Synthetic Biologics, Inc.
Form 10-K/A
May 11, 2012

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K/A

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

For the fiscal year ended December 31, 2011

OR

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

For the transition period from_____ to_____

Commission File Number: 1-12584

SYNTHETIC BIOLOGICS, INC.

(Name of small business issuer in its charter)

Nevada	13-3808303

(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification Number)
3985 Research Park Drive, Suite 200 Ann Arbor, MI	48108
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code:

(734) 332-7800

Securities registered pursuant to Section 12(b) of the Act:	Name of each exchange on which registered
(Title of Class)	
Common Stock, $0.001 par value per share	NYSE AMEX

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of issuer's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every interactive data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T (section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).Yes x No ¨

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

Large accelerated filer	£	Accelerated filer	¨
Non-accelerated filer	£	Smaller reporting company	x

(Do not check if a smaller reporting company)

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2011, was approximately $16,266,000 based on $0.86, the price at which the registrant's common stock was last sold on that date.

As of March 26, 2012, the issuer had 32,701,984 shares of common stock outstanding.

Documents incorporated by reference: None.

EXPLANATORY NOTE

On May 1, 2012, we were informed by Berman & Company, P.A. ("Berman & Company"), our independent registered accounting firm, that during a regular Public Company Accounting Oversight Board ("PCAOB") inspection of Berman & Company, the PCAOB issued a comment that the audit opinion included in our Annual Report on Form 10-K for the year ended December 31, 2011 was issued by a partner at Berman & Company who was not authorized under the PCAOB rules to issue the opinion or act as our named engagement partner with respect to the Form 10-K audit (or prior 2011 Form 10-Q interim reviews) after the original engagement partner rotated off the account under the Securities and Exchange Commission's independence rules as it pertains to partner rotation (S-X Rule 2-01 - Qualifications of Accountants).

We believe that our previously filed financial statements for the year ended December 31, 2011 are accurate. In addition, we have not been informed by Berman & Company or the PCAOB, that our previously filed financial statements for the year ended December 31, 2011 are not accurate or otherwise invalid. As a matter of precaution the new engagement partner at Berman & Company has since: (i) taken full responsibility for the audit as the lead engagement partner on the audit, (ii) performed a detailed review of all audit procedures related to the original audit for sufficiency and (iii) reissued the audit opinion. We are filing this Annual Report on Form 10-K/A solely for the purpose of providing the reissued audit opinion and related disclosure, and subsequent event disclosure regarding the appointment of an independent, non-executive Chairman of the Board on May 10, 2012. The review performed by the new audit partner did not result in any changes to our financial statements or notes to the financial statements for the year ended December 31, 2011, other than the addition of the May 1, 2012 and May 10, 2012 disclosures in the subsequent event note to the financial statements.

SYNTHETIC BIOLOGICS, INC.

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PART I

Forward-Looking Statements

Most of the matters discussed within this report include forward-looking statements on our current expectations and projections about future events. In some cases you can identify forward-looking statements by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and simila These statements are based on our current beliefs, expectations, and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and generally beyond our control, that could cause actual results to differ materially from those expressed, projected or implied in or by the forward-looking statements. Such risks and uncertainties include the risks noted under "Item 1A Risk Factors." We do not undertake any obligation to update any forward-looking statements. Unless the context requires otherwise, references to "we," "us," "our," and "Synthet Biologics," refer to Synthetic Biologics, Inc. (formerly Adeona Pharmaceuticals, Inc.) and its subsidiaries.

Item 1. ***Business***

We are a biotechnology company focused on the development of synthetic DNA-based therapeutics and innovative disease-modifying medicines for serious illnesses. Our initial synthetic biologic product candidate is intended to treat pulmonary arterial hypertension (PAH), a serious life-threatening lung disease, by locally delivering therapeutic DNA to the lungs of PAH patients and controlling long-term expression of such DNA via an oral daily pill. We also intend to expand new and existing collaborations in the area of DNA-based therapeutics. In addition, we have several small molecule clinical-stage programs, the majority of which are being funded, or partially funded, by grants, charitable organizations and corporate partners. In this area we are developing, or have partnered the development of, product candidates to treat relapsing-remitting multiple sclerosis (MS), cognitive dysfunction in MS, fibromyalgia and amyotrophic lateral sclerosis (ALS).

Product Pipeline:

Synthetic Biologics:

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Our initial synthetic biologic 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 the private synthetic biology company Intrexon Corporation (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)

Funded/Small Molecule Clinical Programs:

- 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™ (oral estriol) 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). 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.

- Effirma™ (flupirtine) is being developed for the treatment of fibromyalgia. On May 6, 2010, we entered into a sublicense agreement with Meda AB, a multi-billion dollar international pharmaceutical company, covering all of our patents' rights on the use of flupirtine for fibromyalgia in the U.S., Canada and Japan. According to Meda's 2010 Annual Report, 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.

- AEN-100 (gastroretentive zinc acetate) is being developed under an investigator-initiated Investigational New Drug (IND) application for the treatment of ALS, also known as Lou Gehrig's disease. We intend to sponsor a multi-center, double-blind, placebo-controlled, adaptively designed Phase II/III clinical trial in ALS patients. It is anticipated that the clinical trial will comprise two phases. The first phase of the trial is anticipated to enroll at least 65 patients randomized to receive either AEN-100 or placebo for a period of six months at which time the average change in functional rating between the groups will be compared via an interim analysis conducted on a blinded basis. Should the interim analysis meet the threshold criteria in favor of the treatment group, the second phase of the study will be initiated and will seek to enroll approximately 50 additional subjects to receive treatment for nine months. This study is intended to be conducted by PNA Center for Neurological Research (PNA) which previously sponsored and completed a successful pilot Phase I/II study of oral zinc therapy for ALS. Separately, PNA intends to conduct a Phase I study of AEN-100 in normal volunteers prior to initiating the Phase II/III clinical trial in ALS patients. We have committed to support approximately $400,000 to PNA for the first phase of the Phase II/III clinical trial, payable based upon study enrollment and milestones. 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.

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Product Candidates and Medical Indications

Synthetic Biologic Products

We are engaged in the emerging field of synthetic biology directed for the purpose of developing new human therapeutic products. Synthetic biology in an emerging field that combines molecular biology and automation to design, optimize and construct new biological systems and functions. These technologies utilize a combination of automated processes including, DNA sequencing, computer-aided design, DNA synthesis, fabrication of modular transgenes and high throughput testing to create and optimize biologic products.

Our initial efforts in this area are being conducted in collaboration with Intrexon, and are directed towards the design, optimization and development of synthetic DNA-based therapeutic product candidates utilizing Intrexon's UltraVector® platform for the treatment of PAH. Synthetic DNA-based therapeutics comprise constructs of DNA that can be administered to patients via a single procedure. Once introduced, they are intended to continuously produce therapeutic proteins *in vivo* in a controllable and localized fashion for up to a period of years.

An important feature of our product candidates developed in collaboration with Intrexon may be the incorporation of Intrexon's RheoSwitch Therapeutic System®. Such system is intended to provide unprecedented control of therapeutic protein expression through the use of a highly specific orally available activating ligand that can be taken by patients on a daily basis as one or more pills. In this way, the levels of *in vivo* protein expression may be adjusted from time to time by treating physicians through simple dose adjustment of the oral activating ligand. Such system also provides an important safety mechanism not previously available in gene therapy clinical trials since in the absence of taking an oral pill, protein expression would not be expected to occur.

Pulmonary Arterial Hypertension (PAH)

Synthetic DNA-based Therapy

Disease

PAH is a progressive, disabling and life-threatening disorder characterized by abnormally high blood pressure (hypertension) in the pulmonary artery, the blood vessel that carries blood from the heart to the lungs. Hypertension occurs when most of the very small arteries throughout the lungs narrow in diameter, therefore constricting blood flow through the lungs. The constriction of blood flow causes the pressure to increase in the pulmonary artery and in the

right ventricle (the heart chamber that pumps blood into the pulmonary artery). Signs and symptoms of PAH take place when the increased pressure cannot overcome the constriction and there is insufficient blood flow to the body. Shortness of breath during exertion and fainting spells are the most common early symptoms of PAH. Despite current treatments, PAH generally has a very poor outcome and is associated with high rates of mortality within three to five years of diagnosis.

Synthetic DNA-based Therapeutic for PAH

Our initial synthetic DNA-based therapeutic product candidate is intended for the treatment of PAH, a serious life-threatening lung disease. This product candidate is designed to deliver DNA that encodes a therapeutic protein called PGIS locally to the pulmonary arteries of PAH patients via a single pulmonary catheter procedure and via an oral daily pill, control the long-term local expression of such therapeutic protein.

We are developing this initial product candidate in collaboration with Intrexon. Under the collaboration, we intend to utilize Intrexon's advanced transgene engineering platform for the controlled, precise and continuous *in vivo* cellular production of PGIS. PGIS is a specific effector enzyme that regulates the production of prostacyclin, a potent mediator of arterial dilation that also prevents smooth muscle proliferation and arterial wall thickening. PGIS expression is decreased in the lungs of PAH patients and deficiency in prostacyclin production is strongly implicated in PAH. We anticipate that by continuously producing and delivering prostacyclin directly where it is needed, in the pulmonary arteries of PAH patients via PGIS, this product candidate may overcome the dose limiting side effects of systemic prostacyclin-based treatments for PAH. While systemic prostacyclin-based treatments for PAH are currently a mainstay of PAH therapy, their considerable systemic side effects limit their dose and ultimate long-term utility.

The global market potential for the treatment of PAH is estimated to be up to $3.6 billion by 2015, according to GlobalData, Pulmonary Arterial Hypertension (PAH) – Drug Pipeline Analysis and Market Forecasts for 2016.

Relapsing-Remitting Multiple Sclerosis (MS) in Women

Trimesta (oral estriol)

Disease

MS is a progressive neurological disease in which the body loses the ability to transmit messages along central nervous system nerve cells, leading to a loss of muscle control, paralysis, cognitive impairment and in some cases death. According to the National Multiple Sclerosis Society (NMSS), currently, more than 2.5 million people worldwide (approximately 400,000 patients in the U.S. of which 70% are estimated to be women) have been diagnosed with MS. Young adults, ages 20 to 50, and two to three times as many women than men are predominantly diagnosed with MS. According to the NMSS, approximately 85% of MS patients are initially diagnosed with the relapsing-remitting form, compared to 10-15% with other progressive forms.

There are currently eight Food & Drug Administration (FDA) approved therapies for the treatment of relapsing-remitting MS: Betaseron®, Rebif®, Avonex®, Novantrone®, Copaxone®, Tysabri®, Gilenya® and Extavia®. These therapies provide only a modest benefit for patients with relapsing-remitting MS and therefore serve to only delay progression of the disease. All of these drugs except Gilenya® require frequent (daily, weekly & monthly) injections (or infusions) on an ongoing basis and can be associated with unpleasant side effects (such as flu-like symptoms), high rates of non-compliance among users, and eventual loss of efficacy due to the appearance of resistance in approximately 30% of patients. Despite the availability of multiple FDA-approved therapies for the treatment of relapsing-remitting MS, the disease is highly underserved and exacts a heavy economic toll.

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 in excess of $5 billion annually by 2017.

Background

It has been scientifically documented that pregnant women with certain autoimmune diseases experience a spontaneous reduction of disease symptoms during pregnancy, particularly in the third trimester. The PRIMS (Pregnancy In MS) study, a landmark clinical study published in the *New England Journal of Medicine* followed 254 women with MS during 269 pregnancies and for up to one year after delivery. The PRIMS study demonstrated that relapse rates were significantly reduced by 71 percent ($p < 0.001$) through the third trimester of pregnancy compared to pre-pregnancy-rates, and that relapse rates increased by 120 percent ($p < 0.001$) during the first three months after birth (post-partum) before returning to pre-pregnancy rates. It has been hypothesized that the female hormone, estriol, produced by the placenta during pregnancy, plays a role in “fetal immune privilege”, a process that prevents a mother’s immune system from attacking and rejecting her fetus. Maternal levels of estriol increase in a linear fashion through the third trimester of pregnancy until birth, whereupon they abruptly return to low circulating levels. The anti-autoimmune effects of esteriol is thought to be responsible for the therapeutic effects of pregnancy on MS.

Rhonda Voskuhl, M.D., Director, UCLA MS program, UCLA Department of Neurology, has found that pregnancy levels of estriol have potent immunomodulatory effects. She further postulated and tested in pilot clinical studies that oral doses of estriol may have a therapeutic benefit when administered to non-pregnant female MS patients by, in essence, mimicking the spontaneous reduction in relapse rates seen in MS patients during pregnancy.

Estriol has been approved and marketed for over 40 years throughout Europe and Asia for the oral treatment of post-menopausal symptoms. It has never been approved by the U.S. FDA for any indication.

Clinical Development

Our Trimesta (oral estriol) drug candidate is for the treatment of relapsing-remitting MS in women. An investigator-initiated, 10-patient, 22-month, single-agent, crossover clinical trial to study the therapeutic effects of 8 mg of oral Trimesta taken daily in non-pregnant female relapsing-remitting MS patients was completed in the U.S. The total volume and number of gadolinium-enhancing lesions were measured by brain magnetic resonance imaging (an established neuroimaging measurement of disease activity in MS). Over the next three months of treatment with Trimesta, the median total enhancing lesion volumes decreased by 79% ($p = 0.02$) and the number of lesions decreased by 82% ($p = 0.09$). They remained decreased during the next 3 months of treatment, with lesion volumes decreased by 82% ($p = 0.01$), and numbers decreased by 82% ($p =0.02$). Following a six-month drug holiday during which the patients were not on any drug therapies, median lesion volumes and numbers returned to near baseline pretreatment levels. Trimesta therapy was reinitiated during a four-month retreatment phase of this clinical trial. The relapsing-remitting MS patients again demonstrated a decrease in enhancing lesion volumes of 88% ($p = 0.008$) and a decrease in the number of lesions by 48% ($p = 0.04$) compared with original baseline scores.

A Phase II randomized, double-blind, placebo-controlled clinical trial is currently underway at 15 centers in the U.S. The purpose of this clinical trial is to study whether 8 mg of oral Trimesta taken daily over a two year period will reduce the rate of relapses in a large population of female patients with relapsing-remitting MS. Investigators are administering either Trimesta or matching placebo, in addition to a standard of care, glatiramer acetate (Copaxone®) injections, an FDA-approved therapy for MS, to women between the ages of 18 to 50 who have been recently diagnosed with relapsing-remitting MS. The primary endpoint in this clinical trial being run under an investigator-initiated IND application, is relapse rates at two years. As of January 23, 2012, 164 patients have been enrolled in the clinical trial and the trial enrollment has been closed. The patients will be dosed and monitored for two years.

With over $8 million in grant funding to date, the ongoing Trimesta clinical trial should be funded to its completion.

Cognitive Dysfunction in Multiple Sclerosis

Trimesta (oral estriol)

Disease

According to the NMSS and the Multiple Sclerosis Society of Canada publication, *Hold that Thought! Cognition and MS*, it is fairly common for people with MS to complain of problems remembering things, finding the right words, concentrating on a task or something they are reading, or following a conversation. These are all cognitive symptoms of MS. Of those affected by MS, 50-65% have cognitive dysfunction issues. Despite the fact that most symptoms are mild to moderate, they can have a significant impact on a person's ability to normally function. The overall cognitive dysfunction can be described as a reduction in mental "sharpness."

The major areas of cognition that can be dysfunctional include what are termed complex attention and executive functions. Complex attention involves multitasking, the speed with which information can be processed, learning and memory, and perceptual skills; executive functions include problem solving, organizational skills, the ability to plan, and word finding. Just as the nature, frequency, and severity of MS-related physical problems can widely vary, not all people with MS will display these cognitive issues, and no two people will experience exactly the same types or severity of problems.

Background

In the investigator-initiated, 10-patient, 22-month, single-agent, crossover clinical trial conducted by Dr. Rhonda Voskuhl, a statistically significant 14% improvement from baseline in Paced Auditory Serial Addition Test (PASAT) cognitive testing scores ($p = 0.04$) was observed in relapsing-remitting MS patients after six months of Trimesta therapy. PASAT is a routine cognitive test performed in patients with a wide variety of neuropsychological disorders such as MS. The PASAT scores are expressed as a mean percent change from baseline.

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Clinical Development

Our Trimesta (oral estriol) drug candidate is also being developed for the treatment of cognitive dysfunction in female MS patients. This randomized, double-blind, placebo-controlled Phase II clinical trial to evaluate Trimesta's potential neuroprotective and therapeutic effect on cognitive dysfunction in female MS patients is currently enrolling relapsing-remitting or secondary-progressive female MS patients at UCLA. Up to 64 patients between the ages of 18 and 50 will be randomized 1:1 into the treatment and placebo groups. Dr. Voskuhl will administer either oral Trimesta or a matching placebo, in addition to any FDA-approved MS treatment. Each patient will be dosed and monitored for one year after being enrolled. The primary endpoint in this clinical trial being run under an investigator-initiated IND application is expected to be improvement in PASAT cognitive testing scores versus matching placebo. We and a private foundation have pledged to equally support this new clinical trial, and we will also provide Trimesta drug supply. The trial also received contributions from several other supporters.

Fibromyalgia

Effirma (flupirtine)

Disease

Fibromyalgia is a chronic and debilitating condition characterized by widespread pain and stiffness throughout the body, often accompanied by severe fatigue, insomnia and mood symptoms. Fibromyalgia affects an estimated 3-6% of the population worldwide, including an estimated 10 million people in the U.S. There are presently three FDA products approved for this indication in the U.S. – Lyrica®, Cymbalta ® and Savella ®. Flupirtine is differentiated from these products in that it employs a unique mode of action.

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.

Clinical Development

Our Effirma (flupirtine) product candidate is for the treatment of fibromyalgia. Effirma is a selective neuronal potassium channel opener that also has NMDA receptor antagonist properties. Effirma is a non-opioid, non-NSAID, non-steroidal, analgesic. Preclinical data and clinical experience suggest that Effirma should also be effective for

neuropathic pain since it acts in the central nervous system via a mechanism of action distinguishable from most marketed analgesics. Effirma is especially attractive because it operates through non-opiate pain pathways, exhibits no known abuse potential, and lacks withdrawal effects. In addition, no tolerance to its antinocioceptive effects has been observed. One common link between neuroprotection, nocioception and Effirma may be the N-methyl-D-aspartic acid glutamate system, a major receptor subtype for the excitotoxic neurotransmitter, glutamate. Effirma has strong inhibitory actions on N-methyl-D-aspartic acid-mediated neurotransmission. Flupirtine was originally developed by Asta Medica (subsequently acquired by Meda AB) and has been approved and is marketed by Meda AB in Europe since 1984, as well as other countries, for the treatment of pain. It has never been approved by the FDA for any indication.

Meda Corporate Partnership

On May 6, 2010, we entered into a sublicense agreement with Meda AB, a multi-billion dollar international pharmaceutical company, pursuant to which Meda AB assumed all future development costs and may commercialize flupirtine for fibromyalgia in the U.S. As consideration for such sublicense, we received an up-front payment of $2.5 million and are entitled to milestone payments of $5 million upon the FDA’s acceptance of the New Drug Application (NDA) for flupirtine for fibromyalgia and $10 million upon FDA approval of such NDA. Pursuant to the sublicense agreement, we will also receive a 7% royalty on net sales of flupirtine for fibromyalgia in the U.S., Canada and Japan, with such royalties being shared equally with our licensor, McLean Hospital, a Harvard teaching hospital.

Flupirtine is approved and marketed by Meda AB and its distributors in Europe and other countries for indications other than fibromyalgia and has been prescribed to millions of patients worldwide. We believe that such substantial human experience with flupirtine should greatly assist the FDA in its evaluation of the safety of flupirtine upon review of an NDA of flupirtine for fibromyalgia. According to Meda's 2010 Annual Report, flupirtine for fibromyalgia is currently in Phase II development.

Amyotrophic Lateral Sclerosis (ALS)

AEN-100 (gastroretentive zinc acetate)

Disease

ALS, also known as Lou Gehrig's Disease, is a devastating progressive neurodegenerative disease that affects the motor nerve cells in the brain and the spinal cords. It is estimated that as many as 30,000 Americans may have the disease at any given time. The progressive degeneration of the motor neurons in ALS eventually leads to the death of the patient. Motor neurons reach from the brain to the spinal cord and from the spinal cord to the muscles throughout the body. When motor neurons die, the ability of the brain to initiate and control muscle movement is lost. With voluntary muscle action progressively affected, patients in the later stages of the disease may become totally paralyzed. While non-invasive ventilation and gastrostomy tubes prolong life by 6-12 months, the average lifespan from time of symptom onset is 2-5 years. Currently, RILUTEK® is the only FDA-approved drug for ALS. RILUTEK is a N-methyl d-aspartate (NMDA) receptor antagonist and has been shown to prolong life in patients with ALS by 3 months. Presently, there is no cure for ALS.

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.

Background

Clinical investigators at the PNA cite multiple lines of scientific research that suggest a potential benefit of zinc therapy for ALS patients, including:

- The use of zinc therapy for ALS patients is supported in animal models of ALS. Approximately 2% of ALS diagnoses are associated with a mutation in the copper/zinc superoxide dismutase (SOD1) gene. In ALS mutant

SOD1 animal models, zinc supplementation has been shown to delay death.

- Genetic mutations affecting the ability of a protein known as copper/zinc SOD1 to properly bind zinc are associated with the familial form of ALS, which shares many of the same features as the more prevalent sporadic form of ALS.

- Zinc is an important modifier of glutamate toxicity, a neurotransmitter linked to cell death in ALS patients.

Clinical Development

Preparations are underway to evaluate the safety and efficacy of our proprietary drug candidate, AEN-100, a gastroretentive, sustained-release zinc-based tablet, in a multi-center, double-blind, placebo-controlled clinical trial in ALS patients intended to be conducted under an investigator-initiated IND application. Manufacturing of AEN-100 study material has been completed and stability studies are ongoing.

We intend to provide the study material and support a multi-center, double-blind, placebo-controlled, adaptively designed Phase II/III clinical trial in ALS patients to be conducted by PNA. It is anticipated that the Phase II/III clinical trial will comprise two phases. The first phase of the trial is anticipated to enroll at least 65 patients randomized to receive either AEN-100 or placebo for a period of six months at which time the average change in functional rating between the groups will be compared via an interim analysis conducted on a blinded basis. Should the interim analysis meet the threshold criteria in favor of the treatment group the second phase of the study will be initiated and seek to enroll up to a total of 114 patients, inclusive of the 65 subjects from the first phase who continue to meet eligibility criteria at such time, to receive treatment for nine months.

In November 2011, PNA reported top-line results from its pilot Phase I/II open label, three month safety study of oral high dose zinc therapy in ALS. The clinical study met its primary outcome as no safety issues related to zinc therapy were observed. In addition, an average decrease in the monthly rate of disease progression was observed in the ALS patients on zinc therapy, compared to published historical controls, as well as compared to the average monthly rate of disease progression of the subjects prior to enrollment in the study. AEN-100 is not the same zinc formulation untilized by PNA in its previously completed Phase I/II safety study of zinc for ALS, and PNA intends to conduct a Phase I study of AEN-100 in normal volunteers prior to initiating the Phase II/III clinical trial in ALS patients.

We have committed to support approximately $400,000 to PNA for the first phase of the Phase II/III clinical trial, payable based upon study enrollment and completion milestones.

Intellectual Property

Our goal is to (a) obtain, maintain, and enforce patent protection for our products, formulations, processes, methods, and other proprietary technologies, (b) preserve our trade secrets, and (c) operate without infringing on the proprietary rights of other parties, worldwide. We seek, where appropriate, the broadest intellectual property protection for product candidates, proprietary information, and proprietary technology through a combination of contractual arrangements and patents. Below is a description of our license and development agreements relating to our product candidates.

McLean Hospital Exclusive License Agreement and Meda AB Sublicense Agreement

In 2005, as amended in 2007 and 2010, we entered into an exclusive license agreement with the McLean Hospital, a Harvard University teaching hospital, relating to U.S. Patent No. 6,610,324 and its foreign equivalents, entitled “Flupirtine in the treatment of fibromyalgia and related conditions.” Pursuant to this agreement, we paid an upfront fee and back patent costs of approximately $62,000 and agreed to pay McLean royalties on net sales of oral flupirtine equal to 3.5% of net sales of oral flupirtine for indications covered by the issued patents, reduced to 1.75% if we have a license to other intellectual property covering those indications. In addition, we agreed to use our best efforts to commercialize oral flupirtine for the therapeutic uses embodied in the patent applications. Furthermore, we agreed to reimburse McLean Hospital all future patent costs and pay the following milestone payments: $150,000 upon the initiation of a pivotal Phase III clinical trial of oral flupirtine; $300,000 upon the filing of an NDA for oral flupirtine; and $600,000 upon FDA approval of oral flupirtine. The due diligence requirements of the exclusive license agreement were amended in April of 2010 and further amended by a Non-Disturbance Agreement that was signed with McLean Hospital, Meda and us. The agreement remains in effect until the later of (i) the date all issued patents and filed patent applications within the Patent Rights (as defined in the agreement) expire or are abandoned and (ii)

one year after the last Commercial Sale (as defined in the agreement) for which royalty is due or ten years after expiration or abandonment date set forth in clause (i) above, whichever is earlier. We have the right to terminate the agreement at any time upon 90 days notice. In addition, McLean may terminate the agreement (i) upon 10 days notice for nonpayment unless payment is made within such 10 days, (ii) immediately upon written notice if we fail to maintain required insurance or become insolvent, make an assignment for the benefit of creditors or petition for bankruptcy is filed for or against us or (ii) if we, our affiliates or our sublicensees default in performance of their obligations under the agreement and such default is not cured within 60 days.

Effective May 6, 2010, we entered into a Sublicense Agreement with Meda AB of Sweden. Pursuant to this agreement, Meda has been granted an exclusive sublicense to all of our patents covering the use of oral flupirtine for fibromyalgia. These patents have been issued in the U.S. and are pending in Canada and Japan (the “Territory”). This agreement provides that Meda will assume all future development costs for the commercialization of oral flupirtine for fibromyalgia. As consideration for this sublicense, we received an up-front payment of $2.5 million upon execution of this agreement and are entitled to milestone payments of $5 million upon filing of an NDA with the FDA for oral flupirtine for fibromyalgia and $10 million upon marketing approval. This agreement also provides that we are entitled to receive royalties of 7% of net sales of oral flupirtine approved for the treatment of fibromyalgia covered by issued patent claims in the Territory. Pursuant to the terms of this agreement with our university licensor, we are obligated to share half of the royalties we receive with the university licensor, McLean Hospital, and we were obligated to pay them $375,000 upon receipt of an upfront payment, which we did pay in May 2010 when we received the payment from Meda. The agreement continues in effect country by country until the earlier of the expiration of the Royalty Period (as defined in the agreement) or the termination of the McLean license. Meda has the right to terminate the agreement at any time upon 90 days notice. In addition, a party may terminate the agreement upon 30 days notice if the other party breached material obligations and such breach is not cured within a period of time set forth in the agreement. The parties also have the right to terminate the agreement upon 60 days notice in the event of the filing by a party of a bankruptcy petition, the filing of an involuntary petition not dismissed within 60 days, a party proposes a written agreement of composition or extension of its debt, a party becomes Insolvent (as defined in the agreement), liquidates, dissolves, ceases to conduct business or makes an assignment for the benefit of creditors. Upon a termination, all licenses revert to us.

The Regents of University of California License Agreement

In July 2005, we were granted an exclusive worldwide license agreement with the Regents of the University of California (Regents) relating to issued U.S. Patent No. 6,936,599 and pending patent applications covering the uses of the drug candidate Trimesta (oral esteriol). Pursuant to this agreement, we paid an upfront license fee and reimbursed patent expenses totaling approximately $61,000 and agreed to pay a license fee of $25,000 during 2006. We also agreed to pay annual maintenance fees, milestone payments totaling $750,000 that are payable on filing an NDA, and on approval of an NDA with the FDA, as well as royalties on net sales of Trimesta covered by the licensed patents. We may be permitted to partially pay milestone payments in the form of equity. The duration of this agreement is from the effective date of July 11, 2005 until the last-to-expire patent in Regent's Patent Rights, or until the last patent application licensed under this agreement is abandoned and no patent in Regent's Patent Rights ever issues. We have the right to terminate this agreement at any time and termination will be effective 90 days after the effective date of the termination notice. The Regents may terminate the agreement with a written notice of default if we violate or fail to perform any material term or covenant of this agreement. However, we have 60 days after the effective date of the notice of default to repair the default.

The Intrexon Collaboration

On November 18, 2011, we entered into a Channel Agreement with Intrexon (the "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 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.

The Channel Agreement grants us a worldwide license to use specified patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale, and offer for sale of products involving the production of PGIS through the use of an *in vivo* conditionally regulated embedded controllable bioreactor for the treatment of PAH in humans. Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of Products, and otherwise is non-exclusive. We may not sublicense the rights described without Intrexon's written consent.

Under the Channel Agreement, and subject to certain exceptions, we are responsible for, among other things, the performance of the PAH program including the development, commercialization and certain aspects of manufacturing products. Among other things, Intrexon is responsible for the costs of establishing manufacturing capabilities and facilities for the bulk manufacture of products developed under the PAH program, certain other aspects of manufacturing, costs of discovery-stage research with respect to platform improvements and costs of filing,

prosecution and maintenance of Intrexon's patents.

Subject to certain expense allocations and other offsets provided in the Channel Agreement, we will pay Intrexon 50% of the cumulative net quarterly profits derived from the sale of products, calculated on a product-by-product basis. We have likewise agreed to pay Intrexon 50% of quarterly revenue obtained from a sublicensor in the event of a sublicensing arrangement. During the first 18 months, neither we nor Intrexon may terminate the Channel Agreement, except under limited circumstances. Following the first 18 months, we may voluntarily terminate the Channel Agreement upon 90 days written notice to Intrexon. Following the first 18 months, Intrexon may also terminate the Channel Agreement if we elect not to pursue the development of a PAH program identified by Intrexon that is a "Superior Therapy" as defined in the Channel Agreement.

Upon termination of the Channel Agreement, we may continue to develop and commercialize any Product that, at the time of termination:

- is being commercialized by us,
- has received regulatory approval,
- is a subject of an application for regulatory approval that is pending before the applicable regulatory authority,
- is the subject of at least an ongoing Phase II clinical trial (in the case of a termination by Intrexon due to our uncured breach or a voluntary termination by us), or an ongoing Phase I clinical trial in the Field (as defined in the Channel Agreement) (in the case of a termination by us due to an Intrexon uncured breach or a termination by Intrexon following an unconsented assignment by us or our election not to pursue development of a Superior Therapy), or
- we have spent at least $4.5 million developing.

We will be obligated to pay 50% of net profits or revenue with respect to these “retained” products, which will survive termination of the Channel Agreement.

As partial consideration for execution of the Channel Agreement, we entered into a Stock Purchase Agreement with Intrexon 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 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.

Under the 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 our common stock or equity securities convertible into our common stock in a public or private offering, raising gross proceeds of at least $5 million, where the sale of shares is either registered under the Securities Act of 1933, as amended (the “Securities Act”), at the time of issuance or we agree to register the resale of such shares, and

(ii) without restriction, purchase an additional number of shares of our 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.

The Stock Purchase Agreement contains a standstill provision pursuant to which, among other things, Intrexon has agreed that, for a period of three years, subject to certain exceptions and unless invited in writing by us to do so, neither Intrexon nor its affiliates will, directly or indirectly: (i) effect or seek, initiate, offer or propose to effect, or cause or participate in any acquisition of our securities or assets; any tender or exchange offer, merger, consolidation or other business combination involving us; any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to us; or any "solicitation" of "proxies" or consents to vote any of our voting securities, or in any way advise or, assist any other person in doing so; (ii) form, join or in any way participate in a "group" with respect to any of our securities; (iii) otherwise act to seek to control or influence the management, Board of Directors or our policies; (iv) take any action reasonably expected to force us to make a public announcement regarding any such matters; or (v) enter into any agreements, discussions or arrangements with any third party with respect to any of the foregoing.

In connection with the transactions contemplated by the Stock Purchase Agreement, and pursuant to a Registration Rights Agreement that was executed and delivered by the parties at the First Tranche closing, we agreed to file a "resale" registration statement (the "Registration Statement") registering the resale of the First Tranche shares within 120 days of the First Tranche closing.

AEN-100 – Gastroretentive Zinc Acetate

We intend to file for orphan drug designation in the U.S. and Europe for AEN-100 (gastroretentive, sustained-release zinc-based tablets) for the treatment of ALS. ALS qualifies as an "orphan disease" in that it affects less than 200,000 people in the U.S. Orphan drug designation provides for seven years of market exclusivity following approval in the U.S. and ten years of market exclusivity following approval in Europe. AEN-100, is also the subject of U.S. and international patent pending applications that may provide exclusivity beyond the expiration of orphan drug exclusivity, such as published U.S. patent application Ser. No. 11/621,962 and corresponding international applications that claim priority to January 10, 2006, and 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.

Manufacturing

We utilize contract manufacturing firms to produce our investigational products AEN-100 and Trimesta in accordance with "current good manufacturing processes" (cGMP) guidelines outlined by the FDA.

Research and Development

During the years ended December 31, 2011 and 2010, we spent $3.3 million and $1.6 million, respectively, on research and development.

Competitive Environment

The pharmaceutical and biotechnology industries 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.

In the general area of commercial products for the treatment of serious diseases, we potentially compete with a variety of companies, most of whom are pharmaceutical or biotechnology companies. These include: Actelion Pharmaceuticals, Bayer Health Care, Biogen Idec, Eli Lilly & Co., Genzyme, GlaxoSmithKline Pharmaceuticals, Merck & Co., Pfizer, Novartis, Teva Pharmaceuticals and United Therapeutics.

Our History

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.

Recent Events

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 Amex stock exchange, currently 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 Amex stock exchange under the symbol “AEN”. We are incorporated in the State of Nevada.

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 Adeona Clinical Laboratory, LLC (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) $700,000 payable pursuant to the terms of a two-year non-recourse promissory note secured by all of the assets of the Lab.

During the period from January 1, 2012 through March 26, 2012, 1,120,121 warrants were exercised for gross proceeds of $1.4 million.

Employees

As of March 26, 2012, we employed approximately eight individuals, seven of whom are full-time employees. A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology or medical product companies. None of our employees are covered by collective bargaining agreements, and management considers relations with our employees to be good.

Properties

Our principal executive offices are located at 3985 Research Park Drive, Suite 200, Ann Arbor, Michigan 48108 and we also maintain executive offices in Rockville, Maryland.

Available Information

Additional information about Synthetic Biologics is contained at our website, www.syntheticbiologics.com. Information on our website is not incorporated by reference into this report. We make available on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K as soon as reasonably practicable after those reports are filed with the SEC. The following Corporate Governance documents are also posted on our website: Code of Conduct, Code of Ethics for Financial Management and the Charters for the Audit Committee, Compensation Committee and Nominations Committee of the Board of Directors. Our phone number is (734) 332-7800 and our facsimile number is (734) 332-7878.

Item 1A. ***Risk Factors***

Investing in our common stock involves a high degree of risk. In addition to the risks related to our business set forth in this Form 10-K/A and the other information included and incorporated by reference in this Form 10-K/A, you should carefully consider the risks described below before purchasing our common stock. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations.

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

With the exception of the quarter 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 of 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 December 31, 2011, our accumulated deficit totaled approximately $51.9 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. 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 discontinue 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 quarter 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;

- 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 recent issue raised by the PCAOB with our auditor may have a negative impact on our ability to raise additional capital.

On May 1, 2012, we were informed by Berman & Company that during a regular PCAOB inspection of Berman & Company, the PCAOB issued a comment that the audit opinion included in our Annual Report on Form 10-K for the year ended December 31, 2011 was issued by a partner at Berman & Company who was not authorized under the PCAOB rules to issue the opinion or act as our named engagement partner with respect to the Form 10-K audit (or prior 2011 Form 10-Q interim reviews) after the original engagement partner rotated off the account under the Securities and Exchange Commission’s independence rules as it pertains to partner rotation (S-X Rule 2-01 – Qualifications of Accountants).

We have included with this Annual Report on Form 10-K/A a reissued audit opinion for the year ended December 31, 2011, from a licensed CPA at Berman & Company who: (i) was the manager of our December 31, 2011 audit, (ii) was recently made a partner of the firm, (iii) had performed most of the audit work on the December 31, 2011 audit after the original audit partner rotated off the account (iv) is serving as our engagement partner on a going forward basis and has taken full responsibility for the audit as the lead partner of the audit and (v) has performed a review of all

audit procedures related to the audit sufficiency. We have sought guidance from the SEC staff regarding this matter and intend to file a waiver request to extent it becomes necessary to allow us to use Form S-3, however, no assurance can be given as to the outcome of any such waiver request. If we are unsuccessful in our attempt to obtain a waiver from the SEC, for a period of time up to one year we may be ineligible to utilize our Registration Statement on Form S-3 to issue securities which may negatively impact our ability to raise necessary funds on terms acceptable to us, if at all.

We have a limited operating history on which investors can base an investment decision.

We have not yet demonstrated our ability to perform the functions necessary for the successful commercialization of any of our product candidates. We have only recently entered into the emerging field of synthetic biology, and there can be no assurance that we will be successful in commercializing any products in such field. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

- continuing to undertake preclinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our company, acquiring, developing, and securing our proprietary technology, and undertaking preclinical and clinical trials of our principal product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

The technology on which our channel partnering arrangement with Intrexon is based on early stage technology in the field of synthetic DNA-based therapy.

Our exclusive channel collaboration arrangement with Intrexon 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.

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 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 2010 Annual Report, flupirtine for fibromyalgia is currently 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. Max Lyon served as Chief Executive Officer, President and director from June 26, 2009 until February 6, 2010. 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 agreement with Intrexon provides 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 arrangement with Intrexon.

Pursuant to our exclusive channel collaboration with Intrexon, we are responsible for future research and development expenses of product candidates developed under such collaboration, the effect of which we expect will 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 collaboration with Intrexon.

Because our collaboration with Intrexon is relatively new, we have only recently assumed development responsibility and costs associated with such program. In addition, because development activities are determined pursuant to a joint steering committee 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 collaboration 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. 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. 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 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 (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 March 26, 2012, we had eight employees. We have also engaged regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities and have been and will be required to retain additional consultants and employees in order to fulfill our obligations under our exclusive channel collaboration 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 Jeffrey Kraws, James S. Kuo, Nelson K. Stacks, Scott L. Tarriff, and Jeffrey Wolf, 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. 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 a collaboration agreement for the development of another product candidate, we depend upon our sublicensee and independent investigators and scientific collaborators, such as universities and medical institutions or private physician scientists, to conduct our preclinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs or the timing of their procurement of clinical-trial data or their compliance with applicable regulatory guidelines. Should any of these scientific inventors/advisors or those of our sublicensee become disabled or die unexpectedly, or should they fail to comply with applicable regulatory guidelines, we or our sublicensee may be forced to scale back or terminate development of that program. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking those programs ourselves. Failing to devote sufficient time and resources to our drug-development programs, or substandard performance and failure to comply with regulatory guidelines, could result in delay of any FDA applications and our commercialization of the drug candidate involved.

These collaborators may also have relationships with other commercial entities, some of which may compete with us. Our collaborators assisting our competitors at our expense could harm our competitive position. For example, we are highly dependent on scientific collaborators for our Trimesta 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 (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 (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 as well as their clinical trial capabilities. Although the planned Phase II/III clinical trial that we intend to conduct with PNA has received regulatory approval to proceed, such clinical trial is still the subject of further protocol development and IRB approval, either of which may alter the anticipated timing and budget of such clinical trial. In addition, because AEN-100 is not the same zinc formulation utilized by PNA in its previously completed Phase I/II safety study of zinc for ALS, PNA intends to conduct a Phase I study of AEN-100 in normal volunteers prior to initiating the Phase II/III

clinical trial in ALS patients. The IRB approval process is ongoing for the planned Phase I study of AEN-100 and the planned Phase II/III clinical trial in ALS patients. Such Phase I study of AEN-100 may produce unanticipated and unacceptable safety, tolerability or bioavailability results that may substantially delay initiation of the planned Phase II/III clinical trial in ALS patients.

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 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. 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. If we cannot raise additional funds, we will have to delay development activities of our products candidates.

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

Currently, our directors, executive 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 March 26, 2012. Our executive officers, directors and principal stockholders together beneficially owned approximately 12.1 million shares of our common stock, including the stock options and warrants exercisable within 60 days of March 26, 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 Amex.

We cannot assure you that we will be able to maintain the continued listing standards of the NYSE Amex (formerly the American Stock Exchange). The NYSE Amex requires companies to meet certain continued listing criteria including certain minimum stockholders' equity and equity prices per share as outlined in the NYSE Amex Exchange Company Guide. We may not be able to maintain such minimum stockholders' equity or prices per share or may be required to effect a reverse stock split to maintain such minimum prices and/or issue additional equity securities in exchange for cash or other assets, if available, to maintain certain minimum stockholders' equity required by the NYSE Amex. If we are delisted from the NYSE Amex 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 Amex could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities. In order to remain listed on NYSE Amex, we are required to maintain a minimum stockholders' equity of $6 million.

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.

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, medical foods, conventional foods, homeopathic OTC drugs, 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.

Item 1B. ***Unresolved Staff Comments***

Not applicable.

Item 2. ***Properties***

We currently rent approximately 5,936 square feet of office space in Ann Arbor, Michigan for monthly rent of $2,500, and we rent office space in Rockville, Maryland for monthly rent of $718. We believe our current offices will be adequate for the foreseeable future.

Item 3. ***Legal Proceedings***

Not applicable.

Item 4. ***Mine Safety Disclosures***

Not applicable.

PART II

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

Our common stock has traded on the NYSE Amex under the symbol "SYN" since February 16, 2012. Prior to this time, our common stock traded under the symbol "AEN" since October 16, 2008. The following table states the range of the high and low sales prices of our common stock for each of the calendar quarters during the years ended December 31, 2011 and December 31, 2010. These quotations represent inter-dealer prices, without retail mark-up, markdown, or commission, and may not represent actual transactions. The last price of our common stock as reported on the NYSE Amex on March 26, 2012 was $2.28 per share. As of March 26, 2012, there were approximately 353 stockholders of record of our common stock. This number does not include beneficial owners from whom shares are held by nominees in street name.

	High	Low
YEAR ENDED DECEMBER 31, 2011		
Fourth quarter	$1.42	$0.47
Third quarter	$0.91	$0.57
Second quarter	$2.13	$0.80
First quarter	$1.85	$1.04
YEAR ENDED DECEMBER 31, 2010		
Fourth quarter	$1.40	$0.70
Third quarter	$1.19	$0.77
Second quarter	$2.70	$1.03
First quarter	$2.58	$0.57

Dividend Policy

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

Equity Compensation Plan Information

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

Recent Sales of Unregistered Securities

In August 2011, we issued 130,000 shares of our common stock to Chardan Capital Markets, LLC (Chardan) as compensation for the execution and delivery of a Financial Advisory Agreement that we entered into with Chardan on June 3, 2011. The offer and issuance of the shares of common stock have not been registered under the Securities Act, and therefore such shares of common stock may not be offered or sold in the U.S. absent registration or an applicable exemption from registration requirements. For this issuance, we are relying on the exemption from federal registration under Section 4(2) of the Securities Act, based on our belief that the offer and sale of such shares of stock does not involve a public offering as Chardan is an “accredited investor” as defined under Section 501 promulgated under the Securities Act and no general solicitation has been involved in the offering.

On December 7, 2011 a closing was held for the transaction previously announced on November 21, 2011 between us and Intrexon. We issued 3,123,558 shares of our common stock at a purchase price equal to the $0.001 par value of such shares, which issuance is also deemed paid in partial consideration for the execution and delivery of the exclusive channel collaboration agreement, dated November 18, 2011, between us and Intrexon. The offer and issuance of such shares of common stock have not been registered under the Securities Act, and therefore such shares of common stock may not be offered or sold in the U.S. absent registration or an applicable exemption from registration requirements. For this issuance, we are relying on the exemption from federal registration under Section 4(2) of the Securities Act, based on our belief that the offer and sale of such shares of common stock does not involve a public offering as Intrexon is an “accredited investor” as defined under Section 501 promulgated under the Securities Act and no general solicitation has been involved in the offering.

In March 2012, we issued five year warrants exercisable at the closing price of our common stock on the date of issue for 100,000 shares of our common stock to Griffin Securities, Inc. (Griffin) as compensation for the execution and delivery of a Financial Advisory Agreement that we entered into with Griffin on December 20, 2011. The offer and issuance of the shares of common stock have not been registered under the Securities Act, and therefore such shares of common stock may not be offered or sold in the U.S. absent registration or an applicable exemption from registration requirements. For this issuance, we are relying on the exemption from federal registration under Section 4(2) of the Securities Act, based on our belief that the offer and sale of such shares of stock does not involve a public offering as Griffin is an “accredited investor” as defined under Section 501 promulgated under the Securities Act and no general solicitation has been involved in the offering.

Item 6. ***Selected Financial Data***

Not applicable because we are a smaller reporting company.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2011 found in this report. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward looking statements by using words such as "anticipate," "believe," "intends," or similar expressions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in Part I, Item 1A of this Report.

Overview

We are a biotechnology company focused on the development of synthetic DNA-based therapeutics and innovative disease-modifying medicines for serious illnesses. Our initial synthetic biologic product candidate is intended to treat PAH, a serious life-threatening lung disease, by locally delivering therapeutic DNA to the lungs of PAH patients and controlling long-term expression of such DNA via an oral daily pill. We also intend to expand new and existing collaborations in the area of DNA-based therapeutics. In addition, we have several small molecule clinical-stage programs, the majority of which are being funded, or partially funded, by grants, charitable organizations and corporate partners. In this area we are developing, or have partnered the development of, product candidates to treat relapsing-remitting MS, cognitive dysfunction in MS, fibromyalgia and ALS.

Synthetic Biologics:

- Our initial synthetic biologic 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 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 the private synthetic biology company 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)

Funded/Small Molecule Clinical Programs:

- 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™ (oral estriol) 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). 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.

- Effirma™ (flupirtine) is being developed for the treatment of fibromyalgia. On May 6, 2010, we entered into a sublicense agreement with Meda AB, a multi-billion dollar international pharmaceutical company, covering all of our patents' rights on the use of flupirtine for fibromyalgia in the U.S., Canada and Japan. According to Meda's 2010 Annual Report, 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.

- AEN-100 (gastroretentive zinc acetate) is being developed under an investigator-initiated IND application for the treatment of ALS, also known as Lou Gehrig's disease. We intend to sponsor a multi-center, double-blind, placebo-controlled, adaptively designed Phase II/III clinical trial in ALS patients. It is anticipated that the clinical trial will comprise two phases. The first phase of the trial is anticipated to enroll at least 65 patients randomized to receive either AEN-100 or placebo for a period of six months at which time the average change in functional rating between the groups will be compared via an interim analysis conducted on a blinded basis. Should the interim analysis meet the threshold criteria in favor of the treatment group, the second phase of the study will be initiated and will seek to enroll approximately 50 additional subjects to receive treatment for nine months. This study is intended to be conducted by PNA which previously sponsored and completed a successful pilot Phase I/II study of oral zinc therapy for ALS. Separately, PNA intends to conduct a Phase I study of AEN-100 in normal volunteers prior to initiating the Phase II/III clinical trial in ALS patients. We have committed to support approximately $400,000 to PNA for the first phase of the Phase II/III clinical trial study, payable based upon study enrollment and milestones. 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.

On November 18, 2011, we entered into a Channel Agreement with Intrexon 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 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 Channel Agreement, we entered into a Stock Purchase Agreement with Intrexon 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 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 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. We also announced that we intend to seek marketing partners for our zinc-based products *reaZin*™ and *wellZin*™.

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 Amex stock exchange, currently 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 Amex 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 3985 Research Park Drive, Suite 200, Ann Arbor, MI 48108.

Effective as of June 30, 2010, we emerged from a “Development-Stage Entity” as defined by Financial Accounting Standards Board Accounting Standards Codification (FASB ASC) 915-10. On May 6, 2010, we entered into a sublicense agreement with Meda AB of Sweden. This agreement provides that Meda AB will assume all future development costs for the commercialization of oral flupirtine for fibromyalgia. As consideration for such sublicense, we received an up-front payment of $2.5 million and are entitled to milestone payments of $5 million upon filing of an NDA with the FDA of oral flupirtine for fibromyalgia and $10 million upon marketing approval, plus royalties. We consider the agreement with Meda AB to be an indication that we have commenced our principal operations and therefore are not required to report as a development-stage entity.

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

To date, we have financed our operations primarily through public and private sales of our common stock, and we expect to continue to seek to obtain the required capital in a similar manner. We have incurred an accumulated deficit of $51.9 million through December 31, 2011. 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.

Critical Accounting Policies

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

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

Stock-Based Compensation

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

Revenue Recognition

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

License Revenues

Our licensing agreements may contain multiple elements, such as non-refundable up-front fees, payments related to the achievement of particular milestones and royalties. Fees associated with substantive at risk performance-based milestones are recognized as revenue upon completion of the scientific or regulatory event specified in the agreement. When we have substantive continuing performance obligations under an arrangement, revenue is recognized over the performance period of the obligations using a time-based proportional performance approach. Under the time-based method, revenue is recognized over the arrangement’s estimated performance period based on the elapsed time compared to the total estimated performance period. Revenue recognized at any point in time is limited to the amount

of non-contingent payments received or due. When we have no substantive continuing performance obligations under an arrangement, we recognize revenue as the related fees become due.

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

Laboratory Revenues

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

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

Accounts Receivable and Allowance for Doubtful Accounts

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

Results of Operations

Year Ended December 31, 2011 and 2010

Revenues, net

Total net revenues for the year ended December 31, 2010 were $2.6 million. Total net revenues consisted of $2.1 million from the oral flupirtine sublicense fee with Meda AB, which is net of the $375,000 payment to McLean Hospital and $489,000 of grant revenues from the Qualifying Therapeutic Discovery Project (QTDP) Program to support our clinical programs. There were no net revenues reported for the year ended December 31, 2011; net laboratory revenues for this year are included in discontinued operations. See Note 3 - Discontinued Operations of Adeona Clinical Laboratory.

General and Administrative Expenses

General and administrative expenses increased to $2.6 million for the year ended December 31, 2011 from $2.1 million for the year ended December 31, 2010. This increase of 22% is primarily the result of increased salary expense, consultant fees and stock-based compensation expense. General and administrative expenses also include a non-cash charge relating to stock-based compensation expense of $919,000 for the year ended December 31, 2011, compared to $310,000 for the year ended December 31, 2010. The stock-based compensation expense for year ended December 31, 2011 includes a one-time charge of $398,000 relating to the modification of certain stock options, prior to expiration, held by a member of the Board of Directors.

Research and Development Expenses

Research and development expenses increased to $3.3 million for the year ended December 31, 2011, from $1.6 million for the year ended December 31, 2010. The increase of 111% is primarily the result of recording the fair value ($1.7 million) of the common stock issued to Intrexon as consideration for the Exclusive Channel Collaboration Agreement. This is a non-cash charge. Research and development expenses also include a non-cash charge relating to stock-based compensation expense of $54,000 for the year ended December 31, 2011, compared to $90,000 for the year ended December 31, 2010.

Other Expense, net

Total net other expense was $1.7 million compared to $112,000 for the years ended December 31, 2011 and 2010, respectively. Total net other expense for the year ended December 31, 2011, included $1.7 million relating to the estimated fair value of the warrants associated with the January 2011 and April 2011 financings, adjusted for the change in their fair value for the year ended December 31, 2011. Other income for the year ended December 31, 2011 included $63,000 relating to the settlement of accounts payable previously accrued in prior periods offset by other expenses of $41,000 and $14,000 of interest income from our short-term investments. Total net other expense for the year ended December 31, 2010, included an impairment loss of $121,000.

Net Loss from Continuing Operations

Our net loss from continuing operations for the year ended December 31, 2011, was $7.6 million, or $0.27 per common share, compared to $1.2 million, or $0.06 per common share for the year ended December 31, 2010.

Net Loss from Discontinued Operations

Our net loss from discontinued operations for the year ended December 31, 2011, was $523,000, or $0.02 per common share compared to a $516,000, or $0.02 per common share for the year ended December 31, 2010. 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 Adeona Clinical Laboratory, LLC (the “Lab”) to Hartlab, LLC. This resulted in the classification of the Lab as discontinued operations. See Note 3 – Discontinued Operations of Adeona Clinical Laboratory for summarized statement of operations data for the years ended December 31, 2011 and 2010.

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Liquidity and Capital Resources

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

On January 28, 2011, we entered into a Securities Purchase Agreement with institutional investors, relating to the offering and sale of 2,857,144 shares of common stock, par value $0.001 per share, and warrants to purchase 1,428,572 shares of common stock. We raised gross proceeds of $4 million, before estimated offering expenses of approximately $296,000, which includes placement agent fees.

On April 6, 2011, we entered into a Securities Purchase Agreement with an institutional investor, relating to the offering and sale of 1,688,782 shares of common stock, par value $0.001 per share and a warrant to purchase 844,391 shares of common stock. We raised gross proceeds of $3.5 million, before estimated offering expenses of approximately $243,000, which includes placement agent fees.

Both of these offerings were made pursuant to our shelf registration statement on Form S-3 (File No. 333-166750), which was declared effective by the SEC on June 14, 2010.

Our cash totaled $6.7 million at December 31, 2011, an increase of $4 million from December 31, 2010. During the year ended December 31, 2011, the primary sources of cash were net proceeds from the issuances of common stock to institutional investors of $7 million and stock option and warrant exercises of $15,000. The primary use of cash during the year ended December 31, 2011 was for working capital requirements.

Our cash totaled $2.6 million at December 31, 2010 the primary sources of cash were $2.1 million from the sublicense fee relating to the Meda Agreement and proceeds from the issuance of common stock to a single investor of $885,000 (net of offering costs of $115,000) and stock option exercises of $129,000. The primary uses of cash for the year ended December 31, 2010, included working capital requirements and $12,000 in capital equipment additions.

During the period from January 1, 2012 through March 26, 2012, 1,120,121 warrants were exercised for gross proceeds of $1.4 million.

As of March 26, 2012, our cash balance was approximately $6.9 million.

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

Current and Future Financing Needs

We have incurred an accumulated deficit of $51.9 million through December 31, 2011. With the exception of the quarter ended June 30, 2010, we have incurred negative cash flow from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts.

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

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

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

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

License and Contractual Agreement Obligations

Below is a table of our contractual obligations for the years 2012 through 2016 as of December 31, 2011 *(in thousands)*.

	Year ended December 31,					
	2012	2013	2014	2015	2016	Total
License Agreements	$ 37	$ 5	$ 5	$ 5	$ 5	$ 57

Lease Agreements	22	-	-	-	-	22
Total	$ 59	$ 5	$ 5	$ 5	$ 5	$ 79

Additional In-Licensed Programs

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

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

Not applicable because we are a smaller reporting company.

Item 8. ***Financial Statements and Supplemental Data***

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of:

Synthetic Biologics, Inc.

We have audited the accompanying consolidated balance sheets of Synthetic Biologics, Inc. and Subsidiaries as of December 31, 2011 and 2010 and the related consolidated statements of operations, stockholders' equity and cash flows for the years ended December 31, 2011 and 2010. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly in all material respects, the consolidated financial position of Synthetic Biologics, Inc. and Subsidiaries as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity and cash flows for the years ended December 31, 2011 and 2010, in conformity with accounting principles generally accepted in the United States of America.

Berman &
Company, P.A.

Boca Raton,
Florida

May 11, 2012

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Synthetic Biologics, Inc. and Subsidiaries

(formerly Adeona Pharmaceuticals, Inc.)

Consolidated Balance Sheets

(In thousands except share amounts)

	December 31, 2011	December 31, 2010
Assets		
Current Assets:		
Cash	$ 6,678	$ 2,649
Accounts receivable – net	405	339
Other	16	343
Assets of discontinued operations	23	214
Total Current Assets	7,122	3,545
Property and equipment, net	323	475
Deposits and other assets	31	91
Total Assets	**$ 7,476**	**$ 4,111**
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 388	$ 266
Accrued liabilities	29	210
Liabilities of discontinued operations	-	24
Total Current Liabilities	417	500
Long Term Liabilities:		
Accounts payable	-	32
Total Liabilities	417	532
Stockholders' Equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 31,374,002 issued and 31,292,520 outstanding and 23,420,189 issued and 23,338,707 outstanding	31	23
Additional paid-in capital	58,901	47,280
Accumulated deficit	(51,873)	(43,724)
Total Stockholders' Equity	7,059	3,579
Total Liabilities and Stockholders' Equity	**$ 7,476**	**$ 4,111**

See accompanying notes to consolidated financial statements

Synthetic Biologics, Inc. and Subsidiaries

(formerly Adeona Pharmaceuticals, Inc.)

Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	For the years ended December 31,	
	2011	2010
Revenues:		
License revenue, net	$ -	$ 2,125
Grant revenue	-	489
Total Revenues	-	2,614
Operating Costs and Expenses:		
General and administrative	2,588	2,117
Research and development	3,340	1,580
Total Operating Costs and Expenses	5,928	3,697
Loss from Continuing Operations	(5,928)	(1,083)
Other Income (Expense):		
Warrant expense	(1,492)	-
Change in fair value of warrant liability	(242)	-
Impairment loss on equipment	-	(121)
Interest income	14	-
Other income (expense)	22	9
Total Other Expense, net	(1,698)	(112)
Net Loss from Continuing Operations	(7,626)	(1,195)
Net Loss from Discontinued Operations	(523)	(516)
Net Loss	**$ (8,149)**	**$ (1,711)**
Net Loss Per Share – Basic and Dilutive:		
Continuing Operations	$ (0.27)	$ (0.06)
Discontinued Operations	(0.02)	(0.02)
Net Loss Per Share	$ (0.29)	$ (0.08)
Weighted average number of common shares outstanding during the year – Basic and Dilutive	27,710,428	22,393,568

See accompanying notes to consolidated financial statements

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Synthetic Biologics, Inc. and Subsidiaries

(formerly Adeona Pharmaceuticals, Inc.)

Consolidated Statements of Changes in Stockholders' Equity

(In thousands, except share amounts)

	Common Stock $0.001 Par Value		Additional Paid-in Capital	Accumulated Deficit	Subscription Receivable	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2009	21,449,352	$ 22	$ 45,553	$ (42,013)	$ (17)	$ 3,545
Stock-based compensation	-	-	400	-	-	400
Issuance of common stock for employee compensation	60,521	-	47	-	-	47
Issuance of common stock for license fees	81,035	-	70	-	-	70
Issuance of common stock for consulting fees	279,724	-	213	-	-	213
Issuance of common stock for options exercised	255,954	-	113	-	17	130
Issuance of common stock, net of issuance costs of $115	1,212,121	1	884	-	-	885
Net loss for the year ended December 31, 2010	-	-	-	(1,711)	-	(1,711)
Balance, December 31, 2010	23,338,707	23	47,280	(43,724)	-	3,579
Stock-based compensation	-	-	973	-	-	973
Issuance of common stock for employee compensation	73,585	-	94	-	-	94
Issuance of common stock for exclusive channel collaboration agreement	3,123,558	3	1,684	-	-	1,687
Issuance of common stock for consulting fees	171,796	-	165	-	-	165
Issuance of common stock for options and warrants exercised	38,948	-	15	-	-	15
Issuance of common stock, net of issuance costs of $539	4,545,926	5	6,956	-	-	6,961
Warrant liability reclassified to stockholders' equity	-	-	1,734	-	-	1,734
Net loss for the year ended December 31, 2011	-	-	-	(8,149)		(8,149)
Balance, December 31, 2011	31,292,520	$ 31	$ 58,901	$ (51,873)	$ -	**$ 7,059**

See accompanying notes to consolidated financial statements

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Synthetic Biologics, Inc. and Subsidiaries

(formerly Adeona Pharmaceuticals, Inc.)

Consolidated Statements of Cash Flows

(In thousands)

	For the years ended December 31,	
	2011	2010
Cash Flows From Operating Activities:		
Loss from continuing operations	$ (7,626)	$ (1,195)
Loss from discontinued operations	(523)	(516)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	973	400
Stock issued as employee compensation	94	47
Stock issued for license fee	-	70
Stock issued for exclusive channel collaboration agreement	1,684	-
Stock issued for consulting fees	165	214
Warrant expense	1,492	-
Change in fair value of warrant liability	242	-
Depreciation	144	346
Provision for uncollectible accounts receivable	414	130
Amortization of premium on investments	57	-
Loss on sale of short-term investment	20	-
(Gain) loss on sale of equipment	6	(3)
Impairment loss on equipment	-	121
Gain on the settlement of accounts payable	(63)	-
Changes in operating assets and liabilities:		
Accounts receivable	(480)	(438)
Other current assets	327	(335)
Deposits and other assets	60	-
Assets of discontinued operations	191	13
Accounts payable	153	(196)
Accrued liabilities	(181)	202
Liabilities of discontinued operations	(24)	(5)
Net Cash Used In Operating Activities	(2,875)	(1,145)
Cash Flows From Investing Activities:		
Purchase of short-term investments	(4,370)	-
Proceeds from short-term investments	4,293	-
Purchases of property and equipment	-	(12)
Proceeds from the sale of equipment	2	77
Net Cash Provided By (Used In) Investing Activities	(75)	65

Cash Flows From Financing Activities:		
Proceeds from issuance of common stock for stock option and warrant exercises	15	129
Proceeds from issuance of common stock for exclusive channel collaboration agreement	3	-
Proceeds from the issuance of common stock	7,500	1,000
Cash paid as direct offering costs	(539)	(115)
Net Cash Provided By Financing Activities	6,979	1,014
Net increase (decrease) in cash	4,029	(66)
Cash at beginning of year	2,649	2,715
Cash at end of year	**$ 6,678**	$ 2,649
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ -	$ 10
Cash paid for taxes	$ -	$ -
Supplemental disclosure of non-cash investing and financing activities:		
Exchange of equipment	$ -	$ 64
Reclassification of warrant liability to additional paid-in capital	$ 1,734	$ -

See accompanying notes to consolidated financial statements

Synthetic Biologics, Inc. and Subsidiaries

(formerly Adeona Pharmaceuticals, Inc.)

Notes to Consolidated Financial Statements

December 31, 2011 and 2010

1. Organization and Nature of Operations and Basis of Presentation

Description of Business

Synthetic Biologics, Inc. (the "Company" or "Synthetic Biologics"), formerly Adeona Pharmaceuticals, Inc., is a biotechnology company focused on the development of synthetic DNA-based therapeutics and innovative disease-modifying medicines for serious illnesses. In the area of synthetic biology, the Company is initially developing a product candidate to treat PAH. The Company also intends to expand new and existing collaborations in the synthetic biology area. In addition, Synthetic Biologics has several clinical-stage programs that are being funded, or partially funded, by grants, charitable organizations and corporate partners. In this area we are developing, or have partnered the development of, product candidates to treat relapsing-remitting MS, cognitive dysfunction in MS, fibromyalgia and ALS.

Medical Indication	Product Candidate	Status
PAH	Synthetic DNA-based therapy	Preclinical
Relapsing-remitting MS	Trimesta (estriol)	All patients enrolled in Phase II clinical trial; dosing and monitoring underway
Cognitive dysfunction in MS	Trimesta (estriol)	Patient enrollment underway in Phase II clinical trial
Fibromyalgia	Effirma (oral flupirtine)	Partnered with Meda AB
ALS	AEN-100 (gastroretentive zinc acetate)	Clinical trial preparation underway

On December 21, 2011, Synthetic Biologics announced that the Board of Directors had taken several actions to prioritize its focus on our entry into the emerging field of synthetic biology. The Company also announced that it

intends to seek marketing partners for its zinc-based products *reaZin*™ and *wellZin*™.

Basis of Presentation and Corporate Structure

As of December 31, 2011, the Company had eight active subsidiaries, Pipex Therapeutics, Inc. (“Pipex Therapeutics”), Adeona Clinical Laboratory (formerly Hart Lab, LLC), Effective Pharmaceuticals, Inc. (“EPI”), Solovax, Inc. (“Solovax”), CD4 Biosciences, Inc. (“CD4”), Epitope Pharmaceuticals, Inc. (“Epitope”), Healthmine, Inc. (“Healthmine”) and Putney Drug Corp. (“Putney”). As of December 31, 2011, EPI, Adeona Clinical Laboratory, Healthmine and Putney are wholly owned and Pipex Therapeutics, Solovax, CD4 and Epitope are majority-owned.

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

On March 8, 2012, the Company sold all of its interest in Adeona Clinical Laboratory, LLC (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) $700,000 payable pursuant to the terms of a two-year non-recourse promissory note secured by all the assets of the Lab. Accordingly, this business has been presented in the consolidated financial statements as discontinued operations. This transaction is described in more detail in Note 3 – Discontinued Operations of Adeona Clinical Laboratory.

2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Emerging from the Development Stage

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

Use of Estimates

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

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

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable were reported at realizable value, net of allowances for doubtful accounts, which were estimated and recorded in the period the related revenue was recorded. The Company estimated and reviewed the collectability of its receivables based on a number of factors, including the period they were outstanding. Historical collection and payer reimbursement experience was an integral part of the estimation process related to allowances for doubtful accounts associated with Adeona Clinical Laboratory. In addition, the Company regularly assessed the state of its billing operations in order to identify issues, which impacted the collectability of these receivables or reserve estimates. Revisions to the allowances for doubtful accounts estimates were recorded as an adjustment to bad debt expense. Receivables deemed uncollectible were charged against the allowance for doubtful accounts. Recoveries of receivables previously written-off are recorded as credits to the allowance for doubtful accounts.

Revenue Recognition

The Company records revenue when all of the following have occurred: (1) persuasive evidence of an arrangement exists, (2) the service is completed without further obligation, (3) the sales price to the customer is fixed or determinable, and (4) collectability is reasonably assured. The Company recognizes milestone payments or upfront payments that have no contingencies as revenue when payment is received. For the year ended December 31, 2011, the Company's only stream of revenue was laboratory revenue. During the year ended December 31, 2010, the Company's streams of revenue were license revenue, laboratory revenue and grant revenue. Laboratory revenues are a component of discontinued operations for the years ended December 31, 2011 and 2010. See Note 3 – Discontinued Operations of Adeona Clinical Laboratory.

License Revenues

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

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

On May 6, 2010, the Company entered into the Meda Agreement for the development and commercialization of Effirma (oral flupirtine) for fibromyalgia. As consideration for the sublicense, the Company received an up-front payment of $2.5 million upon execution of the Meda Agreement. This payment was recorded as license revenue in 2010. Pursuant to the Company's license agreement with McLean Hospital, the Company paid 15% of the $2.5 million payment ($375,000), that was netted against the revenues received from Meda AB. The Company is also entitled to additional milestone payments of $5 million upon filing of an NDA with the U.S. FDA for oral flupirtine for fibromyalgia and $10 million upon marketing approval. The Meda Agreement also provides that the Company is entitled to receive net royalties of 7% of net sales of oral flupirtine approved for the treatment of fibromyalgia covered by issued patent claims in the U.S. and Japan. The Meda Agreement provides that Meda AB will assume all future development costs for the commercialization of oral flupirtine for fibromyalgia. Pursuant to the terms of the

Company's agreement with McLean Hospital, the Company is obligated to pay half of all future royalties the Company receives. Future milestone payments will be recorded as revenue when payment is received as there are no future deliverables, and it is non-refundable.

Laboratory Revenues

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

The Company maintained a sales allowance to compensate for the difference in its billing practices and insurance company reimbursements. In determining this allowance, the Company looked at several factors, the most significant of which is the average difference between the amount charged and the amount reimbursed by insurance carriers over the prior 12 months, otherwise known as the yearly average adjustment amount. The allowance taken was the averaged yearly average adjustment amount for these prior periods and multiplied by the period's actual gross sales to determine the actual sales allowance for each period.

The Company generated reimbursement from three significant insurance providers in 2011 and 2010.

Customer	2011	2010
A	70%	65%
B	4%	11%
C	19%	14%

Grant Revenues

On November 4, 2010, the Company was awarded two grants totaling $489,000 under the Qualifying Therapeutic Discovery Project (QTDP) Program to support the Company's clinical programs. The QTDP Grants Program was included in the healthcare reform legislation and established a one-time pool of $1 billion for grants to small biotechnology companies developing novel therapeutics which show potential to: (a) result in new therapies that either treat areas of unmet medical need, or prevent, detect, or treat chronic or acute diseases and conditions; (b) reduce long-term health care costs in the U.S.; or (c) significantly advance the goal of curing cancer within a 30-year period. All grant income was recognized in 2010 and there are no future obligations associated with these grants.

During 2010 and March 2011, all amounts awarded under these grants had been received. See Note 9 regarding the taxability of grant revenues.

Revenues, net (in thousands)

	December 31,	
	2011	2010
License revenue	$ -	$ 2,500
License fees	-	(375)
License revenue, net	-	2,125
Grant revenue	-	489
Total revenues, net	$ -	$ 2,614

Risks and Uncertainties

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

Cash and Cash Equivalents

Cash and cash equivalents include cash and highly liquid short-term investments with original maturities of three months or less. At December 31, 2011 and 2010, respectively, the Company had no cash equivalents.

Classification of Marketable Securities as Held to Maturity, Trading, and Available for Sale

The Company determines the appropriate classification of its investments in debt and equity securities at the time of purchase and reevaluates such determinations at each balance sheet date. Debt securities are classified as held to maturity when the Company has the positive intent and ability to hold the securities to maturity. Debt securities for which the Company does not have the intent or ability to hold to maturity are classified as available for sale. Held to maturity securities are recorded as either short-term or long-term on the balance sheet, based on contractual maturity date and are stated at amortized cost. Marketable securities that are bought and held principally for the purpose of selling them in the near term are classified as trading securities and are reported at fair value, with unrealized gains and losses recognized in earnings. Debt and marketable equity securities not classified as held to maturity or as trading, are classified as available for sale, and are carried at fair market value, with the unrealized gains and losses, net of tax, included in the determination of comprehensive income and reported in shareholders' equity. At December 31, 2011 and 2010, respectively, the Company had no marketable securities.

During the year ended December 31, 2011, the Company held investments in marketable securities that were classified as held to maturity and consisted of corporate bonds and certificates of deposits as follows *(in thousands)*:

	December 31, 2011
Purchase of short-term investments	$ (4,370)
Amortization of premium on investments	57
Proceeds from short-term investments	4,293
Loss on sale of short-term investments	20
Fair value	$ -

Property and Equipment

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

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

Depreciation expense was approximately $144,000 and $346,000 for the years ended December 31, 2011 and 2010, respectively. When assets are disposed of, the cost and accumulated depreciation are removed from the accounts. Repairs and maintenance are charged to expense as incurred.

During 2010, the Company reviewed property and equipment for impairment and determined that certain items had been impaired due to obsolescence. As a result of this review, the Company recorded an impairment loss of approximately $121,000. For the year ended December 31, 2011, there were no significant events or changes in circumstances identified by the Company that would indicate that the carrying value of an asset was not recoverable.

Long-Lived Assets

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

Goodwill

Goodwill was not amortized, and was tested for impairment at the reporting unit level annually and in interim periods if certain events occur indicating that the carrying value of goodwill was impaired. A reporting unit was an operating

segment for which discrete financial information was available and was regularly reviewed by management. The Company had one reporting unit, Adeona Clinical Laboratory, to which goodwill was assigned.

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

At December 31, 2011, in connection with the Company classifying Adeona Clinical Laboratory as discontinued operations, previously recorded goodwill was considered impaired. See Note 3 – Discontinued Operations of Adeona Clinical Laboratory.

Beneficial Conversion Feature

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

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

Derivative Liabilities

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

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

Debt Issue Costs and Debt Discount

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

Original Issue Discount

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

Net Earnings (Loss) per Share

Net earnings (loss) per share is computed by dividing net earnings (loss) less preferred dividends for the period by the weighted average number of common shares outstanding. Diluted earnings (loss) per share is computed by dividing net income (loss) less preferred dividends by the weighted average number of common shares outstanding including

the effect of common share equivalents. Since the Company reported a net loss for the years ended December 31, 2011 and 2010, all common equivalent shares would be anti-dilutive; as such there is no separate computation for diluted loss per share. The number of options and warrants for the purchase of common stock, that were excluded from the computations of net loss per common share for the year ended December 31, 2011 were 2,979,010 and 3,259,186, respectively, and for the year ended December 31, 2010 were 1,990,444 and 1,070,472, respectively.

Research and Development Costs

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

Fair Value of Financial Instruments

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

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

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

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

Stock-Based Payment Arrangements

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

Income Taxes

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

Accounting guidance now codified as FASB ASC Topic 740-20, *"Income Taxes – Intraperiod Tax Allocation,"* clarifies the accounting for uncertainties in income taxes recognized in accordance with FASB ASC Topic 740-20 by prescribing guidance for the recognition, de-recognition and measurement in financial statements of income tax positions taken in previously filed tax returns or tax positions expected to be taken in tax returns, including a decision whether to file or not to file in a particular jurisdiction. FASB ASC Topic 740-20 requires that any liability created for unrecognized tax benefits is disclosed. The application of FASB ASC Topic 740-20 may also affect the tax bases of assets and liabilities and therefore may change or create deferred tax liabilities or assets. The Company would recognize interest and penalties related to unrecognized tax benefits in income tax expense. At December 31, 2011 and 2010, respectively, the Company did not record any liabilities for uncertain tax positions.

Recent Accounting Pronouncements

In May 2011, the FASB issued guidance in regard to fair value measurement. The new guidance results in a consistent definition of fair value and common requirements for measurement of and disclosure about fair value between GAAP and International Financial Reporting Standards (IFRS). This guidance is effective for interim and annual periods beginning after December 15, 2011. The adoption of this guidance is not expected to have a material impact on the Company’s financial position or results of operations.

In September 2011, the FASB issued guidance in regard to goodwill impairment. The new guidance is intended to reduce the cost and complexity of the annual goodwill impairment test by providing entities with the option of performing a "qualitative" assessment to determine whether further impairment testing is necessary. An entity can choose to perform the qualitative assessment on none, some, or all of its reporting units. Moreover, an entity can bypass the qualitative assessment for any reporting unit in any period and proceed directly to step one of the impairment test, and then perform the qualitative assessment in any subsequent period. The new guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011, with early adoption permitted. The adoption of this guidance is not expected to have a material impact on the Company’s financial position or results of operations.

Reclassifications

To conform prior period amounts to current year classifications, the Company has reclassified assets, liabilities, revenues and expenses associated with the sale of Adeona Clinical Laboratory to discontinued operations. These reclassifications had no impact on the Company's previously reported financial condition, results of operations or cash flows.

3. Discontinued Operations of Adeona Clinical Laboratory

On March 8, 2012, the Company sold all of its interest in Adeona Clinical Laboratory, LLC (the "Lab") to Hartlab, LLC, an entity controlled by the Lab's former owner. In connection with the sale of the Lab, the consideration received was (i) the immediate assignment of the Lab's outstanding accounts receivable up through the date of closing, plus (ii) $700,000 payable pursuant to the terms of a two-year non-recourse promissory note secured by all of the assets of the Lab.

In accordance with ASC Topic 205-20 "*Presentation of Financial Statements—Discontinued Operations*" (ASC 205-20), the Company determined that the sale of the Lab should be classified as "held for sale" at December 31, 2011. In accordance with ACS 205-20 all of the following criteria must be met for an entity to be classified as "held for sale":

- Management, having the authority to approve the action, commits to a plan to sell the asset.
- The asset is available for immediate sale in its present condition subject only to terms that are usual and customary for sales of such assets.
- An active program to locate a buyer and other actions required to complete the plan to sell the asset have been initiated.
- The sale of the asset is probable, and transfer of the asset is expected to qualify for recognition as a complete sale within one year.
- The asset is being actively marketed for sale at a price that is reasonable in relation to its current fair value.

The Company determined that all the criteria had been met and has classified the Lab as discontinued operations and its results of operations, financial position and cash flows are separately reported for all periods presented. The assets and liabilities of the discontinued operations are presented separately under the captions "Assets of discontinued operations" and "Liabilities of discontinued operations," respectively, in the accompanying Consolidated Balance Sheets at December 31, 2011, and December 31, 2010, and consist of the following *(in thousands):*

	December 31,

	2011	2010
Assets of discontinued operations:		
Property and equipment, net	$23	$36
Goodwill	-	178
Total assets	$23	$214
Liabilities of discontinued operations:		
Current portion of capital lease	$-	$24
Total liabilities	$-	$24

The summarized statement of operations data for Adeona Clinical Laboratory for the years ended December 31, 2011 and December 31, 2010 are as follows *(in thousands):*

	December 31,	
	2011	2010
Laboratory fees, net	$1,169	$551
Operating Costs and Expenses:		
General and administrative	539	599
Cost of laboratory services	975	468
Impairment loss on goodwill	178	-
Total operating costs and expenses	1,692	1,067
Loss from discontinued operations	$(523)	$(516)

4. Selected Balance Sheet Information

Accounts receivable (in thousands)

	December 31,	
	2011	2010
Accounts receivable	$692	$472
Bad debt allowance - customer	(287)	(133)
Total	$405	$339

Other current assets (in thousands)

	December 31, 2011	2010
Grant receivable	$-	$320
Prepaid expenses	16	23
Total	$16	$343

Property and equipment (in thousands)

	December 31, 2011	2010
Leasehold improvements	$-	$863
Manufacturing equipment	400	333
Computer and office equipment	159	160
Laboratory equipment	136	214
	695	1,570
Less accumulated depreciation	(372)	(1,095)
Total	$323	$475

Accrued expenses (in thousands)

	December 31, 2011	2010
Accrued vendor payments	$1	$105
Bonus	-	100
Compensation	28	5
Total	$29	$210

5. Stock-Based Compensation

Stock Incentive Plan

During 2001, the Company's Board of Directors and stockholders adopted the 2001 Stock Incentive Plan (the "2001 Stock Plan"). As of the date of the merger, there were 1,489,353 options issued and outstanding under the 2001 plan. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2001 Stock Plan shall not exceed 250,000. All awards pursuant to the 2001 Stock Plan shall terminate upon the termination of the grantee's employment for any reason. Awards include options, restricted shares, stock appreciation rights, performance shares and cash-based awards (the "Awards"). The 2001 Stock Plan contains certain anti-dilution provisions in the event of a

stock split, stock dividend or other capital adjustment, as defined in the plan. The 2001 Stock Plan provides for a Committee of the Board to grant awards and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the awards, including acceleration of the vesting of an award at any time. As of December 31, 2011, there were 1,320,354 options issued and outstanding under the 2001 Stock Plan.

On March 20, 2007, the Company's Board of Directors approved the 2007 Stock Incentive Plan (the "2007 Stock Plan") for the issuance of up to 2,500,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. This plan was approved by stockholders on November 2, 2007. The exercise price of stock options under the 2007 Stock Plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2001 plan shall not exceed 250,000. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of December 31, 2011, there are 1,201,156 options issued and outstanding under the 2007 Stock Plan.

On November 2, 2010, the Board of Directors and stockholders adopted the 2010 Stock Incentive Plan ("2010 Stock Plan") for the issuance of up to 3,000,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. The exercise price of stock options under the 2010 Stock Plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. Options become exercisable over various period from the date of grant, and generally expire ten years after the grant date. As of December 31, 2011, there are 457,500 options issued and outstanding under the 2010 Stock Plan.

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

The Company has applied fair value accounting for all share based payment awards since inception. The fair value of each option or warrant granted is estimated on the date of grant using the Black-Scholes option pricing model. The Black-Scholes assumptions used in the years ended December 31, 2011 and 2010 are as follows:

	Year ended December 31,	
	2011	2010
Exercise price	$0.49 - $2.22	$0.56 - $0.87
Expected dividends	0%	0%
Expected volatility	175% - 188%	187% - 207%
Risk fee interest rate	1.30% - 3.58%	2.54% - 3.63%
Expected life of option	5 - 7 years	10 years
Expected forfeitures	0%	0%

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

- immediate vesting,
- half vesting immediately and the remainder over three years,
- quarterly over three years,
- annually over three years,
- one-third immediate vesting and remaining annually over two years,
- one half immediate vesting with remaining vesting over nine months,
- one quarter immediate vesting with the remaining over three years
- one quarter immediate vesting with the remaining over 33 months; and

. monthly over three years.

During 2011, the Company granted 557,002 options to employees and consultants having an approximate fair value of $609,000 based upon the Black-Scholes option pricing model. During 2010, the Company granted 743,332 options to employees and consultants having an approximate fair value of $597,000 based upon the Black-Scholes option pricing model.

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance – December 31, 2009	2,561,332	$ 1.26	7.16 years	$304,000
Granted	743,332	$ 0.80		
Exercised	(255,954)	$ 0.44		
Forfeited	(509,619)	$ 0.69		
Balance – December 31, 2010	2,539,091	$ 1.32	6.97 years	$1,028,000
Granted	557,002	$ 1.26		
Exercised	(23,333)	$ 0.57		
Forfeited	(93,750)	$ 0.59		
Balance – December 31, 2011 – outstanding	2,979,010	$ 1.34	6.01 years	$-
Balance – December 31, 2011 – exercisable	2,454,607	$ 1.46	5.62 years	$-

Grant date fair value of options granted – 2011	$ 609,000
Weighted average grant date fair value – 2011	$ 1.09
Grant date fair value of options granted – 2010	$ 597,000
Weighted average grant date fair value – 2010	$ 0.80
Outstanding options held by related parties – 2011	1,283,160
Exercisable options held by related parties – 2011	1,070,660
Outstanding options held by related parties – 2010	1,083,160
Exercisable options held by related parties – 2010	858,160

The options outstanding and exercisable at December 31, 2011 are as follows:

Options Outstanding				Options Exercisable		
Range of Exercise Price	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
$0.09 - $4.57	2,889,011	$ 1.20	6.11 years	2,364,608	$ 1.29	5.72 years
$4.58 - $9.05	89,999	$ 5.93	2.76 years	89,999	$ 5.93	2.76 years
$0.09 - $9.05	2,979,010	$ 1.34	6.01 years	2,454,607	$ 1.46	5.62 years

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

Options Outstanding				Options Exercisable		
Range of Exercise Price	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
$0.09 - $4.57	2,449,092	$ 1.16	7.09 years	1,900,445	$ 1.28	6.47 years

$4.58 - $9.05	89,999	$ 5.93	3.76 years	89,999	$ 5.93	3.76 years
$0.09 - $9.05	2,539,091	$ 1.32	6.97 years	1,990,444	$ 1.48	6.35 years

The following is a summary of the Company's non-vested stock options at December 31, 2011:

	Unvested Stock Options	Weighted Average **Grant** Date Fair Value
Non-vested – December 31, 2010	548,647	$ 0.77
Granted	557,002	1.09
Vested/Exercised	(528,017)	1.07
Forfeited/Cancelled	(53,229)	0.57
Non-vested – December 31, 2011	524,403	$ 0.82
Weighted average remaining period for vesting	1.67 years	

Stock Warrants and Derivative Liabilities

On July 2, 2010, the Company entered into a Common Stock Purchase Agreement with a single investor. As part of this agreement, the Company issued warrants to purchase 60,606 shares of common stock to the placement agent, or its permitted assigns. The warrants have an exercise price of $1.32 and a life of 5 years. The warrants vested on January 1, 2011 and expire December 31, 2015. Since these warrants were granted as part of an equity raise, the Company has treated them as a direct offering cost. The result of the transaction has no affect to equity. As of December 31, 2011, 30,303 of these warrants remained outstanding.

On January 28, 2011, the Company entered into a Common Stock Purchase Agreement with three institutional investors. As part of this agreement, the Company issued warrants to purchase 1,428,572 shares of common stock. Each warrant was exercisable for thirteen months at $2.00 per share and subsequently exchanged for new warrants with substantially the same terms as the original warrants except that the expiration date was extended for two months. The original warrants had an anti-dilution price protection feature; if the Company issues securities at a price per share that is less than $2.00 per share, the warrant holders will be ratcheted down to the lower offering price. However, the Company had instituted a floor price of $1.40 per share in connection with the price protection.

On April 6, 2011, the Company entered into another Common Stock Purchase Agreement that triggered the ratchet provision and re-set the price of these warrants to $1.40 per share. Due to the re-set to the floor price, the warrant liability was marked-to-market and reclassified to additional paid-in capital since it ceased to contain the provisions of a derivative liability. As of December 31, 2011, all of these warrants remained outstanding.

The warrants were initially recorded as liabilities at their estimated fair value on the commitment date, which was $716,000 with subsequent changes in estimated fair value recorded as a warrant expense in the Company’s statement of operations at each subsequent reporting period. On April 6, 2011, the fair value of the warrant liability was $1.5 million, which represented an increase in fair value of $765,000. The fair value was measured using the Black-Scholes valuation model. The assumptions used by the Company are summarized in the following table:

	Commitment Date	Remeasurement Date April 6, 2011
Closing stock price	$ 1.39	$ 2.08
Expected dividend rate	0%	0%
Expected stock price volatility	117.1%	104.6%
Risk free interest rate	0.28%	0.29%
Expected life (years)	1.08	0.85

On August 10, 2011, the Company entered into an agreement to exchange the warrants issued in connection with the January 28, 2011 financing for new warrants with substantially the same terms as the original warrants except that in the new warrants the expiration date was extended by two months.

On April 6, 2011, the Company entered into a Common Stock Purchase Agreement with an institutional investor. As part of this agreement, the Company issued a warrant to purchase 844,391 shares of common stock. The warrant was initially exercisable for thirteen months at $2.0725 per share. The warrant had an anti-dilution price protection feature; that provided if the Company issues securities at a price per share that is less than $2.0725 per share, the exercise price of the warrant will be ratcheted down to the lower offering price. On July 28, 2011, the warrant was exchanged for a new warrant with substantially similar terms except that in the new warrant (i) the anti-dilution price protection was eliminated, (ii) the exercise price was lowered to $1.00, (iii) the expiration date was extended for an additional three months to August 12, 2012, and (iv) the warrant’s initial exercise date was changed to January 2012. Due to this warrant exchange, the warrant liability was marked-to-market and reclassified to additional paid-in capital since it ceased to contain the provisions of a derivative liability. As of December 31, 2011, all of these warrants remained outstanding.

The warrant is initially recorded as a liability at its estimated fair value on the commitment date, which was $776,000 with subsequent changes in estimated fair value recorded as a warrant expense in the Company's statement of operations at each subsequent period. On July 28, 2011, the fair value of the warrant liability was $253,000, which represented a decrease in fair value of $523,000. The fair value is measured using the Black-Scholes valuation model. The assumptions used by the Company are summarized in the following table:

	Commitment Date	Remeasurement Date July 28, 2011
Closing stock price	$2.08	$0.84
Expected dividend rate	0%	0%
Expected stock price volatility	112.1%	105.6%
Risk free interest rate	0.29%	0.21%
Expected life (years)	1.08	1.04

The following table summarizes the estimated fair value of the warrant liabilities *(in thousands):*

Balance at December 31, 2010	$-
Warrant liability	1,492
Change in fair value of warrant liability	242
Reclassification to additional paid-in capital	(1,734)
Balance at December 31, 2011	$-

A summary of warrant activity for the Company for the year ended December 31, 2010 and for the year ended December 31, 2011 is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance at December 31, 2009	1,070,472	$ 3.27
Granted	60,606	1.32
Exercised	-	-
Forfeited	-	-
Balance as December 31, 2010	1,131,078	3.49
Granted	2,272,963	1.25
Exercised	(15,615)	1.03
Forfeited	(129,240)	2.08
Balance as December 31, 2011	3,259,186	$ 1.95

A summary of all outstanding and exercisable warrants as of December 31, 2011 is as follows:

Exercise Price	Warrants Outstanding	Warrants Exercisable	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
$ 1.00	844,391	844,391	0.61 years	$219,000
$ 1.32	30,303	30,303	4.00 years	-
$ 1.40	1,428,572	1,428,572	0.33 years	-
$ 2.22	517,257	517,257	4.91 years	-
$ 3.30	61,207	61,207	3.41 years	-
$ 3.75	50,000	50,000	4.13 years	-
$ 6.36	327,456	327,456	0.86 years	-
$ 1.95	3,259,186	3,259,186	1.33 years	$219,000

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Options of Subsidiaries

As of December 31, 2011, CD4 Biosciences, Inc., a majority-owned subsidiary of Synthetic Biologics, has a total of 20,000 stock options outstanding and exercisable. These stock options have an exercise price of $0.20 and a remaining contractual life of 0.37 years.

As of December 31, 2011, Epitope, a majority-owned subsidiary of Synthetic Biologics, has 50,000 stock options outstanding and 20,000 stock options exercisable. These stock options have an exercise price of $0.001 and a remaining contractual life of 6.50 years.

6. Stockholders' Equity

Year Ended December 31, 2010

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

During the year ended December 31, 2010, the Company issued 255,954 shares of common stock, in connection with the exercise of stock options, for proceeds of $130,000. The Company also issued 279,724 shares of common stock for consulting services, having a fair value of $214,000 ($0.76 per share), 81,035 shares of common stock for license fees, having a fair value of $70,000 ($0.87 per share), and 60,521 shares of common stock for employment service, having a fair value of $47,000 ($0.77 per share). The fair value of these issuances were based upon the quoted closing trading prices.

Year Ended December 31, 2011

During the year ended December 31, 2011, the Company issued 28,333 shares of common stock in connection with the exercise of stock options and warrants for proceeds of $15,000 and 10,615 shares of common stock related to a cashless exercise of warrants. The Company issued 73,585 shares of common stock for employment service, having a fair value of $94,000 ($1.29 average per share) and 171,796 shares of common stock for consulting services, having a fair value of $165,000 ($0.96 average per share), based on the quoted closing trading prices. The Company also issued 3,123,558 shares of common stock as consideration for the Channel Agreement with Intrexon, having a fair value of

$1.7 million ($0.54 average per share), based on the quoted closing trading price.

On January 28, 2011, the Company sold 2,857,144 shares of common stock and warrants exercisable for 1,428,572 shares of common stock for $4 million. Direct offering costs were approximately $296,000.

On April 6, 2011, the Company sold 1,688,782 shares of common stock and a warrant exercisable for 844,391 shares of common stock for $3.5 million. Direct offering costs were approximately $243,000.

7. License, Collaborative and Employment Agreements and Commitments

License Agreements

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

Research Agreement

In September of 2005, the Company entered into a three-year research agreement with the University of Michigan. Pursuant to that agreement, the Company sponsored research of approximately $460,000 per year. On March 20, 2008, the Company terminated the agreement. On March 24, 2009, the Company entered into a payment plan with the University of Michigan to pay the outstanding balance of $197,000. The Company agreed to pay $5,000 per month, until the balance is paid in full. At December 31, 2011, the balance is approximately $32,000 and is recorded as a short-term accounts payable

Employment Agreements

On February 6, 2010, the Company executed a three-year employment agreement with James S. Kuo, M.D., Chairman, Chief Executive Officer and President. The agreement provided for an annual base salary of $199,000, discretionary performance and transactional bonus payments, and 400,000 stock options with an exercise price equal to the market price on the date of grant. Of these stock options, 100,000 vested immediately upon grant and the remainder will vest pro rata, on a monthly basis, over the following thirty-six months. The fair value of the options totaled $328,000 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 204.5%; risk free interest rate of 3.59% and an expected life of 10 years.

Effective February 3, 2012, Dr. Kuo resigned from his positions as President and Chief Executive Officer. In connection with his resignation, Dr. Kuo entered into a nine-month consulting agreement with the Company (the “Consulting Agreement”). Pursuant to the Consulting Agreement, Dr. Kuo will be entitled to a consulting fee of $17,000 per month and retain the right to exercise the stock options held by him that have vested (324,999) as of the effective date of the Consulting Agreement for a period expiring on the date that is one year from the effective date of the Consulting Agreement.

Effective February 3, 2012, Jeffrey Riley was appointed to serve as the Company's Chief Executive Officer and President. In connection with his appointment, Mr. Riley entered into a three-year employment agreement with the Company (the "Riley Employment Agreement"). Pursuant to the Riley Employment Agreement, Mr. Riley will be entitled to an annual base salary of $348,000 and will be eligible for discretionary performance and transactional bonus payments. Additionally, Mr. Riley was granted options to purchase 750,000 shares of the Company's common stock with an exercise price equal to the per share market price on the date of issue. These options will vest pro rata, on a monthly basis, over thirty-six months. The Company measured the fair value of the stock options at approximately $1.7 million using a Black-Scholes valuation model; these warrants were indexed to the Company's own stock.

Effective February 6, 2012, C. Evan Ballantyne was appointed the Company's Chief Financial Officer. In connection with his appointment, Mr. Ballantyne entered into a three-year employment agreement with the Company (the "Ballantyne Employment Agreement"). Pursuant to the Ballantyne Employment Agreement, Mr. Ballantyne will be entitled to an annual base salary of $298,000 and will be eligible for discretionary performance and transactional bonus payments. Additionally, Mr. Ballantyne was granted options to purchase 425,000 shares of our common stock with an exercise price equal to our per share market price on the date of issue. These options will vest pro rata, on a monthly basis, over thirty-six months. The Company measured the fair value of the stock options at approximately $1 million using a Black-Scholes valuation model; these warrants were indexed to the Company's own stock.

The Black-Scholes assumptions used in calculating the fair value of the stock options are as follows:

Exercise price	$2.30 - $2.47
Expected dividends	0%
Expected volatility	174%
Risk free interest rate	1.93% - 1.97%
Expected life of options	10 years
Expected forfeitures	0%

Other Commitments

As of December 31, 2011, amounts due for license agreements are as follows *(in thousands)*:

Year Ending December 31,	
2012	$37
2013	5
2014	5

2015	5
2016	5
Total	$57

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Operating Lease

During 2007, the Company entered into a non-cancelable operating lease for office, laboratory and production space in Ann Arbor, Michigan. This lease expired on February 28, 2011. In March 2011, the Company entered into a month-to-month lease, at a different location, in Ann Arbor, Michigan.

During the years ended December 31, 2011 and 2010 the Company recognized rent expense of $64,000 and $214,000, respectively.

Capital Lease

In June 2006, the Company acquired $65,000 of equipment under a non-cancelable capital lease. The Company agreed to guarantee and to release the seller from the seller's personal guarantee of the remaining balance and the amount was placed in escrow. The effective interest rate of the lease was 8.51%. Related monthly payments of principal and interest were $1,400 over a period of sixty months. In September 2008, the lessor extended the term for repayment by eight months, with a final maturity date of January 2012. The remaining balance of this capital lease at December 31, 2010 was $24,000. In January 2011, this capital lease was paid in full and the funds were released from escrow. See Note 3 – Discontinued Operations of Adeona Clinical Laboratory.

8. Stock Repurchase Program

On April 3, 2009, the Company's Board of Directors approved a Stock Repurchase Program authorizing the Company to repurchase, from time-to-time and through December 31, 2009, up to $1 million of its common stock, up to a maximum of four million shares at prices of up to $5 per share. As of December 31, 2011, the Company had repurchased 81,482 shares for approximately $50,000 ($0.61 per share), based upon the quoted closing trading price. These treasury shares are not included in the computation of earnings (loss) per share and are deemed to be canceled and retired.

9. Income Taxes

There was no income tax expense for the years ended December 31, 2011 and 2010 due to the Company's net losses.

The Company's tax expense differs from the "expected" tax expense for the years ended December 31, 2011 and 2010, (computed by applying the Federal Corporate tax rate of 34% to loss before taxes and 5.5% for Michigan State Corporate taxes, the blended rate used was 37.63%), as follows *(in thousands):*

	2011	2010
Computed "expected" tax benefit - Federal	$ (2,618)	$(550)
Computed "expected" tax benefit - State	(448)	(94)
Non-taxable federal grant	-	(184)
Meals, entertainment and other	5	5
Non-deductible stock-based compensation	366	150
Warrant expense	56	-
Change in fair value of warrant expense	91	-
Realized loss on debt securities	7	-
Change in valuation allowance	2,035	673
	$-	$-

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The effects of temporary differences that gave rise to significant portions of deferred tax assets at December 31, 2011 and 2010 are as follows *(in thousands):*

Deferred tax assets:	2011	2010
Stock issued for services	$ (321)	$(223)
Bad debt – change in allowance	(205)	(49)
Net operating loss carry-forward	(10,425)	(8,644)
Total gross deferred tax assets	(10,951)	(8,916)
Less valuation allowance	10,951	8,916
Net deferred tax assets	$ -	$-

At December 31, 2011, the Company has a net operating loss carry-forward of approximately $27.7 million available to offset future taxable income expiring through 2031. Utilization of these net operating losses may be limited due to potential ownership changes under Section 382 of the Internal Revenue Code.

The valuation allowance at December 31, 2010 was approximately $8.9 million. The net change in valuation allowance during the year ended December 31, 2011 was an increase of approximately $2 million. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The ultimate realization of deferred income tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred income tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on consideration of these items, Management has determined that enough uncertainty exists relative to the realization of the deferred income tax asset balances to warrant the application of a full valuation allowance as of December 31, 2011.

During 2010, the Company received grant revenue of $489,000. Under the terms of the grant, this revenue is not taxable.

10. Subsequent Event

On December 20, 2011, the Company entered into a consulting agreement for financial advisory services, for a period of twelve months. As compensation for such services, the consultant will be paid a monthly fee of $10,000 and was issued a warrant exercisable for 100,000 shares of the Company’s common stock. The warrant is exercisable upon issuance for a period of five years from the date of issue at an exercise price equal to the price of the Company’s common stock on the date of issue. The issue date of the warrant is February 2, 2012.

The fair value of the warrant approximated $200,000 and was measured using the Black-Scholes valuation model. The assumptions used by the Company are summarized in the following table:

Exercise price	$1.14
Expected dividends	0%
Expected volatility	174%
Risk free interest rate	0.71%
Expected life of warrant	5 years
Expected forfeitures	0%

On May 1, 2012, the Company was informed by Berman & Company, P.A. (“Berman & Company”), the Company’s independent registered accounting firm, that during a regular Public Company Accounting Oversight Board (“PCAOB”) inspection of Berman & Company, the PCAOB issued a comment that the audit opinion included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2011 was issued by a partner at Berman & Company who was not authorized under the PCAOB rules to issue the opinion or act as our named engagement partner with respect to the Form 10-K audit (or prior 2011 Form 10-Q interim reviews) after the original engagement partner rotated off the account under the Securities and Exchange Commission’s independence rules as it pertains to partner rotation (S-X Rule 2-01 - Qualifications of Accountants).

The Company believes that the previously filed financial statements for the year ended December 31, 2011 are accurate. In addition, the Company has not been informed by Berman & Company or the PCAOB, that the previously filed financial statements for the year ended December 31, 2011 are not accurate or otherwise invalid. As a matter of precaution the new engagement partner at Berman & Company has since: (i) taken full responsibility for the audit as the lead engagement partner on the audit, (ii) performed a detailed review of all audit procedures related to the original audit for sufficiency and (iii) reissued the audit opinion. The review performed by the new audit partner did not result in any changes to the Company’s financial statements or notes to the financial statements for the year ended December 31, 2011, other than the addition of the May 1, 2012 and May 10, 2012 disclosures in this subsequent event note to the financial statements.

On May 10, 2012, Jeffrey J. Kraws was appointed as the independent, non-executive Chairman of the Board. For his service as independent, non-executive Chairman of the Board, Mr. Kraws will be issued options exercisable for 100,000 shares of the Company’s common stock and will receive annual compensation of $150,000. The fair value of these options will be measured using the Black-Scholes valuation model.

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

None.

Item 9A. ***Controls and Procedures***

Disclosure Controls and Procedures

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

Management's Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15. The Company's internal control over financial reporting is designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published financial statements. Management conducted an assessment of the Company's internal control over financial reporting based on the framework and criteria established by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on the assessment, management concluded that, as of December 31, 2011, the Company's internal control over financial reporting is effective based on those criteria.

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

Changes in Internal Control

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during our fiscal quarter ended December 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

This Annual Report on Form 10-K/A does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the SEC that permit the Company to provide only management's report in this Annual Report on Form 10-K/A.

Item 9B. ***Other Information***

None.

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PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

Below is certain information regarding our directors and executive officers.

Name	Age	Position
Jeffrey Riley	49	Chief Executive Officer, President and Director
C. Evan Ballantyne	52	Chief Financial Officer
Jeffrey J. Kraws	47	Chairman
Steve H. Kanzer, C.P.A, J.D.	48	Director
James S. Kuo, M.D.	47	Director
Nelson K. Stacks	41	Director
Scott L. Tarriff	52	Director
Jeffrey Wolf, J.D.	49	Director

Jeffrey Riley. Mr. Riley, a member of the Synthetic Biologics' Board of Directors since March 2010 and Chairman of the Board from November 2011 to May 2012, was appointed as the Company's President and Chief Executive Officer in February 2012. Since November 2009 until January 2012, Mr. Riley served as the Managing Director of 526 Ventures, a life science-focused consulting firm with a commercial and transactional focus, and from April 2009 until February 2012 he was the business officer of Ruga Corporation, a Stanford University spin-out oncology drug discovery company focused on targeting tumor adaptive responses. From January 2005 until January 2010, Mr. Riley was a member of the advisory board and a venture partner of Queensland Biocapital Fund, an Australia-based venture fund. Mr. Riley has held senior corporate and commercial development positions with multiple venture-backed biotech companies. In these positions, he was responsible for raising equity and negotiating alliances including in-licensing, out-licensing, distribution agreements, technology acquisitions and research agreements with large pharmaceutical companies and government agencies. Mr. Riley's pharmaceutical experience includes commercial management and mergers and acquisition roles for Pfizer and SmithKline Beecham. Additionally, Mr. Riley served as CFO and VP Corporate Development for Nichols Institute Diagnostics, later acquired by Corning and spun out as Quest Diagnostics. Mr. Riley's education includes: a B.S. degree from Boise State University, coursework at UCSF/Berkeley in drug discovery/development and participation in a dual-degree graduate program, an M.B.A./M.I.M. sponsored by Arizona State University and the Thunderbird School of Global Management.

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

C. Evan Ballantyne. Mr. Ballantyne joined Synthetic Biologics as its Chief Financial Officer in February 2012. From 2006 until its acquisition in April 2011, Mr. Ballantyne served as Executive Vice President and Chief Financial Officer of Clinical Data, Inc., a publicly-traded biopharmaceutical company which was acquired by Forest Laboratories, Inc. for $1.3 billion. While at Clinical Data, he was instrumental in leading corporate financings totaling approximately $220 million as well as a number of acquisition and divestitures totaling $116 million. Mr. Ballantyne has also served as Chief Financial Officer of a number of private medical technology companies, including Avedro and ZymeQuest. Earlier in his career, he served as Vice President and Chief Operating Officer for ACNielsen Europe Middle East & Africa and held the Chief Financial Officer position as well for two years. There, Mr. Ballantyne was responsible for all aspects of operations, strategic planning and finance in more than 45 countries for a corporation with 9,700 employees. He also helped lead the company's successful ISO certification process. He began his career at the Dun & Bradstreet Corporation where he held several senior financial positions. Mr. Ballantyne earned a BA from the University of Western Ontario, and took a post-graduate degree in Business Administration with Honors from the University of Windsor.

Jeffrey J. Kraws. Mr. Kraws has been a director since January of 2006, and was appointed independent, non-executive Chairman of the Board in May 2012. Since 2003, Mr. Kraws has served Chief Executive Officer and co-founder of Crystal Research Associates. Well known and respected on Wall Street, Mr. Kraws has received some of the most prestigious awards in the industry. Among other awards, he was given a "5-Star Rating" in 2001 by Zacks and was ranked the number one analyst among all pharmaceutical analysts for stock performance in 2001 by Starmine.com. Prior to founding Crystal Research Associates, Mr. Kraws served as co-president of The Investor Relations Group (IRG), a firm representing primarily under-followed, small-capitalization companies. Previously, Mr. Kraws served as a managing director of healthcare research for Ryan Beck & Co. and as director of research/senior pharmaceutical analyst and managing director at Gruntal & Co., LLC (prior to its merger with Ryan Beck & Company). Mr. Kraws served as managing director of the healthcare research group and senior pharmaceutical analyst at First Union Securities (formerly EVEREN Securities); as senior U.S. pharmaceutical analyst for the Swedish-Swiss conglomerate Asea Brown Boveri; and as managing director and president of the Brokerage/Investment Banking operation of ABB Aros Securities, Inc. He also served as senior pharmaceutical analyst at Nationsbanc Montgomery Securities, BT Alex Brown & Sons, and Buckingham Research. Mr. Kraws also has industry experience, having been responsible for competitive analysis within the treasury group at Bristol-Myers-Squibb Company. He holds an M.B.A. from Cornell University and a B.S. degree from State University of New York-Buffalo. During 2006 through February of 2007, Mr. Kraws served as our Vice President of Business Development, on a part-time basis.

Mr. Kraws brings a strong business background to Synthetic Biologics, having worked as a pharmaceutical analyst for over 22 years. Mr. Kraws brings to the Board significant strategic, business and financial experience related to the business and financial issues facing pharmaceutical companies. Mr. Kraws has a broad understanding of the operational, financial and strategic issues facing pharmaceutical companies. Through his services as the Company's Vice President of Business Development during 2006 and a part of 2007, he developed extensive knowledge of Synthetic Biologics' business.

Steve H. Kanzer, C.P.A, J.D. Mr. Kanzer is a co-founder and served as our President from our inception in February of 2001 until May of 2006. Since January 2, 2012, Mr. Kanzer has served as our Interim Director of our Biologics Division. Mr. Kanzer previously served as our Chief Executive Officer from September of 2004 until November of 2008, Chairman of the Board until February 6, 2010 and currently serves as a director. Mr. Kanzer has also been a director and officer of our subsidiaries, including Solovax, Inc., Effective Pharmaceuticals, Inc., Putney Drug Corp., Epitope Pharmaceuticals, Inc. and CD4 Biosciences, Inc. Since December 2000, he has served as co-founder and Chairman of Accredited Ventures Inc. and Accredited Equities Inc., a venture capital firm and investment bank, respectively, which both specialize in the biotechnology industry. Prior to founding Accredited Ventures and Accredited Equities in December 2000, Mr. Kanzer served as Senior Managing Director-Head of Venture Capital at Paramount Capital from 1991 until December of 2000. While at Paramount Capital, Mr. Kanzer was involved in the formation and financing of a number of biotechnology companies and held various positions in these companies. Prior to joining Paramount Capital in 1992, Mr. Kanzer was an attorney at the law firm of Skadden, Arps, Slate, Meagher & Flom in New York where he specialized in mergers and acquisitions. Mr. Kanzer received a J.D. from New York University School of Law in 1988 and a B.B.A. in Accounting from Baruch College in 1985, where he was a Baruch Scholar. Mr. Kanzer is active in university-based pharmaceutical technology licensing and has served as Co-Chair of the New York Chapter of the Licensing Executives Society.

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

James S. Kuo, M.D. Dr. Kuo has been a director since February of 2007 and since February 3, 2012 has been a consultant to the Company. From February 6, 2010 until February 3, 2012, Dr. Kuo served as our Chief Executive Officer, Chief Financial Officer and President. He also served as our Chairman of the Board from February 6, 2010 until November 2011. Dr Kuo was the Chairman and Chief Executive Officer of Cordex Pharma, Inc., a public biopharmaceutical company, from September of 2007 until February 1, 2010 and remained as a director until March 13, 2010. From 2003 to 2006, he served as founder, Chairman and Chief Executive Officer of BioMicro Systems, Inc,. a private venture-backed, microfluidics company. Prior to that time, Dr. Kuo was a founder, President and Chief Executive Officer of Discovery Laboratories, Inc. where he raised over $22 million in initial private funding and was instrumental in the company going public. Dr. Kuo was also a founder and board member of Monarch Labs, LLC, a private medical device company. Dr. Kuo is the former Managing Director of Venture Analysis for Healthcare Ventures, LLC, which managed $378 million in venture funds. He has also been a senior licensing and business development executive at Pfizer, Inc., where he was directly responsible for cardiovascular licensing and development. After studying molecular biology and receiving his B.A. at Haverford College, Dr. Kuo simultaneously earned an M.D. from the University of Pennsylvania School of Medicine and an M.B.A. from the Wharton School of Business. He holds a B.A. in molecular biology from Haverford College. From 2004 until October of 2009 Dr. Kuo also served as a director of Soligenix, Inc.

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

Nelson K. Stacks. Mr. Stacks has been a director since February 3, 2012. Mr. Stacks currently serves as CEO and Director of WaveGuide Corporation, a technology spin out from Harvard University. From July 2009 to August 2011, Mr. Stacks has served as the President, CEO and Director of Vascular Pathways Incorporated, a venture capital funded medical device company and as a venture partner with QBF/QIC, a life science venture fund. Prior thereto, Mr. Stacks has held several positions in several biotech companies. From April 2006 until December 2010 he served as the Chairman of Xbio Systems Pty Ltd, an Australian software company with a financial and integrated drug development program. From May 2007 until July 2009, Mr. Stacks served as the Chairman and CEO of Telesso Technologies Limited, a publicly listed Australian healthcare company. From March 2006 until August 2008 he also served as CEO and Executive Director of Xenome Limited, an Australian biotech company as well as director of Columna an Australian medical device company. In 2011, he was appointed a Director of Molecular Insight Pharmaceuticals, Inc., a company focused on cancer diagnostics and therapeutic treatments. In addition, Over his career, Mr. Stacks has been a venture capitalist, most recently as the General Partner at 3i Ventures and earlier at Oak Investment Partners. Mr. Stacks is a member of the fourth class of Kauffman Fellows and has invested in all areas of healthcare and information technology. Mr. Stacks received an M.B.A. from the F.W. Olin Graduate School of Business at Babson College and a BA from The University of Rochester.

Mr. Stacks brings to our Board extensive executive and senior management experience in the biotech industry and is an "audit committee financial expert" as such term is defined under applicable SEC rules. He is further qualified for service on our Board because of his relevant business expertise and leadership experience acquired through his experience serving on several boards of directors of other healthcare-related companies.

Scott L. Tarriff. Mr. Tarriff has been a director since February 3, 2012. Since January 2007 he has served as a director and Chief Executive Officer of Eagle Pharmaceuticals, Inc., a hospital specialty company. Eagle is focused on developing branded parenteral products through the application of various in-licensed drug delivery technologies. Prior to forming Eagle, Mr. Tarriff was president and chief executive officer of Par Pharmaceutical Companies, Inc. Mr. Tarriff joined Par Pharmaceutical Companies, Inc., in 1998 as executive vice president. Mr. Tarriff was named president and Chief Executive Officer of Par Pharmaceutical, Inc., the company's principal operating subsidiary, in 2001, and was elected to the company's Board of Directors in 2002. In September 2003, he was appointed President and Chief Executive Officer of Par Pharmaceutical Companies, Inc. Mr. Tarriff joined Par following a 12-year career at Bristol-Meyers Squibb. He received his M.B.A. from Rider College and his undergr