Synthetic Biologics, Inc.
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Registration Statement No. 333-185457

PROSPECTUS

SYNTHETIC BIOLOGICS, INC.

4,260,855 Shares of Common Stock

This prospectus relates to the resale by the investors listed in the section titled "Selling Stockholders", and we refer to the investors as the Selling Stockholders (the "Selling Stockholders") of up to 4,260,855 shares of our common stock, par value $0.001 per share (the "Shares"), of which 3,625,000 shares of common stock are currently outstanding and 635,855 shares of common stock are issuable upon exercise of warrants (the "Agent Warrants"). The shares and warrants were acquired by the Selling Stockholders in connection with a private placement offering we completed on October 30, 2012 (the "October 2012 Private Placement"). We are registering the resale of the Shares as required by the Registration Rights Agreement we entered into with the Selling Stockholders in connection with the October 2012 Private Placement (the "Registration Rights Agreement").

The Selling Stockholders may offer and sell or otherwise dispose of the Shares described in this prospectus from time to time through public or private transaction at prevailing market prices, at prices related to such prevailing market prices, at varying prices determined at the time of sale, at negotiated prices, or at fixed prices. See "Plan of Distribution" beginning on page 20 for more information.

We will not receive any of the proceeds from the Shares sold by the Selling Stockholders.

Our common stock became eligible for trading on the NYSE MKT, LLC October 16, 2008. Our common stock is eligible for quotation on the NYSE MKT, LLC under the symbol "SYN". The closing price of our stock on December 11, 2012 was $1.60.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 7 of this prospectus for more information.

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

The date of this prospectus is December 21, 2012.

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ABOUT THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference in this prospectus. Neither we nor the Selling Stockholders have authorized anyone to provide you with information that is different from such information. If anyone provides you with different or inconsistent information, you should not rely on it. The Selling Stockholders are offering to sell common stock only in jurisdictions where offers and sales are permitted. You should not assume that the information we have included in this prospectus is accurate as of any date other than the date of this prospectus or that any information we have incorporated by reference is accurate as of any date other than the date of the document incorporated by reference. Our business, financial condition, results of operations and prospects may have changed since that date.

The distribution of this prospectus and the issuance of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the issuance of the common stock and the distribution of this prospectus outside the United States. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, the common stock offered by this prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

It is important for you to read and consider all of the information contained in this prospectus in making your investment decision. To understand the offering fully and for a more complete description of the offering you should read this entire document carefully, including particularly the “Risk Factors” section beginning on page 7. You also should read and consider the information in the documents to which we have referred you in the sections entitled “Where You Can Find Additional Information” and “Incorporation of Certain Information by Reference”.

As used in this prospectus, unless the context requires otherwise, the terms “we”, “us”, “our”, or “the Company” refer to Synthetic Biologics, Inc. and its subsidiaries on a consolidated basis. References to “Selling Stockholders” refer to those stockholders listed herein under “Selling Stockholders” and their successors, assignees and permitted transferees.

ABOUT FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act, about the Company and its subsidiaries. These forward-looking statements are intended to be covered by the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact, and can be identified by the use of forward-looking terminology such as “believes”, “expects”, “may”, “will”, “could”, “should”, “projects”, “plans”, “goal”, “targets”, “potential”, “estimates”, “pro

“intends”, or “anticipates” or the negative thereof or comparable terminology. Forward-looking statements include discussions of strategy, financial projections, guidance and estimates (including their underlying assumptions), statements regarding plans, objectives, expectations or consequences of various transactions, and statements about the future performance, operations, products and services of the Company and its subsidiaries. We caution our stockholders and other readers not to place undue reliance on such statements.

Our businesses and operations are and will be subject to a variety of risks, uncertainties and other factors. Consequently, actual results and experience may materially differ from those contained in any forward-looking statements. Such risks, uncertainties and other factors that could cause actual results and experience to differ from those projected include, but are not limited to, the risk factors set forth in the section entitled “Risk Factors” beginning on page 7 of this prospectus and elsewhere in the documents incorporated by reference in this prospectus, including our Annual Report on Form 10-K/A for the year ended December 31, 2011.

All written or oral forward-looking statements attributable to us or any person acting on our behalf made after the date of this prospectus are expressly qualified in their entirety by the risk factors and cautionary statements contained in and incorporated by reference into this prospectus. Unless legally required, we do not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus; it does not contain all of the information you should consider before investing in our common stock. You should read the entire prospectus before making an investment decision.

Company Overview

We are a biotechnology company focused on the development of synthetic biologics and innovative medicines for serious infections and diseases. We are developing a biologic for the prevention of *C. diff* infection, and a series of monoclonal antibodies (mAbs) for the treatment of serious infectious diseases, including *Acinetobacter* and pertussis. We are also developing a synthetic DNA-based therapy for the treatment of pulmonary arterial hypertension (PAH). In addition, we are developing a drug candidate for the treatment of relapsing-remitting multiple sclerosis (MS) and cognitive dysfunction in MS, and designing a clinical development pathway for the treatment of amyotrophic lateral sclerosis (ALS), and, have partnered the development of a treatment for fibromyalgia. We are also evaluating additional in-licensing opportunities.

Product Pipeline:

Infectious Disease Programs:

- In November 2012, we acquired a series of beta-lactamase compounds (P1A, P2A and P3A) and related assets targeting the prevention of *Clostridium difficile* (*C. diff*) infection, the leading cause of hospital acquired infections (HAI), that may occur secondary to treatment with antibiotics. The assets include a pre-Investigational New Drug (IND) package, Phase I and Phase II clinical data, manufacturing process data and all issued and pending U.S. and international patents intended to support an IND and Biologic License Application (BLA) with the FDA. Utilizing the newly acquired biologic compounds, we intend to develop a proprietary oral beta-lactamase enzyme product candidate, SYN-004. When co-administered with certain beta-lactam antibiotics, it is expected that SYN-004 can degrade the antibiotic and preserve the balance of the patient's gastrointestinal (GI) microflora, thus preventing opportunistic *C. diff* infection (CDI). Beta-lactam antibiotics are a mainstay in hospital infection management and include both penicillins and cephalosporins. In 2011, an estimated 8.7 million Americans were administered

intravenous beta-lactam antibiotics.

In August 2012, we entered into a second worldwide exclusive channel collaboration with Intrexon Corporation (Intrexon) through which we intend to develop and commercialize a series of mAb therapies for the treatment of certain infectious diseases not adequately addressed by existing therapies. Utilizing Intrexon's comprehensive suite of proprietary technologies, including the mAbLogix™ and LEAP™ platforms, we intend to target three infectious disease indications as part of the Intrexon collaboration. In September 2012, we initiated efforts to develop our first mAb therapy for the treatment of acinetobacter infections. Many strains of *Acinetobacter* are multidrug-resistant and pose an increasing global threat to hospitalized patients, wounded military personnel and those affected by natural disasters. A treatment for acinetobacter infections represents a multi-billion dollar market opportunity.

(mAbLogix™ and LEAP™ are registered trademarks of Intrexon Corporation)

Synthetic Biologic Program:

- Our synthetic DNA-based product candidate is intended to treat PAH, a serious life-threatening lung disease. This product is designed to deliver DNA that encodes a therapeutic protein called prostacyclin synthase (PGIS) locally to the pulmonary arteries of PAH patients via a single procedure, and, via an oral daily pill, control the long-term local expression of such therapeutic protein. We are developing this initial product candidate pursuant a global exclusive channel collaboration that we entered into with Intrexon in November 2011. As part of this collaboration, we have access to Intrexon's UltraVector® platform and RheoSwitch Therapeutic System® for this product application. We anticipate that by continuously producing and delivering prostacyclin directly where it is needed, in the pulmonary arteries of PAH patients, this product candidate may overcome the dose limiting side effects of systemic prostacyclin treatments for PAH, a mainstay of PAH treatment. According to GlobalData, the global market for PAH treatments is estimated to exceed $3.6 billion by 2015.

(UltraVector® and RheoSwitch Therapeutic System® are registered trademarks of Intrexon Corporation)

Multiple Sclerosis Program:

- Trimesta™ (oral estriol) is being developed as an oral once-daily treatment for relapsing-remitting MS in women. Patient enrollment of 164 patients is complete in this randomized, double-blind, placebo-controlled Phase II clinical trial being conducted at 15 centers in the U.S. Patients are being dosed and monitored for two years. This clinical trial is supported by grants exceeding $8 million, which should be sufficient to fund the trial through completion. Current sales of injectable disease-modifying therapies for MS are estimated at $8.9 billion annually. According to various reports, sales of oral disease-modifying therapies for MS, of which Trimesta™, if and when approved, would be in such class, are anticipated to grow from $500 million in 2010 to $5 billion annually by 2017.

- Trimesta™ is also being developed for the treatment of cognitive dysfunction in female MS patients. In January 2012, patient enrollment began in a randomized, double-blind, placebo-controlled Phase II clinical trial being conducted at University of California, Los Angeles (UCLA). Patient recruitment and enrollment into this trial is ongoing. The majority of the costs of this trial are being funded by grants from foundations and charitable organizations and we have pledged approximately $500,000 to UCLA to partially fund this trial payable over three years. An estimated 50-65% of MS patients are expected to develop disabilities due to cognitive dysfunction and there is currently no approved treatment.

Other Programs:

- AEN-100 (gastroretentive zinc acetate) is a novel formulation of zinc acetate that may be used for the treatment of ALS, also known as Lou Gehrig’s disease. Previous investigator studies have suggested that alterations in the

handling and disposition of zinc ions in the brain may be important in the initiation and development of ALS. We are currently collaborating with the investigator and, based on feedback from the United States Food & Drug Administration (FDA), intend to design a clinical development pathway for AEN-100 in the treatment of ALS. There is only one approved therapy for ALS, the efficacy of which is considered to be marginal. Based on an estimated annual price of $10,000 per ALS patient, we estimate that the total market potential in the U.S. is $300 million.

- Effirma™ (flupirtine) is being developed for the treatment of fibromyalgia by Meda AB (Meda), a multi-billion dollar international pharmaceutical company. On May 6, 2010, we entered into a sublicense agreement with Meda covering all of our patents' rights on the use of flupirtine for fibromyalgia in the U.S., Canada and Japan. According to Meda's 2011 Annual Report filed in May 2012, flupirtine for fibromyalgia is currently in Phase II development. The sublicense agreement provides that all ongoing and future development costs are to borne by Meda and we are entitled to receive certain payments if milestones are achieved and royalties on sales. Based on an estimated annual price of $1,200 per fibromyalgia patient, we estimate that the total market potential in the U.S. is $6 billion.

Recent Developments

On November 18, 2011, we entered into a Channel Agreement with Intrexon (the "Initial Channel Agreement") that governs an "exclusive channel collaboration" arrangement in which we intend to use Intrexon's technology directed towards the production of PGIS, through the use of *in vivo* conditionally regulated embedded controllable bioreactors for the treatment of PAH. The Initial Channel Agreement establishes committees comprised of our and Intrexon representatives that will govern activities related to the PAH program in the areas of project establishment, chemistry, manufacturing and controls, clinical and regulatory matters, commercialization efforts and intellectual property. As partial consideration for execution of the Initial Channel Agreement, we entered into a Stock Purchase Agreement with Intrexon (the Initial Stock Purchase Agreement") pursuant to which we issued to Intrexon a number of shares of our common stock equal to 9.995% of the number of shares of our common stock issued and outstanding following and giving effect to such issuance (the "First Tranche") at a purchase price equal to the $0.001 par value of such shares, which issuance was deemed paid in partial consideration for the execution and delivery of the Initial Channel Agreement. We also agreed to issue additional shares of our common stock to Intrexon upon dosing of the first patient in a Phase II clinical trial sponsored by us in the U.S., or similar study as the parties may agree in a country other than the U.S.

On December 21, 2011, we announced that the Board of Directors had taken several actions to prioritize our focus on our entry into the emerging field of synthetic biology. In connection with the change in business focus on March 8, 2012, we entered into a Membership Interest Purchase Agreement, and certain related agreements, pursuant to which we sold all of our interest in the Adeona Clinical Laboratory (the "Lab") to Hartlab, LLC, an entity controlled by the Lab's former owner, in consideration for (i) the immediate assignment of the Lab's outstanding accounts receivable up through the date of closing, plus (ii) Seven Hundred Thousand Dollars ($700,000) payable pursuant to the terms of a two-year non-recourse promissory note secured by all of the assets of the Lab.

On February 15, 2012, upon stockholder approval, we amended our Articles of Incorporation to change our name to Synthetic Biologics, Inc. Our common stock continues trade on the NYSE MKT (formerly the NYSE Amex and American Stock Exchange), under the symbol "SYN". Prior to this time and since October 16, 2008, our name was Adeona Pharmaceuticals, Inc. and we traded on the NYSE MKT stock exchange under the symbol "AEN". We are incorporated in the State of Nevada. We continue to maintain our principal executive offices in Ann Arbor, MI, and are currently located at 617 Detroit Street, Suite 100**,** Ann Arbor, MI 48104.

On August 6, 2012, we expanded our relationship with Intrexon and entered into a Second Channel Agreement with Intrexon (the "Second Channel Agreement") that governs an "exclusive channel collaboration" arrangement in which we will use Intrexon's technology relating to the identification, design and production of human antibodies and DNA vectors for the development and commercialization of a series of monoclonal antibody therapies for the treatment of certain serious infectious diseases (the "Program"). The Second Channel Agreement establishes committees comprised of our and Intrexon representatives that will govern activities related to the Program in the areas of project establishment, chemistry, manufacturing and controls, clinical and regulatory matters, commercialization efforts and intellectual property.

On October 16, 2012, a closing was held for the transaction contemplated by the Second Channel Agreement. Pursuant to the terms of a Stock Issuance Agreement with Intrexon (the "Second Stock Purchase Agreement"), we issued 3,552,210 shares of our common stock, $0.001 par value, which issuance is also deemed paid in partial consideration for the execution and delivery of the Second Channel Agreement, dated August 6, 2012, between ourselves and Intrexon. We also agreed to register the shares issued to Intrexon in accordance with the First Amendment to Registration Rights Agreement.

On October 25, 2012, we entered into a Stock Purchase Agreement (the "Purchase Agreement") with certain accredited investors, which include the Selling Stockholders (the "Purchasers"), pursuant to which we agreed to sell to the Purchasers in a private placement an aggregate of 6,750,000 shares of our common stock at a price per share of $1.60 (the "Common Shares") for aggregate gross proceeds of $10.8 million and net proceeds of $10.1 million. On October 30, 2012, we completed the October 2012 Private Placement. We intend to use the net proceeds from the October 2012 Private Placement to develop our monoclonal antibody and synthetic DNA programs through our exclusive channel collaborations with Intrexon, and for general corporate purposes, including the execution of our business plan and expansion of our pipeline.

In connection with the October 2012 Private Placement, we also entered into a registration rights agreement with the Selling Stockholders (the "Registration Rights Agreement"). The Registration Rights Agreement requires that we file a registration statement (the "Initial Registration Statement") with the Securities and Exchange Commission (the "Commission") within forty-five (45) days of the closing date of the October 2012 Private Placement (the "Filing Date") for the resale by the Selling Stockholders of all of the Common Shares owned by the Selling Stockholders and all shares of Common Stock issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect thereto (the "Registrable Securities"). The Initial Registration Statement must be declared effective by the Commission within ninety (90) days of the closing date of the October 2012 Private Placement (the "Effectiveness Date") subject to certain adjustments. Upon the occurrence of certain events (each an "Event"), including, but not limited to, that the Initial Registration Statement is not filed prior to the Filing Date, we will be required to pay to each of the Selling Stockholders liquidated damages of 1.5% of their aggregate purchase price upon the date of the Event and then monthly thereafter until the Event is cured. In no event will the aggregate amount of liquidated damages payable to the Selling Stockholders exceed in the aggregate 10% of the aggregate purchase price paid by such Selling Stockholder for the Registrable Securities.

In connection with the October 2012 Private Placement, we also entered into an agreement with a certain Purchaser that is an affiliate of Intrexon (the "Joinder Agreement") pursuant to which such Purchaser agreed to be bound by the terms of and join Intrexon as a party to its registration rights agreement with us entered into in connection with the Second Channel Agreement.

Griffin Securities, Inc. ("Griffin") served as the placement agent for the October 2012 Private Placement. In consideration for services rendered by Griffin in the October 2012 Private Placement, we agreed to (i) pay to Griffin cash commissions equal to 6.0% of the gross proceeds received in the October 2012 Private Placement, (ii) issue to Griffin, or its designee, the Agent Warrants, which are five-year warrants to purchase 635,855 shares of our common stock with an exercise price of $1.60 per share; and (iii) reimburse Griffin for its reasonable actual out-of-pocket expenses incurred in connection with the October 2012 Private Placement, including reasonable legal fees and disbursements. The Agent Warrants also provide for the same registration rights and obligations, and are subject to certain limitations, as set forth in the Registration Rights Agreement with respect to the Common Shares underlying such warrant.

On November 28, 2012, a closing was held for the transaction contemplated by the Asset Purchase Agreement (the "Prev Agreement") we entered into with Prev ABR LLC ("Prev"), pursuant to which we acquired the *C. diff* program assets of Prev, including pre-Investigational New Drug (IND) package, Phase I and Phase II clinical data, manufacturing process data and all issued and pending U.S. and international patents. Pursuant to the Prev Agreement, we paid Prev an initial cash payment of $100,000 upon execution of the Prev Agreement and at closing paid an additional cash payment of $135,000 and issued 625,000 unregistered shares of our common stock to Prev. In addition, upon the achievement of the milestones set forth below, Prev may be entitled to receive additional consideration payable 50% in cash and 50% in our stock, subject to Prev's option to receive the entire payment in shares of our stock, with the exception of the first milestone payments to be paid in cash: (i) upon commencement of an IND; (ii) upon commencement of a Phase I clinical trial; (iii) upon commencement of a Phase II clinical trial; (iv) upon commencement of a Phase III clinical trial; (v) upon Biologic License Application (BLA) filing in the U.S. and for territories outside of the U.S. (as defined in the Prev Agreement); and (vi) upon BLA approval in the U.S. and upon approval in territories outside the-U.S. The future stock issuances are subject to prior approval of the NYSE MKT, LLC. No royalties are payable to Prev under the Prev Agreement. The Prev Agreement also provides that Prev has a right to the return to it of all assets acquired by us under the Prev Agreement if on or prior to the date that is (i) thirty (30) months after the execution of the Prev Agreement, we have not initiated toxicology studies in non-rodent models or (ii) thirty six (36) months have not filed an IND under the program related to the assets and such failure is not due to action or inaction of Prev or breach of its representations or warranties or covenants or if there is a change of control as defined in the Prev Agreement and after such change of control the assets are not further developed; provided however that such thirty (30) and thirty six (36) month periods can be extended by us for an additional twelve (12) months upon payment of a cash milestone payment.

On December 19, 2012, we entered into a Patent License Agreement (the "License Agreement") with The University of Texas at Austin (the "University") for the exclusive license of the right to use, develop, manufacture, market and commercialize certain research and patents related to pertussis (more commonly known as whooping cough) antibodies developed in the lab of Dr. Jennifer A. Maynard, Assistant Professor of Chemical Engineering. In

connection with the License Agreement, we and the University also entered into a Sponsored Research Agreement pursuant to which the University will perform certain research work related to pertussis under the direction of Dr. Jennifer Maynard and we will obtain certain rights to patents and technology developed during the course of such research.

To date, we have financed our operations primarily through public and private sales of our common stock, and we expect to continue to seek to obtain the required capital in a similar manner. We have incurred an accumulated deficit of $56.9 million through September 30, 2012. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

The description set forth above of the agreements is intended to be a summary of the terms of the agreements that are material to a purchaser of our common stock. It does not purport to be complete and is subject to and qualified in its entirety by reference to the complete text of each agreement filed as exhibits to our Current Reports on Form 8-K.

Corporate and Other Information

Our predecessor, Sheffield Pharmaceuticals, Inc. was incorporated in 1986, and in 2006 engaged in a reverse merger with Pipex Therapeutics, Inc., a Delaware corporation formed in 2001. After the merger, we changed our name to Pipex Pharmaceuticals, Inc., and in October 2008 we changed our name to Adeona Pharmaceuticals, Inc. On October 15, 2009, we reincorporated in the State of Nevada. After reprioritizing our focus on the emerging area of synthetic biologics and entering into a collaboration with Intrexon, on February 15, 2012, we amended our Articles of Incorporation to change our name to Synthetic Biologics, Inc.

Our executive offices are located at 617 Detroit Street, Suite 100, Ann Arbor, Michigan 48104, and our telephone number is (734) 332-7800. Our website address is www.syntheticbiologics.com. The information on our website is not incorporated by reference into this prospectus, and you should not consider it part of this prospectus.

For a complete description of our business, financial condition, results of operations and other important information, we refer you to our filings with the Commission that are incorporated by reference in this prospectus, including our Annual Report on Form 10-K/A for the year ended December 31, 2011. For instructions on how to find copies of these documents, see “Where You Can Find Additional Information.”

THE OFFERING

Issuer	Synthetic Biologics, Inc.
Securities offered	This prospectus covers the sale of up to 4,260,855 shares of common stock, of which 3,625,000 shares of common stock are currently outstanding and 635,855 shares of common stock are issuable upon exercise of Agent Warrants.
Common stock to be outstanding	44,332,748 shares
Use of Proceeds	We will not receive proceeds from the sale or other disposition of the shares of common stock covered by this prospectus. We will receive $1,017,368 if the Agent Warrants are exercised in full for cash; however, these warrants contain a cashless exercise feature. See “Use of Proceeds”.
Risk Factors	You should carefully read and consider the information set forth under “Risk Factors,” together with all of the other information set forth in this prospectus, before deciding to invest in shares of our common stock.
NYSE MKT symbol	Our common stock is listed on the NYSE MKT, LLC under the symbol “SYN”.

The number of shares of common stock outstanding after the offering is based on 44,332,748 shares outstanding as of December 7, 2012 and excludes:

- 1,632,501 shares of common stock issuable upon the exercise of warrants with a weighted average exercise price of $3.10 per share;
- 4,383,746 shares of common stock issuable upon the exercise of options with a weighted average exercise price of $1.77 per share; and
- 934,821 shares of common stock reserved for future grants and awards under our equity incentive plans.

RISK FACTORS

Investing in our common stock involves a high degree of risk, and you should be able to bear the complete loss of your investment. You should carefully consider the risks described below, the other information in this prospectus and the documents incorporated by reference herein when evaluating our company and our business. If any of the following risks actually occur, our business could be harmed. In such case, the trading price of our common stock could decline and investors could lose all or a part of the money paid to buy our common stock.

RISKS RELATING TO OUR BUSINESS

We will need to raise additional capital to operate our business.

With the exception of the three months ended June 30, 2010, we have experienced significant losses since inception and have a significant accumulated deficit. We expect to incur additional operating losses in the future and therefore our cumulative losses to increase. To date, other than the licensing fee we received from Meda AB for the development and commercialization of Effirma (flupirtine) for fibromyalgia in the U.S., Canada and Japan and limited laboratory revenues from Adeona Clinical Laboratory, which we have recently sold, we have generated very minimal revenues. Inasmuch as our sole source of revenue (with the exception of the Meda licensing fee) has been our laboratory revenue and our laboratory was sold recently, we do not expect to derive revenue from any source in the near future until we or our partners successfully commercialize our products. As of September 30, 2012, our accumulated deficit totaled approximately $56.9 million on a consolidated basis. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees and grants. If our current cash, cash equivalents and short-term investments are not sufficient to sustain our operations, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. Our recent loss of S-3 eligibility due to the failure of Berman & Company, P.A. to follow proper partner rotation procedures may also negatively affect our ability to raise capital. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

We have not been able to sustain profitability.

Other than with respect to the three months ended June 30, 2010, we have a history of losses and we have incurred and continue to incur substantial losses and negative operating cash flow. Even if we succeed in developing and commercializing one or more of our product candidates, we may still incur substantial losses for the foreseeable future and may not sustain profitability. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will substantially increase in the foreseeable future as we do the following:

- continue to undertake preclinical development and clinical trials for our product candidates;
- expand our research activities with Intrexon relating to monoclonal antibodies for infectious diseases;
- seek regulatory approvals for our product candidates;
- develop our product candidates for commercialization;
- implement additional internal systems and infrastructure;
- lease additional or alternative office facilities; and
- hire additional personnel, including members of our management team.

We may experience negative cash flow for the foreseeable future as we fund our technology development with capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock and underlying securities.

Our research and development efforts may not succeed in developing commercially successful products and technologies, which may limit our ability to achieve profitability.

We must continue to explore opportunities that may lead to new products and technologies. To accomplish this, we must commit substantial efforts, funds, and other resources to research and development. A high rate of failure is inherent in the research and development of new products and technologies. Any such expenditures that we make will be made without any assurance that our efforts will be successful. Failure can occur at any point in the process, including after significant funds have been invested.

Regardless of whether our clinical trials are deemed to be successful, promising new product candidates may fail to reach the market or may only have limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, inability to obtain necessary regulatory approvals or satisfy regulatory criteria, limited scope of approved uses, excessive costs to manufacture, the failure to establish or maintain intellectual property rights, or infringement of the intellectual property rights of others. Even if we successfully develop new products or enhancements, they may be quickly rendered obsolete by changing customer preferences, changing industry standards, or competitors' innovations. Innovations may not be quickly accepted in the marketplace because of, among other things, entrenched patterns of clinical practice or uncertainty over third-party reimbursement. We cannot state with certainty when or whether any of our products under development will be launched, whether we will be able to develop, license, or otherwise acquire drug candidates or products, or whether any products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause our products to become obsolete, which may limit our ability to achieve profitability.

The technology on which our channel partnering arrangements with Intrexon is based on early stage technology.

We have an exclusive channel collaboration arrangement with Intrexon that contemplates the use of Intrexon’s transgene engineering platform technology and regulatory control technology for the *in vivo* cellular production of PGIS, a specific effector enzyme that regulates the production of prostacyclin. Such technologies have a limited history of use in the design and development of human therapeutic product candidates and may therefore involve unanticipated risks or delays.

On August 8, 2012, we announced an additional exclusive channel collaboration with Intrexon relating to the design, production, testing and commercialization of monoclonal antibodies for the treatment of certain infectious diseases. Although monoclonal antibody therapeutics are well established in the biotechnology and pharmaceutical sectors, their use for the treatment of infectious disease is extremely limited. In order for monoclonal antibodies to be effective for infectious diseases, they must not only properly target the organism of interest (or its toxins), but may also need to

overcome defenses and forms of resistance of such organisms. To accomplish this may require the use of more than one specific monoclonal antibody, and mixtures of different monoclonal antibodies, which may create additional unforeseen complications, including increased manufacturing complexity and expense. In order to be competitive, monoclonal antibodies will be required to be produced at a low enough cost of goods in order to be profitably marketed. We have very limited development and manufacturing experience in the field of monoclonal antibodies and infectious disease. We cannot assure that any monoclonal antibody candidates will provide satisfactory in vitro and in vivo nonclinical results sufficient to warrant the expense of cGMP manufacture and clinical testing in human clinical trials.

DNA-based therapy has not yet been proven to be successful.

The FDA has not yet approved any human DNA-based therapy product for sale. The field of DNA-based therapy, also referred to as gene therapy or gene transfer, is experimental and has not yet proven successful in many clinical trials. Clinical trials with DNA-based therapy have encountered a multitude of significant technical problems in the past, including, unintended integration with host DNA, poor levels of protein expression, transient protein expression, viral overload, immune reactions to either viral capsids utilized to deliver DNA, DNA itself, proteins expressed or cells transfected with DNA. There can be no assurance that our preclinical animals studies or human clinical trials will be successful or that we will receive the regulatory approvals necessary to initiate such studies. To the extent that we utilize viral constructs or other systems to deliver our DNA-based therapies and the same or similar delivery systems demonstrate unanticipated and/or unacceptable side effects in preclinical or clinical trials conducted by ourselves or others we may be forced to, or elect to, discontinue development of such product candidates.

We may not generate additional revenue from our relationships with our corporate collaborators.

On May 6, 2010, we entered into a sublicense agreement with Meda AB whereby we may receive milestone payments totaling $17.5 million (including an upfront payment of $2.5 million that has already been received), plus royalties on our flupirtine program. There can be no assurance that Meda AB will successfully develop flupirtine for fibromyalgia in the U.S., Canada or Japan that would allow us to receive such additional $15 million in milestone payments and royalties on sales in connection with such agreement. The successful achievement of the various milestones set forth in the sublicense agreement is not within our control and we will be dependent upon Meda AB for achievement of such milestones. According to Meda’s 2011 Annual Report filed in May 2012, flupirtine for fibromyalgia is in Phase II development.

We have experienced several management changes.

We have had significant changes in management in the past few years. Jeffrey Riley was appointed Chief Executive Officer and President on February 3, 2012. Effective February 6, 2012, C. Evan Ballantyne was appointed Chief Financial Officer. James S. Kuo, M.D., served as Chief Executive Officer and President from February 6, 2010 until February 3, 2012. Changes in our key positions, as well as additions of new personnel and departures of existing personnel, can be disruptive, might lead to additional departures of existing personnel and could have a material adverse effect on our business, operating results, financial results and internal controls over financial reporting.

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

In addition to our own patent applications, we also currently rely on licensing agreements with third party patent holders/licensors for our products. We have an exclusive license agreement with the McLean Hospital relating to the use of flupirtine to treat fibromyalgia which was sublicensed to Meda AB and an exclusive license agreement with the Regents of the University of California relating to our Trimesta technology. Each of these agreements requires us or our sublicensee to use our best efforts to commercialize each of the technologies as well as meet certain diligence requirements and timelines in order to keep the license agreement in effect. In the event we or our sublicensee are not able to meet our diligence requirements, we may not be able to retain the rights granted under our agreements or renegotiate our arrangement with these institutions on reasonable terms, or at all. Furthermore, we currently have very limited product development capabilities, and limited marketing or sales capabilities. For us to research, develop, and test our product candidates, we would need to contract with outside researchers, in most cases those parties that did the original research and from whom we have licensed the technologies. Our exclusive channel collaboration agreements with Intrexon provide that Intrexon may terminate such agreement if we do not perform certain specified requirements, including developing therapies considered superior.

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

We will incur additional expenses in connection with our exclusive channel collaboration arrangements with Intrexon.

Pursuant to our exclusive channel collaborations with Intrexon, we are responsible for future research and development expenses of product candidates developed under each such collaboration, the effect of which has and will continue to increase the level of our overall research and development expenses going forward. Although all manufacturing, preclinical studies and human clinical trials are expensive and difficult to design and implement, costs associated with the manufacturing, research and development of biologic product candidates are generally greater in comparison to small molecule product candidates. We have added additional personnel and expect to add additional personnel to support our exclusive channel collaborations with Intrexon.

Because our collaborations with Intrexon are relatively new, we have only recently assumed development responsibility and costs associated with such programs. In addition, because development activities are determined pursuant to a joint steering committees comprised of Intrexon and ourselves and we have limited experience, future development costs associated this program may be difficult to anticipate and exceed our expectations. Our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, unanticipated technical challenges, changes in the focus and direction of our development activities or adjustments necessitated by changes in the competitive landscape in which we operate. If we are unable to continue to financially support such collaborations due to our own working capital constraints, we may be forced to delay our activities. If we are unable to obtain additional financing on terms acceptable to us or at all, we may be forced to seek licensing partners or discontinue development.

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

Companies that currently sell or are developing both generic and proprietary products to treat serious diseases include: Actelion Pharmaceuticals, Bayer Health Care, Biogen Idec, Eli Lilly & Co., Genzyme, GlaxoSmithKline Pharmaceuticals, Merck & Co., Pfizer, Novartis, Teva Pharmaceuticals and United Therapeutics. Companies that currently sell or are developing both generic and proprietary products to treat infectious diseases include: MedImmune, Pfizer, Cubist, Optimer Pharmaceuticals, Symphogen, Merus, GlaxoSmithKline Pharmaceuticals, Merck & Co. and Novartis. Many of our competitors have significant financial and human resources. The pulmonary arterial hypertension market is highly competitive and several different product classes currently compete in this space, including prostacyclin-based therapies, endothelin receptor antagonists and phosphodiesterase type 5 inhibitors. Prostacyclin-based therapies for PAH are available in a number of delivery formats, including intravenous, subcutaneous and inhaled routes and an oral prostacyclin-based product candidate is currently under NDA review in the U.S. The infectious disease market is highly competitive with many generic and proprietary intravenous and oral formulations available to physicians and their patients. As monoclonal antibodies, we currently do not expect to be able to deliver our infectious disease candidates via the oral route and may thus be limited to the in-patient and/or acute treatment setting. In addition, academic research centers may develop technologies that compete with our Trimesta, sustained-release zinc preparation - AEN-100, and flupirtine technologies. Should clinicians or regulatory authorities view these therapeutic regiments as more effective than our products, this might delay or prevent us from obtaining regulatory approval for our products, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid and private insurers.

We operate in a highly competitive environment.

The pharmaceutical and biotechnology industries, including the monoclonal antibody industry, are characterized by rapidly evolving technology and intense competition. Our competitors include major multi-national pharmaceutical companies and biotechnology companies developing both generic and proprietary therapies to treat serious diseases. Many of these companies are well-established and possess technical, human, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, many of our potential competitors have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies potential research and development and commercialization advantages in the therapeutic areas we are currently pursuing.

Academic research centers, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those being developed by us. In addition, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before us.

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

Since we do not have composition of matter patent claims for flupirtine, estriol or zinc acetate, others may obtain approvals for other uses of these products that are not covered by our issued or pending patents. For example, the active ingredients in both Effirma (flurpirtine) and Trimesta (oral estriol) have been approved for marketing in overseas countries for different uses and an oral immediate release form of zinc is approved in the U.S. and Europe for the treatment of Wilson's disease. Other companies, including the original developers or licensees or affiliates may seek to develop Effirma or Trimesta or their respective active ingredient(s) for other uses in the U.S. or any country we are seeking approval for. We cannot provide any assurances that any other company may obtain FDA approval for products that contain flupirtine, estriol or zinc in various formulations or delivery systems that might adversely affect our ability or the ability of Meda to develop and market these products in the U.S. We are aware that other companies have intellectual property protection using the active ingredients and have conducted clinical trials of flupirtine, estriol and zinc for different applications than what we are developing. Many of these companies may have more resources than us. We cannot provide any assurances that our products will be FDA-approved prior to our competitors.

If a product containing our active ingredients is already marketed or if the FDA approves other products containing our active ingredients in the future to treat indications, physicians may elect to prescribe and substitute a competitor's products to treat the diseases for which we are intending to commercialize; this is commonly referred to as "off-label" use. While under FDA regulations a competitor is not allowed to promote off-label uses of its product, the FDA does

not regulate the practice of medicine and, as a result, cannot direct physicians to select certain products for their patients. Consequently, we might be limited in our ability to prevent off-label use of a competitor's product to treat the diseases we are intending to commercialize, even if we have issued method of use patents for that indication. If we are not able to obtain and enforce our patents, if any, or otherwise receive orphan drug protection in the case of ALS, a competitor could develop and commercialize similar products for the same indications that we are pursuing. We cannot provide any assurances that a competitor will not obtain FDA approval for a product that contains the same active ingredients as our products.

We rely on method patents and patent applications and various regulatory exclusivities to protect some of our product candidates and our ability to compete may be limited or eliminated if we are not able to protect our products.

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

Our AEN-100 drug candidate (gastroretentive zinc acetate) is the subject of U.S. and international pending patent applications, such as published U.S. patent application Ser. No. 11/621,962 and corresponding international applications that claim priority to January 10, 2006 as well as additional patent applications. On October 26, 2011, we received a final rejection letter with regard to U.S. patent application Ser. No. 11/621,962. On February 15, 2012, we filed a Request for Continued Examination.

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

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

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

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

As of November 30, 2012, we had twelve employees. We have also engaged clinical consultants to advise us on our clinical programs and regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. We have been and will be required to retain additional consultants and employees in order to fulfill our obligations under our exclusive channel collaborations with Intrexon. Our future performance will depend in part on our ability to successfully integrate newly hired officers into our management team and our ability to develop an effective working relationship among senior management.

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

with our interests.

Losing key personnel or failing to recruit necessary additional personnel would impede our ability to attain our development objectives. There is intense competition for qualified personnel in the drug-development field, and we may not be able to attract and retain the qualified personnel we would need to develop our business.

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

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

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards and use in clinical trials of our products and, after approval, for commercial distribution. We have not yet established a cGMP manufacturer for neither our DNA-based nor monoclonal antibody therapies. Our AEN-100 product candidate has limited stability data to date and is the subject of ongoing stability studies. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us, or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

If successful large-scale manufacturing of DNA-based products is not possible, we or our collaborators may be unable to manufacture enough of our product candidates to achieve regulatory approval or market our DNA-based products.

Few companies to date have demonstrated successful large-scale manufacturing of DNA-based products, including those that have had significantly more resources than us and it is anticipated that significant challenges will be faced in the scale-up of our manufacturing process for commercial production. There are a limited number of contract manufacturers qualified to perform large-scale manufacturing of DNA-based products. We or our collaborators may be unable to manufacture commercial-scale quantities of DNA-based products or receive appropriate government approvals on a timely basis or at all. Failure to successfully manufacture or obtain appropriate government approvals on a timely basis or at all would prevent us from achieving our business objectives.

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

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

- obtaining an IND application with the FDA to commence clinical trials;
- identification of, and acceptable arrangements with, one or more clinical sites;
- obtaining IRB approval to commence clinical trials;
- unforeseen safety issues;
- determination of dosing;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unwillingness of the FDA or IRBs to permit the clinical trials to be initiated.

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

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

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

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

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

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

We are also highly dependent on government and private grants to fund certain of our clinical trials for our product candidates. For example, Trimesta (oral estriol) has received grants totaling over $8 million, predominantly from the Southern California Chapter of the NMSS and the National Institutes of Health which funds a majority of the ongoing clinical trial in relapsing-remitting MS for women. Although we believe that the grant funding received to date is sufficient to complete the current clinical trial based upon current cost estimates, if we experience any additional unanticipated costs or require further clinical trials, and our scientific collaborator is unable to maintain or receive additional grants, we might be forced to scale back or terminate the development of this product candidate. We will also need to cross reference our IND with the inventor/IND holder for this program should we elect to file our own corporate IND for our Trimesta (oral estriol) program. The on-going and future development and commercialization of Effirma (flupirtine) for fibromyalgia is the responsibility of Meda AB and no assurance can be given that Meda will gain the FDA's acceptance of the NDA or obtain NDA approval from the FDA of flupirtine for fibromyalgia.

Our AEN-100 program for ALS is reliant on the investigator-initiated IND of PNA. The planned clinical trial that we intend to conduct with PNA is still the subject of further protocol development. In addition, we may need to conduct additional clinical or non-clinical studies to support a New Drug Application or to support further clinical trials. Any additional studies of AEN-100 may produce unanticipated and unacceptable safety, tolerability or bioavailability results that may substantially delay further development work of the planned clinical trial.

With respect to our synthetic biologic product candidates, we are dependent upon Intrexon's synthetic biology facilities and capabilities as we have no such facilities and capabilities of our own. We are also reliant on their vector engineering platform, gene expression switch technology, monoclonal antibody discovery, production cell line development and know-how. If any of the foregoing were to become inaccessible or terminated, it would be difficult for us to develop and commercialize our synthetic biologic product candidates.

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

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

involving our issued patents and pending applications of another entity.

The intellectual property environment in the area of DNA-based therapeutics is particularly complex, constantly evolving and highly fragmented. Other companies and institutions have issued patents and have filed or will file patent applications that may issue into patents that cover or attempt to cover genes, vectors, cell lines, and methods of making and using DNA and DNA-based therapy products used in, or similar to our product candidate, and technologies. The same is true of the monoclonal antibody field in terms of methods of producing monoclonal antibodies for human use. We have not conducted freedom-to-use patent searches on all aspects of our product candidates or potential product candidates, and we may be unaware of relevant patents and patent applications of third parties. In addition, the freedom-to-use patent searches that have been conducted may not have identified all relevant issued patents or pending patents. We cannot provide assurance that our proposed products in this area will not ultimately be held to infringe one or more valid claims owned by third parties which may exist or come to exist in the future or that in such case we will be able to obtain a license from such parties on acceptable terms.

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

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

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

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

RISKS RELATING TO OUR STOCK

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

We expect to seek to raise additional capital in the future to help fund development of our proposed products. If we raise additional capital through the issuance of equity or of debt securities, the percentage ownership of our current stockholders will be reduced. We may also enter into strategic transactions, issue equity as part of license issue fees to our licensors, compensate consultants or settle outstanding payables using equity that may be dilutive. Our stockholders may experience additional dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of the holders of our common stock.

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

Currently, our directors, executive officers, and principal stockholders beneficially own a substantial number of shares of our common stock. As a result, they will be able to exert substantial influence over the election of our Board of Directors and the vote on issues submitted to our stockholders. Our executive officers and directors beneficially owned approximately 8.7 million shares of our common stock, including stock options and warrants exercisable within 60 days of December 1, 2012. Our executive officers, directors and principal stockholders together beneficially owned approximately 18.5 million shares of our common stock, including the stock options and warrants exercisable within 60 days of December 1, 2012. Because our common stock has from time to time been “thinly traded”, the sale of a substantial number of shares by our executive officers, directors and principal stockholders would have an adverse effect on the market for our stock and our share price.

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

Our common stock has from time to time been “thinly-traded,” meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a

large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give stockholders any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

We cannot assure you that the common stock will be liquid or that it will remain listed on the NYSE MKT.

We cannot assure you that we will be able to maintain the continued listing standards of the NYSE MKT (formerly the NYSE Amex and the American Stock Exchange). The NYSE MKT requires companies to meet certain continued listing criteria including certain minimum stockholders' equity and equity prices per share as outlined in the NYSE MKT Exchange Company Guide. We may not be able to maintain such minimum stockholders' equity or prices per share or may be required to effect a reverse stock split to maintain such minimum prices and/or issue additional equity securities in exchange for cash or other assets, if available, to maintain certain minimum stockholders' equity required by the NYSE MKT. If we are delisted from the NYSE MKT then our common stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board securities market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our common stock could depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the NYSE MKT could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities. In order to remain listed on NYSE MKT, we are required to maintain a minimum stockholders’ equity of $6 million. The net proceeds of $10.1 million from our recent financing increased our stockholders’ equity well above the minimum requirement of $6 million. However, we could be subject to certain additional regulatory requirements or additional inquiries from the NYSE MKT, because our stockholders’ equity at September 30, 2012 was $5.4 million.

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

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

Our failure to fulfill all of our registration requirements may cause us to suffer liquidated damages, which may be very costly.

The Registration Rights Agreement that we entered into in connection with the October 2012 Private Placement requires that we file the Initial Registration Statement with the Commission on or prior to the Filing Date and that the Initial Registration Statement is declared effective by the Commission on or prior to the Effectiveness Date subject to certain adjustments. Upon the occurrence of an Event, including, but not limited to, that the Initial Registration Statement is not filed prior to the Filing Date or declared effective prior to the Effectiveness Date, the Company will be required to pay to each of the Purchasers liquidated damages of 1.5% of their aggregate purchase price upon the date of the Event and then monthly thereafter until the Event is cured. In no event will the aggregate amount of liquidated damages payable to each of the Purchasers exceed in the aggregate 10% of the aggregate purchase price paid by such Purchaser. In addition, pursuant to the terms of the registration rights agreement that we entered into with Intrexon and an affiliated entity, we are required to file a registration statement with respect to securities issued to them within a certain time period and maintain the effectiveness of such registration statement. The failure to do so could result in the payment of damages by us. There can be no assurance as to when the Initial Registration Statement will be declared effective or that we will be able to maintain the effectiveness of any registration statement, and therefore there can be no assurance that we will not incur penalties or damages with respect to such agreements.

RISKS RELATED TO OUR INDUSTRY

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

In the U.S., the formulation, manufacturing, packaging, storing, labeling, promotion, advertising, distribution and sale of our products are subject to regulation by various governmental agencies, including (1) the FDA, (2) the Federal Trade Commission, or FTC, (3) the Consumer Product Safety Commission, or CPSC, (4) the U.S. Department of Agriculture, or USDA. Our proposed activities may also be regulated by various agencies of the states, localities and foreign countries in which our proposed products may be manufactured, distributed and sold. The FDA, in particular, regulates the formulation, manufacture and labeling of over-the-counter, or OTC drugs, prescription drugs, conventional foods, dietary supplements, and cosmetics such as those that we intend to distribute. FDA regulations require us and our suppliers to meet relevant cGMP regulations for the preparation, packing, labeling, and storage of all drugs and foods.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing FDA regulation, including record-keeping requirements, reporting of adverse experiences, submitting periodic reports,

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

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

We intend to develop our zinc candidate, AEN-100, as a drug and intend to file an IND with the FDA in order to conduct necessary clinical trials to support new medical claims and ultimately file one or more NDA with respect to such products which would subject us to time, expense and uncertainty associated with achieving approval of such NDA by the FDA.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

USE OF PROCEEDS

All of the shares of common stock covered by this prospectus are being sold by the Selling Stockholders. See “Selling Stockholders” on page 18. We will not receive any proceeds from these sales of shares of our common stock. A portion of the Shares covered by this prospectus are issuable upon exercise of the Agent Warrants to purchase our common stock. Upon any exercise of the Agent Warrants for cash, such Selling Stockholders would pay us the exercise price of the warrants. Cash received from exercise of Agent Warrants will be used for general corporate purposes. Additionally, the Agent Warrants are exercisable on a cashless basis. If any Agent Warrants are exercised on a cashless basis, we would not receive any cash payment from such Selling Stockholders upon any exercise of such Agent Warrants.

The Selling Stockholders will pay any underwriting discounts and commissions and expenses incurred by the Selling Stockholders for brokerage, accounting, tax, or legal services or any other expenses incurred by the Selling Stockholders in disposing of the Shares. We will bear all other costs, fees, and expenses incurred in effecting the registration of the Shares covered by this prospectus, including, without limitation, all registration and filing fees, and fees and expenses of our counsel and our accountants.

SELLING STOCKHOLDERS

We have prepared this prospectus to allow the Selling Stockholders or their successors, assignees or other permitted transferees to sell or otherwise dispose of, from time to time, up to 4,260,855 shares of our common stock. This prospectus covers the offer and disposition by the Selling Stockholders identified below, or their transferee(s), of a total of 4,260,855 shares of our common stock. Of the shares of common stock being offered under this prospectus 3,625,000 were acquired by the purchasers in our October 2012 Private Placement and 635,855 shares are able to be acquired pursuant to the Agent Warrants we issued in connection with our October 2012 Private Placement, which Agent Warrants are currently exercisable.

The Shares sold to the Selling Stockholders in the October 2012 Private Placement were sold pursuant to an exemption from registration provided by Rule 506 of Regulation D under the Securities Act. In connection therewith, the investors made to us certain representations, warranties, covenants, and conditions customary for private placement investments.

The table below presents information regarding the Selling Stockholders and the Shares that they may sell or otherwise dispose of from time to time under this prospectus. The table is based on information supplied to us by the Selling Stockholders and reflects holdings as of December 7, 2012. Percentages of beneficial ownership are based

upon 44,332,748 shares of common stock outstanding as of December 7, 2012. Beneficial ownership is determined under Section 13(d) of the Securities Exchange Act of 1934 (the "Exchange Act of 1934") and generally includes voting or investment power with respect to securities and including any securities that grant the Selling Stockholders the right to acquire common stock within 60 days of December 7, 2012. Unless otherwise noted, each person or group identified possesses sole voting and investment power with respect to the Shares, subject to community property laws where applicable.

We do not know when or in what amounts the Selling Stockholders may sell or otherwise dispose of the Shares covered hereby. We currently have no agreements, arrangements or understandings with the Selling Stockholders regarding the sale of any of the Shares by them other than the registration rights agreements described below. The Selling Stockholders might not sell any or all of the Shares covered by this prospectus or may sell or dispose of some or all of the Shares other than pursuant to this prospectus. Because the Selling Stockholders may not sell or otherwise dispose of some or all of the Shares covered by this prospectus and because there are currently no agreements, arrangements or understandings with respect to the sale or other disposition of any of the Shares, we cannot estimate the number of the Shares that will be held by the Selling Stockholders after completion of the offering.

Each Selling Stockholder has indicated to us that neither it nor any of its affiliates has held any position or office or had any other material relationship with us in the past three years except as described in the footnotes to the table.

The Shares being offered under this prospectus may be offered for sale from time to time during the period the registration statement of which this prospectus is a part remains effective, by or for the accounts of the Selling Stockholders named below.

The Selling Stockholders, or their partners, pledgees, donees, transferees or other successors that receive the Shares and their corresponding registration in accordance with the registration rights agreement to which the Selling Stockholder is party (each also a Selling Stockholder for purposes of this prospectus), may sell up to all of the Shares shown in the table below under the heading "Total Shares Offered By Selling Stockholder in the Offering Covered by this Prospectus" pursuant to this Prospectus in one or more transactions from time to time as described below under "Plan of Distribution." However, the Selling Stockholders are not obligated to sell any of the Shares offered by this prospectus.

Information about the Selling Stockholders may change from time to time. Any changed information with respect to which we are given notice will be included in prospectus supplements.

Selling Stockholder	Shares Beneficially Owned Before the Sale of all Shares Covered by this Prospectus	Percentage of Beneficial Ownership Before the Sale of all Shares Covered by this Prospectus	Total Shares Offered By Selling Stockholder in the Offering Covered by this Prospectus	Shares Beneficially Owned After the Sale of all Shares Covered by this Prospectus	Percentage of Beneficial Ownership After the Sale of all Shares Covered by this Prospectus
Allen Adler	193,750	*	93,750	100,000	*
Helen Hartnett, IRA Custodian	31,250	*	31,250	0	*
Roger J. LaGratta, IRA Custodian	227,500	*	187,500	40,000	*
Eugene Mark Landry, IRA Custodian	31,250	*	31,250	0	*
Barry Peters Roth IRA Custodian	31,250	*	31,250	0	*
Christopher Basta	31,250	*	31,250	0	*
Belmont Ventures, Inc.(1)	1,562,500	3.5%	312,500	1,250,000	2.8%
Capital Ventures International(2)	150,000	*	150,000	0	*
Carruthers Living Trust UAD 4/1/04(3)	100,000	*	100,000	0	*
Chulick Family Trust(4)	93,750	*	93,750	0	*
John LaGratta	300,000	*	100,000	200,000	*
Stephen S. Lipton	15,000	*	15,000	0	*
Mintz and Co.(5)	31,250	*	31,250	0	*
Sean E. McCance	62,500	*	62,500	0	*
Richard Molinsky	30,000	*	30,000	0	*
MSD Credit Opportunity Master Fund, L.P.(6)	2,100,000	4.7%	2,100,000	0	*
Richard R. Redmond	31,250	*	31,250	0	*
Dominick Ruggiero	50,000	*	50,000	0	*
Smokeshire Partners LLC(7)	62,500	*	62,500	0	*
Louis Vigden	30,000	*	30,000	0	*
Laurence Zalk	50,000	*	50,000	0	*
Griffin Securities, Inc.(8)	411,834	*	311,834	100,000	*

Adrian Z. Stecyk (9)	723,667	1.6%	623,667	100,000	*
Salvatore Saraceno(10)	7,500	*	7,500	0	*
George Stephenson(11)	4,688	*	4,688	0	*

*less than 1%

(1) Joel C. Flint is the authorized agent for Belmont Ventures and as such has voting and investment power over the shares listed.

(2) Heights Capital Management, Inc. is the authorized agent for Capital Ventures International ("CVI"), has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc, may also be deemed to have investment discretion and voting power over the shares held by CVI. Mr. Kobinger disclaims any such beneficial ownership of these shares.

(3) James L. Carruthers, Jr. is trustee of the Caruthers Living Trust and as such has voting and investment power over the shares listed.

(4) John Chulick and Kathi Chulick are trustees of the Chulick Family Trust and as such have voting and investment power over the shares listed.

(5) Mintz and Co. is the record and direct beneficial owner of the shares of common stock. Lowell A. Mintz is the senior partner of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, Mintz and Co.

(6) MSD Credit Opportunity Master Fund, L.P. is the record and direct beneficial owner of the securities. MSDC Management, L.P. is the investment manager of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, MSD Credit Opportunity Master Fund L.P. MSDC Management (GP), LLC is the general partner of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, MSDC Management, L.P. Each of Glenn R. Fuhrman, John C. Phelan and Marc R. Lisker is a manager of MSDC Management (GP) and may be deemed to have or share voting and/or dispositive power over, and beneficially own, the common stock beneficially owned by MSDC Management(GP) Each of Mr. Fuhrman, Mr. Phelan and Mr. Lisker disclaim beneficial ownership of such common stock, except to the extent of the pecuniary interest of such person in such shares.

(7) Smokeshire Partners, LLC is the record and direct beneficial owner of the shares of common stock. Mintz and Co. is the manager of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, Smokeshire Partners, LLC. Lowell A. Mintz is the senior partner of, and may be deemed to have or share voting and dispositive power over, and/or beneficially own securities owned by, Mintz and Co.

(8) Includes 311,834 shares of our common stock issuable upon exercise of the Agent Warrants issued to Griffin Securities, Inc. (“Griffin”), as our placement agent in our October 2012 Private Placement and 100,000 shares of our common stock issuable upon exercise of warrants issued to Griffin for financial advisory services in accordance with the terms of a financial advisory agreement we entered into with Griffin in December 2011. Griffin is a registered broker-dealer that served as the placement agent in connection with our October 2012 Private Placement. Adrian Stecyk is the Chief Executive Officer of Griffin and an affiliate of a registered-broker-dealer. Mr. Stecyk has voting and dispositive power with respect to the warrants and the underlying shares.

(9) Includes 411,834 shares of common stock issuable upon exercise of the Agent Warrants issued to Griffin and financial advisor warrants issued to Griffin and 311,833 shares of common stock issuable upon exercise of warrants issued to Mr. Stecyk. Mr. Stecyk has voting and dispositive power with respect to the warrants and the underlying shares.

(10) Consists of shares of common stock issuable upon exercise of the Agent Warrants issued to Mr. Saraceno. Mr. Saraceno is an employee of Griffin. Griffin is a registered broker-dealer that served as the placement agent in connection with our October 2012 Private Placement.

(11) Consists of shares of common stock issuable upon exercise of the Agent Warrants issued to Mr. Stephenson. Mr. Stephenson is an employee of Griffin. Griffin is a registered broker-dealer that served as the placement agent in connection with our October 2012 Private Placement.

DETERMINATION OF OFFERING PRICE

The Selling Stockholders will determine at what price they may sell the offered Shares, and such sales may be made at prevailing market prices, or at privately negotiated prices.

PLAN OF DISTRIBUTION

We are registering the shares of common stock previously issued to the Selling Stockholders to permit the resale of these shares of common stock by the holders of the common stock from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the Selling Stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The Selling Stockholders, or their pledges, donees, transferees, or any of their successors in interest selling shares received from a Selling Stockholder as a gift, partnership distribution or other non-sale related transfer after the date of this prospectus, may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the Selling Stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. The Selling Stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. These sales may be affected in transactions, which may involve crosses or block transactions,

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- through the distribution of the common stock by any Selling Stockholders to its partners, members or Stockholders;
- through one or more underwritten offerings on a firm commitment or best efforts basis;
- sales pursuant to Rule 144;
- broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also transfer the Shares by gift. The Selling Stockholders may engage brokers and dealers, and any brokers or dealers may arrange for other brokers or dealers to participate in effecting sales of the Shares. These brokers, dealers or underwriters may act as principals, or as an agent of a Selling Stockholder. Broker-dealers may agree with a Selling Stockholder to sell a specified number of the Shares at a stipulated price per security. If the broker-dealer is unable to sell the Shares acting as agent for a Selling Stockholder, it may purchase as principal any unsold Shares at the stipulated price. Broker-dealers who acquire Shares as principals may thereafter resell the Shares from time to time in transactions in any stock exchange or automated interdealer quotation system on which the Shares are then listed, at prices and on terms then prevailing at the time of sale, at prices related to the then-current market price or in negotiated transactions. Broker-dealers may use block transactions and sales to and through broker-dealers, including transactions of the nature described above.

The Selling Stockholders may also sell the Shares in accordance with Rule 144 under the Securities Act, rather than pursuant to this prospectus, regardless of whether the Shares are covered by this prospectus.

If the Selling Stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the Selling Stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of common stock or otherwise, the Selling Stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the

shares of common stock in the course of hedging in positions they assume. The Selling Stockholders may also sell shares of common stock short and deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The Selling Stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares.

The Selling Stockholders may pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending, if necessary, the list of Selling Stockholders to include the pledgee, transferee or other successors in interest as Selling Stockholders under this prospectus. The Selling Stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In addition, a Selling Stockholder may, from time to time, sell the Shares short, and, in those instances, this prospectus may be delivered in connection with the short sales and the Shares offered under this prospectus may be used to cover short sales.

The Selling Stockholders and any broker-dealer participating in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of common stock is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of shares of common stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the Selling Stockholders and any discounts, commissions or concessions allowed or reallowed or paid to broker-dealers. The Selling Stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares of common stock against certain liabilities, including liabilities arising under the Securities Act.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any Selling Stockholder will sell any or all of the shares of common stock registered pursuant to the registration statement, of which this prospectus forms a part.

The Selling Stockholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act of 1934 and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act of 1934, which may limit the timing of purchases and sales of any of the shares of common stock by the Selling Stockholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

The shares of common stock offered hereby were originally issued to the Selling Stockholders pursuant to an exemption from the registration requirements of the Securities Act. We agreed to register the shares of common stock under the Securities Act, and to keep the registration statement of which this prospectus is a part effective until the earlier of the date on which the Selling Stockholders have sold all of the securities or one year after the shares were acquired by the Selling Stockholder. We will pay all expenses of the registration of the shares of common stock

pursuant to the Registration Rights Agreement, estimated to be $30,000 in total, including, without limitation, Commission filing fees and expenses of compliance with state securities or "Blue Sky" laws; *provided*, *however*, that a Selling Stockholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the Selling Stockholders against liabilities, including some liabilities under the Securities Act, in accordance with the Registration Rights Agreement, or the Selling Stockholders will be entitled to contribution. We may be indemnified by the Selling Stockholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the Selling Stockholder specifically for use in this prospectus, in accordance with Registration Rights Agreement, or we may be entitled to contribution.

Once sold under the registration statement, of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

DESCRIPTION OF SECURITIES

Our authorized capital consists of 100 million shares of common stock, par value $0.001 per share, and 10 million shares of preferred stock, par value $0.001 per share. As of December 7, 2012, 44,332,748 shares of common stock and no shares of preferred stock were outstanding.

Common Stock

Holders of shares of common stock have the right to cast one vote for each share of common stock in their name on the books of our company, whether represented in person or by proxy, on all matters submitted to a vote of holders of common stock, including election of directors. There is no right to cumulative voting in election of directors. Except where a greater requirement is provided by statute, by our articles of incorporation, or by our bylaws, the presence, in person or by proxy duly authorized, of the one or more holders of a majority of the outstanding shares of our common stock constitutes a quorum for the transaction of business. The vote by the holders of a majority of outstanding shares is required to effect certain fundamental corporate changes such as liquidation, merger, or amendment of our articles of incorporation.

There are no restrictions in our articles of incorporation or bylaws that prevent us from declaring dividends. We have not declared any dividends, and we do not plan to declare any dividends in the foreseeable future.

Holders of shares of our common stock are not entitled to preemptive or subscription or conversion rights, and no redemption or sinking fund provisions are applicable to our common stock. All outstanding shares of common stock are, and the shares of common stock sold in the offering will when issued be fully paid and non-assessable.

Warrants

Outstanding Warrants

As of November 29, 2012, we had issued and outstanding a total of 1,632,501 and 1,432,501 warrants, respectively, to purchase our common stock outstanding at a weighted-average price of $1.99 and $1.96, respectively. Included in the number of outstanding warrants are (a) Agent Warrants to acquire an aggregate of 635,855 shares of our common stock at an exercise price of $1.60 per share for a five year period (subject to a cashless exercise provision) we issued to Griffin and its designees in connection with the closing of our October 2012 Private Placement on October 30, 2012, the underlying shares of which are being registered under the registration statement of which this prospectus forms a part; and (b) additional warrants to acquire 100,000 shares of our common stock issued to our Griffin in December 2012 for financial advisory services in accordance with the terms of our financial advisory agreement we entered into with them.

Contingent Share Issuance-Intrexon – First Exclusive Channel Collaboration Agreement

On December 7, 2011, pursuant to the First Stock Issuance Agreement between us and Intrexon, we issued to Intrexon 3,123,558 shares of our common stock as a technology access fee, in consideration for the execution and delivery of the First Chanel Agreement we entered into with Intrexon. We also agreed to issue additional shares of our common stock to Intrexon upon dosing of the first patient in our sponsored Phase II clinical trial in the United States, or similar study as the parties may agree in a country other than the United States, of a product under the First Channel Agreement. Upon satisfaction of such contingency, we agreed to issue to Intrexon an additional 3,123,558 shares of common stock, subject to certain adjustments, for a purchase price equal to the $0.001 par value of such shares, which issuance was deemed paid in partial consideration for the execution and delivery of the First Channel Agreement.

Equity Participation Right-Intrexon

Under the First Stock Purchase Agreement, Intrexon is entitled, at its election, to (i) participate in our future securities offerings that constitute "Qualified Financings" and purchase securities equal to 19.99% of the number of shares of common stock or other securities sold in such offering. For this purpose, a "Qualified Financing" means a sale of common stock or equity securities convertible into common stock in a public or private offering, raising gross proceeds of at least $5,000,000, where the sale of shares is either registered under the Securities Act, at the time of issuance or we agrees to register the resale of such shares, and (ii) without restriction, purchase an additional number of shares of common stock in the open market, or otherwise, that do not exceed an additional 10% of the number of shares of common stock then issued and outstanding; Intrexon waived its right to participate in the October 2012 Private Placement ..

Second Exclusive Channel Collaboration Agreement

On August 6, 2012, we expanded our relationship with Intrexon and entered into the Second Channel Agreement with Intrexon that governs a "channel collaboration" arrangement in which we will use Intrexon's technology relating to the identification, design and production of human antibodies and DNA vectors for the development and commercialization of a series of monoclonal antibody therapies for the treatment of certain serious infectious diseases (collectively, the "Program"). On October 16, 2012, we issued 3,552,210 shares of our common stock to Intrexon which issuance is deemed paid in partial consideration for the execution and delivery of the Second Channel Agreement.

We also agreed upon the filing of an Investigational New Drug application with the U.S. Food and Drug Administration for a Synthetic Product (as defined in the agreement), or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency (both as applicable, the "IND Milestone Event"), to pay Intrexon either (i) two million dollars ($2M) in cash, or (ii) that number of shares of common stock (the "IND Milestone Shares") having a fair market value equaling two million dollars ($2M) where such fair market value is determined using published market data of the share price for common stock at the close of market on the business day immediately preceding the date of public announcement of attainment of the IND Milestone Event.

We also agreed upon the first to occur of either first commercial sale of a Synthetic Product in a country or the granting of the regulatory approval of that Synthetic Product (both as applicable, the "Approval Milestone Event"), to pay to Intrexon either (i) three million dollars ($3M) in cash, or (ii) that number of shares of common stock (the "Approval Milestone Shares") having a fair market value equaling three million dollars ($3M) where such fair market value is determined using published market data of the share price for common stock at the close of market on the business day immediately preceding the date of public announcement of attainment of the Approval Milestone Event.

We has also agreed that we will pay an optional and varying fee whereby we remit a payment, in cash or equity at our sole discretion, to Intrexon calculated as a multiple of the number of targets in excess of three (3) total that we desire to elect (the "Field Expansion Fee"). The Field Expansion Fee must be paid completely in either common stock or cash, and will comprise either (i) two million dollars ($2M) in cash for each target in excess of three (3) total that we will elect, or (ii) that number of shares of common stock (the "Field Expansion Fee Shares") having a fair market value equaling two million dollars ($2M) for each such target that we will elect in excess of three where such fair market value is determined using published market data establishing the volume-weighted average price for a share of common stock over the thirty (30) day period immediately preceding the date of the Field Expansion Fee Closing.

Prev Contingent Share Issuances

On November 28, 2012, a closing was held for the transaction contemplated by the Prev Agreement we entered into with Prev pursuant to which we acquired the *C. diff* program assets of Prev, including pre-Investigational New Drug (IND) package, Phase I and Phase II clinical data, manufacturing process data and all issued and pending U.S. and international patents. Pursuant to the Prev Agreement, we paid Prev an initial cash payment of $100,000 upon execution of the Prev Agreement and at closing paid an additional cash payment of $135,000 and issued 625,000 unregistered shares of our common stock to Prev. In addition, upon the achievement of the milestones set forth below, Prev may be entitled to receive additional consideration payable 50% in cash and 50% in our stock, subject to Prev's option to receive the entire payment in shares of our stock, with the exception of the first milestone payments to be paid in cash: (i) upon commencement of an IND; (ii) upon commencement of a Phase I clinical trial; (iii) upon commencement of a Phase II clinical trial; (iv) upon commencement of a Phase III clinical trial; (v) upon Biologic License Application (BLA) filing in the U.S. and for territories outside of the U.S. (as defined in the Prev Agreement); and (vi) upon BLA approval in the U.S. and upon approval in territories outside the-U.S. The future stock issuances are subject to prior approval of the NYSE MKT, LLC. No royalties are payable to Prev under the Prev Agreement.

Registration Rights

In connection with the October 2012 Private Placement, we entered into a registration rights agreement with each of the Selling Stockholders (the "Registration Rights Agreement"). The Registration Rights Agreement requires us to file a registration statement (the "Registration Statement") with the Commission within 45 days of the closing date of the October 2012 Private Placement (the "Filing Date") for the resale by the Selling Stockholders of all of the Registrable Securities. We agreed to use our commercially reasonable efforts to cause the Registration Statement to be declared effective by the Commission no later than 90 days after the closing date of the October 2012 Private Placement (the "Effectiveness Date") subject to certain adjustments. Upon the occurrence of an Event, including, but not limited to, that the Registration Statement is not declared effective prior to the Effectiveness Date, we will be required to pay liquidated damages to each of the Selling Stockholders equal to 1.5% of the aggregate purchase price paid by such Selling Stockholders for the Registrable Securities upon the date of the Event and then monthly thereafter until the earlier of: (i) the Event is cured, or (ii) the Registrable Securities are eligible for resale without subsequent registration under the Securities Act. In no event shall the aggregate amount of liquidated damages payable to each of the Selling

Stockholders exceed in the aggregate 10% of the aggregate purchase price paid by such Selling Stockholders for the Registrable Securities. We also agreed to use our commercially reasonable efforts to keep the Registration Statement effective for resales until the earlier of the date that all of the shares of our common stock included in the Registration Statement have been resold thereunder or under Rule 144 promulgated under the Securities Act. The registration rights agreement contains cross-indemnification provisions between us and the Selling Stockholders.

In connection with the transactions contemplated by the Second Stock Issuance Agreement, and pursuant to the First Amendment to Registration Rights Agreement executed and delivered by the parties in August 2012 (the "First Amendment to Registration Rights Agreement"), the Company agreed to file a "resale" registration statement registering the resale of the shares issued and to be issued under the Second Stock Issuance Agreement on or prior to April 30, 2013. Under that agreement, we are obligated to use our reasonable best efforts to cause the "resale" registration statement to be declared effective as promptly as practicable after filing and to maintain the effectiveness of the registration statement until all securities therein are sold or are otherwise can be sold pursuant to Rule 144, without any restrictions. In addition, we also entered into a Joinder Agreement with a certain purchaser in the October 2012 Private Placement that is an affiliate of Intrexon pursuant to which such party agreed to be bound by the terms of and join Intrexon as a party to the First Amendment to Registration Rights Agreement.

In connection with the transactions contemplated by the First Stock Purchase Agreement, and pursuant to the Registration Rights Agreement executed and delivered by us to Intrexon, we agreed to file a "resale" registration statement registering the resale of the First Tranche Shares within 120 days of the closing date of such issuance. The registration statement registering such shares was declared effective on April 13, 2012, but is no longer valid due to certain issues regarding the failure of our prior auditor to follow proper partner rotation. Intrexon has agreed not to require us to file a post effective registration statement on Form S-1 with respect to the First Tranche Shares and instead has agreed to wait until we are once again S-3 eligible to require registration of such shares.

Preferred Stock

Our Board of Directors has the authority, without action by our stockholders, to designate and issue up to 10 million shares of preferred stock in one or more series or classes and to designate the rights, preferences and privileges of each series or class, which may be greater than the rights of our common stock. We do not have any shares of preferred stock either designated or outstanding. It is not possible to state the actual effect of the issuance of any shares of preferred stock upon the rights of holders of our common stock until our Board of Directors determines the specific rights of the holders of the preferred stock. However, the effects might include:

- restricting dividends on our common stock;
- diluting the voting power of our common stock;
- impairing liquidation rights of our common stock; or
- delaying or preventing a change in control of us without further action by our stockholders.

The Board of Directors' authority to issue preferred stock without stockholder approval could make it more difficult for a third-party to acquire control of our company, and could discourage such attempt. We have no present plans to issue any shares of preferred stock.

Listing of Common Stock

Our common stock is currently traded on the NYSE MKT, LLC under the trading symbol "SYN."

Transfer Agent

We have retained Corporate Stock Transfer as our transfer agent. They are located at 3200 Cherry Creek Drive, Denver, Colorado 80209. Their telephone number is (303) 282-4800 and facsimile is (303) 282-5800.

EXPERTS

The financial statements as of December 31, 2011 and 2010 and for the years then ended included in this Form S-1 Registration Statement have been so included in reliance on the reports of Berman & Company, P.A., an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION

FOR SECURITIES ACT LIABILITIES

Our Articles of Incorporation provide that no officer or director shall be personally liable to us or our stockholders for monetary damages except as provided pursuant to the Nevada Revised Statutes. Our bylaws and Articles of Incorporation also provide that we will indemnify and hold harmless each person who serves at any time as a director, officer, employee or agent of us from and against any and all claims, judgments and liabilities to which such person shall become subject by reason of the fact that he is or was a director, officer, employee or agent of us, and shall reimburse such person for all legal and other expenses reasonably incurred by him or her in connection with any such claim or liability. We also have the power to defend such person from all suits or claims in accordance with the Nevada Revised Statutes. The rights accruing to any person under our bylaws and Articles of Incorporation do not exclude any other right to which any such person may lawfully be entitled, and we may indemnify or reimburse such person in any proper case, even though not specifically provided for by the bylaws and Articles of Incorporation.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the small business issuer pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the small business issuer for expenses incurred or paid by a director, officer or controlling person of the small business issuer in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

LEGAL MATTERS

The validity of our common stock offered hereby will be passed upon for us by Gracin & Marlow, LLP, New York, New York.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act of 1934, and file annual and current reports, proxy statements and other information with the Commission. These reports, proxy statements and other information filed by us can be read and copied at the Commission's Public Reference Room at 100 F Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330.

The Commission also maintains a website that contains reports, proxy statements, information statements and other information concerning our company located at http://www.sec.gov. This prospectus does not contain all the information required to be included in the registration statement (including the exhibits), which we have filed with the Commission under the Securities Act and to which reference is made in this prospectus.

You may obtain, free of charge, a copy of any of our filings by writing or calling us at the following address and telephone number: 617 Detroit Street, Suite 100, Ann Arbor, Michigan 48104 or calling (734) 332-7800.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The Commission allows us to "incorporate by reference" into this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. Information incorporated by reference is considered to be part of this prospectus, except for any information that is superseded by information included directly in this prospectus. Any statement contained in this prospectus or a document incorporated by reference in this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in any other subsequently filed document that is incorporated by reference in this prospectus modifies or superseded the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus. We incorporate by reference the documents listed below (excluding any portions of such documents that have been "furnished" but not "filed" for purposes of the Securities Act).

- Our Annual Report on Form 10-K/A for the year ended December 31, 2011, filed with the Commission on March 30, 2012, as amended on May 11, 2012;
- Our Definitive Proxy Statement on Schedule 14A, filed with the Commission on January 4, 2012 and September 11, 2012;
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Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2012, June 30, 2012 and September 30, 2012, filed with the Commission on May 15, 2012 and August 14, 2012, as amended on September 11, 2012, and November 14, 2012, respectively; and

- Our Current Reports on Form 8-K, filed December 21, 2012, December 6, 2012, December 3, 2012, November 14, 2012, November 13, 2012, October 31, 2012, October 17, 2012, October 5, 2012, August 14, 2012, August 9, 2012, July 18, 2012, July 10, 2012, June 18, 2012, May 15, 2012, May 11, 2012, May 3, 2012, April 24, 2012, March 30, 2012, March 12, 2012, February 16, 2012, February 13, 2012, February 7, 2012, February 6, 2012 and our amendment to a Current Report on Form 8-K filed February 3, 2012 and May 30, 2012.

We will provide a copy of any and all of the information that is incorporated by reference in this prospectus to any person, including a beneficial owner, to whom a prospectus is delivered, without charge, upon written or oral request. Written requests for copies should be directed to Attention: C. Evan Ballantyne, Chief Financial Officer, Synthetic Biologics, Inc. 617 Detroit Street, Suite 100, Ann Arbor, Michigan, 48104. Telephone requests for copies should be directed to the Chief Financial Officer at (734) 332-7800.

We maintain an Internet website at www.syntheticbiologics.com where the incorporated reports listed above can be accessed. Neither this website nor the information on this website is included or incorporated in, or is a part of, this prospectus or any supplement to the prospectus.

4,260,855 SHARES OF COMMON STOCK

SYNTHETIC BIOLOGICS, INC.

PROSPECTUS

December 21, 2012

Neither we nor the Selling Stockholders have authorized any dealer, salesperson or other person to give any information or to make any representations not contained in this prospectus or any prospectus supplement. You must not rely on any unauthorized information. This prospectus is not an offer to sell these securities in any jurisdiction where an offer or sale is not permitted. The information in this prospectus is current as of the date of this prospectus. You should not assume that this prospectus is accurate as of any other date.