts to develop and commercialize our products, to obtain regulatory approval

to sell our products, the timing and progress of our research and development activities, changes in regulatory requirements, and other unforeseen regulatory or compliance costs. The costs and timing of research and development activities, particularly conducting clinical trials and obtaining regulatory clearance or approval, are highly uncertain, subject to substantial risks and can often change. Depending on the outcome of these activities, our plans and priorities may change and we may apply the net proceeds of this offering differently than we currently anticipate. Moreover, you will not have the opportunity to influence our decision on how to use the proceeds from this offering. We may use the proceeds for corporate purposes that do not immediately enhance our prospects for the future or increase the value of your investment. See the section entitled "Use of Proceeds" elsewhere in this prospectus.

We have not paid dividends in the past and do not expect to pay dividends for the foreseeable future, and any return on investment may be limited to potential future appreciation on the value of our common stock.

We currently intend to retain any future earnings to support the development and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our board of directors after taking into account various factors, including without limitation, our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. To the extent we do not pay dividends, our stock may be less valuable because a return on investment will only occur if and to the extent our stock price appreciates, which may never occur. In addition, investors must rely on sales of their common stock after price appreciation as the only way to realize their investment, and if the price of our stock does not appreciate, then there will be no return on investment. Investors seeking cash dividends should not purchase our common stock.

Our officers, directors and principal stockholders can exert significant influence over us and may make decisions that are not in the best interests of all stockholders.

Our officers, directors and principal stockholders (greater than 5% stockholders) collectively own approximately 45.3% of our outstanding common stock, and approximately 58.7% of our fully-diluted common stock. As a result of such ownership and the Voting Agreement that is in place, these stockholders will be able to affect the outcome of, or exert significant influence over, all matters requiring stockholder approval, including the election and removal of directors and any change in control. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a change of control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our stockholders from realizing a premium over the market prices for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders, and accordingly, they could cause us to enter into transactions or agreements that we would not otherwise consider.

Anti-takeover provisions may limit the ability of another party to acquire us, which could cause our stock price to decline.

Our amended and restated certificate of incorporation, our bylaws and Delaware law contain provisions that could discourage, delay or prevent a third party from acquiring us, even if doing so may be beneficial to our stockholders. In addition, these provisions could limit the price investors would be willing to pay in the future for shares of our common stock.

# There is no public market for the warrants offered hereby.

There is no established public trading market for the warrants included in the securities being sold in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing the warrants on any securities exchange. Without an active market, the liquidity of these securities will be limited.

The warrants may no	t have an	v value.
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In the event that our common stock price does not exceed the exercise price of the warrants before they expire, they will not have any value.

Holders of the warrants will have no rights as a common stockholder until they acquire our common stock.

Until you acquire shares of our common stock upon exercise of your warrants, you will have no rights with respect to the shares of our common stock underlying our warrants. Upon exercise of your warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

#### FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "predict," "potential," "intends," "may," "will" "would," "could," or "should" or, in each case, their negative, or other or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time for which our existing resources will enable us to fund our operations; plans regarding our efforts to gain U.S. regulatory approval for our bile salts technology for the regression of atherosclerotic plaque deposits; the possibility, timing and outcome of submitting regulatory filings for our products under development; our research and development programs for our bile salt technology and other possible indications of the use of bile salts in reducing lipid deposits, including planning for and timing of any clinical trials and potential development milestones; the development of financial, clinical, licensing and distribution plans related to the potential commercialization of our drug products, if approved; and plans regarding potential strategic alliances and other collaborative arrangements with pharmaceutical companies and others to develop, license, manufacture and market our products.

Forward-looking statements are based on information we have when those statements are made or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Moreover, new risks regularly emerge and it is not possible for us to predict or articulate all risks we face, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements.

All forward-looking statements included in this prospectus are based on information available to us on the date of this prospectus. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained above and throughout this prospectus.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause actual results to differ materially from any future results expressed or implied by the forward-looking statements. We caution you therefore against relying on any of these forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. Examples of the risks and uncertainties include, but are not limited to:

risks related generally to our efforts to gain regulatory approval, in the United States and elsewhere, for our drug product candidates, including our lead compounds that we are developing to address atherosclerotic plaque regression and other possible applications of bile salts for the regression or dissolution of lipid deposits;

the risk that we and the FDA or other regulatory authorities will not be able to agree on matters raised during the regulatory review process, or that we may be required to conduct significant additional activities to potentially gain approval of our product candidates, if ever;

the risk that the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file, or may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;

risks relating to the rigorous regulatory approval processes, including pre-filing activities, required for approval of any drug or possible combination drug-device products that we may develop, whether independently, with strategic development partners or pursuant to collaboration arrangements;

the risk that the FDA will not be satisfied with the results of our efforts to file an application for an IND based on the data accumulated in our pre-clinical research;

risks relating to our research and development activities, which involve time-consuming and expensive preclinical studies and other efforts for which we depend on collaborative arrangements with commercial and academic entities, who may not complete activities on schedule or conduct such activities in accordance with regulatory requirements or our trial designs;

risks relating to the transfer of our manufacturing technology to third-party contract manufacturers and assemblers;

the risk that we, our licensing partners or any third-party suppliers may encounter problems or delays in manufacturing or assembling drug products, drug product substances, ancillary devices and related components and other materials on a timely basis or in an amount sufficient to support our development efforts and, if our products are approved, commercialization;

the risk that we may be unable to identify potential strategic partners or collaborators with whom we can develop and, if approved, commercialize our products in a timely manner, if at all;

the risk that we or our strategic partners or collaborators will not be able to attract or maintain qualified personnel;

the risk that, if approved, market conditions, the competitive landscape or other factors may make it difficult to compete against competitive products and/or entities;

the risk that we may not be able to raise additional capital or enter into strategic alliances or collaboration agreements (including strategic alliances for development, licensing or commercialization of our drug products);

the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten our ability to continue as a going concern;

the risks that we may be unable to obtain patents related to our products and/or uses thereof;

the risks that we may be unable to maintain and protect the patents and licenses related to our products and that other companies may develop competing therapies and/or technologies;

the risk that we may become involved in securities, product liability and other litigation;

risks related to reimbursement and health care reform that may adversely affect us; and

other risks and uncertainties detailed in the section entitled "Risk Factors" elsewhere in this prospectus.

Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. After gaining approval of a drug product, pharmaceutical companies face considerable challenges in marketing and distributing their products, and may never become profitable.

The forward-looking statements contained in this prospectus speak only as of their respective dates. Factors or events that could cause our actual results to differ may emerge from time to time and it is not possible for us to predict them all. Except to the extent required by applicable laws, rules or regulations, we do not undertake any obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise. You should, however, review additional disclosures we make in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the SEC.

#### **USE OF PROCEEDS**

We estimate that the net proceeds to us from the sale of the 4,000,000 shares of our common stock and warrants to purchase 5,000,000 shares of common stock in this offering will be approximately \$2,349,319, after deducting the underwriting discount and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full to purchase 600,000 additional shares of our common stock and/or warrants to purchase 750,000 shares of common stock, we estimate that the net proceeds to us will be approximately \$2,767,826, after deducting the underwriting discount and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering for general corporate purposes, including working capital, operating expenses and capital expenditures. We anticipate making capital expenditures in the fourth quarter of 2014 of approximately \$20,000 to \$30,000, and we may use a portion of the net proceeds to fund our anticipated capital expenditures. We also may use a portion of the net proceeds to acquire businesses, products, services or technologies. However, we do not have any agreements or commitments for any acquisitions at this time. We cannot specify with certainty the particular uses of net proceeds that we will receive from this offering. Accordingly, we will have broad discretion in using these proceeds. Pending the use of proceeds from this offering as described above, we plan to invest the net proceeds that we receive from this offering in short-term, interest bearing investments.

#### **CAPITALIZATION**

The following table sets forth our cash, cash equivalents and capitalization, as of June 30, 2014, as follows:

on an actual basis;

on a pro forma as adjusted basis, giving effect to (i) the sale and issuance by us of the securities in this offering at the public offering price of \$0.75 per share and \$0.00001 per warrant, after deducting the underwriting discount and estimated offering expenses payable by us and (ii) the issuance and sale of \$500,000 aggregate principal amount of 8% senior secured convertible promissory notes and warrants by us in September 2014; and

excludes the accounting for any derivative liability that may arise in the issuance of the warrants issued in connection with this offering on in the sale of the convertible notes.

You should read this information together with our consolidated financial statements and related notes that are included elsewhere in this prospectus.

	As of June 30, 2014	
	Actual	Pro Forma as Adjusted
Cash, cash equivalents and short-term investments 2.5% Senior secured convertible notes, net of discount 6% Senior secured convertible notes, net of discount	\$319,779 \$761,762 \$245,110	\$ 3,169,098 \$ 761,762 \$ 245,110
8% Senior secured convertible notes, net of discount Stockholders' equity (deficit): Preferred stock, par value \$0.0001 per share: 10,000,000 shares authorized; none issued and outstanding, actual or pro forma as adjusted	\$ 	\$ 500,000
Common stock, par value \$0.0001 per share: 100,000,000 shares authorized, 4,770,207 shares issued and outstanding, actual; 8,770,207 shares issued and outstanding, pro forma as adjusted Additional paid-in capital	477 22,953,135	877 25,302,054
Accumulated deficit Total stockholders' equity (deficiency)	(27,632,441) (4,678,829)	(27,632,441)
Total capitalization	\$ (3,671,957)	\$ (822,638 )

The above table is based on 4,770,207 shares of our common stock outstanding as of June 30, 2014, assumes no exercise of the over-allotment option and excludes the following:

1,352,990 shares of our common stock issuable upon the exercise of common stock purchase warrants with a weighted average exercise price of approximately \$3.83 per share;

548,950 shares of our common stock issuable upon the exercise of stock options with an exercise price of approximately \$8.42 per share;

2,998,785 shares of our common stock (including 391,937 shares accounting for accrued interest through maturity) issuable upon conversion of convertible promissory notes at a weighted average conversion price of approximately \$1.31;

292,297 additional shares of common stock reserved for issuance under our 2010 Stock Incentive Plan, as of August 31, 2014;

5,000,000 shares of common stock initially issuable upon exercise of the warrants to be sold in this offering, subject to adjustment as described herein;

200,000 shares of common stock underlying the warrants that will be issued to the representative in connection with this offering. See "Underwriting – Representative's Warrant."; and

84,000 shares of common stock are estimated to be issuable to an investor and research provider based on current progress if the final milestone of our collaborative research plan is achieved. See "Business-Strategic Alliances and Collaboration Agreements".

#### **DILUTION**

If you invest in our securities in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after completion of this offering.

Net tangible book value per share is determined by dividing our total tangible assets less our total liabilities by the number of shares of our common stock outstanding. Our historical net tangible deficit as of June 30, 2014 was approximately \$4,678,829, or \$0.98 per share, based on 4,770,207 shares of our common stock outstanding on that date.

After giving effect to the sale by us of 4,000,000 shares of our common stock and warrants to purchase 5,000,000 shares of common stock in this offering at the public offering price of \$0.75 per share and \$0.00001 per warrant, and after deducting the underwriting discount and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2014 would have been a deficit of approximately \$2,329,510, or \$0.27 per share. This represents an immediate increase in pro forma net tangible book value of \$0.71 per share to our existing stockholders and an immediate dilution of \$1.02 per share to new investors participating in this offering at the offering price. The following table illustrates this dilution:

Public offering price per share		\$0.75
Net tangible book value (deficit) per share as of June 30, 2014, before this offering	\$(0.98)	
Increase in pro forma net tangible book value (deficit) per share attributable to new investors in this offering	\$0.71	
Pro forma as adjusted net tangible book value (deficit) per share as of June 30, 2014, immediately after this offering		\$(0.27)

Dilution in pro forma net tangible book value per share to new investors in this offering \$1.02

The information above is as of June 30, 2014 and excludes the following:

1,352,990 shares of our common stock issuable upon the exercise of common stock purchase warrants, with a weighted average exercise price of approximately \$3.83 per share;

548,950 shares of our common stock issuable upon the exercise of stock options, with an exercise price of approximately \$8.42 per share;

2,998,785 shares of our common stock (including 391,937 shares accounting for accrued interest through maturity) issuable upon conversion of convertible promissory notes at a weighted average conversion price of approximately \$1.31;

292,297 additional shares of common stock reserved for issuance under our 2010 Stock Incentive Plan;

5,000,000 shares of common stock initially issuable upon exercise of the warrants to be sold in this offering, subject to adjustment as described herein;

200,000 shares of common stock underlying the warrants that will be issued to the representative in connection with this offering. See "Underwriting – Representative's Warrant"; and

84,000 shares of common stock are estimated to be issuable to an investor and research provider based on current progress if the final milestone of our collaborative research plan is achieved. See "Business-Strategic Alliances and Collaboration Agreements".

The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, our pro forma as adjusted net tangible book value (deficit) per share would be \$(0.20) per share, representing an immediate increase in pro forma net tangible book value of \$0.78 per share to our existing stockholders and an immediate dilution of \$0.95 per share to new investors. If any shares are issued upon exercise of outstanding options, warrants (including the warrants offered hereby) or convertible notes, new investors will experience further dilution.

# MARKET PRICE OF OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Our common stock is quoted on the OTCQB under the symbol "AHRO." The following table sets forth, for the periods indicated, the high and low bid information for our common stock, as determined from sporadic quotations on the OTCQB. The following quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions. These prices reflect the 1-for-10 reverse stock split effected on April 22, 2014 as well as rounding.

	High		Low	
Year Ended December 31, 2012				
First Quarter	\$	13.20	\$	8.40
Second Quarter	\$	10.70	\$	4.50
Third Quarter	\$	9.70	\$	5.00
Fourth Quarter	\$	8.50	\$	4.40
Year Ended December 31, 2013				
First Quarter	\$	8.00	\$	0.35
Second Quarter	\$	7.90	\$	0.50
Third Quarter	\$	7.40	\$	0.51
Fourth Quarter	\$	5.70	\$	0.35
Year Ended December 31, 2014				
First Quarter	\$	5.50	\$	3.50
Second Quarter	\$	4.39	\$	1.35
Third Quarter	\$	2.55	\$	1.35
Fourth Quarter (through October 27, 2014)	\$	2.00	\$	1.25

On October 27, 2014, the closing sales price of our common stock as reported on the OTCQB was \$1.62 per share. As of October 3, 2014, there were approximately 152 record holders of our common stock, excluding shareholders for whom shares are held in "nominee" or "street name."

#### **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant.

Under the terms and conditions of the notes issued by us in 2010, 2012 and 2014, we cannot declare or pay any cash dividends for as long as there remains an outstanding and unpaid balance on these notes. A declaration or payment of any dividend would be a covenant violation of the notes whose remedy may include making the entire balance of the outstanding principal and accrued interest immediately due and payable.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This discussion summarizes the significant factors affecting our operating results, financial condition and liquidity and cash flows for the periods ended December 31, 2013 and 2012 and for the six months ended June 30, 2014 and 2013. The discussion and analysis that follows should be read together with the consolidated financial statements and the notes to the consolidated financial statements included elsewhere in this prospectus. Management's Discussion and Analysis of Financial Condition and Results Of Operations is provided as a supplement to the accompanying consolidated financial statements and notes thereto to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. Except for historical information, the matters discussed in this Management's Discussion and Analysis of Financial Condition and Results of Operations are forward looking statements that involve risks and uncertainties and are based upon judgments concerning various factors that are beyond our control. Our actual results could differ materially from the results anticipated in any forward-looking statements as a result of a variety of factors, including those discussed in the section entitled "Risk Factors" elsewhere in this prospectus.

#### Overview

Z&Z Medical Holdings, Inc. ("Z&Z Nevada") was incorporated in the State of Nevada on December 13, 2006 with contributed intellectual property from its founders. Z&Z Nevada was engaged in developing the contributed intellectual property while seeking sources of funding to conduct further research and development. In November 2009 Z&Z Nevada incorporated Z&Z Delaware and merged Z&Z Nevada into Z&Z Delaware in March 2010. On March 26, 2010 we entered into a merger agreement with Z&Z Merger Corporation, our wholly-owned subsidiary and Z&Z Delaware, and on May 13, 2010, Z&Z Merger Corporation merged into Z&Z Delaware with Z&Z Delaware surviving as our operating subsidiary. Concurrent with the Merger, Z&Z Delaware changed its name to AtheroNova Operations, Inc. and we changed our name from Trist Holdings, Inc. to AtheroNova Inc. The business of AtheroNova Operations, pharmaceuticals and pharmaceutical intellectual property, became our business upon consummation of the Merger.

We have developed intellectual property, covered by our issued and pending patent applications, which uses certain pharmacological compounds for the treatment of atherosclerosis, which is the primary cause of cardiovascular diseases. Atherosclerosis occurs when cholesterol of fats are deposited and form as plaques on the walls of the arteries. This buildup reduces the space within the arteries through which blood can flow. The plaque can also rupture, greatly restricting or blocking blood flow altogether. Through a process called reverse cholesterol transport, such compounds dissolve the plaques so they can be eliminated through normal body processes and avoid such rupturing or restriction of blood flow. Such compounds may be used both to treat and prevent atherosclerosis.

In the near future, we plan to continue studies and trials to demonstrate the efficacy of our IP. Ultimately, we plan to use or license our technology to various licensees throughout the world who may use it in treating or preventing atherosclerosis and other medical conditions or sublicense the IP to other such users. Our potential licensees may also produce, market or distribute products which utilize or add our compounds and technology in such treatment or prevention.

#### General

Operating expenses consist primarily of payroll and related costs and corporate infrastructure costs. We expect that our operating expenses will increase as we continue executing our business plan, in addition to the added costs of operating as a public company.

Historically, we have funded our working capital needs primarily through the sale of shares of our capital stock and debt financing.

The Merger was accounted for as a reverse merger (recapitalization) with AtheroNova Operations deemed to be the accounting acquirer, and our Company deemed to be the legal acquirer. Accordingly, the following discussing represents a discussion of the operations of our wholly-owned subsidiary, AtheroNova Operations for the periods presented.

## **Results of Operations**

Six months ended June 30, 2014 Compared to the six months ended June 30, 2013

	Six months ended June 30,		Increase	
	2014	2013	(decrease)	
Costs and expenses:				
Research and development:				
Share-based compensation	\$1,137,097	\$1,198,297	\$(61,200)	
Other research and development expenses	1,401,046	872,916	528,130	
<b>Total research and development expenses</b>	2,538,143	2,071,213	466,930	
General and administrative:				
Share-based compensation	249,528	1,001,873	(752,345)	
Other general and administrative expenses	975,928	735,951	239,977	
Total general and administrative expenses	1,225,456	1,737,824	(512,368)	
Interest expense	(736,553)	(381,518)	355,035	
Private placement costs	(3,340,030)		3,340,030	
Change in fair value of derivative liabilities	2,239,082		(2,239,082)	
Other income (expense)	(1,547)	728	2,275	
<b>Total other income (expense)</b>	(1,839,048)	(380,790)	1,458,258	
Net loss	\$(5,602,647)	\$(4,189,827)	\$(1,412,820)	

During the six month periods ended June 30, 2014 and 2013, we did not recognize any revenues. We are considered a development stage company and do not expect to have revenues relating to our products in the foreseeable future, if at all.

For the six months ended June 30, 2014 and 2013, research and development expenses increased to \$2,538,143 from \$2,071,231. This increase is primarily the result of expenses associated with the toxicology testing program undertaken to support regulatory filings in the United States for AHRO-001 and increased costs for patent filing, prosecution and related costs when compared to the same period in the prior year.

General and administrative costs decreased to \$1,225,456 in the six months ended June 30, 2014 compared to \$1,737,824 for the six months ended June 30, 2013, or a decrease of \$512,368. The decrease in costs incurred in 2014 is due primarily to lower share-based compensation costs as there were no below market purchases or gifts of stock involving a controlling stockholder as were recorded in 2013 as well as reduced costs recorded in the current year with a number of option grants reaching full vesting. Partially offsetting the decreased share based compensation was increased expenses for legal and professional costs for the preparation of reverse stock split documentation as well as the Registration Statement on Form S-1 of which this prospectus forms a part.

For the six month period ended June 30, 2014 interest expense was \$736,553 compared to \$381,518 in the six month period ended June 30, 2013. This change is due to recognition of the note discounts on a higher outstanding Senior Note balance in the current year when compared to 2013 as well as the associated additional interest expense recorded.

For the six months ended June 30, 2014 private placement costs increased to \$3,340,030 with no comparable expense in the same period of 2013. This increase is due to recognition of the fair value of the embedded derivative in the 6% Senior Secured Convertible Notes (the "6% Notes") and warrants issued in the current period with variable conversion price and exercise price, net of the principal amount of \$1,906,500. Additionally, the cost of cash and equity commissions totaling \$94,115 paid to an accredited broker that assisted in the placement of a portion of the note offering were also expenses in the current period.

Change in fair value of derivative liabilities was income of \$2,239,082 in the six months ended June 30, 2014 for the change in the fair value during the period in which the 6% Notes and warrants were issued and outstanding. The fair value of these variable financial instruments is computed at the end of each periodic reporting date and any change is recorded as income or expense in the current period. There was no comparable charge in the same period of 2013.

Net loss for the six month period ended June 30, 2014 was \$5,602,647 compared to \$4,189,827 for the six month period ended June 30, 2013 due to the private placement costs recognized for the 6% Notes and warrants issued in the February 2014 offering, the cost of the research and development paid and payable through the issuance of our common stock and generally higher operating costs associated with our research and development

Year ended December 31, 2013 Compared to the year ended December 31, 2012

Years ended December 31,

Increase

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	2013	2012	(decrease)
Costs and expenses:			
Share-based compensation	2,369,009		2,369,009
Other research and development expenses	2,030,285	986,261	1,044,024
<b>Total research and development expenses</b>	4,399,294	986,261	3,413,033
General and administrative:			
Share-based compensation	1,359,579	1,182,920	176,659
Other general and administrative expenses	1,455,277	1,468,805	(13,528)
Total general and administrative expenses	2,814,856	2,651,725	163,131
Other (income) expense:			
Interest expense	601,664	871,431	(269,767)
Cost to induce conversion of 12% notes		866,083	(866,083)
Change in fair value of derivative liabilities		(2,640,497)	2,640,497
Gain on extinguishment of derivative liability		(97,975)	97,975
Other (income)/expense	(1,092	(1,467)	375
<b>Total other (income) expense</b>	(600,572	(1,002,425)	1,602,997
Net loss	\$(7,814,722)	\$(2,635,561)	\$5,179,161

During the years ended December 31, 2013 and 2012, we did not recognize any revenues. We are considered a development stage company and do not expect to have revenues relating to our products in the foreseeable future, if at all.

For the twelve months ended December 31, 2013, research and development expenses increased to \$4,399,294 from \$986,261 in the same period in 2012. This is due to significant increases in spending in 2013 for Phase 1 clinical trial drug product, consultants and employees added to oversee our clinical trial programs as well as expenses recognized with the issuance of common stock upon achievement of two milestones and accrual based upon the probability of another milestone as of December 31, 2013 pursuant to the CardioNova clinical trial program. The expenses in the period ended December 31, 2012 included purchase of active pharmaceutical ingredient, formulation development and additional pre-clinical research as reported in that that period.

General and administrative costs increased by \$163,131, to \$2,814,856, in 2013 compared to \$2,651,725 for 2012 due to slight increases in travel, lodging and professional fees due to increased activity with CardioNova and increased participation in financial and investor conferences during the current year We incurred non-cash stock-based compensation expense of \$878,179 for our officers, directors and consultants in 2013, compared to \$1,182,920 for the same provision of services in 2012. Also recognized in 2013 was \$422,500 for below market purchases by directors and \$58,900 for the cost of shares gifted to officers, both from a controlling stockholder of the Company.

For the year ended December 31, 2013, interest expense was \$601,664 compared to \$871,431 for the year ended December 31, 2012. The decrease in interest expense was due to the recognition of unamortized discounts on a larger balance of converted notes in 2012 when compared to 2013. The period ended December 31, 2012 also recognized amortization expense on the short term convertible notes issued and matured in 2012 with no comparable activity in 2013.

For the twelve months ended December 31, 2012, cost to induce conversion of 12% notes was \$866,083. These costs related to the expensing of the Beneficial Conversion Feature recorded on the 12% convertible notes upon conversion in 2012 as well as the fair value of warrants issued to the holders of our short-term convertible notes as inducement to convert the notes in October 2012. There was no comparable expense in 2013.

For the year ended December 31, 2012, there was a gain of \$2,640,497 recorded for the change in fair value of derivative liabilities during the period. There was no comparable gain in the same period of 2013.

For the year ended December 31, 2012, gain on extinguishment of derivative liability was \$97,975 compared to \$0 for the comparable period in 2013. This gain is due to the extinguishment of a portion of the derivative liability due to the partial conversion of the Convertible Notes during the prior year period with no corresponding gain in the current

year.

Net loss for the year ended December 31, 2013, was \$7,814,722 compared to a loss of \$2,635,561 for the year ended December 31, 2012. The increased net loss was due to the increased spending as the Company increased its research and development activities, recognition of expenses of research and development expenses paid or to be paid by issuance of our common stock and the corresponding consultants and employee expenses for staffing to monitor and conduct our clinical research. Additionally, there were no gains associated with revaluation or extinguishing derivative liabilities as were recorded in fiscal year 2012.

### **Liquidity and Capital Resources**

We had stockholders deficit of \$4,678,829 at June 30, 2014, and have an accumulated deficit of \$27,632,441 primarily as a result of our losses from operations and the non-cash costs relating to the accounting of debt, derivative and warrant issuances as well as research and development costs paid and expected to be paid through the issuance of our common stock. We expect to continue to incur additional losses for at least the next twelve months and for the foreseeable future. These losses have been incurred through a combination of research and development activities as well as patent work related to our technology, expenses related to the Merger and to public reporting obligations and the costs to supporting all of these activities.

We have financed our operations since inception primarily through equity and debt financings. During the six months ended June 30, 2014, we had a net increase in cash and cash equivalents of \$53,569. This increase resulted largely from net cash generated in the 6% note financing of \$1,906,500 mostly offset by cash used in operating activities of \$1,850,790. Additionally, on September 12, 2014, we generated net cash from the placement of 8% notes of \$500,000. Total liquid resources as of June 30, 2014 were \$319,779 compared to \$266,210 at December 31, 2013. During the twelve months ended December 31, 2013, we had a net decrease in cash and cash equivalents of \$2,477,836. This decrease resulted largely from net cash provided by financing activities of \$787,048, offset by net cash used in operating activities of \$3,261,824. Total cash as of December 31, 2013 was \$266,210 compared to \$2,744,046 at December 31, 2012.

As of June 30, 2014, we had a working capital deficit of \$1,612,326, when excluding the derivative liability of \$2,348,484, compared to a working capital deficit of \$599,218 at December 31, 2013. As of December 31, 2013, we had working capital deficit of \$989,341 compared to working capital of \$2,121,023 at December 31, 2012. We have reported net losses of \$7,814,722 and \$2,635,561 for the years ended December 31, 2013 and 2012, respectively. We have reported net losses of \$5,602,647 and \$4,189,827 for the six month periods ending June 30, 2014 and 2013, respectively. The net loss attributable from date of inception, December 13, 2006 to December 31 2013, amounts to \$22,029,794. Management believes that we will continue to incur net losses through at least December 31, 2014.

These matters raise substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Our available working capital and capital requirements will depend upon numerous factors, including progress of our research and development programs, our progress in and the cost of ongoing and planned nonclinical and clinical testing, the timing and cost of obtaining regulatory approvals, the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights, in-licensing activities, competing technological and market developments, the resources that we devote to developing manufacturing and commercializing capabilities, the status of our competitors, our ability to establish collaborative arrangements with other organizations and our need to purchase additional capital equipment.

Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing, other collaborative agreements, strategic alliances, and our ability to realize the full potential of our technology in development. Such additional funds may not become available on acceptable terms and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term. Through June 30, 2014, a significant portion of our financing has been through private placements of common stock and warrants and debt financing. Unless our operations generate significant revenues and cash flows from operating activities, we will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. We believe that we will continue to incur net losses and negative cash flows from operating activities for the foreseeable future.

Based on our resources available at June 30, 2014, including the gross proceeds of the 6% Secured Note financing completed in February 2014, which provided gross cash proceeds of \$1,906,500, plus the net cash proceeds from our September 2014 8% financing described below in the amount of \$500,000, management believes that we have sufficient capital to fund our operations through October of 2014. Management believes that we will need additional equity or debt financing, or to generate revenues through licensing of our products or entering into strategic alliances as well as reduce and defer expenses where possible to be able to sustain our operations further into 2014. Furthermore, we will need additional financing thereafter to complete development and commercialization of our intellectual property. There can be no assurances that we can successfully complete development and commercialization of our intellectual property.

#### 2.5% Senior Secured Convertible Notes Payable

On May 13, 2010, we entered into a Securities Purchase Agreement with W-Net Fund I, L.P. ("W-Net"), Europa International, Inc. ("Europa") and MKM Opportunity Master Fund, Ltd. ("MKM" and together with W-Net and Europa, the "Purchasers"), pursuant to which the Purchasers, on May 13, 2010, purchased from us (i) 2.5% Senior Secured Convertible Notes for a cash purchase price of \$1,500,000 (the "Senior Notes"), and (ii) Common Stock Purchase Warrants pursuant to which the Purchasers may purchase up to 190,880 shares of our common stock at an exercise price equal to approximately \$3.90 per share. The warrants may be exercised on a cashless basis by choice of the holder at any time. On May 13,2010, we also entered into a Security Agreement and an Intellectual Security Agreement with the Purchasers and AtheroNova Operations, pursuant to which all of our obligations under the Senior Notes are secured by first priority security interest in all of our assets and the assets of AtheroNova Operations,

including intellectual property. Upon event of default under the Senior Notes or such agreements, the Senior Note holders may be entitled to foreclose on any of such assets or exercise the rights available to a secured creditor under California and Delaware law. In addition, under a Subsidiary Guarantee, AtheroNova Operations guaranteed all of our obligations under the Senior Notes. As discussed in Note 3 to the financial statement included elsewhere in this prospectus, we have twice amended the terms and conditions of the Senior Notes and, in 2012, we issued an additional \$1,500,000 in Senior Notes under the same amended terms and conditions. The Senior Notes accrue 2.5% interest per annum with a maturity of four years after issuance. No periodic cash interest payments were required, except that accrued and unconverted interest is due on the maturity date and on each conversion date with respect to the principal amount being converted.

From issuance through December 31, 2013, the Purchasers exercised their option to convert a portion of the Senior Notes into our common stock. During that period, aggregate principal of \$1,400,500 and accrued interest of \$48,767 was converted into 474,070 and 20,704 shares, respectively, of our common stock. During the period ended June 30, 2014, principal in the amount of \$416,667 was converted at a per share price of \$2.90 into 143,678 shares of our common stock. In addition, we also issued 5,170 shares of our common stock with a market value of \$19,646 to settle \$14,994 of accrued interest relating to these notes. The aggregate balance of the Senior Notes outstanding as of June 30, 2014 amounted to \$1,181,167, of which, \$427,500 is presented as part of current liabilities in the accompanying balance sheet.

The Senior Notes may not be prepaid, or forced by us to be converted in connection with an acquisition of us, except in limited cases. The Senior Notes greatly restrict the ability of us and AtheroNova Operations to issue indebtedness or grant liens on our or its respective assets without the Senior Note holders' consent. They also limit and impose financial costs on our acquisition by any third party.

On October 14, 2014, the Company and the holder of a Senior Note agreed to amend such holder's Senior Note to provide the Company with the option to trigger conversion of all amounts due under such Senior Note into common stock upon the consummation of a private placement or registered offering generating gross proceeds to the Company of at least \$4,000,000.

On May 9, 2014, the holder of the Senior Note issued on May 13, 2010 signed an agreement extending the maturity date from May 12, 2014 to September 12, 2014, and on September 9, 2014 again agreed to extend the maturity date to November 12, 2014.

Total 2.5% convertible notes purchased and held by Europa were \$1,094,167 at both June 30, 2014 and December 31, 2013. Europa is an entity controlled by Knoll Capital Management of which Mr. Knoll, one of our directors, is the managing director.

### **6% Secured Convertible Notes Payable**

In February 2014, we entered into Securities Purchase Agreements with approximately 31 accredited investors (the "Investors"), pursuant to which the Investors, on February 12, 2014, purchased from us (i) 6% Senior Secured Convertible Notes (the "6% Notes") for a cash purchase price of \$1,906,500, and (ii) Common Stock Purchase Warrants pursuant to which the Investors may purchase up to 414,457 shares of our common stock at an exercise price equal to approximately \$2.30 per share (the "6% Notes Placement"). In connection with this note placement, we paid fees and commissions of \$70,720 and issued 6,535 shares of common stock, with a fair value of \$23,395, to an accredited broker that assisted in this note placement. The 6% Notes have a three year term and are convertible into common

stock at any time at the lesser of i) \$2.30 per share and ii) seventy percent of the average of the three lowest daily volume-weighted average prices ("VWAPs") occurring during the 20 consecutive trading days immediately preceding the applicable conversion date. The associated warrants are exercisable at \$2.30 per share. The warrants may be exercised on a cashless basis under which a portion of the shares subject to exercise are not issued in payment of the purchase price, based on the then fair market value of the shares. Additionally, as an incentive, the life of existing warrants held by participants in the 6% Notes Placement were extended to ten years from the date of each respective warrant's original issuance.

The 6% Notes accrue 6% interest per annum, and do not require cash interest payments, except that accrued and unconverted interest is due on the maturity date and on each conversion date with respect to the principal amount being converted, provided that such interest may be added to and included with the principal amount being converted. If there is an uncured event of default (as defined in the 6% Notes), the holder of each 6% Note may declare the entire principal and accrued interest amount immediately due and payable. Default interest will accrue after an event of default at an annual rate of 12%. If there is an acceleration, a mandatory default amount equal to 120% of the unpaid 6% Note principal plus accrued interest may be payable.

On February 12, 2014, we also entered into a Security Agreement and an Intellectual Property Security Agreement with the Investors and AtheroNova Operations, pursuant to which all of our obligations under the 6% Notes are secured by security interests in all of our assets and the assets of AtheroNova Operations, including intellectual property on a pari passu basis with the 2.5% Senior Secured Convertible Notes outstanding. Upon an event of default under the 6% Notes or such agreements, the 6% Note holders may be entitled to foreclose on any of such assets or exercise other rights available to a secured creditor under California and Delaware law. In addition, under a Subsidiary Guarantee, AtheroNova Operations guaranteed all of our obligations under the 6% Notes.

On October 14, 2014, the Company and the holders of a majority of the outstanding principal amount under the 6% Notes agreed to amend the 6% Notes to provide the Company with the option to trigger conversion of all amounts due under the 6% Notes into common stock upon the consummation of a private placement or registered offering generating gross proceeds to the Company of at least \$4,000,000.

The 6% Notes and associated warrants include an anti-dilution provision that allows for the automatic reset of the conversion or exercise price upon any future sale of common stock instruments at or below the current conversion or exercise price, as applicable. We considered the current Financial Accounting Standards Board (FASB) guidance of "Determining Whether an Instrument Indexed to an Entity's Own Stock" which indicates that any adjustment to the fixed amount (either conversion price or number of shares) of the instrument regardless of the probability or whether or not in the issuers' control, means the instrument is not indexed to the issuers own stock. Accordingly, we determined that the conversion price of the 6% Notes and the strike price of the associated warrants contain conversion or exercise prices, as applicable, that may fluctuate based on the occurrence of future offerings or events, and, as such, are not fixed amounts. As a result, we determined that the conversion features of the 6% Notes and the associated warrants are not considered indexed to our own stock and characterized the fair value of the 6% Notes and the associated warrants as derivative liabilities upon issuance.

As of June 30, 2014, Europa held \$300,000 in aggregate principal amount of the 6% Notes. Europa is an entity controlled by Knoll Capital Management of which Mr. Knoll, one of our directors, is the managing director.

**8% Secured Convertible Notes Payable** 

In September 2014, we entered into Securities Purchase Agreements with approximately 7 accredited investors (the "Investors"), pursuant to which the Investors, on September 12, 2014, purchased from us (i) \$500,000 aggregate principal amount of our 8% Senior Secured Convertible Notes (the "8% Notes") for a cash purchase price of \$500,000, and (ii) Common Stock Purchase Warrants pursuant to which the Investors may purchase up to 225,258 shares of our common stock at an exercise price equal to approximately \$2.00 per share (the "8% Notes Placement"). The 8% Notes have a one year term and are convertible into common stock at any time at \$1.11 per share. The associated warrants are exercisable at \$2.00 per share. The warrants may be exercised on a cashless basis under which a portion of the shares subject to exercise are not issued in payment of the purchase price, based on the then fair market value of the shares.

The 8% Notes accrue 8% interest per annum, and do not require cash interest payments, except that accrued and unconverted interest is due on the maturity date and on each conversion date with respect to the principal amount being converted, provided that such interest may be added to and included with the principal amount being converted. If there is an uncured event of default (as defined in the 8% Notes), the holder of each 8% Note may declare the entire principal and accrued interest amount immediately due and payable. Default interest will accrue after an event of default at an annual rate of 12%. If there is an acceleration, a mandatory default amount equal to 120% of the unpaid 8% Note principal plus accrued interest may be payable.

On September 12, 2014, we also entered into a Security Agreement and an Intellectual Property Security Agreement with the Investors and AtheroNova Operations, pursuant to which all of our obligations under the 8% Notes are secured by security interests in all of our assets and the assets of AtheroNova Operations, including intellectual property on a pari passu basis with the 2.5% and 6% Senior Secured Convertible Notes outstanding. Upon an event of default under the 8% Notes or such agreements, the 8% Note holders may be entitled to foreclose on any of such assets or exercise other rights available to a secured creditor under California and Delaware law. In addition, under a Subsidiary Guarantee, AtheroNova Operations guaranteed all of our obligations under the 8% Notes.

The 8% Notes and associated warrants include a beneficial conversion feature whereby the conversion price was below the fair market price of the underlying common stock at the time of issuance. We considered the current Financial Accounting Standards Board (FASB) guidance of "Determining Whether an Instrument Indexed to an Entity's Own Stock" which indicates that any adjustment to the fixed amount (either conversion price or number of shares) of the instrument regardless of the probability or whether or not in the issuers' control, means the instrument is not indexed to the issuers own stock. Accordingly, we determined that the conversion price of the 8% Notes and the strike price of the associated warrants contain conversion or exercise prices, as applicable, that are the fair value of the common stock of the underlying notes and warrants and will record a note and warrant valuation discount, which will be amortized over the life of the notes.

At issuance, Europa held \$100,000 in aggregate principal amount of the 8% Notes. Europa is an entity controlled by Knoll Capital Management of which Mr. Knoll, one of our directors, is the managing director.

#### **Commitments**

#### **Development Commitments**

In October 2011, we entered into two definitive agreements with OOO CardioNova, a wholly-owned subsidiary of Maxwell Biotech Group, a Russian biotech fund, covering our AHRO-001 compound. The agreements cover a territory represented by the Russian Federation, the Ukraine and various countries in central Asia (the "Territory").

Under the licensing agreement OOO CardioNova ("CardioNova") became an equity investor in our company in exchange for the funding of Phase 1 and 2 human clinical trials conducted by a Clinical Research Organization ("CRO") located in Russia. A Joint Steering Committee was subsequently established between both entities and determined the final clinical protocols and approved a research budget of \$3.8 million.

Pursuant to the agreement, common stock equal to specified percentages of the approved research budget of \$3.8 million would be issued to CardioNova upon achievement of four milestones in the research plan. Through December 31, 2013, we had issued a total of 199,730 of non-refundable shares of common stock representing the first two milestones and 30% of the total budget with a fair value of \$1,198,297, or \$6.00 per share. Additionally, we determined that the achievement of the third milestone was probable and the percentage of achievement at 80% complete, therefore accrued additional research and development expense – related party of \$1,170,712 as of December 31, 2013. There had been no work performed with respect to the fourth and last milestone through that date.

In the period ending June 30, 2014, the third milestone was achieved and, in accordance with the licensing agreement, we issued a total of 422,105 of non-refundable shares of common stock with a fair value of \$2,152,735. In December 31, 2013, we had recorded \$1,170,712 of these costs. Accordingly, during the three and six month periods ending June 30, 2014, \$0 and \$982,024 was recorded to research and development expense - related party, respectively. Additionally, as of June 30, 2014, we determined that the achievement of the final milestone was probable and the percentage of achievement at 15% complete. Accordingly, we accrued additional research and development expense-related party in the accompanying statement of operations of \$155,074 and \$155,074 for the three and six months ended June 30, 2014, respectively.

If CardioNova successfully develops and commercializes AHRO-001 in the Territory, we will be entitled to receive a quarterly royalty, based on net sales during the period using an escalating scale. The royalty agreement shall remain in force for the period in which intellectual property rights for AHRO-001 are in full force and effect in the Territory.

Under the Securities Purchase Agreement, CardioNova purchased a total of 27,526 shares of our common stock for a cash purchase price of \$9.70 per share, which took place in two installments. The first installment, which took place on December 22, 2011, was for the issuance of 15,464 shares upon receipt of \$150,000 as specified in the Licensing Agreement. The second installment of 12,062 shares took place on June 14, 2013 upon delivery of final clinical product to be used in Phase 1 clinical trials.

#### **Research and Development Projects**

We have a research agreement signed in September 2012, amended in April 2013 and again in September 2013, with a major university in Southern California to conduct contract research in bile acid compounds, the use of which may be covered under our issued patents and pending patent applications. This agreement calls for payment of all research costs relating to the study of dosage and efficacy of bile salts on the atherosclerotic plaque in a non-human model. The total potential cost of the amended project is \$236,323, to be paid in four installments over the estimated one year length of the study. As of December 31, 2013, \$236,323 has been expensed, of which \$120,327 has been recorded as part of Research and development costs on the statement of operations for the year ended December 31, 2013. The final report on this research project was received in early 2014.

The Company has multiple testing agreements signed in September 2012, August 2013 and February 2014 for testing of the oral toxicity of AHRO-001 in non-human models. Each agreement can be terminated anytime and there are no commitments or guarantees other than to reimburse costs incurred prior to termination.

The study initiated in September 2012, with a cost of approximately \$507,000, has completed active phase of testing and is in the data write-up stage of the project. The process is ongoing and to date, \$488,530 has been expensed, of which \$389,785 has been recorded as part of research and Development costs on the statement of operations for the year ended December 31, 2013.

The studies authorized in August 2013, with a cost of approximately \$224,600, have both completed the active phase of testing and are in the initial data analysis stage of the projects. The process is ongoing and to date, \$175,950 has been expensed, all of which has been recorded as part of research and development costs on the statement of operations for the period ended December 31, 2013.

We have additional studies authorized in February and April 2014 for toxicology and other metabolic evaluations with expected cost of approximately \$738,000, that are in various stages of planning or active execution of their protocols. The process is ongoing and to date, \$349,785 and \$521,965 has been expensed to Research and development costs on the accompanying statement of operations for the three and six month periods ended June 30, 2014, respectively. The remaining \$216,035 will be recorded in future periods once service has been rendered.

We also have a research agreement finalized in March 2014 with an Australian hospital/research institution for a metabolic study of AHRO-001 in a standard animal model used in evaluation of plaque regression. The study plan has been completed and a pilot study to measure tolerability will be undertaken in the 3<sup>rd</sup> quarter of 2014, with the main study to commence after successful completion of the pilot study. The total cost of approximately \$187,400 (based on current currency exchange rates) will be recognized as Research and development costs in the company's statement of operations in future periods once services have been rendered.

### Formulation Development Agreement

We have a development agreement entered into in February 2014 with a Pennsylvania-based Clinical Research Organization ("CRO") specializing in formulation and manufacturing of clinical research grade pharmaceutical products. The agreement calls for the CRO to use our API to manufacture clinical trial pharmaceutical products for use in the next clinical trial conducted in Russia. The total expected cost of the project is \$220,650, as amended, to be paid in progress installments over the length of the manufacturing and packaging process. The process is ongoing and to date, \$67,715 and \$160,309 has been recorded as part of Research and development costs on the accompanying statement of operations for the three and six month periods ending June 30, 2014. The remaining \$60,341 will be

recorded in future periods once service has been rendered.

#### Bioanalytical Analysis Agreements

We have analysis agreements for our next clinical trial in Russia entered into in May 2014, as amended, with several analytical laboratories to perform specialized serum analyses for biomarkers of certain gene expressions activated in previous non-human experiments when exposed to our Active Pharmaceutical Ingredient. The expected cost of these agreements is approximately \$339,400 to be paid upon progress completion points as the analyses are performed. The process is ongoing and to date, \$96,047 has been recorded as part of Research and development costs on the accompanying statement of operations for both the three and six month periods ended June 30, 2014. The remaining \$243,353 will be recorded in future periods once services have been rendered.

### **Summary of Contractual Commitments**

#### **Employment Agreements**

On April 28, 2014, the Compensation Committee of our Board of Directors approved and on May 7, 2014 entered into one year contracts for the Company's Chief Executive and Chief Financial Officers.

### **Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements.

## **Critical Accounting Policies**

In December 2001, the SEC requested that all registrants discuss their most "critical accounting policies" in management's discussion and analysis of financial condition and results of operations. The SEC indicated that a "critical accounting policy" is one which is both important to the portrayal of the Company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

## 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 certain reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgment, including those related to revenue recognition, accrued expenses, financing operations and contingencies and litigation. Management bases its estimates and judgment on historical experience and on 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 value of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates under different assumptions or conditions. The following represents a summary of our critical accounting policies.

## Research and Development Expenses

Research and development costs are expensed as incurred and include costs of consultants and contract research facilities who conduct research and development on our behalf and on behalf of AtheroNova Operations. We have contracted with third parties to facilitate, coordinate and perform agreed upon research and development of our technology. We have expensed all costs associated with the conduct of the laboratory research as well as the costs associated with peripheral clinical researchers as period costs.

### Accounting for Share Based Research and Development Costs

Under its Research and Development (R&D) agreements, the Company is obligated to issue shares of common stock if milestones are met by the R&D vendor. It is the Company's policy to recognize expense for these shares when it is estimated that there is a high probability of meeting the milestone. The Company accrues the share based expense based upon the estimated percentage of completion of the milestone. The shares are valued at the market price at the end of the period and revalued at each period until issued. At June 30, 2014, the Company had recorded the R&D expense of \$155,074 associated with the issuance of shares of common stock for the fourth tranche milestone under the agreement and was reflected as Common stock issuable in the accompanying balance sheet. At December 31, 2013, approximately 300,000 shares of common stock were to be issued pursuant to the agreement with a fair value of \$1,170,712. The liability was recorded as part of Research and Development costs - payable in stock in the accompanying balance sheet below long term liabilities as it is only payable in shares of common stock.

### **Stock-Based Compensation**

We periodically issue stock options and warrants to employees and non-employees in non-capital raising transactions for services and for financing costs. We account for stock option and warrant grants issued and vesting to employees based on current accounting guidance, whereby the award is measured at its fair value at the date of grant and is amortized ratably over the vesting period. We account for stock option and warrant grants issued and vesting to non-employees based on current accounting guidance, whereby the fair value of the stock compensation is based on the measurement date as determined at either (a) the date at which a performance commitment is reached, or (b) at the date at which the necessary performance to earn the equity instrument is complete.

We estimate the fair value of stock options using the Black-Scholes-Merton option-pricing model, which was developed for use in estimating the fair value of options that have no vesting restrictions and are fully transferable. This model requires the input of subjective assumptions, including the expected price volatility of the underlying stock and the expected life of stock options. Projected data related to the expected volatility of stock options is based on the historical volatility of the trading prices of our common stock and the expected life of stock options is based upon the average term and vesting schedules of the options. Changes in these subjective assumptions can materially affect the fair value of the estimate, and therefore the existing valuation models do not provide a precise measure of the fair value of our employee stock options.

#### **Derivative Financial Instruments**

We evaluate our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative

instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. For stock-based derivative financial instruments, we use both the Black-Scholes-Merton and Binomial option pricing models to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date.

## Recently Issued Accounting Standards

On August 27, 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which provides guidance on determining when and how to disclose going-concern uncertainties in the financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued. An entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going concern. The ASU applies to all entities and is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted.

In June 2014, the FASB has issued Accounting Standards Update (ASU) No. 2014-10, *Development Stage Entities* (*Topic 915*): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. The amendments in this ASU remove all incremental financial reporting requirements from U.S. GAAP for development stage entities, including the removal of Topic 915, *Development Stage Entities*, from the FASB Accounting Standards Codification<sup>TM</sup>. In addition, the ASU: (a) adds an example disclosure in Topic 275, Risks and Uncertainties, to illustrate one way that an entity that has not begun planned principal operations could provide information about the risks and uncertainties related to the company's current activities; and (b) removes an exception provided to development stage entities in Topic 810, Consolidation, for determining whether an entity is a variable interest entity. For public business entities, the presentation and disclosure requirements in Topic 915 will no longer be required for the first annual period beginning after December 15, 2014. The revised consolidation standards are effective one year later, in annual periods beginning after December 15, 2015. Early adoption is permitted and the Company adopted the provisions of this standard as of June 30, 2014.

In April 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-08, "Presentation of Financial Statements (Topic 205) and Property, Plant and Equipment (Topic 360)." ASU 2014-08 amends the requirements for reporting discontinued operations and requires additional disclosures about discontinued operations. Under the new guidance, only disposals representing a strategic shift in operations or that have a major effect on our operations and financial results should be presented as discontinued operations. This new accounting guidance is effective for annual periods beginning after December 15, 2014. We are currently evaluating the impact of adopting ASU 2014-08 on our results of operations or financial condition.

Other accounting pronouncements did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statements.

#### **BUSINESS**

### **Corporate History**

We are a Delaware corporation, with our principal offices located at 2301 Dupont Drive, Suite 525, Irvine, California. We were incorporated in Delaware in 1997. Our telephone number is (949) 476-1100 and our website address is www.atheronova.com.

On March 26, 2010, we entered into an Agreement and Plan of Merger with Z&Z Merger Corporation, a Delaware corporation and our wholly-owned subsidiary ("MergerCo"), and AtheroNova Operations, Inc., a Delaware corporation then known as Z&Z Medical Holdings, Inc. ("Z&Z Delaware"). At the closing of the merger on May 13, 2010, (i) MergerCo was merged with and into Z&Z Delaware (the "Merger"), whose name was concurrently changed to AtheroNova Operations, Inc. ("AtheroNova Operations"); (ii) Z&Z Delaware, as AtheroNova Operations, become our wholly-owned subsidiary; (iii) all of AtheroNova Operations' shares, warrants and options outstanding prior to the Merger were exchanged (or assumed, in the case of warrants and options) for comparable securities of our company; and (iv) approximately 98% of our fully-diluted shares (excluding the shares issuable in the Capital Raise Transaction described below) were owned by AtheroNova Operations' former stockholders, warrant holders and option holders.

As a result of the Merger we are solely engaged in AtheroNova Operations' business, AtheroNova Operations' officers became our officers and three of AtheroNova Operations' directors became members of our seven-member board of directors. Unless the context otherwise requires, all references to "we," "our," and the "Company" refer to AtheroNova Inc. and its wholly-owned subsidiary AtheroNova Operations, Inc.

### **Business Overview**

We have developed intellectual property ("IP"), covered by our pending patent applications, which uses certain pharmacological compounds for the treatment of atherosclerosis, which is the primary cause of various cardiovascular diseases. Atherosclerosis occurs when cholesterol or fats are deposited on arterial walls and form as plaques. Such deposits are theorized as occurring due to weaknesses or imperfections in the arterial walls. Another theory is that these plaques develop at the site of arterial inflammations. Once the plaque has lodged on or in the arterial wall, additional deposits can build up due to the existence of areas of resistance in the path of blood flow from the walls of arteries. Such accumulations are known as atheromas. These atheromas can form a protective barrier known as a "fibrous cap." These fibrous caps are thought to be the result of inflammation of the arterial wall from the formation of the deposit. The fibrous cap is a porous fiber which is an attempt to stabilize the deposit and prevent it from suddenly breaking loose. In some instances, the plaque still can rupture and greatly restrict or block altogether blood flow, resulting in such cardiac events as heart attack or stroke. Even if the plaque remains stable, it can lead to reduction of

the space within the arteries through which blood can flow and cause such diseases as Peripheral Artery Disease, Erectile Dysfunction, Kidney failure, Macular Degeneration and Hypertension. There is also some evidence that Cognitive Impairment is also a manifestation of reduced blood supply to the brain.

Cholesterol deposits or "plaque" accumulate over the lifetime of an individual based on factors such as diet, heredity and other blood chemistry factors. The building block of the plaque accumulations is the amount of Low-density lipoprotein cholesterol, or "LDL," contained in the blood circulating is a person's body. The accepted medical opinion is that a higher LDL reading in a person's blood chemistry can lead to plaque accumulations in the arteries. High-density-lipoprotein cholesterol, or "HDL," is considered the "good" cholesterol and can assist in transporting the LDL out of the bloodstream to the digestive system and elimination from the body. Many different factors play into how much of each of these cholesterols make their way into the bloodstream and lead to possible plaque deposits. The general accepted thinking in the medical community is that the plaque allowed to form and accumulate in the arteries will remain in the arteries indefinitely. Diet and exercise are the two most common factors cited by medical professionals in controlling the balance of HDL and LDL in hopes of minimizing the amount of plaque accumulation during a person's lifetime.

This accumulated plaque has not been addressed by any current medical and drug technology, although many approaches and concepts have been tried. The most effective measure to date in the fight to prevent atherosclerosis has been the development of statin drugs. Statins work on the body's ability to simultaneously decrease the LDL and increase the HDL in a patient's blood. One of the drawbacks of statin drugs has been the tolerability of the drugs, both in the dosage prescribed as well as the long term exposure. Some liver functions must be tested on a periodic basis to insure that a patient's liver is functioning normally.

Until several years ago the general belief was that a patient who exhibited the genetic, dietetic or disease characteristics prone to accumulations of plaque should be put on a course of lifestyle and diet changes in hopes of controlling blood cholesterol levels. If such changes did not lower cholesterol levels, then one of the statin drugs in the varying acceptable dose levels would be introduced with an expectation that once a patient was started on a statin drug, they would be a patient for life. Such prescription characteristics have made statin drugs the most successful drug family in the history of medicine.

Currently we have developed and contracted to have manufactured the Active Pharmaceutical Ingredient ("API"), AHRO-001, needed to conduct toxicology studies and Phase 1 and 2 human clinical trials, Through an agreement completed in 2011, we have partnered with a Russian venture fund for the development of AHRO-001 for their Territory including utilizing contract research organizations to conduct Phase 1 and 2 clinical trials in Russia. This partnership will help demonstrate the efficacy our API as first demonstrated in our pre-clinical studies conducted in 2009, 2010 and 2011. As the active drug in our research and clinical work, our API uses naturally occurring bile acids normally found in a non-human digestive tract to activate genetic signaling mechanisms to act on the portions of the soft, vulnerable plaque that are accessible through the fibrous cap. This process breaks down plaque deposits into molecules small enough to pass safely through the fibrous cap without causing harm to the fibrous cap itself. The body then processes the cholesterol through the liver in the normal process of cholesterol metabolism. Additionally, our API also demonstrated an effect of lipid panel improvements of the test subjects during the active treatment phase of our pre-clinical studies. The research conducted in pre-clinical studies demonstrated the ability of bile salts to dissolve, or regress, a statistically significant portion of the atheromas induced in test subjects in a safe and effective manner in non-human subjects as well as improving lipid panel scores. Finally, our compound reduced the amount of intestinal cholesterol absorption in a similar fashion to ezetimibe. At the conclusion of these non-human studies, we determined that the results showed a superior regression model effective enough to take the next step in the

development of the API for introduction into human clinical trials. A pre-Investigational New Drug meeting with the United States Food and Drug Administration ("FDA") in October 2011, established the necessary protocols and study designs for our Phase 1 and 2 clinical trials. If our premise is confirmed, then this would introduce the first clinically proven method to regress soft, vulnerable plaque. Such treatment, when tested, reviewed and approved by the varying government regulatory agencies worldwide, would offer the first treatment to the millions of patients currently undergoing treatment for atherosclerosis risk, as well as promise to those who have genetic, dietetic or disease predisposition to the potentially disastrous "first event" where the patient's only experience with an atherosclerotic event is a fatal heart attack or stroke. In 2013, we commenced the first-in-human Phase 1 clinical trial with our Russian partner using a randomized, double-blind, placebo controlled protocol with AHRO-001which enrolled and treated a total of 54 subjects. Enrollment, dosing and follow-up visits were concluded in 2013 and in 2014 our Russian partner submitted, received approval for and, in July, commenced a Phase 1b study on 48 subjects for a treatment period of three months. This study is expected to conclude the active treatment phase in Q4 2014. We continue to develop and execute a portion of our clinical trial portfolio in Russia to enable our Russian partner's commercialization efforts in their Territory.

An important priority is to secure strategic and financial resources to potentially maximize the value of our IP surrounding the use of bile salts in medical applications. The first step in this strategy was the successful consummation of the research agreement with OOO CardioNova ("CardioNova"), a wholly-owned subsidiary of the OOO Maxwell Biotech Group ("Maxwell"). This agreement is a critical first step in the development and potential commercialization of our IP. We would prefer to accomplish additional steps of our objectives through additional strategic alliances and selective licensing rights. Although we are actively engaged in discussions with potential strategic and/or financial partners, there can be no assurance that any strategic alliance or other financing transaction will be successfully concluded. Until such time as we secure sufficient strategic and financial resources to support the continuing development of our IP, and to support our operations, we will continue to conserve our resources, predominantly by pacing expenditures and research programs in our plan to develop a full line of IP surrounding the use of bile salts.

## **Business Strategy**

Our goal is to develop a complete line of products based on our IP involving bile salts to address a number of medical conditions with the goal of introducing naturally occurring compounds to improve the medical conditions of those suffering from the effects of atherosclerosis caused by diabetes, heredity, poor diet and other plaque inducing states. Mortality and morbidity from the effects of atherosclerosis total in the billions of dollars each year for the United States healthcare system alone, with many times that for the worldwide market.

Our primary product goal is to develop AHRO-001 to address the disease of atherosclerosis. We have contracted for the manufacture of a significant quantity of our API necessary for use in clinical trials plus any requirements needed for toxicology testing. We have formulated and refined the oral administration tablet necessary to deliver our API to the ideal site in the digestive tract and continue to work on improvements and refinements to the formula. We have manufactured drug product tablets to be used in our Phase 1b human clinical trials by our Russian development partner. The shipment of the tablets to be used in these additional clinical trials conducted there was in June 2014 with the commencement of enrollment of patients in July 2014, which was approved by Russian regulators in May 2014. The active treatment phase is planned to be for a period of twelve weeks and data should be available 6-8 months after commencement. A successful completion of that trial will allow CardioNova to move forward with a clinical study intended to enable the possible drug registration application for commercial sale in its distribution territory.

Concurrently, we have a toxicology program in progress at a Good Laboratory Practices ("GLP") registered facility to compile the data necessary for submission of an Investigational New Drug ("IND") application with the United Stated Food and Drug Administration ("FDA"). By submitting the IND application, expected to be during 2015, we will be able to initiate clinical trials in the United States and other counties that follow FDA guidelines. We expect to conduct these trials concurrent with the development program being conducted by CardioNova with the intent of using data generated in multiple trials to support and expand AHRO-001.

Additionally, we continue to develop additional bile acid compounds for potential commercialization based on our current patent filings in the United States as well as foreign jurisdictions.

### **Our Industry**

We compete against well-capitalized pharmacological companies as well as smaller companies and universities. The market for our products is highly competitive as well as highly regulated. The pharmacological sector is evolving and growing rapidly, and companies are continually introducing new products and services. Many companies are exploring competing and complementary technologies. Pharmaceutical development is a cost intensive project with millions of dollars necessary to successfully develop, test and market compounds successfully. We expect to seek multiple financial or strategic financing opportunities in our development of our IP.

### **Business Operations**

Research and Development

Our research and development activities are initially focused on the atherosclerosis regression potential of bile salts. We continually evaluate our research and development priorities in light of a number of factors, including our cash flow requirements and financial liquidity, the availability of third party funding, advances in technology, the results of ongoing development projects and the potential for development partnerships and co-development agreements. In connection with these evaluations, we modify and adapt our research and development plans from time to time and expect to do so in the future.

We are actively assessing various strategic and financial alternatives to secure necessary capital to advance our IP to maximize stockholder value, although we would prefer to accomplish our objectives through strategic alliances and licensing agreements that would provide financial support (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses), development

capabilities, and ultimately commercial expertise to maximize the potential of our bile salt IP. We are reviewing various financial alternatives that would provide infusions of capital and other resources to advance our current API development programs. Although we are considering several potential opportunities, there can be no assurance that any strategic alliance or other financing alternatives will be successfully concluded. Until such time as we secure sufficient strategic and financial resources to support the continuing development of our IP technology and support our operations, we will continue to conserve our resources, predominantly by curtailing and pacing investments in our development programs.

If we are able to secure the necessary capital, we also plan to invest opportunistically in bile salt IP addressing other health indications complimentary to our primary market of atherosclerosis regression, which we believe represent potentially significant market opportunities. We plan to initially develop these programs through a proof-of-concept phase and, if successful, thereafter determine whether to seek strategic alliances or collaboration arrangements or utilize other financial alternatives to fund their further development and/or worldwide commercialization, if approved. There can be no assurance, however, that we will succeed in demonstrating proof of concept or entering into any such alliance.

To support our research and development activities, we have:

a medical advisory staff with expertise in cardiology and lipid sciences as well as consultants who are leading researchers in these fields;

expertise in the design and implementation of protocols and guidelines for experiments and studies to support human drug development. We conduct certain development-related experiments and bench studies in-house and also engage professional research laboratories as well as academic and education centers to conduct animal and human studies and experiments requiring specialized equipment and expertise;

regulatory consultants with expertise in FDA regulatory matters. We also consult extensively with independent FDA and international regulatory experts; and

engineering expertise that supports development of novel molecules, conjugates and analogs of the existing compounds to strengthen our intellectual property position through work with third-party collaborators to advance the development of these compounds.

Research and development costs are charged to operations as incurred. During the six months ended June 30, 2014, and for the years ended December 31, 2013 and 2012, our research and development expenses were \$2,538,143, \$4,399,294, and \$986,261, respectively.

General and Administrative

We intend to continue investing in general and administrative resources primarily to support our intellectual property portfolios (including building and enforcing our patent and trademark positions), our business development initiatives, financial systems and controls, legal requirements, and general management capabilities.

Strategic Alliances and Collaboration Arrangements

## OOO CardioNova Agreement

In October 2011, we entered into two definitive agreements with OOO CardioNova, a wholly-owned subsidiary of Maxwell Biotech Group, a Russian biotech fund, covering our AHRO-001 compound. The agreements cover a territory represented by the Russian Federation, the Ukraine and various countries in central Asia (the "Territory").

Under the licensing agreement OOO CardioNova ("CardioNova") became an equity investor in our company in exchange for the funding of Phase 1 and 2 human clinical trials conducted by a Clinical Research Organization ("CRO") located in Russia. A Joint Steering Committee was subsequently established between both entities and determined the final clinical protocols and approved a research budget of \$3.8 million.

Pursuant to the agreement, common stock equal to specified percentages of the approved research budget of \$3.8 million would be issued to CardioNova upon achievement of four milestones in the research plan. Through December 31, 2013, we had issued a total of 199,730 of non-refundable shares of common stock representing the first two milestones and 30% of the total budget with a fair value of \$1,198,297, or \$6.00 per share. Additionally, we determined that the achievement of the third milestone was probable and the percentage of achievement at 80% complete, therefore accrued additional research and development expense – related party of \$1,170,712 as of December 31, 2013. There had been no work performed with respect to the fourth and last milestone through that date.

In the period ending June 30, 2014, the third milestone was achieved and, in accordance with the licensing agreement, we issued a total of 422,105 of non-refundable shares of common stock with a fair value of \$2,152,735. In December 31, 2013, we had recorded \$1,170,712 of these costs. Accordingly, during the three and six month periods ending June 30, 2014, \$0 and \$982,024 was recorded to research and development expense - related party, respectively. Additionally, as of June 30, 2014, we determined that the achievement of the final milestone was probable and the percentage of achievement at 15% complete. Accordingly, we accrued additional research and development expense-related party in the accompanying statement of operations of \$155,074 and \$155,074 for the three and six months ended June 30, 2014, respectively.

If CardioNova successfully develops and commercializes AHRO-001 in the Territory, we will be entitled to receive a quarterly royalty, based on net sales during the period using an escalating scale. The royalty agreement shall remain in force for the period in which intellectual property rights for AHRO-001 are in full force and effect in the Territory. As of December 31, 2013, no royalty has been recorded as AHRO-001 has not been successfully developed and commercialized.

Under the Securities Purchase Agreement, CardioNova purchased 27,526 shares of our common stock for a cash purchase price of \$9.07 per share, which took place in two installments. The first installment, which took place on December 22, 2011, was for the issuance of 15,464 shares upon receipt of \$150,000 as specified in the Licensing Agreement. The 2<sup>nd</sup> installment of 12,062 shares took place on June 14, 2013 upon delivery of final clinical product to be used in Phase 1 clinical trials for proceeds of \$117,000.

Potential Alliances and Collaboration Arrangements

We continue to seek strategic alliances and other collaborative arrangements for the development and/or commercialization of our bile salt IP product candidates that would provide financial support (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses), development capabilities, and ultimately commercial expertise to advance our bile salt technology. We also are reviewing various financial alternatives that would provide infusions of capital and other resources needed to advance our bile salt development programs. Although we are considering several potential opportunities, there can be no assurance that any strategic alliance or other financing alternatives will be successfully concluded.

## Licensing, Patents and Other Proprietary Rights and Regulatory Designations

We continue to invest in maintaining and enforcing our potential competitive position through a number of means: (i) by protecting our exclusive rights in our bile salt intellectual property through patents and patent applications, and (ii) by seeking regulatory exclusivities, including potential new application for an existing drug and new drug product exclusivities.

Patents and Proprietary Rights

## Atherosclerosis and Bile Salt-Related Patents and Patent Rights

We have been active in seeking patent protection for our innovations relating to new applications for existing natural compounds previously used for other indications. Our patent activities have focused particularly on different uses of bile salts in regression of atherosclerotic plaque in various forms of administration, including transdermally, sublingually and intravenously. Such administrations bypass the normal physical sequestration of bile salts within the digestive tract. The function of bile salts in the normal process of digestion is to break down ingested fats to allow absorption by the intestines. The process of digestion returns the bile salts to the liver for re-processing or excretion in feces.

Between 2005 and 2014, we have filed with U.S., international, and foreign patent offices a total of 39 patent applications in 11 families relating to the use of bile salts in the regression of atherosclerotic plaque, reduction of subcutaneous fat, and treatment of obesity via pharmacological preparations in various forms of administration. Such filings have been received and acknowledged by the respective filing offices.

In July 2012 we were notified of the U.S. patent office's intent to grant our first patent in the use of bile acids for dissolution of arterial plaque. In November 2012 the U.S. patent office issued patent #No. 8,304,383 titled "Dissolution of Arterial Plaque", with an expiration date of October 18, 2028.

In November 2013, we were notified of the U.S. Patent Office's intent to grant a second patent in the use of bile acids for dissolution of arterial plaque. On April 15, 2014 the U.S. Patent Office issued patent No. 8,697,633 titled "Dissolution of Arterial Plaque", with an expiration date of March 13, 2026.

## Obesity Patents and Patent Rights

Included in the patent applications discussed above, are filings relating to the use of biocompatible emulsifiers in systemic circulation to treat obesity. Such filings elaborate on the scientific theories that exposure to bile salts could reduce fat accumulation in adipose tissue.

Regulatory Designations

### Food, Drug & Cosmetic Act 505(b)(2)New Drug Application

The FDA new drug application ("NDA") process has certain provisions under Section 505(b)(2) in which a compound previously approved as a reference listed drug ("RLD") can be considered for use for a new indication or condition. 505(b)(2) designation for a compound potentially allows sponsors to rely on certain data generated in the original RLD application. This designation can provide potential cost savings to companies seeking approvals for new indications or conditions by bypassing or demonstrating bioequivalence to the RLD and, if approved, market exclusivity for a limited period of time following approval. This exclusivity is separate and distinct from any patent(s) protection that may exist for the compound.

## Competition

We are engaged in highly competitive fields of pharmaceutical research and development. Competition from numerous existing companies and others entering the fields in which we operate is intense and expected to increase. We expect to compete with, among others, conventional pharmaceutical companies. Most of these companies have substantially greater research and development, manufacturing, marketing, financial, technological personnel and managerial resources than we do. Acquisitions of competing companies by large pharmaceutical or health care companies could further enhance such competitors' financial, marketing and other resources. Moreover, competitors that are able to complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before we do may enjoy a significant competitive advantage over us. There are also existing therapies that may compete with the products we are developing.

Currently, the FDA has approved bile salts as pharmaceutical therapy for dissolution of gallstones for certain patients with a profile either not suitable for surgical intervention or not willing to undergo surgery for gallstone disease. Such use has been well tolerated and has a significant history of safety and efficacy in treatment of gallstone disease. Surgical intervention, specifically laparoscopic cholecystectomy, has become the preferred method of treatment of gallstone disease for patients who are acceptable surgical candidates. High surgical risk patients as well as those who choose to forego surgery as a method of treating gallstones, have used Actigall© for the treatment of gallstone disease for more than 20 years. Actigall© is based on the ursodeoxycholic acid, one of a family of bile salts (deoxycholic acids), or "DCA", that occur naturally in various forms in the digestive tracts of mammals. Our use of hyodeoxycholic acid ("HDCA") in our preliminary research is a different iteration of the forms of DCA found in the mammalian digestive tract. We intend to use HDCA, one of its conjugates or derivatives, to validate the initial in vivo study and as the basis for our IND filing.

### **Government Regulation**

The development, manufacture, distribution, marketing and advertising of drug products are subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA, and by similar agencies in other countries. Any product that we develop must receive all relevant regulatory approvals or clearances before it may be marketed in a particular country. Gaining regulatory approval of a drug product candidate requires the expenditure of substantial resources over an extended period of time. As a result, larger companies with greater financial resources will likely have a competitive advantage over us.

Development Activities: To gain regulatory approval of our bile salt products, we must demonstrate, through experiments, preclinical studies and clinical trials that each of our drug product candidates meets the safety and efficacy standards established by the FDA and other international regulatory authorities. In addition, we and our suppliers and contract manufacturers must demonstrate that all development-related laboratory, clinical and manufacturing practices comply with regulations of the FDA, other international regulators and local regulators. Regulations establish standards for such things as drug substances and materials; drug manufacturing operations and facilities and analytical laboratories and medical development laboratories processes and environments; in each instance, in connection with research, development, testing, manufacture, quality control, labeling, storage, record keeping, approval, advertising and promotion, and distribution of product candidates, on a product-by-product basis.

<u>Pre-clinical Studies and Clinical Trials</u>: Development testing generally begins with laboratory testing and experiments, as well as research studies using animal models to obtain preliminary information on a product's efficacy and to identify any safety issues. The results of these studies are compiled along with other information in an IND application, which is filed with the FDA. After resolving any questions raised by the FDA, which may involve additional testing and animal studies, clinical trials may begin. Regulatory agencies in other countries generally require a Clinical Trial Application (CTA) to be submitted and approved before each trial can commence in each country.

Clinical trials normally are conducted in three sequential phases and may take a number of years to complete. Phase 1 consists of testing the drug product in a small number of humans, normally healthy volunteers, to determine preliminary safety and tolerable dose range. Phase 2 usually involves studies in a limited patient population to evaluate the effectiveness of the drug product in humans having the disease or medical condition for which the product is indicated, determine dosage tolerance and optimal dosage and identify possible common adverse effects and safety risks. Phase 3 consists of additional controlled testing at multiple clinical sites to establish clinical safety and effectiveness in an expanded patient population of geographically dispersed test sites to evaluate the overall benefit-risk relationship for administering the product and to provide an adequate basis for product labeling. Phase 4 clinical trials may be conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication.

The conduct of clinical trials is subject to stringent medical and regulatory requirements. The time and expense required to establish clinical sites, provide training and materials, establish communications channels and monitor a trial over a long period of time is substantial. The conduct of clinical trials at institutions located around the world is subject to foreign regulatory requirements governing human clinical trials, which vary widely from country to country. Delays or terminations of clinical trials could result from a number of factors, including stringent enrollment criteria, slow rate of enrollment, size of patient population, having to compete with other clinical trials for eligible patients, geographical considerations and others. Clinical trials are monitored by the regulatory agencies as well as medical advisory and standards boards, which could determine at any time to reevaluate, alter, suspend, or terminate a trial based upon accumulated data, including data concerning the occurrence of adverse health events during or related to the treatment of patients enrolled in the trial, and the regulator's or monitor's risk/benefit assessment with respect to patients enrolled in the trial. If they occur, such delays or suspensions could have a material impact on our bile salt development programs.

Regulatory Review: The results of preclinical and clinical trials are submitted to the FDA in an NDA, with comparable filings submitted to other international regulators. After the initial submission, the FDA has a period of time in which it must determine if the NDA is complete. After an NDA is submitted, although the statutory period provided for the FDA's review is less than one year, dealing with questions or concerns of the agency and, taking into account the statutory timelines governing such communications, may result in review periods that can take several years. If an NDA is accepted for filing, following the FDA's review, the FDA may grant marketing approval, request additional information, or deny the application if it determines that the application does not provide an adequate basis for approval. If the FDA grants approval, the approval may be conditioned upon the conduct of post-marketing clinical trials or other studies to confirm the product's safety and efficacy for its intended use. Until the FDA has issued its approval, no marketing activities can be conducted in the United States. Similar regulations apply in other countries.

Manufacturing Standards: The FDA and other international regulators establish standards and routinely inspect facilities and equipment, analytical and quality laboratories and processes used in the manufacturing and monitoring of products. Prior to granting approval of a drug product, the agency will conduct a pre-approval inspection of the manufacturing facilities, and the facilities of suppliers, to determine that the drug product is manufactured in accordance with current good manufacturing practices ("cGMP") regulations and product specifications. Following approval, the FDA will conduct periodic inspections. If, in connection with a facility inspection, the FDA determines that a manufacturer does not comply with cGMP regulations and product specifications, the FDA will issue an inspection report citing the potential violations and may seek a range of remedies, from administrative sanctions, including the suspension of our manufacturing operations, to seeking civil or criminal penalties.

International Approvals: If we succeed in gaining regulatory approval to market our products in the United States, we will still need to apply for approval with other international regulators. Regulatory requirements and approval processes are similar in approach to that of the United States. With certain exceptions, although the approval of the FDA carries considerable weight, international regulators are not bound by the findings of the FDA and there is a risk that foreign regulators will not accept a clinical trial design or may require additional data or other information not requested by the FDA. In Europe, there is a centralized procedure available under which the EMEA will conduct the application review and recommend marketing approval to the European Commission, or not, for the sale of drug products in the EU countries.

Post-approval Regulation: Following the grant of marketing approval, the FDA regulates the marketing and promotion of drug products. Promotional claims are generally limited to the information provided in the product package insert for each drug product, which is negotiated with the FDA during the NDA review process. In addition, the FDA enforces regulations designed to guard against conflicts of interest, misleading advertising and improper compensation of prescribing physicians. The FDA will review, among other things, direct-to-consumer advertising, prescriber-directed advertising and promotional materials, sales representative communications to healthcare professionals, promotional programming and promotional activities on the Internet. The FDA will also monitor scientific and educational activities. If the FDA determines that a company has promoted a product for an unapproved use ("off-label"), or engaged in other violations, it may issue a regulatory letter and may require corrective advertising or other corrective communications to healthcare professionals. Enforcement actions may also potentially include product seizures, injunctions and civil or criminal penalties. The consequences of such an action and the related

adverse publicity could have a material adverse effect on a developer's ability to market its drug and its business as a whole.

Following approval, the FDA and other international regulators will continue to monitor data to assess the safety and efficacy of an approved drug. A post-approval discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or a recall or withdrawal of the product from the market, as well as possible civil or criminal sanctions. Similar oversight is provided by international regulators.

None of our products under development has been approved for marketing in the United States or elsewhere. We may not be able to obtain regulatory approval for any of our products under development. If we do not obtain the requisite governmental approvals or if we fail to obtain approvals of the scope we request, we or our licensees or strategic alliance or marketing partners may be delayed or precluded entirely from marketing our products, or the commercial use of our products may be limited. Such events would have a material adverse effect on our business, financial condition and results of operations.

Certain of our product candidates may qualify for Fast Track designation. Fast Track designation means that the FDA has determined that the drug is intended to treat a serious or life-threatening condition and demonstrates the potential to address unmet medical needs. An important feature is that it provides for accelerated approval and the possibility of rolling submissions and emphasizes the critical nature of close, early communication between the FDA and sponsor to improve the efficiency of product development. The FDA generally will review an NDA for a drug granted Fast Track designation within six months instead of the typical one to three years.

#### **Employees**

As of August 31, 2014, we had 3 full-time employees all employed in the United States. No employees are subject to a collective bargaining agreement. These employees are subject to the confidentiality/non-disclosure provisions of their terms of employment.

## **Description of Property**

We maintain our principal executive offices at 2301 Dupont Drive, Suite 525, Irvine, California 92612-7525, which consists of 1,930 square feet of office space, for which we entered into a lease in June 2012. Under that lease, which will run for a period of 66 months, we are obligated to pay an annual rent of approximately \$42,846. The lease, which commenced on October 1, 2012, also contains an annual escalator clause of approximately 2.5% each April 1st throughout the term of the lease. We do not occupy any other facility or own any real property.

# **Legal Proceedings**

We are not aware of any pending or threatened legal actions to which we are a party or of which our property is the subject that would, if determined adversely to us, have a material adverse effect on our business and operations.

We have from time to time been involved in disputes and proceedings arising in the ordinary course of business. In addition, as a public company, we are also potentially susceptible to litigation, such as claims asserting violations of securities laws. Any such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. There can be no assurance that an adverse result in any future proceeding would not have a potentially material adverse effect on our business, results of operations or financial condition.

#### **MANAGEMENT**

The following table sets forth the names, ages and positions of our current executive officers and directors as of the date of this prospectus. All directors serve until the next annual meeting of stockholders or until their successors are elected and qualified. Officers are appointed by our board of directors and their terms of office are, except to the extent governed by an employment contract, at the discretion of our board of directors

Name	Age	Position Held
Thomas W. Gardner	60	Chairman, Chief Executive Officer and President
Mark Selawski	58	Chief Financial Officer and Secretary
Gary Freeman	46	Director and Chairman of the Audit Committee
Boris Ratiner, M.D.	46	Director and Chairman of the Medical Committee
Paul DiPerna	55	Director and Chairman of the Compensation Committee
Alexander Polinsky, Ph.D.	58	Director
Chaim Davis	36	Director
Johan (Thijs) Spoor	41	Director
Fred Knoll	58	Director

## **Biographical Information**

Thomas W. Gardner has served as our Chairman, Chief Executive Officer and President since May 2010, and as the Chief Executive Officer, the President and a director of AtheroNova Operations Inc. since its formation in December 2009. He held the same positions with Z&Z Medical Holdings, Inc., the predecessor in interest to AtheroNova Operations, Inc. from December 2006 until its merger into AtheroNova Operations Inc. in March 2010. Since September 2008, he also has been the President of PhyGen LLC, which designs, manufactures and sells instruments and implants for spine surgery. He is a senior medical industry executive with twenty-six years' experience in healthcare. He has extensive hands-on experience with successful start-up ventures, having helped found six healthcare companies, three of them that were publicly traded. He has served as President/CEO of Urogen, a San Diego-based Biotech company, President of Endocare, an Orange County-based urologic products company; President/CEO of AutoCath, an Orange County based vascular access company, and Executive Vice President of Medstone International, an Orange County medical products company. Mr. Gardner also serves as a member of the board of directors of each MMR Holdings, Inc., and Gardner Syndication Management. Mr. Gardner's twenty-six

years of experience in the healthcare industry and his substantial experience with successful start-up ventures and public companies enables him to offer valuable perspectives on the operation of our business.

Mark Selawski has served as our Chief Financial Officer and Secretary since May 2010. Mr. Selawski joined AtheroNova Operations Inc. and Z&Z Medical Holding, Inc. in January 2010 as Chief Financial Officer. He became the Secretary of AtheroNova Operations Inc. in March 2010. From June 2004 to December 2009 he served as Chief Financial Officer of United Polychem, Inc., a privately held petrochemical distribution company. From 1988 to 2004, he held several positions at Medstone International, during the last 9 years being the Vice President-Finance, Chief Financial Officer and Corporate Secretary. Medstone was a NASDAQ-listed capital medical device manufacturer dedicated to urology products. Before joining Medstone, he held various financial positions with a number of manufacturing and high-tech companies in Southern California. He received his Bachelor of Science in Accounting from Bowling Green State University in 1978.

Gary Freeman has served as one of our directors since July 2007 and currently serves as the Chairman of the Audit Committee of our board of directors. Mr. Freeman is currently a Partner in Beach, Freeman, Lim & Cleland LLP's Audit and Accounting services division. In conjunction with various consulting engagements, Mr. Freeman has assumed interim senior level management roles at numerous public and private companies during his career, including Co-President and Chief Financial Officer of Trestle Holdings, Inc., Chief Financial Officer of Silvergraph International and Chief Financial Officer of Novica United, Inc. Mr. Freeman served as a member of the board of directors of Blue Holdings, Inc. Trestle Holdings, Inc. and GVI Security Solutions. Mr. Freeman also serves as a member of the board of directors of Saleen Automotive Inc. (SLNN). Mr. Freeman's previous experience includes ten years with BDO Seidman, LLP, including two years as an Audit Partner. Mr. Freeman received his Bachelor's degree in Business from University of Notre Dame in 1990. Mr. Freeman brings to our board his extensive experience in accounting and financial matters for public companies.

Boris Ratiner, M.D. has served as one of our director since May 2010 and currently serves as the Chairman of the Medical Committee of our board of directors. Dr. Ratiner has been a director of AtheroNova Operations, Inc. since December 2009 and was a director of Z&Z Medical Holdings, Inc. from December 2006 until March 2010. He received an Advanced Bachelor's degree in Chemistry at Occidental College in Los Angeles. He then attended Medical School at LSU in New Orleans, followed by an Internal Medicine Residency and Rheumatology Fellowship at the University of California San Francisco (UCSF). He is Board Certified in Internal Medicine and Rheumatology and is in private practice in Tarzana, California. He is the medical director and founder of Rheumatology Therapeutics, where he leads a team of 23 staff members that care for patients with Arthritis and Autoimmune Diseases. He also serves on the board of the San Fernando Valley Branch of the Arthritis Foundation and is the Program Director for the Southern California Rheumatism Society. He is a founder and active board member of 4Medica, a successful medical informatics company that he co-founded in 1999. He is also a member of the board of directors of Therakine Ltd., a novel drug delivery company for biologics and small molecules. Dr. Ratiner is also a Clinical Instructor of Medicine at the David Geffen School of Medicine at the University of California Los Angeles (UCLA) and an instructor at the Northridge Family Medicine Teaching Program. He is an active clinical investigator and is actively involved in trials of new medications for gout, lupus, rheumatoid arthritis, osteoarthritis, psoriatic arthritis, ankylosing spondylitis and fibromyalgia. He is published in peer-reviewed papers, abstracts and textbooks. He is a frequent speaker at local hospitals to physicians on Rheumatology related diseases. He has authored several book chapters on osteoarthritis and research papers on Hepatitis C arthritis. Dr. Ratiner's extensive experience in various aspects of medical practice and research provides valuable insights with respect to our research and development activities.

Paul DiPerna has served as a member of our board of directors since November 2010 and currently serves as the Chairman of the Compensation Committee of our board of directors. Since March, 2011, Mr. DiPerna has been the Chief Executive Officer of Concert Innovators, a private company, where he is acting as a consultant. Mr. DiPerna is the Founder, and former Chief Technical Officer and sat as a Board Member of Tandem Diabetes Care prior to its recent public offering. Tandem has developed technology used in the care of diabetes. In this venture Mr. DiPerna has over 18 patents issued and in process. Prior to forming Tandem, Mr. DiPerna worked at Baxter Healthcare for 14 years where he held progressive management positions as a Technologist for cell separation systems, Program Manager of the largest and most complex system Baxter had undertaken, Director of Business Develop in the corporate technology group creating new technologies and integrating acquisitions into Baxter and as the General Manager of Digital Dental Sciences, a CT-based startup within the organization. Mr. DiPerna had 10 patents issued at Baxter. Mr. DiPerna was also a Senior VP of Technology and Operations at Hepahope, a startup developing liver dialysis systems for end stage liver failure patients prior to funding of Tandem. Mr. DiPerna received a Masters in

Engineering Management from Northeastern University in 1983 and a BS in Mechanical Engineering from the University of Massachusetts Lowell in 1980. He is a member of the American Diabetes Association and the American Society of Clinical Oncology. Mr. DiPerna brings to our board of directors his extensive management experience in the healthcare industry.

**Alexander Polinsky, Ph.D.** has served as a member of our board of directors since October 2010. Dr. Polinsky received his Ph.D. in Physical Chemistry from Moscow University, Russia, in 1982, followed by post-doctoral training at the Institute for Biochemistry at the Russian Academy of Science. He was on the faculty at Moscow University for 5 years studying the mechanisms of action of synthetic vaccines. After moving to the U.S. in 1988, he spent 2.5 years as a Visiting Scientist at UCSD developing new methods for computer-aided drug design. In 1991, Dr. Polinsky co-founded the Alanex Corporation and built the company from scratch around novel computational and combinatorial chemistry technologies; he served as Alanex's Chief Scientific Officer until it was acquired by Agouron in 1997. After the acquisition by Pfizer in 2000, Dr. Polinsky became Vice President, Head of Discovery Technologies, at the Pfizer La Jolla Labs. In 2001 he established Pfizer's global chemistry outsourcing network and between 2001 and 2006, managed a \$750 million investment in the creation of modern drug screening collection. In 2006, he moved into Pfizer Global Research Technology where he led the development of Pfizer External Research Network and Pharma Incubator concepts. In 2007, Dr. Polinsky established The Pfizer Incubator (TPI) and became its CEO, starting three biotechnology companies. He left Pfizer in 2008 to pursue his own entrepreneurial interests and in 2009 started a biotech company Tartis, Inc. developing oncology drugs, and joined Maxwell Biotech Venture Fund as its Managing Partner. In 2013, Dr. Polinsky's role in Maxwell Biotech Fund was reduced to a Venture Partner. Over the years, Dr. Polinsky invested and served on boards of several private biotech startups, including Tartis, Inc., Onco Tartis, Inc., Tartis-Aging., 4Medica, Inc. and Gowan Co. Dr. Polinsky brings to our board of directors his extensive experience in the pharmaceutical industry.

Chaim Davis has served as one of our directors since May 2010. He is currently the Managing Partner of Revach Fund L.P., an investment fund focused on life science industries. He served as a Healthcare Analyst at The Garnet Group from April 2001 through June 2004. Mr. Davis is also a member of the board of directors of Entera Bio, a private biotechnology company. He received his bachelor's degree from Columbia University. Mr. Davis' experience in various aspects of life science and healthcare industry investments provides valuable insights with respect to capitalizing our operations.

Johan (Thijs) M. Spoor was appointed as a member of our board of directors on January 3, 2012. Mr. Spoor has been serving as the Chairman and Chief Executive Officer, and is a director, of FluoroPharma Medical, Inc.(FPMI) since September 2010. He previously held the title of Chief Financial Officer for Sunstone BioSciences. Prior to joining Sunstone BioSciences, from December 2008 to February 2010, he worked as a consultant at Oliver Wyman focusing on helping pharmaceutical and medical device companies evaluate their global revenue potential given the complex interplay of regulatory approvals, the reimbursement environment, as well as the impact of physician preference within constantly evolving standards of care. He further specialized on the implications of healthcare reform on new product approval and health insurance reform. Mr. Spoor has also been an equity research analyst at J.P. Morgan and Credit Suisse covering the Biotechnology and Medical Device industries. He worked in the pharmaceutical industry spending 10 years with Amersham / GE Healthcare where he worked in seven countries in a variety of roles including setting up GMP facilities meeting ISO 9001 standards, accountability for the entire nuclear cardiology portfolio and most recently as the Director of New Product Opportunities leading the PET strategic plan. Mr. Spoor received a Nuclear Pharmacy degree from the University of Toronto in 1994 as well as an M.B.A. from Columbia University with concentrations in finance and accounting in 2006. He has been a guest lecturer at Columbia Business School, Kings College in London and the University of Newcastle in Australia and has presented at medical grand rounds and psychiatric grand rounds at various hospitals on the role of brain imaging. Mr. Spoor also serves as chairman of the board of directors of MetaStat, Inc. (MTST) and serves on the board of directors of Protea BioSciences. Mr. Spoor's experience managing a publicly traded company and his experience in the pharmaceutical and medical device

industries provides valuable insights with respect to our operational activities.

Fred Knoll was appointed as a member of our board of directors on November 6, 2012. Since 1989, Mr. Knoll has been the principal and portfolio manager at Knoll Capital Management, an investment company managing funds over the last two decades in areas such as emerging growth companies, restructurings and China. During the 1980's and early 1990's, he was Chairman of the Board of Directors of Telos Corporation, a computer systems integration company, served as investment manager for General American Investors, was the United States representative on investments in leveraged buyouts and venture capital for Murray Johnstone, Ltd. of Glasgow, UK, and headed the New York investment group of Robert Fleming, Inc., at the time, a leading United Kingdom merchant bank subsequently acquired by JP Morgan, managing a venture capital fund and the U.S. research team. Mr. Knoll started his investment career as an investment analyst at Capital Research (Capital Group) in the 1980s and held positions in sales and marketing with Wang Inc. and Data General and software engineering with Computer Sciences Corporation in the 1970s. Mr. Knoll holds a Bachelor's of Science in Electrical Engineering and Computer Science from Massachusetts Institute of Technology (M.I.T.), a Bachelor's of Science in Management from the Sloan School at M.I.T., and a M.B.A. from Columbia University in Finance and was a member of the Columbia University International Fellows Program. Mr. Knoll's experience as an investor provides valuable insights with respect to capitalizing our operations.

On May 13, 2010, Filiberto Zadini, Giorgio Zadini, Thomas W. Gardner and Boris Ratiner (collectively the "Z&Z Shareholders"), and W-Net Fund I, L.P. ("W-Net"), Europa International, Inc. ("Europa") and MKM Opportunity Master Fund, Ltd. ("MKM" and together with W-Net and Europa, the "Purchasers"), entered into a Voting Agreement, as amended on November 6, 2012, pursuant to which such parties became obligated, for four years, to vote to elect members of our board of directors as described below. The Voting Agreement provides that the authorized number of directors will be eight, consisting of three directors whose replacements will be determined under the terms of the Voting Agreement by the holders of a majority of the shares held by the Z&Z Shareholders currently Thomas W. Gardner, Boris Ratiner, M.D. and Paul DiPerna, three directors whose replacements will be determined under the Voting Agreement by the holders of a majority of the shares held by the Purchasers, currently Gary Freeman, Chaim Davis and Fred Knoll, and two additional directors whose replacements will be determined jointly by the holders of a majority of the shares held by the Z&Z Shareholders and the holders of a majority of the shares held by the Purchasers, currently Alexander Polinsky, Ph.D. and Johan (Thijs) M. Spoor.

## **Board Leadership Structure**

We do not currently separate the roles of chief executive officer and chairman of the board Our board of directors is committed to promoting our effective, independent governance. Our board believes it is in our best interests and the best interests of our stockholders for the board to have the flexibility to select the best director to serve as chairman at any given time, regardless of whether that director is an independent director or the chief executive officer. Consequently, we do not have a policy governing whether the roles of chairman of the board and chief executive officer should be separate or combined. This decision is made by our board of directors, based on our best interests considering the circumstances at the time.

#### **Director Independence**

Our Audit Committee currently consists of Messrs. Davis, Freeman and Spoor. Our Audit Committee is responsible for selecting and engaging our independent accountant, establishing procedures for the confidential, anonymous submission by our employees of, and receipt, retention and treatment of concerns regarding accounting, internal controls and auditing matters, reviewing the scope of the audit to be conducted by our independent public accountants, and periodically meeting with our independent public accountants and our chief financial officer to review matters relating to our financial statements, our accounting principles and our system of internal accounting controls. Our Audit Committee reports its recommendations as to the approval of our financial statements to our board of directors. The role and responsibilities of our Audit Committee are more fully set forth in an amended and restated written charter adopted by our board of directors on June 17, 2010. Our Audit Committee reviews and reassesses the Audit Committee Charter annually and recommends any changes to our board of directors for approval. We are not a "listed company" under SEC rules and are therefore not required to have an audit committee comprised of independent directors. We have, however, determined that Messrs. Davis and Freeman are "independent" as that term is defined in the Listing Rules of The NASDAQ Stock Market.

Our Compensation Committee currently consists of Messrs. DiPerna, Davis and Freeman. Generally, our Compensation Committee is responsible for considering and making recommendations to our board of directors regarding executive compensation and for administering the Plan. The role and responsibilities of our Compensation Committee are more fully set forth in a written charter adopted by our board of directors on June 17, 2010. Our Compensation Committee reviews and reassesses the Compensation Committee Charter annually and recommends any changes to our board of directors for approval. We are not a "listed company" under SEC rules and are therefore not required to have a compensation committee comprised of independent directors. We have, however, determined that Messrs. Davis and Freeman are "independent" as that term is defined in the Listing Rules of The NASDAQ Stock Market.

We do not have a nominating committee or nominating committee charter for persons to be proposed as directors for election to our board of directors. The duties and functions performed by such committee are performed by the full

board of directors. We do not have any restrictions on stockholder nominations under our amended and restated certificate of incorporation or bylaws. The only restrictions are those applicable generally under the Delaware General Corporation Law and the federal proxy rules. Currently, our entire board of directors decides on nominees, on the recommendation of one or more members of our board of directors. We are not a "listed company" under SEC rules and are therefore not required to have a nominating committee comprised of independent directors. We have, however, determined that Messrs. Davis and Freeman are "independent" as that term is defined in the Listing Rules of The NASDAQ Stock Market.

# **Family Relationships**

There is no family relationship between any director, executive officer or person nominated to become a director or executive director.

#### **EXECUTIVE COMPENSATION**

## **Summary Compensation Table**

The following table and related footnotes show the compensation paid during the fiscal years ended December 31, 2013 and 2012, to our named executive officers:

Name and Principal	Year	Sa	lary	Bo	onus	-	otion vards		l Other ompensation	To	tal
Position			<b>(\$)</b>		(\$)(3)		(\$)		(\$)		(\$)
Thomas W. Gardner (1)	2013	\$		\$		\$		\$	160,000	\$	160,000
Chairman, Chief											
<b>Executive Officer and</b>	2012	\$		\$	48,000	\$		\$	146,667	\$	194,667
President											
Mark Selawski (2)	2013	\$	168,000	\$		\$		\$		\$	168,000
Chief Financial Officer	2012	\$	178.000	\$	50,400	\$		\$		\$	228,400
and Secretary	2012	Ψ	170,000	Ψ	50,400	Ψ		Ψ		Ψ	220,400

Mr. Gardner serves as our Chairman, Chief Executive Officer and President under a Management Consulting (1) Agreement dated May 7, 2014, the terms of which are described below, and has served in these capacities since May 2010.

(2) Mr. Selawski serves as our Chief Financial Officer and Secretary under an Employment Agreement dated May 7, 2014, the terms of which are described below, and has served in these capacities since May 2010.

Messrs. Gardner and Selawski accrued cash bonuses equal to 30% of their then current salary during 2012 upon

(3) successful financing transactions of at least \$3,500,000 during the terms of their employment agreements. The bonuses were paid during 2013 after completion of our annual audit for the 2012 fiscal year and are reflected in the 2012 compensation amounts.

## **Management Consulting Agreement**

On May 7, 2014, we entered into a Management Consulting Agreement with Thomas W. Gardner effective as of April 28, 2014 (the "Management Agreement").

The Management Agreement has a term of one year. Under the terms of the Management Agreement, Mr. Gardner will provide consulting and management services to us relating to the functions of our chief executive officer and will have the full range of executive duties and responsibilities that are customary for public company chief executive

officers, reporting to our board of directors (the "Board"). Mr. Gardner will spend 90% of his business time on our matters.

Mr. Gardner will receive an annual fee at an initial rate of \$180,000, with an increase to \$220,000 in the event that the Registrant completes a capital raise transaction of at least \$12,000,000 (a "Funding") at no more than a 25% discount to the volume weighted average price of our common stock over the 30-day period terminating on the date the Management Agreement is executed (the "VWAP"), and an increase to \$250,000 in the event that the Registrant completes a Funding at no more than a 5% discount to the VWAP and Mr. Gardner devotes 100% of his business time to us.

Mr. Gardner is also entitled to receive the following bonuses in connection with licensing transactions: 20% of his then applicable annual base compensation for any Board-approved licenses of AHRO-003 to third parties; 10% of his then applicable annual base compensation for any Board-approved licenses of AHRO-001 or AHRO-003 to third parties; 10% of his then applicable annual base compensation for any Board-approved licenses to the Company of pre-clinical products with United States rights; and 20% of his then applicable annual base compensation for any Board-approved licenses to the Company of clinical products with United States rights. In addition, Mr. Gardner is entitled to receive a bonus of 10% of his then applicable annual base compensation upon hiring, on or before December 31, 2014, a new president or chief executive officer for the Company approved by the Board.

All bonuses must be paid to Mr. Gardner within 10 days after the triggering event. Payments under the Management Agreement shall be grossed up to cover any taxes, interest and/or penalties incurred as a result of any payment under the Management Agreement being subject to the excise tax imposed by Section 4999 of the Internal Revenue Code of 1986, as amended.

The Management Agreement will terminate upon Mr. Gardner's death or Disability (as defined in the Management Agreement), our termination of the Management Agreement for Cause (as defined in the Management Agreement) or without Cause, or Mr. Gardner's termination of the Management Agreement for Good Reason (as defined in the Management Agreement) or without Good Reason. Upon the termination of the Management Agreement for any reason we have agreed to pay Mr. Gardner his then current annual base compensation then earned and unpaid reimbursements due to Mr. Gardner for expenses incurred by Mr. Gardner prior to the date of termination, subject to the applicable provisions of the Management Agreement. Upon the termination of the Management Agreement as a result of Mr. Gardner's death or as a result of our termination thereof without Cause or Mr. Gardner's termination thereof for Good Reason, we have also agreed to pay Mr. Gardner a prorated annual bonus (based on his then current annual base compensation), to the extent earned. In addition, upon our termination of the Management Agreement without cause or upon Mr. Gardner's termination of the Management Agreement for Good Reason, we have agreed to pay Mr. Gardner, as severance, subject to the parties' entry into a general release, a lump sum payment of three months' then current annual base compensation.

Mr. Gardner has agreed to a non-competition covenant during the term of the Management Agreement and for a period of six months thereafter if he is receiving severance, and to a non-solicitation covenant during the term of the Management Agreement and for a period of 2 years thereafter. The parties have agreed to resolve disputes under the Management Agreement through arbitration.

## **Employment Agreement**

On May 7, 2014, we also entered into an Employment Agreement with Mark Selawski effective as of April 28, 2014 (the "Employment Agreement").

The Employment Agreement has a term of one year. Under the terms of the Employment Agreement, Mr. Selawski will be employed as our chief financial officer reporting to our chief executive officer.

Mr. Selawski will receive an annual salary at an initial rate of \$190,000, with an increase to \$210,000 in the event that we complete a Funding at no more than a 25% discount to the VWAP (as of the date the Employment Agreement is executed), and an increase to \$220,000 in the event that we complete a Funding at no more than a 5% discount to the VWAP.

Mr. Selawski is also entitled to receive the following bonuses in connection with licensing transactions: 20% of his then applicable annual base salary for any Board-approved licenses of any of the Company's current or future products to third parties in the United States; 10% of his then applicable annual base salary for any Board-approved licenses of the Company's current or future products to third parties outside of the United States; 10% of his then applicable annual base salary for any Board-approved licenses to the Company of pre-clinical products with United States rights; and 20% of his then applicable annual base salary for any Board-approved licenses to the Registrant of clinical products with United States rights. In addition, Mr. Selawski is entitled to receive a bonus of 10% of his then applicable annual base salary for any approval of fast-track or other accelerated regulatory pathways in the United States by December 31, 2014. All bonuses must be paid to Mr. Selawski within 10 days after the triggering event.

Mr. Selawski will receive an automobile allowance of \$300 per month, or with his consent, we may lease a vehicle for Mr. Selawski's use in lieu of paying such automobile allowance, and will be entitled to three weeks annual paid vacation. Payments under the Employment Agreement shall be grossed up to cover any taxes, interest and/or penalties incurred as a result of any payment under the Employment Agreement being subject to the excise tax imposed by Section 4999 of the Internal Revenue Code of 1986, as amended.

The Employment Agreement will terminate upon Mr. Selawski's death or Disability (as defined in the Employment Agreement), the Company's termination of the Employment Agreement for Cause (as defined in the Employment Agreement) or without Cause, or Mr. Selawski's termination of the Employment Agreement for Good Reason (as defined in the Employment Agreement) or without Good Reason. Upon the termination of the Employment Agreement for any reason the Company has agreed to pay Mr. Selawski his then current annual base salary then earned, accrued vacation and unpaid reimbursements due to Mr. Selawski for expenses incurred by Mr. Selawski prior to the date of termination, subject to the applicable provisions of the Employment Agreement. Upon the termination of the Employment Agreement as a result of Mr. Selawski's Disability or as a result of the Company's termination thereof without Cause or Mr. Selawski's termination thereof for Good Reason, we have agreed to offer COBRA coverage without administrative markup for a period of 18 months, or the maximum term permitted by then applicable law, if Mr. Selawski is not covered by any other comprehensive insurance that provides a comparable level of benefits to those provided under our then effective health plan. Upon the termination of the Employment Agreement by Mr. Selawski's without Good Reason or as a result of our termination thereof for Cause, we have agreed to make available to Mr. Selawski, at his own expense, COBRA coverage for a period of 18 months, or the maximum term permitted by then applicable law. Upon the termination of the Employment Agreement as a result of Mr. Selawski's death we have agreed to pay Mr. Selawski a prorated annual bonus (based on his then current annual base salary) to the extent earned. In addition, upon our termination of the Employment Agreement without Cause or upon Mr. Selawski's termination of the Employment Agreement for Good Reason, we have agreed to pay Mr. Selawski, as severance, subject to the parties' entry into a general release, a lump sum payment of four months' then current annual base salary.

Mr. Selawski has agreed to a non-competition covenant during the term of the Employment Agreement and for a period of eight months thereafter if he is receiving severance, and to a non-solicitation covenant during the term of the Employment Agreement and for a period of 2 years thereafter. The parties have agreed to resolve disputes under the Employment Agreement through arbitration.

## **Outstanding Equity Awards at Fiscal Year-End**

The following table provides information regarding outstanding options held by our named executive officers as of the end of our fiscal year ended December 31, 2013.

	Number of	Number of			
	Securities	Securities	Option	Option  Expiration  Date	
Name	Underlying	Underlying	Exercise		
	Unexercised	Unexercised	Price (\$)		
	Options (#)	Options (#)	(1)	- ****	
	Exercisable	Unexercisable			
Thomas W. Gardner (2)	81,250	18,750	11.10	08/30/17	
Mark Selawski (3)	53,806	1,144	2.20	01/06/17	
Mark Selawski (2)	20,313	4,687	11.10	08/30/17	
Mark Selawski (4)	1,896	1,604	12.50	10/11/18	

- (1) Subject to certain conditions, the exercise price may be paid by delivery of already owned shares and the tax withholding obligations related to exercise may be paid by reduction of the underlying shares.
  - The options granted vested 25% on the first anniversary of the grant date and 6.25% every three months thereafter until fully vested. The options are for a 7-year term, subject to earlier termination in certain events related to
- (2) termination of employment. The option vesting ceases if there is a termination of employment and are forfeited entirely if termination is for cause. The Compensation Committee retains discretion, subject to the option plans' limits, to modify the terms of outstanding options. Although the contracts under which these options were granted have expired, the options remain outstanding and continue to vest per the original agreements.
  - The option granted vested 25% on the first anniversary of the grant date and 2.0833% every month thereafter until fully vested. The options are for a 7-year term, subject to earlier termination in certain events related to termination
- of employment. The option vesting ceases if there is a termination of employment and are forfeited entirely if termination is for cause. The Compensation Committee retains discretion, subject to the option plans' limits, to modify the terms of outstanding options. The option remains outstanding and continues to vest per the option agreement for as long as Mr. Selawski remains employed by us.
  - The options granted vest 1/48th on the monthly anniversary date of the grant until fully vested. The options are for a 7-year term, subject to earlier termination in certain events related to termination of employment. The option
- vesting ceases if there is a termination of employment and are forfeited entirely if termination is for cause. The Compensation Committee retains discretion, subject to the option plans' limits, to modify the terms of outstanding options. The option remains outstanding and continues to vest per the option agreement for as long as Mr. Selawski remains employed by us.

None of the executive officers listed in the above table exercised options during the fiscal year ended December 31, 2013.

## **Compensation of Directors**

Independent directors are compensated at a base rate of \$7,500 per year, paid in quarterly installments. Directors serving as chairman of a standing committee of our board of directors also receive an additional \$5,000 per year, also paid in quarterly installments. Directors who are also employees or officers of our company do not receive any amounts over and above their compensation as an employee of our company. Each director has received cash compensation commensurate with their election to our board of directors. Each director also receives stock options upon his/her election to our board of directors and will receive annual option grants on the date of each successive stockholders' meeting in which they are elected to serve a successive term. Such grants for committee chairmen is an initial grant of an option to purchase 7,500 shares of common stock on the date of election and a grant of an option to purchase 3,700 shares of common stock at each successive annual stockholders meeting. Directors not serving as the chairman of a committee receive an option to purchase 5,000 shares of common stock on the date of election and an option to purchase 2,500 shares of common stock at each successive annual stockholders meeting. Vesting on all non-employee director stock options is 25% upon the date of grant and 25% on each anniversary of the date of grant until fully vested. The options expire seven years after the grant date of the option.

The following table presents information regarding compensation paid to our non-employee directors for our fiscal year ended December 31, 2013

	Fees Earned	Option	Total
Name	or Paid in Cash	Awards	Total (\$)
	( <b>h</b> )	(\$)	
Gary Freeman	(\$) 12,500	13,530	26,030
Boris Ratiner	12,500	82,200	94,700
Chaim Davis	7,500	9,020	16,520
Alexander Polinsky	7,500	9,020	16,520
Paul DiPerna	12,500	13,530	26,030
Johan (Thijs) Spoor	7,500	9,020	16,520
Fred Knoll	7,500		