

Synthetic Biologics, Inc.  
Form POS AM  
July 12, 2012

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**POST-EFFECTIVE AMENDMENT NO. 1 TO FORM S-3**

**ON**

**FORM S-1**

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**SYNTHETIC BIOLOGICS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Nevada**

(State or Other Jurisdiction of Incorporation or Organization)

**2834**

(Primary Standard Industrial Classification Code Number)

**13-3808303**

(I.R.S. Employer Identification No.)

**617 Detroit Street, Suite 100**

**Ann Arbor, MI 48104**

**(734) 332-7800**

(Address and telephone number of principal executive offices)

*Copy to:*

**Leslie Marlow, Esq.**

**Hank Gracin, Esq.**

**Gracin & Marlow, LLP**

**The Chrysler Building**

**405 Lexington Avenue, 26th Floor**

**New York, New York 10174**

**(212) 907-6457**

(Name, address and telephone number of agent for service)

Approximate Date of Proposed Sale to the Public: From time to time after the date this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

|   |                          |                           |                          |
|---|--------------------------|---------------------------|--------------------------|
| Large accelerated filer                       | <input type="checkbox"/> | Accelerated filer         | <input type="checkbox"/> |
| Non-accelerated filer                         | <input type="checkbox"/> | Smaller reporting company | <input type="checkbox"/> |
| (Do not check if a smaller reporting company) |                          |                           |                          |

## EXPLANATORY NOTE

The Registrant filed a registration statement on Form S-3 (Registration No. 333-166750) (the “Original Registration Statement”) declared effective by the Securities and Exchange Commission on June 14, 2010, which registered shares of common stock of the Registrant. This Post-Effective Amendment No. 1 to Form S-3 on Form S-1 Registration Statement is being filed to amend the Original Registration Statement into a registration statement on Form S-1 to maintain the registration of certain securities previously registered on the Original Registration Statement. On June 12, 2012, Synthetic Biologics, Inc. (the “Company”) was notified by the Securities and Exchange Commission (“SEC”) staff that under its guidelines it was unable to grant a waiver request for the Company’s continued use of its existing Form S-3 because of the failure of Berman & Company, P.A. (“Berman & Co.”) to follow proper partner rotation procedures that resulted in the Company’s Annual Report on Form 10-K for the year ended December 31, 2011 being deemed to be filed late. Consequently, the Registrant is no longer eligible to use Form S-3 in connection with the current offering. The Registrant is filing this Post-Effective Amendment No.1 to Form S-3 on Form S-1 to amend the Original Registration Statement into a registration statement on Form S-1 to (i) continue the registration of: (a) 94,391 shares of common stock issuable upon exercise of the warrants originally issued in the April 2011 offering subject to the April 11, 2011 Prospectus Supplement, and exchanged for warrants issued in July 2011 and (b) 18,182 shares of common stock issuable upon exercise of the warrants issued in the July 2010 offering subject to the July 2, 2010 Prospectus Supplement, all previously registered on the Original Registration Statement, and (ii) remove from registration the unsold portion of securities registered under the Original Registration Statement. All filing fees payable in connection with the registration of these securities were previously paid in connection with the filing of the original registration statement.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

**THE INFORMATION CONTAINED IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. THESE SECURITIES MAY NOT BE SOLD UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS DECLARED EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IT IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.**

**SUBJECT TO COMPLETION, DATED JULY 12, 2012**

**PRELIMINARY PROSPECTUS**

**SYNTHETIC BIOLOGICS, INC.**

**112,573 Shares of Common Stock**

This prospectus covers the sale of up to:

- 94,391 shares of common stock issuable upon the exercise of warrants sold in our April 11, 2011 offering which were exchanged for warrants issued in July 2011 and may be exercised at a price of \$1.00 per share, and
- 18,182 shares of common stock issuable upon the exercise of warrants sold in our July 2, 2010 offering which may be exercised at a price of \$1.32 per share.

Our common stock became eligible for trading on the NYSE Amex October 16, 2008. Our common stock is eligible for quotation on the NYSE Amex under the symbol "SYN". The closing price of our stock on July 11, 2012 was \$2.01.

**Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 4 of this prospectus for more information.**

Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

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

The date of this prospectus is July \_\_, 2012.

**TABLE OF CONTENTS**

|  | Page |
|--|------|
| PROSPECTUS SUMMARY   | 1    |
| RISK FACTORS   | 4    |
| USE OF PROCEEDS  | 15   |
| DILUTION   | 16   |
| CAPITALIZATION   | 16   |
| BUSINESS   | 17   |
| MARKET PRICE OF COMMON STOCK AND OTHER STOCKHOLDER MATTERS                             | 28   |
| PLAN OF DISTRIBUTION   | 30   |
| MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION                              | 31   |
| DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS                           | 37   |
| EXECUTIVE COMPENSATION   | 41   |
| SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT                         | 44   |
| CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS   | 46   |
| DESCRIPTION OF SECURITIES  | 47   |
| EXPERTS  | 49   |
| DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT<br>LIABILITIES | 50   |
| LEGAL MATTERS  | 50   |
| WHERE YOU CAN FIND MORE INFORMATION  | 50   |
| INDEX TO FINANCIAL STATEMENTS  | 64   |
| PART II  | 88   |

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that which is contained in this prospectus. This prospectus may be used only where it is legal to sell these securities. The information in this prospectus may only be accurate on the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of securities.



## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus; it does not contain all of the information you should consider before investing in our common stock. You should read the entire prospectus before making an investment decision. Throughout this prospectus, the terms “Synthetic Biologics, Inc.,” “we,” “us,” “our,” and “our company” refer to Synthetic Biologics, Inc., a Nevada corporation.*

### Company 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 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:*

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 2011 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.

**Corporate Information**

Our executive offices are located at 617 Detroit Street, Suite 100, Ann Arbor, Michigan 48104, and our telephone number is (734) 382-7800. Our website address is [www.syntheticbiologics.com](http://www.syntheticbiologics.com). The information on our website is not incorporated by reference into this prospectus, and you should not consider it part of this prospectus.

## The Offering

**Issuer** Synthetic Biologics, Inc.

|  |   |
|--|---|
| Securities offered                                 | This prospectus covers the sale of up to: <ul style="list-style-type: none"><li>• 94,391 shares of common stock issuable upon the exercise of warrants which may be exercised at a price of \$1.00 per share, and</li><li>• 18,182 shares of common stock issuable upon the exercise of warrants which may be exercised at a price of \$1.32 per share.</li></ul> |
| Common stock to be outstanding after this offering | 33,413,720 shares (assuming all the warrants are exercised)   |
| Use of Proceeds                                    | We will receive proceeds from the exercise of the warrants if the warrants are exercised for cash. See “Use of Proceeds”.   |

**Risk Factors** You should carefully read and consider the information set forth under “Risk Factors,” together with all of the other information set forth in this prospectus, before deciding to invest in shares of our common stock.

NYSE Amex symbol We list our common stock on the NYSE Amex under the symbol “SYN”.

The number of shares of common stock outstanding before and after the offering is based on 33,301,147 shares outstanding as of June 30, 2012 and excludes:

- 1,418,493 shares of common stock issuable upon the exercise of warrants with a weighted average exercise price of \$3.10 per share;
- 3,968,746 shares of common stock issuable upon the exercise of options with a weighted average exercise price of \$1.73 per share; and
- 1,349,821 shares of common stock reserved for future grants and awards under our equity incentive plans.

## **RISK FACTORS**

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

### **RISKS RELATING TO OUR BUSINESS**

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

With the exception of the 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 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 March 31, 2012, our accumulated deficit totaled approximately \$53.1 million on a consolidated basis. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees and grants. If our current cash, cash equivalents and short-term investments are not sufficient to sustain our operations, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. Our recent loss of S-3 eligibility due to the failure of Berman & Company, P.A. to follow proper partner rotation procedures may also negatively affect our ability to raise capital. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

*We have not been able to sustain profitability.*

## Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

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 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 2011 Annual Report, flupirtine for fibromyalgia is in Phase II development.

***We have experienced several management changes.***

We have had significant changes in management in the past few years. Jeffrey Riley was appointed Chief Executive Officer and President on February 3, 2012. Effective February 6, 2012, C. Evan Ballantyne was appointed Chief Financial Officer. James S. Kuo, M.D., served as Chief Executive Officer and President from February 6, 2010 until February 3, 2012. 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 regimens 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 (flurpiratine) and Trimesta (oral estriol) have been approved for marketing in overseas countries for different uses and an oral immediate release form of zinc is approved in the U.S. and Europe for the treatment of Wilson's disease. Other companies, including the original developers or licensees or affiliates may seek to develop Effirma or Trimesta or their respective active ingredient(s) for other uses in the U.S. or any country we are seeking approval for. We cannot provide any assurances that any other company may obtain FDA approval for products that contain flurpiratine, 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 flurpiratine, 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 June 30, 2012, we had nine 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, 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 (oral estriol) has received grants totaling over \$8 million, predominantly from the Southern California Chapter of the NMSS and the National Institutes of Health which funds a majority of the ongoing clinical trial in relapsing-remitting MS for women. Although we believe that the grant funding received to date is sufficient to complete the current clinical trial based upon current cost estimates, if we experience any additional unanticipated costs or require further clinical trials, and our scientific collaborator is unable to maintain or receive additional grants, we might be forced to scale back or terminate the development of this product candidate. We will also need to cross reference our IND with the inventor/IND holder for this program should we elect to file our own corporate IND for our Trimesta (oral estriol) program. The on-going and future development and commercialization of Effirma (flupirtine) for fibromyalgia is the responsibility of Meda AB and no assurance can be given that Meda will gain the FDA's acceptance of the NDA or obtain NDA approval from the FDA of flupirtine for fibromyalgia.

Our AEN-100 program for ALS is reliant on the investigator-initiated IND of PNA 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.

***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 8.9 million shares of our common stock, including stock options and warrants exercisable within 60 days of June 30, 2012. Our executive officers, directors and principal stockholders together beneficially owned approximately 12 million shares of our common stock, including the stock options and warrants exercisable within 60 days of June 30, 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.

## **USE OF PROCEEDS**

We estimate that the net proceeds to us from this offering will be approximately \$118,391 if all of the warrants are exercised.

We intend to use the net proceeds from this offering to fund research and development and for working capital and general corporate purposes.

Pending use of the net proceeds of this offering, we intend to invest such net proceeds in short-term, interest-bearing investment grade securities.

## DILUTION

Our net tangible book value as of March 31, 2012 was \$7.9 million or \$0.24 per share of common stock. Net tangible book value per share represents total tangible assets less total liabilities, divided by the number of shares of common stock outstanding. After giving effect to our sale in this offering of 94,391 warrants to purchase common stock at an exercise price of \$1.00 per share and 18,182 warrants to purchase common stock at an exercise price of \$1.32, our net tangible book value as of March 31, 2012 would have been \$8 million, or \$0.24 per share. The following table illustrates this calculation.

|   |        |
|---|--------|
| Offering price per share of common stock (weighted average price) | \$1.05 |
| Net tangible book value per share as of March 31, 2012            | \$0.24 |
| Increase per share attributable to this offering                  | \$0.00 |
| As adjusted tangible book value per share after this offering     | \$0.24 |
| Dilution per share to new investors in this offering              | \$0.81 |

The number of shares of common stock outstanding used for existing stockholders in the table and calculations above is based on 32,776,127 outstanding as of March 31, 2012 and excludes:

- 2,414,922 shares of common stock issuable upon the exercise of warrants outstanding at March 31, 2012 with a weighted average exercise price of \$2.36 per share;
- 3,843,465 shares of common stock issuable upon the exercise of options outstanding at March 31, 2012 with a weighted average exercise price of \$1.79 per share; and
- 1,349,821 shares of common stock reserved for future grants and awards under our equity incentive plans as of March 31, 2012.

## CAPITALIZATION

The following table sets forth our capitalization as of March 31, 2012:

- on an actual basis; and

- on a pro forma basis to give effect to:

the issuance of 112,573 warrants to purchase common stock and our receipt of \$118,391 in cash proceeds from that issuance

You should read the information in this table together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the accompanying notes.

|  | March 31, 2012 |           |
|--|----------------|-----------|
|  | Actual         | Pro forma |
|  | (Unaudited)    |           |
| Cash and cash equivalents  | \$6,802        | \$6,920   |
| Stockholders’ equity:  |                |           |
| Common stock, \$.001 par value: 100,000,000 shares authorized, 32,970,182 shares issued and outstanding, actual; 32,888,700 shares issued and outstanding, pro forma | \$33           | \$33      |
| Additional paid-in capital   | 60,946         | 61,064    |
| Accumulated deficit  | (53,073)       | (53,073)  |
| Total stockholders’ equity   | 7,906          | 8,024     |
| Total capitalization   | \$7,906        | \$8,024   |

The number of shares of common stock outstanding used for existing stockholders is based on 32,776,127 shares outstanding as of March 31, 2012 and excludes:

- 2,414,922 shares of common stock issuable upon the exercise of warrants outstanding at March 31, 2012 with a weighted average exercise price of \$2.36 per share;
- 3,843,465 shares of common stock issuable upon the exercise of options outstanding at March 31, 2012 with a weighted average exercise price of \$1.79 per share; and

## **BUSINESS**

### **History**

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.

### *Product Pipeline:*

### *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<sup>®</sup> platform and RheoSwitch Therapeutic System<sup>®</sup> 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<sup>®</sup> and RheoSwitch Therapeutic System<sup>®</sup> 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 2011 Annual Report, flupirtine for fibromyalgia is 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.

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 617 Detroit Street, Suite 100, Ann Arbor, MI 48104.

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.

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 \$53.1 million through March 31, 2012. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

## **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 is 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 prostacyclin synthase (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<sup>®</sup>, Rebif<sup>®</sup>, Avonex<sup>®</sup>, Novantrone<sup>®</sup>, Copaxone<sup>®</sup>, Tysabri<sup>®</sup>, Gilenya<sup>®</sup> and Extavia<sup>®</sup>. 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<sup>®</sup> 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 estriol are 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.

#### *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 antinociceptive effects has been observed. One common link between neuroprotection, nociception 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 2011 Annual Report, flupirtine for fibromyalgia is 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<sup>®</sup> is the only FDA-approved drug for ALS. RILUTEK is an 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 utilized 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.

*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.

### **Employees**

As of June 30, 2012, we employed approximately nine 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 617 Detroit Street, Suite 100, Ann Arbor, Michigan 48104 and we also maintain executive offices in Rockville, Maryland.

**Available Information**

Additional information about Synthetic Biologics is contained at our website, [www.syntheticbiologics.com](http://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.

**MARKET PRICE OF COMMON STOCK AND OTHER STOCKHOLDER MATTERS**

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 July 11, 2012 was \$2.01 per share. As of June 30, 2012, there were approximately 349 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    |
|-------------------------------------|--------|--------|
| <b>YEAR ENDED DECEMBER 31, 2012</b> |        |        |
| Second quarter                      | \$2.25 | \$1.51 |
| First quarter                       | \$2.80 | \$1.27 |
| <b>YEAR ENDED DECEMBER 31, 2011</b> |        |        |
| 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.

## **PLAN OF DISTRIBUTION**

We will deliver the shares of common stock being issued to the purchasers electronically upon receipt of purchaser funds for the exercise of the warrants, if any, offered pursuant to this prospectus. We have agreed to indemnify the holders of the securities offered in this offering against some civil liabilities, including liabilities under the Securities Act and the Exchange Act. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.



## 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 2011 Annual Report, flupirtine for fibromyalgia is 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.

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 617 Detroit Street, Suite 100, Ann Arbor, MI 48104.

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.

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 \$53.1 million through March 31, 2012. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

### **Critical Accounting Policies**

In December of 2001, the SEC requested that all registrants discuss their most “critical accounting policies” in management’s discussion and analysis of financial condition and results of operations. The SEC indicated that a “critical accounting policy” is one which is both important to the portrayal of the company’s financial condition and results and requires management’s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. We believe that the following discussion regarding research and development expenses, general and administrative expenses and non-cash compensation expense involve our most critical accounting policies.

#### ***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. We estimated and reviewed the collectability of our 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, we regularly assessed the state of our 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***

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. For the three months ended March 31, 2012 and 2011, our only stream of revenue was laboratory revenue. Laboratory revenues are a component of discontinued operations for the three months ended March 31, 2012 and 2011. *See Note 4 to the Notes to the Consolidated Financial Statements –*

*Discontinued Operations of Adeona Clinical Laboratory and Note Receivable.*

*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, 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, we have not received any royalty revenues.

### *Laboratory Revenues*

We 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.

We maintained a sales allowance to compensate for the difference in our billing practices and insurance company reimbursements. In determining this allowance, we 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.

### *Research and Development Expenses*

We expense 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 our product candidates.

### *Share-Based Payment Arrangements*

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

### **Results of Operations**

***Three Months Ended March 31, 2012 and 2011***

*General and Administrative Expenses*

General and administrative expenses increased to \$1.5 million for the three months ended March 31, 2012, from \$1.2 million for the three months ended March 31, 2011. This increase of approximately 19% is primarily the result of the increased salary expense and consulting fees. The non-cash charge relating to stock-based compensation expense was \$499,000 for the three months ended March 31, 2012, compared to \$759,000 for the three months ended March 31, 2011. The stock-based compensation expense for the three months ended March 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 \$386,000 for the three months ended March 31, 2012, from \$231,000 for the three months ended March 31, 2011. This increase of approximately 67% is primarily the result of the expansion of our pipeline, including the initiation of preclinical and clinical programs. Research and development expenses also include a non-cash charge relating to stock-based compensation expense of \$9,000 for the three months ended March 31, 2012 and 2011.

*Other Income (Expense), net*

Other income was \$5,000 for the three months ended March 31, 2012. Other expense was \$759,000 for the three months ended March 31, 2011. Other expense for the three months ended March 31, 2011, included \$810,000 relating to the estimated fair value of the warrants associated with the January 2011 financing, adjusted for the change in their fair value at March 31, 2011. Other income for the three months ended March 31, 2011 included \$63,000 relating to the settlement of accounts payable previously accrued in prior periods.



*Net Loss from Continuing Operations*

Our net loss from continuing operations was \$1.8 million, or \$0.06 per common share for the three months ended March 31, 2012, compared to a net loss of \$2.2 million, or \$0.09 per common share for the three months ended March 31, 2011. The decrease in net loss from continuing operations resulted from no warrant liability offset by increases in general and administrative expenses and research and development expenses for the three months ended March 31, 2012.

*Net Income from Discontinued Operations*

Our net income from discontinued operations was \$649,000, or \$0.02 per common share for the three months ended March 31, 2012, compared to net income of \$37,000, or \$0.00 per common share for the three months ended March 31, 2011. On March 8, 2012, we entered into a Membership Interest Purchase Agreement, and certain related agreements, pursuant to which we sold all of our interest in the Adeona Clinical Laboratory, LLC (the "Lab") to Hartlab, LLC for a gain of \$677,000. This resulted in the classification of the Lab as discontinued operations. *See Note 4 – Discontinued Operations of Adeona Clinical Laboratory and Note Receivable* for summarized statement of operations data for the three months ended March 31, 2012 and 2011.

**Results of Operations**

*Years 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.

**Liquidity and Capital Resources**

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

Our cash totaled \$6.8 million as of March 31, 2012, an increase of approximately \$100,000 from December 31, 2011. During the three months ended March 31, 2012, the primary sources of cash were proceeds from the stock option exercises of \$68,000 and warrant exercises of \$1.5 million. The primary use of cash during the three months ended March 31, 2012 was for working capital requirements. During the first and second quarters of 2012, we received proceeds of \$1.9 million from the exercise of warrants.

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.

Our continued operations will primarily depend on our ability to raise additional capital from various sources including equity and debt financings, as well as, license fees from potential corporate partners and joint ventures. 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 assurance that any additional capital that we are able to obtain will be sufficient to meet our needs.

### **Current and Future Financing Needs**

We have incurred an accumulated deficit of approximately \$53.1 million as of March 31, 2012. 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.

## **DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS**

### **Officers and Directors**

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            | 53  | Chief Financial Officer, Corporate Secretary and Treasurer |
| Jeffrey J. Kraws              | 48  | Chairman   |
| Steve H. Kanzer, C.P.A., J.D. | 48  | Director   |
| James S. Kuo, M.D.            | 48  | Director   |
| Nelson K. Stacks              | 41  | Director   |
| Scott L. Tarriff              | 53  | 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. He also serves as our Corporate Secretary and Treasurer. 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, and since February 2012, he has served as partner and co-founder of TopHat Capital, LLC. 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 Nationsbank 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 synthetic 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. He currently serves as CEO of ApoLife, a privately held biotechnology company. 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 undergraduate degree from Pennsylvania State University.

Mr. Tarriff brings to our Board of Directors significant knowledge of and experience in the pharmaceutical and medical industries. He has extensive business, managerial, executive and leadership experience that further qualify him to serve as a member of the Board and a valuable understanding of the role played by the Board of Directors acquired through service on the boards of many companies. He has had a long and successful career in top executive leadership positions with leading, publicly traded pharmaceutical companies including Par Pharmaceuticals and Bristol-Myers Squibb.

**Jeffrey Wolf, J.D.** Mr. Wolf, a director since 2006, has substantial experience in creating, financing, nurturing and growing new ventures based upon breakthrough research and technology. In August 2008, Mr. Wolf founded Heat Biologics, Inc., a company engaged in research and development of drugs focused on combating cancer and other diseases. Since April 2010, Mr. Wolf has served as the Chief Executive Officer of Heat Biologics, Inc. From 2006 until April 2010, Mr. Wolf served as the Chairman and Chief Executive Officer of GenerationOne, a company that was focused on mobile-based collaborative care. Mr. Wolf is the founding partner of Seed-One Ventures, LLC, a venture capital group formed in 1997 and focused on seed-stage technology-based investments. Mr. Wolf has been a founder of Elusys Therapeutics, Inc., an antibody-based therapeutic company, Tyrx Pharma, Inc., a biopolymer-based company, Sensatex, Inc., a medical device company and Generation Mobile, Inc. a telecommunications company. Prior to founding Seed-One Ventures, Mr. Wolf served as the Managing Director of The Castle Group, Ltd., a biomedical venture capital firm. At both organizations, Mr. Wolf was responsible for supervising the formation and funding of new technology, biomedical, and service oriented ventures. Mr. Wolf currently sits on the board of Elusys Therapeutics and Netli, Inc. Mr. Wolf received an M.B.A. from Stanford Business School, a J.D. from New York University School of Law and a B.A. with honors in Economics from the University of Chicago.

Mr. Wolf has extensive knowledge of the industry and in particular research and development. His legal and business background provide him with a broad understanding of the legal, operational, financial and strategic issues facing

Synthetic Biologics. Having served as a board member on other public company boards, Mr. Wolf has an extensive understanding of the operational, financial and strategic issues facing public companies.

### **Directors' Term of Office**

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

### **Audit Committee**

The Audit Committee is comprised of Mr. Wolf and Mr. Stacks. The Audit Committee is responsible for recommending our independent public accounting firm and reviewing management's actions in matters relating to audit functions. The Committee reviews with our independent public accountants the scope and results of the audit engagement and the system of internal controls and procedures. The Committee also reviews the effectiveness of procedures intended to prevent violations of laws. The Committee also reviews, prior to publication, our reports on Form 10-K and Form 10-Q. Our Board has determined that all audit committee members are independent under applicable SEC regulations. Our Board of Directors has determined that Mr. Stacks qualifies as an "audit committee financial expert" as that term is used in Section 407 of Regulation S-K. Our Audit Committee charter is located on our website [www.syntheticbiologics.com](http://www.syntheticbiologics.com).

### **Compensation Committee**

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

### **Nominations Committee**

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

### **Section 16(a) Beneficial Ownership Reporting Compliance**

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

Based solely on a review of the copies of such forms that were received by us, or written representations from certain reporting persons that no Form 5s were required for those persons, we are not aware of any failures to file reports or report transactions in a timely manner during the year ended December 31, 2011.

### **Code of Ethics**

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

## DIRECTORS

Directors are elected at each annual meeting of shareholders and hold office until the next annual meeting of shareholders following their election. To date, none of our directors have received any compensation from us, whether in the form of cash or securities, for their service as directors. None of our directors are independent directors.

## EXECUTIVE COMPENSATION

The following table summarizes all compensation awarded to, earned by or paid to Max Lyon and James S. Kuo, M.D., during the fiscal year ended December 31, 2011 or 2010.

| Name and Principal Position                           | Year | Salary (\$)   | Bonus (\$) | Options Awards(\$)<br>(1) | All Other Compensation (\$)<br>(2) | Total (\$) |
|---|------|---------------|------------|---------------------------|------------------------------------|------------|
| James S. Kuo, M.D., President, CEO and CFO            | 2011 | \$199,000     | \$ -       | \$ -                      | \$ 12,000                          | \$211,000  |
|   | 2010 | \$179,000 (3) | \$ 20,000  | \$ 328,000                | \$ 10,000                          | \$527,000  |
| Max Lyon, Former President, Former CEO and Former CFO | 2010 | \$43,000 (4)  | \$ -       | \$ -                      | \$ -                               | \$43,000   |

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

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

(3) Dr. Kuo resigned as our President, Chief Executive Officer and Chief Financial Officer on February 3, 2012. Dr. Kuo remains as a consultant to the Company.

(4) Mr. Lyon resigned as our President, Chief Executive Officer and Chief Financial Officer effective as of February 10, 2010. This amount represents the amount earned by Mr. Lyon prior to his resignation and severance in the amount of \$23,000 paid in shares of our common stock.

### Outstanding Equity Awards at Fiscal Year End

The table below reflects all outstanding equity awards made to each of the named executive officers that are outstanding at December 31, 2011. We currently grant stock-based awards pursuant to our 2010 Stock Incentive Plan (the "2010 Stock Plan") and have outstanding awards under our 2001 Stock Incentive Plan (the "2001 Stock Plan") and 2007 Stock Incentive Plan (the "2007 Stock Plan").

| Name         | Grant Date (1) | Number of Securities Underlying Unexercised Options Exercisable | Number of Securities Underlying Unexercised Options Unexercisable | Option Exercise Price (\$) | Option Expiration Date |
|--------------|----------------|---|---|----------------------------|------------------------|
| James S. Kuo | 02/06/10(2)    | 275,000   | 125,000   | \$ 0.82                    | 02/06/20               |
|              | 12/22/09       | -   | 8,333   | \$ 0.53                    | 12/22/19               |
|              | 10/02/08       | -   | 8,333   | \$ 0.53                    | 10/02/18               |
|              | 11/02/07       | -   | 8,333   | \$ 5.85                    | 11/02/17               |
|              | 02/07/07       | -   | 25,000  | \$ 3.87                    | 02/07/17               |

(1) Unless otherwise noted, options vest immediately on the date of grant.

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

### Employment Agreements

On February 3, 2012, Jeffrey Riley was appointed to serve as our Chief Executive Officer and President, and on February 6, 2012, C. Evan Ballantyne was appointed to serve as our Chief Financial Officer. On February 3, 2012, James S. Kuo, M.D., resigned as our Chief Executive Officer, President and Chief Financial Officer. Dr. Kuo remains as a consultant to the Company. On February 6, 2010, Max Lyon resigned as President, Chief Executive Officer and

Chief Financial Officer, and James S. Kuo, M.D., was thereby appointed Chairman, Chief Executive Officer, Chief Financial Officer and President. The following are summaries of the agreements that were executed in connection with these changes.

***Jeffrey Riley Employment Agreement***

In connection with his appointment, Mr. Riley entered into a three-year employment agreement with us (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 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 Riley Employment Agreement also includes confidentiality obligations and inventions assignments by Mr. Riley.



If Mr. Riley's employment is terminated for any reason, he or his estate as the case may be, will be entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by him to the extent not previously paid (the "Accrued Obligations"); provided, however, that if his employment is terminated (1) by us without Just Cause (as defined in the Riley Employment Agreement) or by Mr. Riley for Good Reason (as defined in the Riley Employment Agreement) then in addition to paying the Accrued Obligations, (x) we shall continue to pay his then current base salary and continue to provide benefits at least equal to those which were provided at the time of termination for a period of six months and (y) he shall have the right to exercise any vested options until the earlier of the expiration of the severance or the expiration of the term of the option, or (2) by reason of his death or Disability (as defined in the Riley Employment Agreement), then in addition to paying the Accrued Obligations, he would have the right to exercise any vested options until the expiration of the term of the option. In such event, if Mr. Riley commenced employment with another employer and becomes eligible to receive medical or other welfare benefits under another employer-provider plan, the medical and other welfare benefits to be provided by us as described herein will terminate.

### ***C. Evan Ballantyne Employment Agreement***

Effective February 6, 2012, C. Evan Ballantyne was appointed our Chief Financial Officer. In connection with his appointment, Mr. Ballantyne entered into a three-year employment agreement with us (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 Ballantyne Employment Agreement also includes confidentiality obligations and inventions assignments by Mr. Ballantyne.

If Mr. Ballantyne's employment is terminated for any reason, he or his estate as the case may be, will be entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by him to the extent not previously paid (the "Accrued Obligations"); provided, however, that if his employment is terminated (1) by us without Just Cause (as defined in the Ballantyne Employment Agreement) or by Mr. Ballantyne for Good Reason (as defined in the Ballantyne Employment Agreement) then in addition to paying the Accrued Obligations, (i) we shall continue to pay his then current base salary and continue to provide benefits at least equal to those which were provided at the time of termination for a period of six months and (ii) he shall have the right to exercise any vested options until the earlier of the expiration of the severance or the expiration of the term of the option, or (2) by reason of his death or Disability (as defined in the Ballantyne Employment Agreement), then in addition to paying the Accrued Obligations, he would have the right to exercise any vested options until the expiration of the term of the option. In such event, if Mr. Ballantyne, commenced employment with another employer and becomes eligible to receive medical or other welfare benefits under another employer-provider plan, the medical and other welfare benefits to be provided by us as described herein will terminate.

### ***Dr. Kuo's Agreements***

Effective February 3, 2012, James S. Kuo, M.D., resigned from his positions as our President and Chief Executive Officer. In connection with his resignation, Dr. Kuo entered into a nine-month consulting agreement with us (the "Consulting Agreement"). Pursuant to the Consulting Agreement, Dr. Kuo will be entitled to a consulting fee of \$16,666 per month during the term of the Consulting Agreement, receive health and dental benefits for one year and retain the right to exercise the stock options held by him that have vested as of the effective date of the Consulting Agreement for a period expiring on the date that is one (1) year from the effective date of the Consulting Agreement. The Consulting Agreement also includes confidentiality obligations and inventions assignments by Dr. Kuo.

In February 2010, Dr. Kuo had entered into a three-year employment agreement with us (the "Kuo Employment Agreement"). Pursuant to the Kuo Employment Agreement, Dr. Kuo was entitled to an annual base salary of \$199,000 and was eligible for discretionary performance and transactional bonus payments. Additionally, Dr. Kuo was granted an initial stock option to purchase 400,000 shares of our common stock (with an exercise price of \$0.82, the fair market value on February 6, 2010, which is the date of grant). Of this stock option grant, 300,000 shares vested prior to his resignation

#### ***Mr. Lyon's Agreement***

In connection with his resignation, Mr. Lyon received \$23,000 paid in shares of our common stock, as a severance payment. This payment was made pursuant to a Separation Agreement, dated February 6, 2010, between Mr. Lyon and us.

## Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2011 regarding the compensation of our directors who at December 31, 2011 were not also named executive officers.

| Name             | Fees Earned or<br>Paid in Cash | Option<br>Awards(1) | Other<br>Compensation | Total    |
|------------------|--------------------------------|---------------------|-----------------------|----------|
| Steve H. Kanzer  | \$ 13,000                      | \$ 37,000           | \$ -                  | \$50,000 |
| Jeffrey J. Kraws | \$ 12,000                      | \$ 37,000           | \$ -                  | \$49,000 |
| Jeffrey Riley(2) | \$ 14,000                      | \$ 85,000           | \$ -                  | \$99,000 |
| Jeffrey Wolf     | \$ 17,000                      | \$ 37,000           | -                     | \$54,000 |

- (1) The amounts in the “Option awards” column reflect the dollar amounts recognized as compensation expense for the financial statement reporting purposes for stock options for the fiscal year ended December 31, 2011 in accordance with SFAS 123(R). The fair value of the options was determined using the Black-Scholes model.
- (2) In consideration of Jeffrey Riley serving as our independent, non-executive Chairman, in November 2011 we issued Jeffrey Riley options exercisable for an additional 100,000 shares of our common stock.

During 2007, director compensation for members who are not employees was approved at \$2,000 per board meeting that they attend in person, \$1,000 per telephonic board meeting and \$500 per committee meeting. In addition, we grant non-employee members of the Board of Directors upon appointment 25,000 stock options to purchase shares of our common stock at an exercise price equal to the fair market value of the our common stock on the date of grant, and an additional 8,333 stock options each year. Directors who are employees or who are compensated for board service pursuant to a separate agreement or arrangement do not receive additional compensation for attending board, committee or shareholder meetings. We also reimburse directors for travel and other out-of-pocket expenses incurred in attending Board of Director and committee meetings. We have agreed to pay Mr. Kraws for his services as our independent, non-executive Chairman of the Board annual compensation of \$150,000 as well as a one- time grant of options exercisable for an additional 100,000 shares of our common stock.

## Equity Compensation Plan Information

The following table sets forth information about the securities authorized for issuance under our equity compensation plans for the fiscal year ended December 31, 2011.

Plan Category

Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

|   | Number of Securities to be Issued Upon Exercise of Outstanding Options | Weighted-Average Exercise Price of Outstanding Options | Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans |
|---|--|--|--|
| Equity compensation plans approved by stockholders:   |  |  |  |
| 2001 Stock Incentive Plan                             | 1,320,354  | \$ 1.15  | 22,690   |
| 2007 Stock Incentive Plan                             | 1,201,156  | \$ 1.67  | 1,033,932  |
| 2010 Stock Incentive Plan                             | 457,400  | \$ 1.05  | 2,542,500  |
| Equity compensation plans not approved by stockholder | N/A  | N/A  | N/A  |
| Total   | 2,979,010  | \$ 1.46  | 3,599,122  |

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth information, as of June 30, 2012, or as otherwise set forth below, with respect to the beneficial ownership of our common stock (i) all persons know to us to be the beneficial owners of more than 5% of the outstanding shares of our common stock, (ii) each of our directors and our executive officer named in the Summary Compensation Table, and (iii) all of our directors and our executive officer as a group.

**Principal Stockholders Table**

| Name and Address of Beneficial Ownership (2)      | Shares Owned (1) |                          |   |
|---|------------------|--------------------------|---|
|   | Number of Shares | Percentage of Shares (3) |   |
| Accredited Venture Capital, LLC (4)               | 7,086,380        | 21.28                    | % |
| Intrexon Corporation (5)                          | 3,123,558        | 9.38                     | % |
| C. Evan Ballantyne (6)                            | 70,833           |                          | * |
| Steve H. Kanzer (7)                               | 7,766,017        | 23.11                    | % |
| Jeffrey J. Kraws (8)                              | 312,105          |                          | * |
| James S. Kuo (9)                                  | 354,499          | 1.05                     | % |
| Jeffrey Riley (10)                                | 233,333          |                          | * |
| Nelson K. Stacks (11)                             | 25,000           |                          | * |
| Scott L. Tarriff (12)                             | 25,000           |                          | * |
| Jeffrey Wolf (13)                                 | 83,332           |                          | * |
| Randall J. Kirk(14)                               | 3,123,558        | 9.38                     | % |
| All officers and directors as a group (8 persons) | 8,870,119        | 25.56                    | % |

\* represents less than 1% of our common stock

- (1) The address for each beneficial owner except Intrexon Corporation and Randall J. Kirk is 617 Detroit Street, Suite 100, Ann Arbor, MI 48104. The address for Intrexon Corporation is 20358 Seneca Meadows Pkwy, Germantown, Maryland 20876 and the address for Mr. Kirk is The Governor Tyler, 1881 Grove Avenue, Radford, Maryland 24141.

- (2) Beneficial ownership is determined in accordance with SEC rules and generally includes voting or investment power with respect to securities. Except as indicated in the footnotes to the table, to the knowledge of the Company, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them, subject to community property laws, where applicable. Pursuant to the rules of the SEC, the number of shares of our common stock deemed outstanding includes shares issuable pursuant to options held by the respective person or group that are currently exercisable or may be exercised within 60 days of June 30, 2012.
- (3) As of June 30, 2012, we had 33,301,147 shares of common stock outstanding.
- (4) Consists of 7,086,380 shares of common stock issued to Accredited Venture Capital, LLC. Pharmainvestors, LLC is the managing member of Accredited Venture Capital, LLC, and Mr. Kanzer is the managing member of Pharmainvestors, LLC. As such, Mr. Kanzer may be considered to have control over the voting and disposition of the shares registered in the name of Accredited Venture Capital, LLC, and therefore, such shares are also included in the shares listed as held by Mr. Kanzer. Mr. Kanzer disclaims beneficial ownership of those shares, except to the extent of his pecuniary interest.
- (5) Does not include additional shares that have not yet been earned but may in the future be earned under the terms of agreements with Intrexon Corporation.
- (6) Includes 70,833 shares issuable upon exercise of options held by Mr. Ballantyne that are exercisable within the 60-day period following June 30, 2012. Does not include an additional 354,167 shares issuable upon exercise of options held by Mr. Ballantyne that are not exercisable within the 60-day period following June 30, 2012.

Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

- Includes 7,086,380 shares of common stock issued to Accredited Venture Capital, LLC and 304,391 shares
- (7) issuable upon exercise of options held by Mr. Kanzer that are exercisable within the 60-day period following June 30, 2012.
  - (8) Includes 312,105 shares issuable upon exercise of options held by Mr. Kraws that are exercisable within the 60-day period following June 30, 2012.
  - (9) Includes 349,999 shares issuable upon exercise of options held by Dr. Kuo that are currently exercisable.

- Includes 233,333 shares issuable upon exercise of options held by Mr. Riley that are exercisable within the
- (10) 60-day period following June 30, 2012. Does not include an additional 625,000 shares issuable upon exercise of options held by Mr. Riley that are not exercisable within the 60-day period following June 30, 2012.
  - (11) Includes 25,000 shares issuable upon exercise of options held by Mr. Stacks that are exercisable within the 60-day period following June 30, 2012.

- (12) Includes 25,000 shares issuable upon exercise of options held by Mr. Tarriff that are exercisable within the 60-day period following June 30, 2012.
- (13) Includes 83,332 shares issuable upon exercise of options held by Mr. Wolf that are exercisable within the 60-day period following June 30, 2012.
- All such shares are held by Intrexon Corporation. Mr. Kirk, directly and through certain affiliates, has voting and disposition power over a majority of the outstanding capital of Intrexon Corporation. Mr. Kirk disclaims
- (14) beneficial ownership of the shares held by Intrexon Corporation, except to the extent of any pecuniary interest therein.

## **CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

Pursuant to our charter, our Audit Committee shall review on an on-going basis for potential conflicts of interest, and approve if appropriate, all our “Related Party Transactions” as required by Section 120 of the NYSE Amex Company Guide. For purposes of the Audit Committee Charter, “Related Party Transactions” shall mean those transactions required to be disclosed pursuant to SEC Regulation S-K, Item 404. On January 2, 2012, Steve H. Kanzer was engaged as our Interim Director of our Biologics Division. In connection with his appointment, Mr. Kanzer entered into a six month employment agreement with us on a full time basis (the “Kanzer Employment Agreement”), which was extended for an additional three (3) months Pursuant to the Kanzer Employment Agreement, Mr. Kanzer will be entitled to a base salary of \$90,000 for the six month term, healthcare coverage pursuant to our healthcare insurance plan, reimbursement for certain relocation expenses and rent expense. The Kanzer Employment Agreement also includes confidentiality obligations and inventions assignments by Mr. Kanzer. Mr. Kanzer is not entitled to severance pay upon termination of his employment.

## **CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS AND AUDITORS**

On July 3, 2012, we dismissed Berman & Company, P.A. (“Berman & Co.”) as our independent registered public accounting firm and on July 9, 2012, we selected BDO USA, LLP (“BDO”) as our new independent registered public accounting firm responsible for auditing its financial statements.

Berman & Co.’s reports on our financial statements as of and for the two years ended December 31, 2011 and 2010, did not contain an adverse opinion or disclaimer of opinion, and were not qualified or modified as to uncertainty, audit scope, or accounting principles; however, after being filed with the Securities and Exchange Commission (“SEC”) on March 30, 2012, the original audit opinion included in our Annual Report on Form 10-K for the year ended December 31, 2011, was withdrawn due to the failure of Berman & Co. to follow proper partner rotation procedures. On May 11, 2012, a new audit opinion for the year ended December 31, 2011 and an amended Annual Report on Form 10-K/A for such year was filed with the SEC.

The decision to dismiss Berman & Co. and the selection of BDO was recommended by the audit committee and unanimously approved by our board of directors.

During the years ended December 31, 2011 and 2010, and in the subsequent interim period through July 3, 2012 (the date of dismissal of Berman & Co.), there were no disagreements with Berman & Co. on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Berman & Co., would have caused it to make reference to the subject matter of the disagreement in connection with its reports on our financial statements for such years.

During the year ended December 31, 2011 and in the subsequent interim period through July 3, 2012, there were no events otherwise reportable under Item 304(a)(1)(v) of Regulation S-K other than the following which was previously reported by us: the failure of Berman & Co. to follow proper partner rotation procedures that resulted in the withdrawal of Berman & Co.'s audit opinion included in our Annual Report on Form 10-K for the year ended December 31, 2011 and being unable to rely upon such audit opinion. Such matters have been discussed by both our audit committee and board of directors with Berman & Co., and Berman & Co. is authorized to fully respond to inquiries of BDO concerning such matter.

During our two most recent years and in the subsequent interim period through July 3, 2012, we did not consult with BDO regarding the application of accounting principles to a specified transaction, either contemplated or proposed, or the type of audit opinion that might be rendered on our financial statements, and neither a written report nor oral advice was provided that was an important factor considered by us in reaching a decision as to the accounting, auditing or financial reporting issue, or with any of the matters outlined in Item 304(a)(2)(ii) of Regulation S-K.



We provided Berman & Co. with a copy of the Current Report on Form 8-K that disclosed the foregoing information prior to its filing with the SEC, and Berman & Co. furnished us with a letter addressed to the SEC that was filed as an exhibit to such Current Report on Form 8-K stating that it agreed with the statements we made in such Current Report on Form 8-K.

## **DESCRIPTION OF SECURITIES**

Our authorized capital consists of 100 million shares of common stock, par value \$0.001 per share, and 10 million shares of preferred stock, par value \$0.001 per share. As of June 30, 2012, 33,301,147 shares of common stock and no shares of preferred stock were outstanding.

### ***Common Stock***

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

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

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

### ***Warrants***

#### ***Outstanding Warrants***

As of June 30, 2012, we had issued and outstanding a total of 1,418,493 warrants to purchase our common stock outstanding at a weighted-average price of \$3.10.

*Warrants Issued in our July 2, 2010 Offering*

Each warrant represents the right to purchase one share of common stock at an exercise price of \$1.32 per share. Each warrant was exercisable 183 days after the date of issuance (July 2, 2010) and before the fifth anniversary of its date of issuance.

Exercisability. Holders of the warrants may exercise their warrants to purchase shares of our common stock on or before the expiration date by delivering (i) notice of exercise, appropriately completed and duly signed, and (ii) if such holder is not utilizing the cashless exercise provisions with respect to the warrants, payment of the exercise price for the number of shares with respect to which the warrant is being exercised. Warrants may be exercised in whole or in part, but only for full shares of common stock. We provide certain additional payments if we fail to deliver the shares of common stock underlying the warrants by the date on which delivery of the stock certificate is required by the warrant.

In addition, the warrant holders are entitled to a “cashless exercise” at their option. The number of shares to be issued would be determined by a formula based on the total number of shares with respect to which the warrant is being exercised, the volume weighted average of the prices per share of our common stock on the five trading days immediately prior to the date of exercise and the applicable exercise price of the warrants.

The shares of common stock issuable on exercise of the warrants will be, when issued and paid for in accordance with the warrants, duly and validly authorized, issued and fully paid and non-assessable.

**Fundamental Transaction.** In the event of a merger, consolidation, business combination, tender offer, exchange of shares, reclassification of our common stock, redemption or recapitalization or similar event as a result of which the shares of common stock are converted into or exchanged for our or another company's securities, cash or property, each, a "Fundamental Transaction," then the holder shall have the right thereafter to receive, upon exercise of the warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of warrant shares then issuable upon exercise of the warrant, and any additional consideration payable as part of the Fundamental Transaction. Any successor to us or surviving entity shall assume the obligations under the warrant.

**Delivery of Certificates.** Upon the holder's exercise of a warrant, we will promptly, but in no event later than three trading days after the exercise date, issue and deliver, or cause to be issued and delivered, a certificate for the shares of common stock issuable upon exercise of the warrant. In addition, if the transfer agent participates in the Depository Trust Company Fast Automated Securities Transfer program we shall issue and deliver the shares electronically through The Depository Trust Corporation through its Deposit Withdrawal Agent Commission System (DWAC) or another established clearing corporation performing similar functions. If we fail to deliver certificates evidencing the warrant shares by such date, we are required to pay to the holder, in cash, as liquidated damages and not as a penalty the amount to be determined as set forth in the warrant.

**Limitations on Exercise.** The number of warrant shares that may be acquired by any holder upon any exercise of the warrant shall be limited to the extent necessary to insure that, following such exercise (or other issuance), the total number of shares of common stock then beneficially owned by such holder and its affiliates and any other persons whose beneficial ownership of common stock would be aggregated with the holder's for purposes of Section 13(d) of the Exchange Act, does not exceed 4.99% of the total number of issued and outstanding shares of common stock (including for such purpose the shares of common stock issuable upon such exercise), or beneficial ownership limitation.

**Certain Adjustments.** The exercise price and the number of shares of common stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of our common stock.

**Additional Provisions.** We are not required to issue fractional shares upon the exercise of the warrants. No holders of the warrants will possess any rights as a stockholder under those warrants until the holder exercises those warrants. The warrants may be transferred independent of the common stock they were issued with, on a form of assignment, subject to all applicable laws.

*Warrants Originally Issued in our April 11, 2011 Offering*

The warrants were originally issued in April 2011 and exchanged for warrants issued in July 2011. Each warrant represents the right to purchase one share of common stock at an exercise price of \$1.00 per share. Each warrant may be exercised after January 28, 2012 and before August 10, 2012.

**Exercisability.** Holders of the warrants may exercise their warrants to purchase shares of our common stock on or before the expiration date by delivering (i) notice of exercise, appropriately completed and duly signed, and (ii) if such holder is not utilizing the cashless exercise provisions with respect to the warrants, payment of the exercise price for the number of shares with respect to which the warrant is being exercised. Warrants may be exercised in whole or in part, but only for full shares of common stock.

In addition, the warrant holders are entitled to a “cashless exercise” at their option if, at any time of exercise, there is no effective registration statement registering, or no current prospectus available for, the issuance or resale of the shares of common stock underlying the warrants. The number of shares to be issued would be determined by a formula based on the total number of shares with respect to which the warrant is being exercised, the volume weighted average of the prices per share of our common stock on the five trading days immediately prior to the date of exercise and the applicable exercise price of the warrants.

The shares of common stock issuable on exercise of the warrants will be, when issued and paid for in accordance with the warrants, duly and validly authorized, issued and fully paid and non-assessable. We will authorize and reserve at least that number of shares of common stock equal to the number of shares of common stock issuable upon exercise of all outstanding warrants.

**Fundamental Transaction.** If, at any time while the warrants are outstanding, we issue options, convertible securities or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of common stock then the holder shall have the right thereafter to acquire the same amount and kind of securities, cash or property as it would have been entitled to receive upon the exercise of the warrant if it had exercised before such event or it may require us to repurchase its warrant.

**Pro Rata Distributions.** If, at any time while the warrants are outstanding, we distribute evidences of our indebtedness, assets, or rights or warrants to purchase any security other than our common stock to all holders of our common stock, then the then the holder shall have the right thereafter to receive, the same distribution as the other holders as if it had exercised its warrant. upon exercise of the warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the exercise of the warrant if it had exercised before such event exercise price will adjust pursuant to a volume weighted average price based ratio.

**Certain Adjustments.** The exercise price and the number of shares of common stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of our common stock.

**Delivery of Certificates.** Upon the holder's exercise of a warrant, we will promptly, but in no event later than three trading days after the exercise date, issue and deliver, or cause to be issued and delivered, a certificate for the shares of common stock issuable upon exercise of the warrant. In addition, if the transfer agent participates in the Depository Trust Company Fast Automated Securities Transfer program we shall issue and deliver the shares electronically through The Depository Trust Corporation through its DWAC system or another established clearing corporation performing similar functions. If we fail to deliver certificates evidencing the warrant shares by such date, we are required to pay to the holder, in cash, as liquidated damages and not as a penalty, in the amount to be determined as set forth in the warrant.

**Limitations on Exercise.** The number of warrant shares that may be acquired by any holder upon any exercise of the warrant shall be limited to the extent necessary to insure that, following such exercise (or other issuance), the total number of shares of common stock then beneficially owned by such holder and its affiliates and any other persons whose beneficial ownership of common stock would be aggregated with the holder's for purposes of Section 13(d) of the Exchange Act, does not exceed 4.99% of the total number of issued and outstanding shares of common stock (including for such purpose the shares of common stock issuable upon such exercise), or beneficial ownership limitation.

**Additional Provisions.** No holders of the warrants will possess any rights as a stockholder under those warrants until the holder exercises those warrants. The warrants may be transferred independent of the common stock they were issued with, on a form of assignment, subject to all applicable laws.

***Preferred Stock***

There are no shares of preferred stock outstanding.

***Stock Options***

We currently have 3,968,746 options outstanding.

***Transfer Agent***

We have retained Corporate Stock Transfer as our transfer agent. They are located at 3200 Cherry Creek Drive, Denver, Colorado 80202. Their telephone number is (303) 282-4800 and facsimile is (303) 282-4801.

**EXPERTS**

The financial statements as of December 31, 2011 and 2010 and for the years then ended included in this Post-Effective Amendment No. 1 to Form S-3 on Form S-1 Registration Statement have been so included in reliance on the reports of Berman & Company, P.A., an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## **DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION**

### **FOR SECURITIES ACT LIABILITIES**

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

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

## **LEGAL MATTERS**

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

## **WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the Securities and Exchange Commission this Post-Effective Amendment No. 1 to Form S-3 on Form S-1 to maintain the registration of certain securities previously registered on the Original Registration Statement under the Securities Act. We are subject to the informational requirements of the Exchange Act, and file annual and

## Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

current reports, proxy statements and other information with the Commission. These reports, proxy statements and other information filed by Synthetic Biologics, Inc. can be read and copied at the Commission's Public Reference Room at 100 F Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330.

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

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



**Synthetic Biologics, Inc. and Subsidiaries****Consolidated Balance Sheets****(In thousands, except share amounts)**

|   | March 31,<br>2012<br>(Unaudited) | December 31,<br>2011 |
|---|----------------------------------|----------------------|
| Assets  |                                  |                      |
| Current Assets:   |                                  |                      |
| Cash  | \$ 6,802                         | \$ 6,678             |
| Accounts receivable - net   | 440                              | 405                  |
| Other   | 83                               | 16                   |
| Assets of discontinued operations   | -                                | 23                   |
| Total Current Assets  | 7,325                            | 7,122                |
| Property and equipment, net   | 303                              | 323                  |
| Long-term note receivable   | 700                              | -                    |
| Deposits and other assets   | 21                               | 31                   |
| Total Assets  | \$ 8,349                         | \$ 7,476             |
| Liabilities and Stockholders' Equity  |                                  |                      |
| Current Liabilities:  |                                  |                      |
| Accounts payable  | \$ 316                           | \$ 388               |
| Accrued liabilities   | 127                              | 29                   |
| Total Current Liabilities   | 443                              | 417                  |
| Total Liabilities   | 443                              | 417                  |
| 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, 32,857,609 issued and 32,776,127 outstanding and 31,374,002 issued and 31,292,520 outstanding | 33                               | 31                   |
| Additional paid-in capital  | 60,946                           | 58,901               |
| Accumulated deficit   | (53,073)                         | (51,873)             |
| Total Stockholders' Equity  | 7,906                            | 7,059                |
| Total Liabilities and Stockholders' Equity  | \$ 8,349                         | \$ 7,476             |

See accompanying notes to unaudited consolidated financial statements.



**Synthetic Biologics, Inc. and Subsidiaries****Consolidated Statements of Operations****(In thousands, except share and per share amounts)****(Unaudited)**

|  | Three months ended March 31, |             |
|--|------------------------------|-------------|
|  | 2012                         | 2011        |
| Operating Costs and Expenses:  |                              |             |
| General and administrative   | \$ 1,468                     | \$ 1,233    |
| Research and development   | 386                          | 231         |
| Total Operating Costs and Expenses   | 1,854                        | 1,464       |
| Loss from Continuing Operations  | (1,854 )                     | (1,464 )    |
| Other Income (Expense):  |                              |             |
| Warrant expense  | -                            | (716 )      |
| Change in fair value of warrant liability  | -                            | (94 )       |
| Loss on the sale of equipment  | -                            | (5 )        |
| Other income   | 5                            | 56          |
| Total Other Income (Expense), net  | 5                            | (759 )      |
| Net Loss from Continuing Operations  | (1,849 )                     | (2,223 )    |
| Net Income from Discontinued Operations  | 649                          | 37          |
| Net Loss   | \$ (1,200 )                  | \$ (2,186 ) |
| Net Income (Loss) Per Share - Basic and Dilutive:                                    |                              |             |
| Continuing operations  | \$ (0.06 )                   | \$ (0.09 )  |
| Discontinued operations  | 0.02                         | -           |
| Net Loss Per Share   | \$ (0.04 )                   | \$ (0.09 )  |
| Weighted average number of shares outstanding during the period - Basic and Dilutive | 32,003,164                   | 25,220,694  |

See accompanying notes to unaudited consolidated financial statements.

**Synthetic Biologics, Inc. and Subsidiaries****Consolidated Statements of Cash Flows****(In thousands)****(Unaudited)**

|   | Three months ended March 31, |             |
|---|------------------------------|-------------|
|   | 2012                         | 2011        |
| Cash Flows From Operating Activities:                                       |                              |             |
| Net loss  | \$ (1,849                    | ) \$ (2,223 |
| Net income from discontinued operations                                     | 649                          | 37          |
| Adjustments to reconcile net loss to net cash used in operating activities: |                              |             |
| Stock-based compensation  | 508                          | 768         |
| Stock issued as employee compensation                                       | -                            | 76          |
| Stock issued for consulting fees  | -                            | 58          |
| Warrant expense   | -                            | 716         |
| Change in fair value of warrant liability                                   | -                            | 94          |
| Depreciation  | 20                           | 80          |
| Provision for uncollectible accounts receivable                             | 8                            | 21          |
| Loss on sale of equipment   | -                            | 5           |
| Gain on the settlement of accounts payable                                  | -                            | (63         |
| Changes in operating assets and liabilities:                                |                              | )           |
| Accounts receivable   | (43                          | ) (111      |
| Other current assets  | (67                          | ) 268       |
| Note receivable   | (700                         | ) -         |
| Deposits and other assets   | 10                           | 68          |
| Assets of discontinued operations   | 23                           | 3           |
| Accounts payable  | (72                          | ) 154       |
| Accrued liabilities   | 98                           | (192        |
| Liabilities of discontinued operations                                      | -                            | (40         |
| Net Cash Used In Operating Activities                                       | (1,415                       | ) (281      |
|   |                              | )           |
| Cash Flows From Investing Activities:                                       |                              |             |
| Proceeds from the sale of equipment   | -                            | 1           |
| Net Cash Provided By Investing Activities                                   | -                            | 1           |
| Cash Flows From Financing Activities:                                       |                              |             |
| Proceeds from issuance of common stock for stock option exercises           | 68                           | 8           |
| Proceeds from issuance of common stock for warrant exercises                | 1,471                        | -           |
| Proceeds from issuance of common stock                                      | -                            | 4,000       |
| Cash paid as direct offering costs  | -                            | (296        |
| Net Cash Provided By Financing Activities                                   | 1,539                        | 3,712       |
|   |                              | )           |
| Net increase in cash  | 124                          | 3,432       |

Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

|  |          |          |
|--|----------|----------|
| Cash at beginning of period                        | 6,678    | 2,649    |
| Cash at end of period                              | \$ 6,802 | \$ 6,080 |
| Supplemental disclosures of cash flow information: |          |          |
| Cash paid for interest                             | \$ -     | \$ -     |
| Cash paid for taxes                                | \$ -     | \$ -     |

See accompanying notes to unaudited consolidated financial statements.

**Synthetic Biologics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements****March 31, 2012****(Unaudited)****1. Organization**

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 pulmonary arterial hypertension (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 multiple sclerosis (MS), cognitive dysfunction in MS, fibromyalgia and amyotrophic lateral sclerosis (ALS).

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

**2. Basis of Presentation**

The accompanying unaudited consolidated interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and the rules and regulations of the United

States Securities and Exchange Commission for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X.

The financial information as of December 31, 2011, is derived from the audited financial statements presented in the Company's Annual Report on Form 10-K/A for the year ended December 31, 2011. The unaudited consolidated interim financial statements should be read in conjunction with the Company's Annual Report on Form 10-K/A, which contains the audited financial statements and notes thereto, together with the Management's Discussion and Analysis, for the year ended December 31, 2011.

Certain information or footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been consolidated or omitted, pursuant to the rules and regulations of the Securities and Exchange Commission for interim financial reporting. Accordingly, they do not include all the information and footnotes necessary for a comprehensive presentation of financial position, results of operations, or cash flows. It is management's opinion, however, that all material adjustments (consisting of normal recurring adjustments) have been made which are necessary for a fair financial statement presentation. The interim results for the period ended March 31, 2012, are not necessarily indicative of results for the full year.

The Company has seven subsidiaries, Pipex Therapeutics, Inc. (“Pipex Therapeutics”), 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 March 31, 2012, EPI, Healthmine and Putney are wholly owned and Pipex Therapeutics, Solovax, CD4 and Epitope are majority-owned.

### **3. Summary of Significant Accounting Policies**

#### *Principles of Consolidation*

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

#### *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 three months ended March 31, 2012 and 2011, the Company's only stream of revenue was laboratory revenue. Laboratory revenues are a component of discontinued operations for the three months ended March 31, 2012 and 2011. *See Note 4 – Discontinued Operations of Adeona Clinical Laboratory and Note Receivable.*

### ***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 reimbursements from 3 significant insurance providers in March 31, 2012 and 2011, as follows:

| Customer | 2012 | 2011 |
|----------|------|------|
| A        | 68 % | 69 % |

|   |   |   |    |   |
|---|---|---|----|---|
| B | 5 | % | 18 | % |
| C | 9 | % | 5  | % |

### ***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 March 31, 2012 and 2011, respectively, the Company had no cash equivalents.

### ***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 4 – Discontinued Operations of Adeona Clinical Laboratory and Note Receivable.*

### ***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 three months ended March 31, 2012 and 2011, 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 three months ended March 31, 2012 were 3,843,465 and 2,414,922, respectively, and for the three months ended March 31, 2011 were 2,273,072 and 2,554,650, 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.

### ***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.

### ***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.

### **4. Discontinued Operations of Adeona Clinical Laboratory and Note Receivable**

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 bearing interest at 5.7% per annum secured by all of the assets of the Lab. The note and all unpaid interest are due on March 1, 2014.

In accordance with ASC Topic 205-20 “*Presentation of Financial Statements—Discontinued Operations*” (ASC 205-20), the Company determined that all the criteria had been met and 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 of the discontinued operations are presented separately under the caption “Assets of discontinued operations” in the accompanying Consolidated Balance Sheets at March 31, 2012, and December 31, 2011, and consist of the following (*in thousands*):

|                                    | March 31, 2012 | December 31, 2011 |
|------------------------------------|----------------|-------------------|
| Assets of discontinued operations: |                |                   |
| Property and equipment, net        | \$ -           | \$ 23             |
| Total assets                       | \$ -           | \$ 23             |

The summarized statement of operations data for Adeona Clinical Laboratory for the three months ended March 31, 2012 and March 31, 2011 are as follows (*in thousands*):

|  | March 31, |       |
|--|-----------|-------|
|  | 2012      | 2011  |
| Laboratory fees, net                           | \$115     | \$323 |
| Operating Costs and Expenses:                  |           |       |
| General and administrative                     | 27        | 35    |
| Cost of laboratory services                    | 116       | 251   |
| Total operating costs and expenses             | 143       | 286   |
| Income (loss) from discontinued operations     | (28 )     | 37    |
| Other Income:                                  |           |       |
| Gain on the sale of Adeona Clinical Laboratory | 677       | -     |
| Net income from discontinued operations        | \$649     | \$37  |

## 5. Selected Balance Sheet Information

Accounts receivable consisted of the following at March 31, 2012 and December 31, 2011 (*in thousands*):

|                               | March 31, 2012 | December 31, 2011 |
|-------------------------------|----------------|-------------------|
| Accounts receivable           | \$ 736         | \$ 692            |
| Bad debt allowance - customer | (296 )         | (287 )            |
| Accounts receivable, net      | \$ 440         | \$ 405            |

Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

Property and Equipment consisted of the following at March 31, 2012, and December 31, 2011 (*in thousands*) :

|                               | March 31, 2012 | December 31, 2011 |
|-------------------------------|----------------|-------------------|
| Manufacturing equipment       | \$ 400         | \$ 400            |
| Computer and office equipment | 159            | 159               |
| Laboratory equipment          | 136            | 136               |
| Total                         | 695            | 695               |
| Less accumulated depreciation | (392 )         | (372 )            |
| Property and equipment, net   | \$ 303         | \$ 323            |

Depreciation expense for the three months ended March 31, 2012 and 2011 was \$20,000 and \$80,000, respectively.

## 6. Stock-Based Compensation

During 2001, Pipex Therapeutics' board of directors and stockholders adopted the 2001 Stock Incentive Plan (the "2001 Stock Plan"). This plan was assumed by Pipex in the October 2006 merger with Sheffield. As of the date of the merger, there were 1,489,353 options issued and outstanding under the 2001 plan. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2001 plan shall not exceed 250,000. All awards pursuant to the 2001 Stock Plan shall terminate upon the termination of the grantee's employment for any reason. Awards include options, restricted shares, stock appreciation rights, performance shares and cash-based awards (the "Awards"). The 2001 Stock Plan contains certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment, as defined in the plan. The 2001 Stock Plan provides for a Committee of the Board to grant awards and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the awards, including acceleration of the vesting of an award at any time. As of March 31, 2012, there were 1,066,007 options issued and outstanding under the 2001 Stock Plan.

On March 20, 2007, the Company's board of directors approved the Company's 2007 Stock Incentive Plan (the "2007 Stock Plan") for the issuance of up to 2,500,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. This plan was approved by stockholders on November 2, 2007. The exercise price of stock options under the 2007 Stock Plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2001 plan shall not exceed 250,000. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of March 31, 2012, there are 1,031,394 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 periods from the date of grant, and generally expire seven to ten years after the grant date. As of March 31, 2012, there are 1,746,064 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.



## Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

The Company has applied fair value accounting for all stock-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 months ended March 31, 2012 and 2011 are as follows:

|                          | Three Months Ended March 31, |                   |
|--------------------------|------------------------------|-------------------|
|                          | 2012                         | 2011              |
| Exercise price           | \$1.14 – \$2.47              | \$1.21 – \$2.22   |
| Expected dividends       | 0%                           | 0%                |
| Expected volatility      | 108% – 174%                  | 185% – 188%       |
| Risk free interest rates | 0.37% – 1.98%                | 2.81% – 3.58%     |
| Expected life options    | 10 years                     | 5 years – 7 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,  
one-half vesting immediately and the remainder over three years

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

During the three months ended March 31, 2012, the Company granted 1,300,000 options to employees and consultants having a fair value of approximately \$3 million based upon the Black-Scholes option pricing model. During the same period of 2011, the Company granted 324,502 options to employees having a fair value of approximately \$433,000 based upon the Black-Scholes option pricing model.

A summary of stock option activities as of March 31, 2012, and for the year ended December 31, 2011, is as follows:

|  | Options    | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Life | Aggregate<br>Intrinsic<br>Value |
|--|------------|--|---|---------------------------------|
| Balance – December 31, 2010            | 2,539,091  | \$ 1.32                                  |   |                                 |
| Granted                                | 557,002    | 1.26                                     |   |                                 |
| Exercised                              | (23,333 )  | 0.57                                     |   |                                 |
| Forfeited or expired                   | (93,750 )  | 0.59                                     |   |                                 |
| Balance – December 31, 2011            | 2,979,010  | 1.34                                     |   |                                 |
| Granted                                | 1,300,000  | 2.35                                     |   |                                 |
| Exercised                              | (289,343 ) | 0.23                                     |   |                                 |
| Forfeited or expired                   | (146,202 ) | 0.80                                     |   |                                 |
| Balance – March 31, 2012 – outstanding | 3,843,465  | \$ 1.79                                  | 7.18 years  | \$2,230,000                     |
| Balance – March 31, 2012 – exercisable | 2,323,320  | \$ 1.62                                  | 5.73 years  | \$1,814,000                     |

The options outstanding and exercisable as of March 31, 2012, are as follows:

| Options Outstanding | Weighted | Weighted Average | Options Exercisable | Weighted | Weighted Average |
|---------------------|----------|------------------|---------------------|----------|------------------|
|---------------------|----------|------------------|---------------------|----------|------------------|

Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

| Range of Exercise Price | Options   | Average Exercise Price | Remaining Contractual Life | Options   | Average Exercise Price | Remaining Contractual Life |
|-------------------------|-----------|------------------------|----------------------------|-----------|------------------------|----------------------------|
| \$0.09 - \$4.57         | 3,753,466 | \$ 1.69                | 7.29 years                 | 2,233,321 | \$ 1.44                | 5.86 years                 |
| \$4.58 - \$9.05         | 89,999    | 5.93                   | 2.51 years                 | 89,999    | 5.93                   | 2.51 years                 |
| \$0.09 - \$9.05         | 3,843,465 | \$ 1.79                | 7.18 years                 | 2,323,320 | \$ 1.62                | 5.73 years                 |

The options outstanding and exercisable as of March 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         | 2,721,921 | \$ 1.22                         | 6.75 years                                  | 2,183,073           | \$ 1.32                         | 6.27 years                                  |
| \$4.58 - \$9.05         | 89,999    | 5.93                            | 3.51 years                                  | 89,999              | 5.93                            | 3.51 years                                  |
| \$0.09 - \$9.05         | 2,811,926 | \$ 1.37                         | 6.65 years                                  | 2,273,072           | \$ 1.50                         | 6.16 years                                  |

*Options of Subsidiary*

During 2004 and 2007, CD4 granted 30,000 options. On August 5, 2009, 10,000 of these options expired. As of March 31, 2012, a total of 20,000 options were outstanding and exercisable with an exercise price of \$0.20 and a remaining contractual life of 0.12 years.

As of March 31, 2012, Epitepe has 50,000 options outstanding and 20,000 options exercisable with an exercise price of \$0.001 and a remaining contractual life of 6.25 years. These options were granted during 2008, vest annually over 5 years, and have a fair value of \$50, which was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%; expected volatility of 200%, risk free interest rate of 2.47% and an expected life of 10 years.

**7. Stock Purchase Warrants**

On March 15, 2012, the Company entered into a consulting agreement for a financial communications program, for a period of twelve months that began on February 20, 2012. As compensation for such program, the consultant is paid a monthly fee and will be issued a performance warrant exercisable for 250,000 shares of the Company's common stock based on achievement of certain milestones. Upon initiation of the program, 50,000 of the performance warrants vested. The performance warrant is exercisable for a period of two years from the date the agreement was executed for an exercise price equal to the price of the Company's common stock on the date of execution. The fair value of the warrant approximated \$61,000 and was measured using the Black-Scholes valuation model. The assumptions used by the Company are summarized in the following table:

|                          |        |       |
|--------------------------|--------|-------|
| Exercise price           | \$2.20 |       |
| Expected dividends       | 0      | %     |
| Expected volatility      | 108    | %     |
| Risk free interest rate  | 0.37   | %     |
| Expected life of warrant | 2      | years |
| Expected forfeitures     | 0      | %     |

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 is paid a monthly fee and on February 2, 2012, 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 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 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 warrants have an exercise price of \$1.00 and a life of fifteen months. The warrants vested immediately and expire August 10, 2012. As of March 31, 2012, 344,391 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. The warrants have an exercise price of \$1.40 and a life of fifteen months. The warrants vested immediately and expire May 1, 2012. As of March 31, 2012, 746,429 of these warrants remained outstanding.

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 March 31, 2012, 18,182 of these warrants remained outstanding.

A summary of warrant activities as of March 31, 2012, and for the year ended December 31, 2011, is as follows:

|  | Warrants    | Weighted<br>Average Exercise Price |
|--|-------------|------------------------------------|
| Balance – December 31, 2010            | 1,131,078   | \$ 3.49                            |
| Granted                                | 2,272,963   | 1.25                               |
| Exercised                              | (15,615 )   | 1.03                               |
| Expired                                | (129,240 )  | 2.08                               |
| Balance – December 31, 2011            | 3,259,186   | 1.95                               |
| Granted                                | 350,000     | 1.90                               |
| Exercised                              | (1,194,264) | 1.24                               |
| Expired                                | -           | -                                  |
| Balance – March 31, 2012 - outstanding | 2,414,922   | \$ 2.36                            |
| Balance – March 31, 2012 – exercisable | 2,214,922   | \$ 2.37                            |

The warrants outstanding as of March 31, 2012, are as follows:

| Exercise Price | Warrants Outstanding | Warrants Exercisable | Weighted Average Remaining Contractual Life | Aggregate Intrinsic Value |
|----------------|----------------------|----------------------|---|---------------------------|
| \$ 1.00        | 344,391              | 344,391              | 0.36 years                                  | \$ 443,000                |
| \$ 1.14        | 100,000              | 100,000              | 4.84 years                                  | 106,000                   |
| \$ 1.32        | 18,182               | 18,182               | 3.75 years                                  | 16,000                    |
| \$ 1.40        | 746,429              | 721,429              | 0.08 years                                  | 577,000                   |
| \$ 2.20        | 250,000              | 50,000               | 1.96 years                                  | -                         |
| \$ 2.22        | 517,257              | 517,257              | 4.66 years                                  | -                         |
| \$ 3.30        | 61,207               | 61,207               | 3.30 years                                  | -                         |
| \$ 3.75        | 50,000               | 50,000               | 3.88 years                                  | -                         |
| \$ 6.36        | 327,456              | 327,456              | <u>0.61 years</u>                           | -                         |
|                | 2,414,922            | 2,214,922            | <u>1.81 years</u>                           | \$ 1,142,000              |

## 8. Stockholders' Equity

During the three months ended March 31, 2012, the Company issued 289,343 shares of common stock, in connection with the exercise of stock options, for proceeds of approximately \$68,000. The Company also issued 1,194,264 shares of common stock in connection with the exercise of warrants, for proceeds of approximately \$1.5 million.

## 9. Subsequent Events

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 received funds from the exercise of warrants but will not issue any shares under any of its outstanding registration statements on Form S-3 until such time as it receives guidance from the SEC whether the issue disclosed herein affects the Company’s ability to continue to issue securities thereunder. The Company intends to return all of the funds to the warrant holders. The Company has sought guidance from the SEC staff regarding this matter and intends to file a waiver request to the extent it becomes necessary.

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 receive annual compensation of \$150,000. Additionally, Mr. Kraws was granted options to purchase 100,000 shares of the Company's common stock with an exercise price equal to our per share market price on the date of issue. These options will vest pro rata, quarterly over a two year period with the first quarterly issuance of 12,500 options vesting immediately. The Company measured the fair value of the stock options at approximately \$166,000 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           | \$1.70 |       |
| Expected dividends       | 0      | %     |
| Expected volatility      | 171    | %     |
| Risk free interest rate  | 1.28   | %     |
| Expected life of options | 7      | years |
| Expected forfeitures     | 0      | %     |



|  | Page |
|--|------|
| Report of Independent Registered Public Accounting Firm    | 65   |
| Consolidated Balance Sheets                                | 66   |
| Consolidated Statements of Operations                      | 67   |
| Consolidated Statements of Changes in Stockholders' Equity | 68   |
| Consolidated Statements of Cash Flows                      | 69   |
| Notes to Consolidated Financial Statements                 | 70   |

**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



**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



**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<br>Shares | Amount | Additional Paid-in Capital | Accumulated Deficit | Subscriptions Receivable | Total Stockholders' Equity |
|--|--|--------|----------------------------|---------------------|--------------------------|----------------------------|
| 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





**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          |

Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

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<br>(estriol)                     | All patients enrolled in Phase II clinical trial;<br>dosing and monitoring underway |
| Cognitive dysfunction in MS | Trimesta<br>(estriol)                     | Patient enrollment underway in Phase II<br>clinical trial                           |
| Fibromyalgia                | Effirma<br>(oral flupirtine)              | Partnered with Meda AB  |
| ALS                         | AEN-100<br>(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*<sup>™</sup> and *wellZin*<sup>™</sup>.

***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.



## Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

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 – Intra-period 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<br>31,<br>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,<br>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<br>31,<br>2011 2010 |       |
|------------------|------------------------------|-------|
| Grant receivable | \$-                          | \$320 |
| Prepaid expenses | 16                           | 23    |
| Total            | \$16                         | \$343 |

*Property and equipment (in thousands)*

|                               | December 31,<br>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<br>31,<br>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 free 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.

Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

|  | Options    | Weighted<br>Average Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Life | Aggregate<br>Intrinsic<br>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<br>Exercise Price | Options   | Weighted<br>Average<br>Exercise Price | Weighted Average<br>Remaining<br>Contractual Life | Options             | Weighted<br>Average<br>Exercise Price | Weighted Average<br>Remaining<br>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<br>Exercise Price | Options   | Weighted<br>Average<br>Exercise Price | Weighted Average<br>Remaining<br>Contractual Life | Options             | Weighted<br>Average<br>Exercise Price | Weighted Average<br>Remaining<br>Contractual Life |  |
| \$0.09 - \$4.57            | 2,449,092 | \$ 1.16                               | 7.09 years  | 1,900,445           | \$ 1.28                               | 6.47 years  |  |



Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

|                 |           |         |            |           |         |            |
|-----------------|-----------|---------|------------|-----------|---------|------------|
| \$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:

|   | <b>Unvested</b> | <b>Grant</b>    | <b>Weighted Average</b> |
|---|-----------------|-----------------|-------------------------|
|   | Stock Options   | 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<br>Date |   | Remeasurement<br>Date<br>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<br>Date | Remeasurement<br>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<br>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:

Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

| 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                |

### *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 |

### *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.

Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

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     |
|   | \$-       | \$-     |

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*):

|                                  | 2011     | 2010     |
|----------------------------------|----------|----------|
| Deferred tax assets:             |          |          |
| 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.

**PART II - INFORMATION NOT REQUIRED IN PROSPECTUS**

**ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION**

We estimate that expenses in connection with the distribution described in this registration statement (other than brokerage commissions, discounts or other expenses relating to the sale of the shares of common stock underlying the Warrants by the selling security holders) will be as set forth below. We will pay all of the expenses with respect to the distribution, and such amounts, with the exception of the Securities and Exchange Commission registration fee, are estimates.

|                                  |             |
|----------------------------------|-------------|
| SEC registration fee             | \$1,069.50  |
| Accounting fees and expenses     | 5,000.00    |
| Legal fees and expenses          | \$5,000.00  |
| Printing and related expenses    | \$1,000.00  |
| Transfer agent fees and expenses | 1,000.00    |
| Miscellaneous                    | 930.50      |
| Total                            | \$14,000.00 |

**ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS**

Under the provisions of Section 78.138 of Nevada Revised Statutes and our Articles of Incorporation, we may indemnify our directors, officers, employees and agents and maintain liability insurance for those persons. Section 78.138 provides that a corporation may indemnify a person made a party to a proceeding because the person is or was a director against liability incurred in the proceeding if the person's conduct was in good faith. In the case of conduct in an official capacity with the corporation, the person may be indemnified if the person reasonably believed that such conduct was in the corporation's best interests. In all other cases, the corporation may indemnify the person if the person reasonably believed that such conduct was at least not opposed to the corporation's best interests. In the case of any criminal proceeding, the person may be indemnified if the person had no reasonable cause to believe the person's conduct was unlawful.

Our Articles of Incorporation obligate us to indemnify our directors and officers to the fullest extent permitted under Nevada law. Additionally, our Articles of Incorporation and Bylaws grant us the authority to the maximum extent permitted by Nevada law to purchase and maintain insurance providing such indemnification. We have purchased directors' and officers' liability insurance policies for our directors and officers.

In the employment agreement that we entered into with all of our officers, we agreed to indemnify our officers for all claims arising out of performance of their duties as officers of the company, other than those arising out of his breach of the agreement or his gross negligence or willful misconduct.

Insofar as indemnification for liabilities for damages arising under the Securities Act of 1933, as amended (the "Securities Act") may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provision, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

#### **ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES**

The following information sets forth certain information with respect to all securities which we have sold during the last three years. We did not pay any commissions in connection with any of these sales.

In January, February and March 2009, we issued a total of 139,935 shares of our common stock to two consultants for services rendered. These offerings and sales of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuances did not involve a public offering. The offerings were not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the offering. This offering was done with no general solicitation or advertising by us. Based on an analysis of the above factors, we met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for these sales.



In February 2009, we issued a total of 257,813 shares of our common stock to a university for license fees. These offerings and sales of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuances did not involve a public offering. The offerings were not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the offering. The offerings were done with no general solicitation or advertising by us. Based on an analysis of the above factors, we met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

During the second quarter of 2009, we issued a total of 72,840 shares of our common stock to three consultants for services rendered. These offerings and sales of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuances did not involve a public offering. The offerings were not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the offering. This offering was done with no general solicitation or advertising by us. Based on an analysis of the above factors, we met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

In May 2009, in connection with our acquisition of all of the outstanding membership interests in Hartlab LLC, an Illinois limited liability company and CLIA-certified clinical laboratory, in May 2009, as partial consideration for the purchase of the lab, we issued 50,000 unregistered shares of our common stock to the owner of the lab. This offering and sale of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuance did not involve a public offering. The offering was not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the offering. This offering was done with no general solicitation or advertising by us. Based on an analysis of the above factors, we met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for this issuance.

During the third quarter of 2009, we issued a total of 19,697 shares of our common stock to three consultants for services rendered. These offerings and sales of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuances did not involve a public offering. The offerings were not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the offering. This offering was done with no general solicitation or advertising by us. Based on an analysis of the above factors, we met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

During the fourth quarter of 2009, we issued 104,633 shares of common stock, in connection with the exercise of stock options, for proceeds of \$27,834 and issued 3,066 shares of common stock for consulting fees, having a fair value of \$65,786 (\$0.28 per share), based on the quoted closing trading prices. These offerings and sales of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuances did not involve a public offering. The offerings were not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the offering. This offering was done with no general solicitation or advertising by us. Based on an analysis of the above factors, we met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

During the first three months of 2010, we issued a total of 33,118 shares of our common stock to two consultants for services rendered. These offerings and sales of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuances did not involve a public offering. The offerings were not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the offering. This offering was done with no general solicitation or advertising by us. Based on an analysis of the above factors, we met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

In July 2010, we issued warrants to the placement agent and its designees in connection with our sale of shares of our common stock pursuant to our registration statement on Form S-3. The warrants are exercisable for 60,606 shares of common stock at an exercise price of \$1.32 for a period of five years. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof since the issuances did not involve a public offering. The issuances were not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the issuances. These issuances were done with no general solicitation or advertising by us. Based on an analysis of the above factors, we met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

In October of 2010, we issued 52,180 shares of common stock to Thomas Jefferson University having a fair value of \$41,250 (\$0.79 per share) and 28,855 shares of common stock to the University of Southern California having a fair value of \$29,087 (\$1.01 per share) in payment for licensing fees. The fair value of these issuances was based upon the quoted closing price. These issuances and sales of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuances did not involve a public offering. The issuances were not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the issuances. These issuances were done with no general solicitation or advertising by us. Based on an analysis of the above factors, we met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

On July 28, 2011, we exchanged the warrant issued in connection with the April 6, 2011 financing for a new warrant with substantially the same terms as the original warrant. We exchanged our warrant with existing security holders and no remuneration or commission was paid in reliance on Section 3(a)(9) of the Securities Act of 1933.

On August 2, 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. This issuance and sale of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuance did not involve a public offering. The issuance was not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the issuance. This issuance was done with no general solicitation or advertising by us. Based on an analysis of the above factors, we met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

On August 10, 2011, we entered into an agreement to exchange the warrants issued in connection with the January 28, 2011 financing for new warrants. We exchanged our warrant with existing security holders and no remuneration or commission was paid in reliance on Section 3(a)(9) of the Securities Act of 1933.

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. This issuance and sale of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuance did not involve a public offering. The issuance was not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the issuance. This issuance was done with no general solicitation or advertising by us. Based on an analysis of the above factors, we met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

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. This issuance and sale of warrants qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuance did not involve a public offering. The issuance was not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the issuance. This issuance was done with no general solicitation or advertising by us. Based on an analysis of the above factors, we met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

**ITEM 16. EXHIBITS**

- 3.1 Certificate of Incorporation, as amended (Incorporated by reference to (i) Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 16, 2008, (ii) Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2001 filed August 14, 2001 and (iii) Exhibits 3.1, 4.1 and 4.2 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1998 filed August 14, 1998)
- 3.2 Articles of Merger (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009.)
- 3.3 Certificate of Merger filed with the Secretary of State of Delaware (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 19, 2009.)
- 3.4 Articles of Incorporation filed with the Nevada Secretary of State (Incorporated by reference to Exhibit 3.3 of the Registrant's Current Report on Form 8-K filed October 19, 2009.)
- 3.5 By-Laws (Incorporated by reference to (i) Exhibit 3.4 of the Registrant's Current Report on Form 8-K filed October 19, 2009 and (ii) Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed June 3, 2010. )
- 3.6 Amended and Restated Bylaws Adopted and Effective October 31, 2011 (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed November 2, 2011.)
- 3.7 Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed February 16, 2012.)
- 4.1 Form of Warrant Certificate (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed December 1, 2006.)
- \*4.2 2001 Stock Incentive Plan (Incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-8 filed January 18, 2008.)
- \*4.3 2007 Stock Incentive Plan (Incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-8 filed January 18, 2008.)
- \*4.4 2010 Stock Incentive Plan (Incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-8 filed November 29, 2010.)

- 4.5 Form of Warrant Certificate issued to Enclave Capital LLC (Incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed July 6, 2010.)
- 4.6 Form of Warrant to Purchase Common Stock issued January 2011 (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed February 2, 2011.)
- 4.7 Form of Warrant to Purchase Common Stock issued April 2011 (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed April 6, 2011.)
- 4.8 Form of Exchange Warrant to Purchase Common Stock issued in exchange of the Warrant issued April 2011 (Incorporated by reference to Exhibit 4.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 filed August 15, 2011.)
- 4.9 Form of Exchange Warrant to Purchase Common Stock issued in exchange of the Warrant issued February 2011 (Incorporated by reference to Exhibit 4.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 filed August 15, 2011.)

- 4.10 Form of Warrant to Purchase Common Stock issued February 2012 (Incorporated by reference to Exhibit 4.10 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011 filed March 30, 2012.)
- 4.11 Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 4.10 of the Registrant's Annual Report on Form 10-K filed March 30, 2012.)
- 5.1 Legal Opinion of Gracin & Marlow, LLP (1)
- 10.1 Unit Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed December 1, 2006.)
- 10.2 License Agreement between The Regents of the University of California and Epitope Pharmaceuticals, Inc. (Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2008 filed November 14, 2008.)
- \*10.3 Form of Director/Officer Indemnification Agreement (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed January 6, 2009.)
- 10.4 Warrant Cancellation and Registration Rights Agreement between Accredited Adventures Capital LLC and Adeona (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed January 20, 2009.)\*
- 10.5 Stock Purchase Agreement with Neil O. Colwell and Connie Colwell (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed April 16, 2009.)
- 10.6 Escrow Agreement Nayaran Torke (Incorporated by reference to Exhibit 10.5 of the Registrant's Current Report on Form 8-K filed July 16, 2009.)
- 10.7 Consulting Agreement with Nayaran Torke (Incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed July 16, 2009.)
- 10.8 Purchase Agreement 1st Amendment HartLab LLC (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed July 16, 2009.)
- 10.9 Purchase Agreement 2nd Amendment Hartlab LLC (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed July 16, 2009.)
- 10.10 Agreement and Plan of Reincorporation Merger (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009.)

- \*10.11 Employment Agreement with James S. Kuo, M.D., (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed February 9, 2010.)
  
- \*10.12 Separation Agreement with Max Lyons (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed February 9, 2010.)
  
- 10.13 Sublicense Agreement between Meda AB, Adeona Pharmaceuticals, Inc. and Pipex Therapeutics, Inc. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed May 11, 2010.)
  
- 10.14 Non-Disturbance Agreement among Pipex Therapeutics, Inc., Mclean Hospital Corp and Meda AB (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed May 11, 2010.)
  
- 10.15 Placement Agent Agreement with Enclave Capital LLC (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed July 6, 2010.)
  
- 10.16 Common Stock Purchase Agreement with Seaside 88,LP (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed July 6, 2010.)



- 10.17 Agreement with Chardan Capital Markets, LLC (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed February 2, 2011.)
- 10.18 Securities Purchase Agreement with investors (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed February 2, 2011.)
- 10.19 McLean Hospital Corporation Exclusive License Agreement (Incorporated by reference to Exhibit 10.21 of the Registrant's Annual Report on Form 10-K filed March 31, 2011)
- 10.20 Agreement with Chardan Capital Markets, LLC (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed April 6, 2011.)
- 10.21 Securities Purchase Agreement with investors (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed April 6, 2011.)
- 10.22 Exchange Agreement with respect to Warrant issued April 2011 (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 filed August 15, 2011.)
- 10.23 Exchange Agreement with respect to Warrant issued February 2011 (Incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 filed August 15, 2011.)
- 10.24 Exclusive Cannel Collaboration Agreement with Intrexon Corporation (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed November 21, 2011.)
- 10.25 Stock Purchase Agreement with Intrexon Corporation (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed November 21, 2011.)
- 10.26 Registration Rights Agreement with Intrexon Corporation (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed November 21, 2011.)
- \*10.27 Employment Agreement with Jeffrey Riley (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed February 6, 2012.)
- 10.28 Consulting Agreement with Dr. James Kuo (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed February 6, 2012.)

Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

\*10.29 Employment Agreement with C. Evan Ballantyne (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed February 7, 2012.)

\*10.30 Employment Agreement with Steve H. Kanzer (1) Incorporated by reference to Exhibit 10.304 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011 filed March 30, 2012.)

10.31 Membership Interest Purchase Agreement by and among Synthetic Biologics, Inc., Hartlab LLC, and Adeona Clinical Laboratory, LLC, dated as of March 7, 2012 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed March 12, 2012.)

10.32 Pledge and Security Agreement between Synthetic Biologics, Inc. and Hartlab, LLC dated as of March 7, 2012 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed March 12, 2012.)

10.33 Non-Recourse Promissory Note between Synthetic Biologics, Inc. and Hartlab, LLC dated as of March 7, 2012 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed March 12, 2012.)

10.34 Financial Advisory Agreement with Griffin Securities, Inc. (Incorporated by reference to Exhibit 10.34 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011 filed March 30, 2012.)

<sup>21</sup> List of Subsidiaries (Incorporated by reference to Exhibit 10.34 of the Registrant's Annual Report on Form 10-K filed March 30, 2012.)

23.1 Consent of Independent Registered Accounting Firm (1)

23.2 Consent of Gracin & Marlow, LLP (Included in its opinion filed as Exhibit 5)

24 Power of Attorney (Included on signature page)

(1) Filed herewith.

\* Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this report

## ITEM 28. UNDERTAKINGS

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrants, pursuant to the provisions described under Item 15 or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification by it is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) to reflect in the prospectus any acts or events arising after the effective date of this registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in this registration statement (notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of a prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement); and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in this registration statement or any material change to such information in this registration statement; provided, however, that subparagraphs (i), (ii) and (iii) do not apply if the information required to be included in a post-effective amendment by those subparagraphs is contained in periodic reports filed with or furnished to the SEC by the Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, that are incorporated by reference in this registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration, by means of a post-effective amendment, any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) if the Registrant is relying on Rule 430B: (A) each prospectus filed by the Registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and (B) each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

(ii) if the Registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: the undersigned Registrant undertakes that in a primary offering of securities of the undersigned Registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser: (i) any preliminary prospectus or prospectus of the undersigned Registrant relating to the offering required to be filed pursuant to Rule 424; (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned Registrant or used or referred to by the undersigned Registrant; (iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned Registrant or its securities provided by or on behalf of the undersigned Registrant; and (iv) any other communication that is an offer in the offering made by the undersigned Registrant to the purchaser.

(6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(7) That for purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.

(8) That, for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(9) To file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of Section 310 of the Trust Indenture Act in accordance with the rules and regulations prescribed by the Commission under Section 305(b)(2) of the Act.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on the Post-Effective Amendment No. 1 to Form S-3 on Form S-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Ann Arbor, State of Michigan, July 12, 2012.

SYNTHETIC  
BIOLOGICS, INC.  
By: /s/ Jeffrey Riley  
Jeffrey Riley  
Chief Executive  
Officer and Director  
(Principal Executive  
Officer)  
Date: July 12, 2012

By: /s/ C. Evan Ballantyne  
C. Evan Ballantyne  
Chief Financial Officer  
(Principal Financial and  
Principal Accounting  
Officer)  
Date: July 12, 2012



## POWER OF ATTORNEY

We, the undersigned hereby severally constitute and appoint each of Jeffrey Riley and C. Evan Ballantyne our true and lawful attorney and agent, with full power to each to sign for us, and in our names in the capacities indicated below, any and all amendments to this registration statement, any subsequent registration statements pursuant to Rule 462 of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof. This power of attorney may be executed in counterparts.

Pursuant to the requirements of the Securities Act of 1933, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Date: July 12, 2012 By: /s/ Jeffrey Riley  
Jeffrey Riley  
Chief Executive  
Officer and Director  
(Principal Executive  
Officer)

Date: July 12, 2012 By: /s/ Jeffrey J. Kraws  
Jeffrey J. Kraws  
Chairman

Date: July 12, 2012 By: /s/ Steve H. Kanzer  
Steve H. Kanzer  
Director

Date: July 12, 2012 By:  
James S. Kuo  
Director

Date: July 12, 2012 By:  
Nelson K. Stacks  
Director

Edgar Filing: Synthetic Biologics, Inc. - Form POS AM

Date: July 12, 2012 By:/s/ Scott L. Tarriff  
Scott L. Tarriff  
Director

Date: July 12, 2012 By:/s/ Jeffrey Wolf  
Jeffrey Wolf  
Director