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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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(Mark One)

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

For the fiscal year ended December 31, 2012

or

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

For the transition period from _____ to _____

Commission file number 000-23776

DARA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

04-3216862

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

8601 Six Forks Road, Suite 160

Raleigh, North Carolina

(Address of principal executive offices)

27615

(Zip Code)

Registrant's telephone number, including area code: (919) 872-5578

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

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, Par Value \$.01 Per Share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None
(Title of Class)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of

Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 30, 2012 was approximately \$8,300,231.

The number of shares outstanding of the Registrant's common stock as of March 21, 2013 was approximately 25,000,961.

Documents Incorporated by Reference

Portions of the Proxy Statement for the Annual Meeting of Stockholders to be held on May 10, 2013 are incorporated by reference into Part III of this Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. When used in this Form 10-K, the words “believe,” “anticipates,” “intends,” “plans,” “estimates,” and similar expressions are forward-looking statements. Such forward-looking statements contained in this Form 10-K are based on management’s current expectations and are subject to factors that could cause actual results to differ materially for us from those projected. Those factors include risks and uncertainties relating to our current cash position and our need to raise additional capital in order to be able to continue to fund our operations, the potential delisting of our common stock from the NASDAQ Capital Market, the potential stockholder dilution that may result from future capital raising efforts, our limited operating history which may make it difficult to evaluate our business and future viability, our ability to retain our managerial personnel and to attract additional personnel, any revenue we generate will come from a small group of commercialized products, our ability to successfully develop and out license our drug candidates as anticipated, the current regulatory environment in which we develop and sell our products, the market acceptance of those products, dependence on partners and third-party manufacturers, successful performance under collaborative and other commercial agreements, potential product liability risks that could exceed our liability coverage, potential risks related to healthcare fraud and abuse laws, competition from other pharmaceutical companies, biotechnology companies and other research and academic institutions, the strength of our intellectual property, the intellectual property of others and other risk factors identified in the documents we have filed, or will file, with the Securities and Exchange Commission. We caution investors that there can be no assurance that actual results, outcomes or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors, including, among others, the potential risks and uncertainties described in “*Part I, Item 1A — Risk Factors*” below.

You should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission (the “SEC”). Except as required by law, we undertake no obligation to update any forward-looking statements.

In this Form 10-K, we refer to information regarding potential markets for our drug candidates and other industry data. We believe that all such information has been obtained from reliable sources that are customarily relied upon by companies in our industry. However, we have not independently verified any such information.

PART I

Item 1. Business

Overview

DARA BioSciences, Inc. is a specialty pharmaceutical company focused on the development and commercialization of oncology treatment and oncology supportive care pharmaceutical products. Through our acquisition of Oncogenerix, Inc., which occurred on January 17, 2012, we acquired our first commercial, FDA-approved proprietary product license Soltamox® (tamoxifen citrate) oral solution. Soltamox has been approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of breast cancer. On September 12, 2012, we entered into a license agreement with Helsinn Healthcare SA (“Helsinn”) to distribute, promote, market and sell Gelclair® a unique oral gel whose key ingredients are polyvinylpyrrolidone (PVP) and sodium hyaluronate (hyaluronic acid) for the treatment of certain approved indications. Gelclair is an FDA-cleared product indicated for the treatment of oral mucositis. In addition, we have a marketing agreement with Innocutis Holdings, LLC pursuant to which we will promote Bionect® (hyaluronic acid sodium salt, 0.2%) within the oncology and radiation oncology marketplace. Bionect has been cleared by the FDA for the management of irritation of the skin as well as first and second degree burns.

We continue to have an internal clinical development program focused on KRN5500, a phase 2 drug targeted for treating cancer patients with painful chronic chemotherapy induced peripheral neuropathy (CCIPN) and we are pursuing out-licensing opportunities for DB959 which is targeted for treating diabetes and is outside the scope of our therapeutic focus.

We were incorporated on June 22, 2002. Our executive offices are located at 8601 Six Forks Road, Suite 160, Raleigh, North Carolina 27615, and our telephone number is (919) 872-5578.

Product Commercialization and Development

Our primary focus is on the commercialization and development of the following types of oncology treatment and oncology supportive care pharmaceutical products:

- Soltamox, an FDA-approved oral solution of tamoxifen citrate and other liquid formulation products; and
- Cancer support therapeutics, including Gelclair, an FDA-cleared product indicated for the treatment of oral mucositis and Bionect, an FDA cleared product for the management of irritation of the skin as well as first and second degree burns

KRN5500 is a novel, non-narcotic/non-opioid intravenous product for the treatment of cancer patients with painful chronic chemotherapy induced peripheral neuropathy which has completed Phase 2a development. We have improved and simplified the formulation and manufactured new drug substance for the next clinical trial and we are looking to partner the drug with an established oncology development company to undertake and support the cost for the Phase 2b program.

Oral liquid formulations of FDA approved products

Oral liquids can provide an attractive and effective alternative to solid dose formulations for those patients with dysphagia, or difficulty swallowing, or those who simply prefer to take drug products in liquid form. Those suffering from dysphagia often have difficulty or experience pain when using oral tablet or capsule products and can benefit greatly from liquid formulations of drugs. In addition, breast cancer patients receiving chemotherapeutic agents are subject to oral mucositis, which makes liquid medical formulations preferable.

Soltamox

Soltamox (tamoxifen citrate) oral solution, our first proprietary, FDA approved product, is a drug primarily used to treat breast cancer. Soltamox is the only liquid formulation of tamoxifen available for sale in the United States. As a result of our acquisition of Oncogenex, we became party to an exclusive license and distribution agreement with Rosemont Pharmaceuticals, Ltd., a U.K. based manufacturer, for rights to market Soltamox in the United States. Previously, Soltamox was marketed only in the U.K. and Ireland by Rosemont Pharmaceuticals, Ltd. Soltamox is protected by a U.S. issued patent which expires in June 2018. We launched Soltamox in the U.S. in the fourth quarter of 2012.

Soltamox is used primarily for the chronic treatment of breast cancer or for cancer prevention in certain susceptible breast cancer subgroups. The National Cancer Institute (NCI) estimated in 2011 that 230,480 women would be diagnosed with breast cancer and 39,520 women would die as a result of the disease. Tamoxifen therapy is generally indicated for breast cancer patients for up to 5 years.

In order to commercialize Soltamox, we have established a specialty commercial sales force which markets Soltamox to oncologists. Current physicians who prescribe tablet forms of tamoxifen in the United States are well known and easily identified by data sources such as IMS and Wolters Kluwer, providers of information services for the healthcare industry.

We are employing a multi-disciplinary approach to reach and educate health care providers, dispensers, patient advocacy groups, foundations, caregivers and patients directly. We believe we can accomplish this through utilization of a combination of our own specialized sales organization and independent sales representatives, innovative marketing programs, partnerships with Specialty Pharmacy Providers, working with Patient Advocacy Groups and Foundations as well as collaborative arrangements with third party sales organizations.

Cancer support therapeutics

We are also focusing on the commercialization and development of cancer support therapeutics.

Gelclair

On September 12, 2012, we entered into a distribution and license agreement with Helsinn Healthcare SA. The Company was granted an exclusive license to distribute, promote, market and sell Gelclair for treatment of certain approved indications in the United States. Gelclair, a unique oral gel whose key ingredients are polyvinylpyrrolidone (PVP) and sodium hyaluronate (hyaluronic acid) is an FDA-cleared product indicated for the treatment of oral mucositis. Under the License Agreement, the Company is obligated to meet minimum sales thresholds during the License Agreement's ten-year term. The License Agreement also provides that the Company will receive exclusive rights to distribute, promote, market and sell Gelclair for an additional indication if Helsinn is able to obtain regulatory approval for such indication.

Bionect

On March 23, 2012, we entered into an Exclusive Marketing Agreement with Innocutis Holdings, LLC pursuant to which we will promote Bionect (hyaluronic acid sodium salt, 0.2%) within the oncology and radiation oncology marketplace. Bionect has been approved by the FDA for the management of irritation of the skin as well as first and second degree burns. Bionect is currently being promoted and sold by Innocutis in the dermatology market. The Company will be compensated by Innocutis for each unit sold in the oncology and radiation oncology market. The Company began promoting Bionect in the U.S. in the second quarter of 2012.

Gemcitabine

In February 2012, we entered into an Exclusive Distribution Agreement with Uman Pharma Inc. pursuant to which we received an exclusive license to import, sell, market and distribute Uman's gemcitabine lyophilized powder product in 200mg and 1g dosage sizes in the U.S. Gemcitabine went off patent in 2011 in the U.S. and is widely prescribed as first-line therapy for ovarian, breast, lung and pancreatic cancers. Uman originally intended to file an Abbreviated New Drug Application for gemcitabine with the FDA in the second half of 2012.

Due to the pricing deterioration in the U.S. market with gemcitabine lyophilized generics, Uman did not file an Abbreviated New Drug Application for gemcitabine with the FDA in 2012. In fact, downward pricing pressure on gemcitabine makes it unlikely that Uman will be able to manufacture it. Therefore we will not be able to commercialize gemcitabine in the U.S. at prices competitive enough to be commercially viable. As a result, we believe it is unlikely we will ever launch gemcitabine in the U.S. under our Exclusive Distribution Agreement with Uman.

Internal Development of Drug Candidates

We had two internal drug candidates in clinical development prior to the acquisition of Oncogenerix in January 2012:

- KRN5500, a phase 2a drug targeted for treating painful chronic chemotherapy induced peripheral neuropathy in cancer patients; and

- DB959, a first-in-class drug candidate for the treatment of type 2 diabetes and dyslipidemia.

KRN5500 is a novel, non-narcotic/non-opioid intravenous product for the treatment of painful chronic chemotherapy induced peripheral neuropathy in patients with cancer. The drug has successfully completed a Phase 2a proof of concept study in patients with end-stage cancer and analgesia-resistant neuropathic pain where it showed statistically-significant pain reduction versus placebo ($p = 0.03$) using standardized pain test scores. There were no serious safety concerns although nausea and vomiting were a common occurrence. The FDA has designated KRN5500 a Fast Track drug, based on its potential usefulness in treating a serious medical condition and in fulfilling an unmet medical need. We have recently improved and simplified the formulation and manufactured new drug substance for the next clinical trial. We are working with the National Cancer Institute (NCI) to design an additional clinical trial under joint DARA-NCI auspices. Since KRN5500 would complement our portfolio of oncology treatment and supportive care pharmaceuticals, we are looking to partner the drug with an established oncology development company to undertake and support the cost for the Phase 2b program.

On November 8, 2012 we submitted a request seeking Orphan designation for KRN5500 to the Office of Orphan Products Development at the FDA. The orphan indication we are seeking is in cancer patients with painful chronic chemotherapy induced peripheral neuropathy (CCIPN).

DB959 comes from a family of PPAR alpha/delta/gamma agonists licensed from Bayer Pharmaceuticals Corporation. DB959 is a first-in-class, small molecule, non-TZD PPAR delta/gamma agonist for the treatment of diabetes and hyperlipidemia. The drug activates genes involved in the metabolism of sugars and fats, thereby improving the body's ability to regulate both aspects of diabetes. DB959 has successfully completed Phase I trials, in which it demonstrated a good safety profile even when dosed at approximately 10 times the anticipated human dose. DB959 is outside the scope of our therapeutic focus and therefore is targeted for out-licensing to partners more able to sustain the prolonged timelines and significant costs involved in diabetes drug development.

Investments

Prior to our merger with Point Therapeutics, Inc. in February 2008, we made minority investments in several companies. At December 31, 2012 we held marketable securities in MRI Interventions, Inc. ("MRI"), (OTBB: MRIC), formerly SurgiVision, Inc. MRI Interventions became a publicly traded company on May 18, 2012. As of January 14, 2013, we no longer hold marketable securities in MRI Interventions or any minority investments in other companies.

Competition

In general, the pharmaceutical and biotechnology industries are intensely competitive. The technological areas in which we work continue to evolve at a rapid pace. Competition from pharmaceutical, chemical and biotechnology companies, universities and research institutions is intense and we expect it to increase. Many of these competitors are substantially larger than we are and have substantially greater capital resources, research and development capabilities and experience, manufacturing, marketing, sales, financial and managerial resources than we do. Acquisitions of competing companies by large pharmaceutical companies or other companies could enhance the financial, marketing and other resources available to these competitors.

An important factor in our ability to compete will be the timing of market introduction of competitive products. Accordingly, the relative speed with which we and competing companies can in license and market products will be an important element of market success. Other significant competitive factors include:

- product safety and efficacy;
- timing and scope of regulatory approval;
- product availability;

- marketing and sales capabilities;
- reimbursement coverage from insurance companies and others;
- the extent of clinical benefits and side effects of our products relative to their cost;
- price;
- patent protection; and
- capabilities of partners with whom we may collaborate.

Intellectual Property

Patent Portfolio

Presently, we have rights to a number of issued U.S. and foreign patents and pending patent applications with varying expiration dates. Our patent rights categorized by individual drug development programs are summarized below.

- KRN5500 – four issued U.S. patents directed to spicamycin and derivatives thereof, including KRN5500, and their use in methods of decreasing or preventing pain; one pending U.S. patent application and three pending U.S. provisional patent applications directed to formulations of spicamycin derivatives, including KRN5500, and their use in methods of treating or preventing pain; six issued foreign patents and four pending foreign applications directed to spicamycin and derivatives thereof, including KRN5500, and their use in methods of decreasing or preventing pain.
- DB959 and DB900 – six issued U.S. patents and three pending U.S. patent applications with corresponding foreign patents and patent applications and one pending PCT application related to indane acetic acid derivative compounds and use thereof for treating type 2 diabetes, obesity, cardiovascular disease, liver disorders, Alzheimer's disease, autoimmune disorders, psoriasis and other diseases, and the process and intermediates for preparing compounds.

For information concerning the license agreements relating to these patents, see “*Licenses*” below.

We decided to allow patents and patent applications relating to DB160 and DB200 to lapse, as we determined that further development of these compounds is not of interest to DARA or other parties. This reduces our costs for our patent portfolio and allows us to use our capital to support the intellectual property for our active development programs and those programs which we believe contain future value and benefit to the company.

Licenses

We hold an exclusive license for the U.S. marketing rights to Soltamox from Rosemont Pharmaceuticals, Ltd., a U.K. based oral liquids specialty pharmaceutical company. We acquired this license on January 17, 2012 in connection with our acquisition of Oncogenex. The term of the license is the later of (i) seven years from June 29, 2011; or (ii) the expiry of the last-to- expire Licensed Patent. We are obligated to pay certain milestones and quarterly royalties based upon net revenues. Rosemont is responsible for the manufacturing and supply of Soltamox to us based on mutually agreed upon forecasts and purchase orders from us.

We have an exclusive license with Helsinn Healthcare SA (“Helsinn”), to distribute, promote, market and sell Gelclair for treatment of certain approved indications in the United States. Gelclair is an FDA-cleared product indicated for the treatment of oral mucositis. We acquired this license on September 12, 2012 for a term of ten years. Under the license agreement we are required to make certain up-front payments, milestone payments and royalty payments based upon net revenues. Helsinn is responsible for the manufacturing and supply of Gelclair to

us based on mutually agreed upon forecasts and purchase orders from us. We have licensed exclusive worldwide rights (excluding Australia, New Zealand and Asia) to compounds from Kirin Brewery Co., Ltd. (now Kyowa Hakko Kirin Co., Ltd.) of Japan for the treatment of pain and central and peripheral nervous system conditions or diseases. This license was effective July 1, 2004. We have also entered into an exclusive worldwide license with Massachusetts General Hospital related to the use of certain spicamycin derivatives for use in treating pain. The effective date of this agreement was May 3, 2004.

We halted development of and patent maintenance for compounds acting as DPP-IV inhibitors for the treatment of type 2 diabetes and other metabolic diseases that we had previously licensed from Nuada, LLC on December 22, 2006.

We have licensed exclusive worldwide rights to compounds from Bayer Pharmaceuticals, Corp. for the treatment of metabolic diseases, including type 2 diabetes. The license has no restrictions on disease indications for therapeutic use. Bayer retains certain commercialization rights. This license was acquired October 8, 2007.

We ended our license agreement with Tufts University on July 20, 2011. This license had previously granted exclusive worldwide rights to certain compounds, including talabostat. This action was a cost-saving measure after our decision that further development of talabostat or related compounds was not of interest to DARA or other parties.

Governmental Regulation

The manufacture, advertising, marketing, distribution and sale of medical devices and drugs are subject to regulation principally by the FDA, but also by other federal agencies, and state and local authorities in the United States. The Federal Trade Commission (“FTC”), the FDA and state and local authorities regulate the advertising of medical devices, prescription drugs, over-the-counter drugs and cosmetics. The Federal Food, Drug and Cosmetic Act, as amended (“FDCA”) and the regulations promulgated thereunder, and other federal and state statutes and regulations, govern, among other things, the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, sale, distribution, advertising and promotion of our products. Both the FDCA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The FDA requires a Boxed Warning (sometimes referred to as a “Black Box” Warning) for products for significant risk of severe or life-threatening adverse events. Soltamox has a Black Box warning related to uterine malignancies, stroke and pulmonary embolism. The FDA added this requirement for a Boxed Warning on all tamoxifen products in 2002. This warning can be found in the full Soltamox prescribing information at www.soltamox.com.

We are also subject to various federal and state laws pertaining to health care “fraud and abuse” issues, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescribing of a particular drug. False claims laws prohibit anyone from knowingly and willfully presenting, or causing to be presented for payment to the United States government, including Medicare and Medicaid, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. We have adopted the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, which is a voluntary industry code developed to establish standards for interactions with and communications to healthcare professionals and we have adopted processes that we believe enhance compliance with this code and applicable federal and state laws.

The drug candidates we are developing internally are subject to an extensive regulatory review and approval process by the U.S. Food and Drug Administration (the “FDA”) and by comparable agencies outside the United States. The process of obtaining FDA and other required regulatory approvals for drug and biological products, including required pre-clinical and clinical testing, is lengthy, expensive and uncertain. Changes in existing regulations or adoption of new regulations or policies could prevent us from obtaining, or could affect the timing of, future regulatory approvals. Even if regulatory clearance is obtained, a marketed product is subject to

continual review and possible later discovery of previously unknown problems. Failure to comply with applicable regulatory requirements on an on-going basis may result in restrictions on a product's marketing or withdrawal of the product from the market. Noncompliance with applicable requirements can result in fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal to authorize the marketing of new products or criminal prosecution.

Sales and Marketing Activities

We have built a commercial organization comprised of professionals in a variety of disciplines, including regional business directors, a trade and national account director, a U.S. head of marketing and a sales administration and operations assistant.

Our sales organization consists of field-based regional business directors who focus their efforts on sales and marketing of our product portfolio. Our trade and national accounts manager works to establish and maintain contracts with wholesalers, retail pharmacy chains, group purchasing organizations, hospital systems and integrated delivery networks, certain large individual hospital accounts and specialty pharmacies. The trade and national account director also works with commercial and government payers to assure market access and achieve reimbursement coverage for our products.

Our marketing team works to develop and implement strategies and tactics to support our products and the healthcare professionals who administer our products, including promotional materials, speaker programs, patient co-payment assistance, health care provider education, information to further support patient compliance and participation at national medical conventions.

Our customers consist of drug wholesalers, retail drug stores, hospitals, health care clinics, specialty pharmacies, mass merchandisers and grocery store pharmacies in the United States. We primarily sell products directly to drug wholesalers, which in turn distribute the products to retail drug stores, hospitals, mass merchandisers and grocery store pharmacies. Our top three customers, who represented 61% of our recognized gross sales of product in 2012, are drug wholesalers: Cardinal Health, McKesson Corporation and Amerisource Bergen Corporation.

Consistent with industry practice, we maintain a returns policy that allows our customers to return products within a specified period prior and subsequent to the expiration date. Occasionally, we may also provide additional discounts to some customers to ensure adequate distribution of our products.

We rely on Integrated Commercialization Solutions, or ICS, a third-party logistics provider, for the distribution of our products to drug wholesalers, retail drug stores, mass merchandisers and grocery store pharmacies. ICS ships our products from its warehouse in Louisville, Kentucky to our customers throughout the United States and its territories as orders are placed through our customer service center also at ICS.

Research and Development Activities

Research and development costs include personnel costs, patent costs, clinical and related drug manufacturing and testing costs, laboratory and animal supplies, outside services and contract laboratory costs. For a discussion of the amount spent on research and development activities, see "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations*" below.

Employees

We currently have 17 full-time employees and one part-time employee.

Available Information

Our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q and any Current Reports on Form 8-K that we may file or furnish to the SEC pursuant to Sections 13(a) or 15(d) of the Securities Exchange Act of 1934 as well as any amendments to any of those reports are available free of charge on or through our website as soon

as reasonably practicable after we file them with or furnish them to the SEC electronically. Our website is located at www.darabio.com. In addition, you may receive a copy of any of our reports free of charge by contacting our corporate headquarters.

Item 1A. Risk Factors.

An investment in our common stock involves a number of very significant risks. You should carefully consider the following risks and uncertainties in addition to other information in this report in evaluating our company and its business before purchasing shares of our company's common stock. Our business, operating results and financial condition could be seriously harmed due to any of the following risks. You could lose all or part of your investment due to any of these risks.

Risks Related to Our Company

Our limited operating history may make it difficult to evaluate our business to date and our future viability.

We are in the early stage of operations and development and have only a limited operating history on which to base an evaluation of our current business and prospects. For example, we are in the early stages of building our sales and marketing strategy and organization. Our operations and development are subject to all of the risks inherent in the growth of an early stage company. We will be subject to the risks inherent in the ownership and operation of a company with a limited operating history such as regulatory setbacks and delays, fluctuations in expenses, competition, the general strength of regional and national economies and governmental regulation. Any failure to successfully address these risks and uncertainties could seriously harm our business and prospects. We may not succeed given the technological, marketing, strategic and competitive challenges we face. The likelihood of our success must be considered in light of the expenses, difficulties, complications, problems and delays frequently encountered in connection with the growth of a new business, the continuing development of new drug development technology and the competitive and regulatory environment in which we operate or may choose to operate in the future.

We expect to continue to incur losses.

We have incurred losses since inception and expect to continue to incur losses for the foreseeable future. Our losses are likely to be primarily attributable to personnel costs, working capital costs, marketing costs, research and development costs and regulatory approval costs as well as the costs associated with in-licensing of our products. We may never achieve sustained profitability.

We may need additional financing.

We may need additional financing to maintain and expand our business, and such financing may not be available on favorable terms, if at all. We intend to finance our business, in part, through the private placement and public offering of equity and debt securities as needed. We have historically financed our operations primarily from proceeds of registered direct offerings and private placements of equity securities and the sale of securities we acquired through investments made in other companies. In the event that we raise additional equity capital, investors' interests in the Company will be diluted and investors may suffer dilution in their net book value per share depending on the price at which such securities are sold. If we issue any such additional equity securities, such issuances also will cause a reduction in the proportionate ownership and voting power of all other stockholders. Further, any such issuance may result in a change in control.

When we need additional financing, we cannot provide assurance that it will be available on favorable terms, if at all. If we need funds and cannot raise them on acceptable terms, we may not be able to:

- continue marketing and sales efforts with respect to Soltamox and Bionect and begin commercialization of Gelclair or any other products;
- successfully build a portfolio of additional products for commercialization;
- continue the development of our active drug development programs;
- successfully out-license, otherwise monetize or commercialize any of our programs; or

continue operations.

Our business depends on successful license and other collaborative arrangements.

Our business strategy requires us to in-license products for commercialization, enter into collaborative agreements with drug manufacturers and out-license or sell our internally developed drug candidates that have reached a certain level of clinical development. These measures are critical to successfully building our portfolio of oncological products for commercialization. We may not be able to secure needed licensing or other partnering arrangements, and any such arrangements, even if completed successfully, may not be on terms favorable to us, may not perform as expected, may result in unexpected liabilities and may never contribute significant revenues or cash flow. We depend to a significant extent on the expertise of and dedication of sufficient resources by our licensors, licensees and partners to develop and commercialize products. Each individual licensor, licensee or corporate partner will control the amount and timing of resources devoted by it to these activities. Moreover, the success of any such licenses or other alliances depends in part upon such partners' own marketing and strategic considerations, including the relative advantages of alternative marketing partners and strategies. Corporate partners may pursue alternative technologies or develop products that are competitive with our products. Disputes may arise between us and one or more of our collaborative partners regarding our collaborative arrangements. In such an event, we may be required to initiate or defend expensive litigation or arbitration proceedings or to seek and attempt to reach agreement with another collaborative partner. We may not be able to resolve successfully a dispute with a collaborative partner or to enter into a satisfactory arrangement with a replacement collaborative partner.

The success of any products we may commercialize will depend on the degree of market acceptance by physicians, patients, healthcare payers and others in the medical community.

Any products that we bring to the market may not gain market acceptance by physicians, patients, healthcare payers and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects;
- the efficacy and potential advantages of alternative treatments;
- the prices of our product candidates;
- the willingness of physicians to prescribe our products; and
- sufficient third-party coverage or reimbursement.

Commercialization of a new or newly launched product or a new method of use for an existing product involves risks of failure inherent in the development of products based on innovative technologies and the risks associated with drug development generally.

Commercialization of a new product, including Soltamox and Gelclair, or a new method of use for an existing product involves risks of failure inherent in the development of products based on innovative technologies and the risks associated with drug development generally. These risks include the following:

- the products, even if safe and effective, may be difficult to manufacture on a large scale or uneconomical to market;
- proprietary rights of third parties may prevent us from exploiting technologies or marketing products; and
- third parties may market superior or equivalent products.

Our ability to commercialize our products will depend on our ability to:

- complete any necessary studies;
- obtain and maintain necessary intellectual property rights to our products;
- obtain and maintain necessary regulatory approvals related to the efficacy and safety of our products;
- enter into arrangements with manufacturers to provide manufacturing resources; and
- establish marketing and sales channels.

We may not be successful in some or all of these initiatives.

We cannot guarantee that we will be able to effectively market our potential products.

A significant part of our success depends on the various marketing strategies we plan to implement. Our business model was historically focused solely on product development, and until the launch of Soltamox, we have never attempted to commercialize any product. We are in the early stages of building our sales and marketing strategy and organization. There can be no assurance as to the success of any such marketing strategy or that we will be able to build a successful sales and marketing organization. If we cannot effectively market those products we seek to commercialize directly, such products' prospects will be harmed.

We anticipate that initially a relatively small group of products that we commercialize directly will represent a significant portion of net revenues. If the volume or pricing of any of these products declines, or we are unable to satisfy market demand for these products, it could have a material adverse effect on our business, financial position and results of operations.

We anticipate that initially sales of a limited number of our products will collectively represent a significant portion of our projected revenues. If the volume or pricing of our largest selling products declines in the future or we are unable to satisfy market demand for these products, our business, financial position and results of operations could be materially adversely affected, and our stock price could decline.

If we are unable to continue to commercialize additional products in a timely and cost-effective manner, we may not achieve our expected revenue growth or profitability or such revenue growth and profitability, if any, could be delayed.

Our future success will depend to a substantial degree on our ability to continue to commercialize new products in a timely and cost-effective manner. The acquisition, development and commercialization of new products is complex, time-consuming and costly and involves a high degree of business risk. We may, however, encounter unexpected delays in the launch of these products, or these products, when fully commercialized by us, may not perform as we expect.

The success of our new product offerings will depend upon several factors, including our ability to properly anticipate customer needs, obtain timely regulatory approvals and locate and establish collaborations for product development and finished product manufacturing in a timely and cost-effective manner. In addition, the acquisition, development and commercialization of new products is characterized by significant up-front costs, including costs associated with product development, obtaining regulatory approval, building inventory and sales and marketing. Furthermore, the development and commercialization of new products is subject to inherent risks, including the possibility that any new product may:

- fail to receive or encounter unexpected delays in obtaining necessary regulatory approvals;
- be difficult or impossible to manufacture on a larger scale;

- be uneconomical to market;
- fail to be developed prior to the successful marketing of similar or superior products by third parties; and
- infringe on the proprietary rights of third parties.

We may not achieve our expected revenue growth or profitability or such revenue growth and profitability, if any, could be delayed if we are not successful in continuing to develop and commercialize new products.

We plan to rely on third parties for the manufacture of our potential products, and if such parties fail to supply us with finished products in the quantities we require on a timely basis, sales of our products could be delayed or prevented, our revenues could decline and we may not achieve profitability.

We currently do not intend to manufacture any products ourselves. Instead, we plan to rely on third parties to manufacture the products we seek to commercialize. If the third parties we contract with do not continue to provide these services to us as contracted, we may not be able to obtain these services from others in a timely manner or on commercially acceptable terms. Likewise, if we encounter delays or difficulties with our manufacturing partners in producing our products, the distribution, marketing and subsequent sales of these products could be adversely affected. If, for any reason, our third party manufacturers are unable to obtain or deliver sufficient quantities of finished products on a timely basis or we develop any significant disagreements with such parties, the manufacture or supply of our products could be disrupted, which may decrease our sales revenue, increase our operating expenses or otherwise negatively impact our operations. In addition, if we are unable to engage and retain third parties for the supply of finished products on commercially acceptable terms, we may not be able to sell our products as planned.

The manufacture of pharmaceutical products is highly exacting and complex and our manufacturing partners may experience problems during the manufacture of finished products for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, manufacturing quality concerns, problems with raw materials, natural disaster related events or other environmental factors. If problems arise during the production, storage or distribution of a batch of product, that batch of product may have to be discarded. If we are unable to find alternative sources of finished products, this could, among other things, lead to increased costs, lost sales and damage to customer relations. If problems are not discovered before the product is released to market, voluntary recalls, corrective actions or product liability related costs may also be incurred. Problems with respect to the manufacture, storage or distribution of our products could materially disrupt our business and reduce our revenues and prevent or delay us from achieving profitability.

Any loss of our license rights to use certain critical intellectual property from Rosemont, Helsinn or other licensors for any reason would have a material adverse effect on our business.

Soltamox (tamoxifen citrate) oral solution, our first proprietary, FDA approved product, is a drug primarily used to treat breast cancer. We are party to an exclusive license and distribution agreement with Rosemont Pharmaceuticals, Ltd., a U.K. based manufacturer, for rights to market Soltamox in the United States. If we breach or fail to perform the material conditions of, including the minimum sales requirement, or fail to extend the term of the agreements under which we license critical intellectual property from Rosemont or other licensors, we may lose all or some of our rights to such intellectual property, and such loss would have a material adverse effect on our business.

Gelclair is an FDA-cleared product indicated for the treatment of oral mucositis. We are party to an exclusive license and distribution agreement with Helsinn, a Switzerland based company, for rights to market Gelclair in the United States. If we breach or fail to perform the material conditions of the agreement, including the launch and minimum sales requirements, we may lose all or some of our rights to such intellectual property, and such loss could have a material adverse effect on our business.

The drug candidate we are developing is in the early stages of development, and we may not be able to successfully develop this drug candidate into a commercially viable drug.

The drug development process is highly uncertain, and we have not developed and may never develop a drug candidate that ultimately leads to a commercially viable drug. KRN5500 is in the early stages of development and has not been approved for commercial sale. Before a drug product is approved by the FDA for commercial marketing, it must be tested for safety and effectiveness in clinical trials that can take many years. Promising results in preclinical development or early clinical trials may not be predictive of results obtained in later clinical trials. A number of pharmaceutical companies have experienced significant setbacks in advanced clinical trials, even after obtaining promising results in earlier preclinical and clinical trials. At any time, new safety information may lead the FDA to place a clinical trial on clinical hold, or permanently stop the trial. We or our collaborators may experience numerous unforeseen events during, or as a result of, the clinical development process that could delay or prevent our drug candidate from being successfully commercialized, including:

- failure to achieve clinical trial results that indicate a product candidate is effective in treating a specified condition or illness in humans;
- safety issues, including the presence of harmful side effects;
- determination by the FDA that the submitted data do not satisfy the criteria for approval;
- new information that suggests lack of commercial viability of the drug;
- failure to acquire, on reasonable terms, intellectual property rights necessary for commercialization; and
- development of competing therapeutics that are more effective.

Our success depends on our ability to retain our managerial personnel and to attract additional personnel (including a sales force).

Our success depends largely on our ability to attract and retain managerial personnel. Competition for desirable personnel is intense, and there can be no assurance that we will be able to attract and retain the necessary staff. We currently have seventeen full-time employees and one part-time employee, including a sales organization to commercialize products in accordance with our business plan. The loss of one or more members of managerial or scientific staff could have a material adverse effect on our future operations and on successful development of products for our target markets. The failure to maintain management, particularly our Chief Executive Officer/Chief Medical Officer and our Chief Operating Officer/President, and to attract additional key sales and other personnel could materially adversely affect our business, financial condition and results of operations.

The success of our business depends on our ability to develop and protect our intellectual property rights, which could be expensive.

Our success depends to a significant extent on our ability to obtain patent protection on technologies and products and preserve trade secrets and to operate without infringing the proprietary rights of others. There can be no assurance that any patent applications or patents we are able to license will afford any competitive advantages or will not be challenged or circumvented by third parties. Furthermore, there can be no assurance that others will not independently develop similar technologies or duplicate any technology developed or licensed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before any of our potential products can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. Further, important legal issues remain to be resolved as to the extent and scope of available patent protection for biotechnology products and processes in the U.S. and other important markets outside the U.S., such as Europe and Japan. Foreign markets may not provide the same level of patent protection as provided under the U.S. patent system. In addition, changes in, or different interpretations of, patent laws in the U.S. and other countries may

result in patent laws that allow others to take advantage of our discoveries or develop and commercialize our products. We cannot assure you that the patents we obtain or the unpatented technology we hold will afford us significant commercial protection.

We also rely on trademarks, copyrights, trade secrets and know-how to develop, maintain and strengthen our competitive positions. While we take steps to protect our proprietary rights to the extent possible, there can be no assurance that third parties will not know, discover or develop independently equivalent proprietary information or techniques, that they will not gain access to our trade secrets or disclose our trade secrets to the public. Therefore, we cannot guarantee that we can maintain and protect unpatented proprietary information and trade secrets. Misappropriation of our intellectual property would have an adverse effect on our competitive position and may cause us to incur substantial litigation costs.

Our inability to manage our planned growth could harm our business.

As we work toward building a portfolio of oncology treatment and supportive care pharmaceutical products and a sales organization that will market such products for sale we expect to require additional personnel. As a result, our operating expenses and capital requirements may increase significantly. Our ability to manage our growth effectively requires us to forecast accurately our sales and growth and manufacturing needs and to expend funds to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage our anticipated growth effectively, our business could be harmed.

We may not achieve the benefits we expect from our acquisition of Oncogenex, Inc., which may have a material adverse effect on the combined company's business, financial, and operating results.

We consummated the acquisition of Oncogenex with the expectation that the transaction will result in benefits to the combined company. Post-transaction challenges include the following:

- successfully combining the operations of both companies;
- potentially higher than expected costs required to achieve the anticipated benefits of the acquisition; and
- retaining and integrating management and employees.

If the combined company is not successful in addressing these and other challenges, then the benefits of the acquisition may not be realized and, as a result, the combined company's operating results and the market price of our common stock may be adversely affected.

Risks Relating to the Pharmaceutical Business

The pharmaceutical and biotechnology industries are intensely competitive and we may be unable to successfully compete against competitors with substantially more resources than we have.

In general, the pharmaceutical and biotechnology industries are intensely competitive. The technological areas in which we work continue to evolve at a rapid pace. Competition from pharmaceutical, chemical and biotechnology companies, universities and research institutions is intense and we expect it to increase. Many of these competitors are substantially larger than we are and have substantially greater capital resources, research and development capabilities and experience, manufacturing, marketing, financial and managerial resources than we do. Acquisitions of competing companies by large pharmaceutical companies or other companies could enhance the financial, marketing and other resources available to these competitors.

An important factor in our ability to compete will be the timing of market introduction of competitive products. Accordingly, the relative speed with which we and competing companies can in-license and develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market will be an important element of market success. Other significant competitive factors include:

- product safety and efficacy;
- timing and scope of regulatory approval;
- product availability;
- marketing and sales capabilities;
- reimbursement coverage from insurance companies and others;
- the extent of clinical benefits and side effects of our products relative to their cost;
- price;
- patent protection; and
- capabilities of partners with whom we may collaborate.

There can be no assurance that we can develop products that are more effective or achieve greater market acceptance than competitive products, or that our competitors will not succeed in developing products and technologies that are more effective than ours or that render our products and technologies less competitive or obsolete.

We may be subject to claims that we infringe the intellectual property rights of others, and unfavorable outcomes could harm our business.

Our future operations may be subject to claims, and potential litigation, arising from our alleged infringement of patents, trade secrets or copyrights owned by other third parties. We intend to fully comply with the law in avoiding such infringements. However, within the drug development industry, established companies have actively pursued such infringements, and have initiated such claims and litigation, which has made the entry of competitive products more difficult. We may experience such claims or litigation initiated by existing, better-funded competitors. We could also become involved in disputes regarding the ownership of intellectual property rights that relate to our technologies. These disputes could arise out of collaboration relationships, strategic partnerships or other relationships. Any such litigation could be expensive, take significant time, and could divert management's attention from other business concerns. Our failure to prevail in any such legal proceedings, or even the mere occurrence of such legal proceedings, could substantially affect our ability to meet our expenses and continue operations.

If the healthcare system or reimbursement policies change, the prices of our potential products may be lower than expected and our potential sales may decline.

The levels of revenues and profitability of bio-pharmaceutical companies like ours may be affected by the continuing efforts of government and third party payers to contain or reduce the costs of healthcare through various means. For example, in certain foreign markets, pricing or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the U.S. there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. While we cannot predict whether any legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability. In addition, in the U.S. and elsewhere, sales of therapeutic and other pharmaceutical products depend in part on the availability of reimbursement to the consumer from third party payers, such as government and private insurance plans. Third party payers are increasingly challenging the prices charged for medical products and services. We cannot assure you that any of our potential products will be considered cost effective or that reimbursement to the consumer will be available or will be sufficient to allow us to sell our potential products on a competitive and profitable basis.

Government regulation of our business is extensive and drug approvals are uncertain, expensive and time-consuming.

The research, development, pre-clinical and clinical trials of most of our intended products are subject to an extensive regulatory approval process by the FDA and other regulatory agencies in the U.S. and abroad, such as in Europe and Japan. The process of obtaining FDA and other required regulatory approvals for drug and biological products, including required pre-clinical and clinical testing, is lengthy, expensive and uncertain. Even if regulatory clearance is obtained, a marketed product is subject to continual review, and later discovery of previously unknown adverse events or failure to comply with the applicable manufacturing, packaging, distribution and marketing requirements may result in restrictions on a product's marketing or withdrawal of the product from the market as well as possible criminal sanctions.

Currently we have only one drug candidate in development. A delay or setback in the clinical development of KRN5500 would likely have a material adverse effect on our business, financial condition and results of operations.

Our business, as well as that of our manufacturers, is strictly regulated by the federal and other governments, and there can be no assurance that either we or our manufacturers will be able to maintain full compliance with all applicable regulations.

Clinical testing and manufacture of our proposed products are subject to extensive regulation by numerous governmental authorities in the U.S., principally the FDA, and corresponding foreign regulatory agencies. Changes in existing regulations or adoption of new regulations or policies could prevent us from obtaining, or affect the timing of, future regulatory approvals or clearances. We cannot assure you that we will be able to obtain necessary regulatory clearances or approvals on a timely basis, or at all, or that we will not be required to incur significant costs in obtaining or maintaining such regulatory approvals. Delays in receipt of, or failure to receive, such approvals or clearances, the loss of previously obtained approvals or clearances or the failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

Any enforcement action by regulatory authorities with respect to past or future regulatory noncompliance could have a material adverse effect on our business, financial condition and results of operations. Noncompliance with applicable requirements can result in fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal to authorize the marketing of new products and criminal prosecution.

Even if our proposed products are approved for market, we will be subject to continuing regulation. We and our collaborative partners, including our manufacturers, will continuously be subject to routine inspection by the FDA and will have to comply with the host of regulatory requirements that usually apply to pharmaceutical products marketed in the U.S., including labeling regulations, the FDA's Good Manufacturing Practice requirements, Good Clinical Practices and Good Laboratory Practices, review and response to adverse drug experience reports and regulation governing marketing and promotion of approved drug products. Our failure to comply with applicable regulatory requirements could result in enforcement action or sanctions by the FDA, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation, product seizures or recalls, operational restrictions or criminal prosecutions, any of which could have a material adverse effect on our business, financial condition and results of operations.

Our business exposes us to potential liability for personal injury or product liability claims that could affect our financial condition.

Our business involves the testing of new drugs on human volunteers and the use of our marketed products by patients. This exposes us to the risk of liability for personal injury or death to patients resulting from, among other things, possible unforeseen adverse side effects or improper administration of a drug. Many study volunteers and participants are already seriously ill and are at risk of further illness or death. If we are required to pay damages or

incur defense costs in connection with any personal injury claim that is outside the scope of indemnification agreements we have with clients and collaborative partners, if any indemnification agreement is not performed in accordance with its terms or if our liability exceeds the amount of any applicable indemnification limits or available insurance coverage, we could be materially and adversely affected both financially and reputationally. Any such claims may also prevent us from being able to obtain adequate insurance for these risks at reasonable rates in the future.

If we market our products in a manner that violates healthcare fraud and abuse laws, or if we violate false claims laws or fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, we may be subject to civil or criminal penalties or additional reimbursement requirements and sanctions, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to FDA restrictions on the marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include anti-kickback statutes and false claims statutes. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare program. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing or recommending such healthcare items or services may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement in order to have a claim paid. Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers, reporting inflated average wholesale prices to pricing services that were then used by federal programs to set reimbursement rates and engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered, off-label uses. Such activities have been alleged to cause the resulting claims for reimbursement to be “false” claims. Most states also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

We anticipate that we will participate in the federal Medicaid Rebate Program established by the Omnibus Budget Reconciliation Act of 1990, as well as several state supplemental rebate programs, in connection with the sale of Soltamox and Gelclair and other future products we may commercialize. Under the Medicaid rebate program, we anticipate paying a rebate to each state Medicaid program for our products that are reimbursed by those programs. Federal law requires that any company that participates in the Medicaid rebate program extend comparable discounts to qualified purchasers under the Public Health Service Act pharmaceutical pricing program, which requires us to sell our products to certain customers at prices lower than we otherwise might be able to charge. If products are made available to authorized users of the Federal Supply Schedule, additional pricing laws and requirements apply. Pharmaceutical companies have been prosecuted under federal and state false claims laws in connection with allegedly inaccurate information submitted to the Medicaid Rebate Program or for knowingly submitting or using allegedly inaccurate pricing information in connection with federal pricing and discount programs.

Pricing and rebate calculations vary among products and programs. The calculations are complex and may be subject to interpretation by us or our contractors, governmental or regulatory agencies and the courts. Our

methodologies for calculating these prices could be challenged under false claims laws or other laws. We or our contractors could make a mistake in calculating reported prices and required discounts, revisions to those prices and discounts, or determining whether a revision is necessary, which could result in retroactive rebates (and interest, if any). Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. If this were to occur, we could face, in addition to prosecution under federal and state false claims laws, substantial liability and civil monetary penalties, exclusion of our products from reimbursement under government programs, criminal fines or imprisonment or the entry into a Corporate Integrity Agreement, Deferred Prosecution Agreement, or similar arrangement.

In addition, federal legislation now imposes additional requirements. For example, as part of the PPACA, a federal physician payment disclosure provision based on the Physician Payments Sunshine Act was enacted, which requires pharmaceutical manufacturers to report certain gifts and payments to physicians beginning in 2013. These reports will then be placed on a public database. Failure to so report could subject companies to significant financial penalties.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities conducted by our sales team in the sale of Soltamox and Gelclair, are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Relating to Our Common Stock

If we issue additional shares in the future, it will result in the dilution of our existing shareholders.

Our articles of incorporation authorize the issuance of up to 75,000,000 shares of common stock with a par value of \$0.01 per share. Our Board of Directors may choose to issue some or all of such shares to acquire one or more products and to fund our overhead and general operating requirements. The issuance of any such shares will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. If we issue any such additional shares, such issuance will reduce the proportionate ownership and voting power of all current shareholders. Further, such issuance may result in a change of control of our corporation.

Our stock price could be volatile and our trading volume may fluctuate substantially.

The price of our common stock has been and may in the future continue to be extremely volatile. Many factors could have a significant impact on the future price of our common stock, including:

- our inability to raise additional capital to fund our operations, whether through the issuance of equity securities or debt;
- our failure to successfully commercialize products we license for commercial sale;
- our failure to successfully advance the development of our programs or otherwise implement our business objectives;
- changes in our intellectual property portfolio or developments or disputes concerning the proprietary rights of our product candidates;

- our ability to successfully enter into and maintain manufacturing relationships for our products;
- progress or results of any of our clinical trials;
- progress of regulatory approval of our product candidates and compliance with ongoing regulatory requirements;
- market acceptance of our products;
- technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors;
- changes in government regulations;
- issuance of new or changed securities analysts' reports or recommendations;
- general economic conditions and other external factors;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- the degree of trading liquidity in our common stock; and
- our ability to meet the minimum standards required for remaining listed on the NASDAQ Capital Market.

A significant number of shares of our common stock are issuable pursuant to outstanding shares of convertible preferred stock, options and warrants, and we expect to sell additional shares of our common stock in the future. Sales of these shares will dilute the interests of other security holders and may depress the price of our common stock.

As of March 21, 2013, we had 25,000,961 shares of common stock outstanding. As of March 21, 2013, there were 331,200 shares of common stock issuable upon the conversion of outstanding shares of Series A preferred stock, 65,789 shares of common stock issuable upon the conversion of outstanding shares of Series B-2 preferred stock, 328,947 shares of common stock issuable upon the conversion of outstanding shares of Series B-4 preferred stock, 14,494,575 shares of common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of \$1.90 per share, 3,084,399 shares of common stock issuable upon the exercise of outstanding options with a weighted average exercise price of \$1.28 per share, 2,968,427 shares of common stock reserved for future grants and awards under our equity incentive plans and 891,648 shares of common stock reserved for issuance to former Oncogenerix, Inc. stockholders, based upon our achievement of certain revenue or market capitalization milestones during the five year period ending January 2017. In addition, we may issue additional common stock and warrants from time to time to finance our operations. We may also issue additional shares in connection with additional stock options or restricted stock granted to our employees, officers, directors and consultants under our equity compensation plans. The issuance of the shares of common stock underlying these instruments, or perception that issuance may occur, will have a dilutive impact on other stockholders and could have a material negative effect on the market price of our common stock.

If we fail to satisfy applicable listing standards, including maintenance of at least \$2.5 million of stockholders' equity and maintenance of a \$1.00 minimum bid price, our common stock may be delisted from the NASDAQ Capital Market.

If our common stock were delisted from NASDAQ, among other things, it could lead to a number of negative implications, including reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing.

We have never paid cash dividends and do not intend to do so.

We have never declared or paid cash dividends on our common stock. We currently plan to retain any earnings to finance the growth of our business rather than to pay cash dividends. Payments of any cash dividends in the future will depend on our financial condition, results of operations and capital requirements, as well as other factors deemed relevant by our board of directors.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal property is our corporate headquarters located at 8601 Six Forks Road, Suite 160, Raleigh, North Carolina. We lease this office space (7,520 square feet) under a lease agreement with Highwoods DLF Forum, LLC that has a term that runs through March 31, 2018.

Item 3. Legal Proceedings.

On November, 2012, a suit was filed in the United States District Court District of Columbia naming DARA as a defendant. Plaintiff in the suit is GlycoBioSciences, Inc. Also named as defendant is Innocutis Holdings, LLC (“Innocutis”), Plaintiff alleges that defendants’ distribution and sale of Bionect infringes on certain of plaintiff’s patents and plaintiff seeks to enjoin defendants’ alleged patent infringement and seeks unspecified damages and costs. Pursuant to our license agreement with Innocutis, Innocutis is required to indemnify us in connection with this lawsuit. As a result, Innocutis has assumed our defense. The defendants filed a motion to dismiss the complaint on February 1, 2013. We believe the claim to be substantially without merit, and while no assurance can be given regarding the outcome of this litigation, we believe that the resolution of this matter will not have a material adverse effect on our financial position or results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

The following table sets forth for the periods indicated the range of high and low reported sales price per share of our common stock as reported on The Nasdaq Capital Market.

	<u>High (\$)</u>	<u>Low (\$)</u>
2012		
First Quarter	2.77	1.19
Second Quarter	1.40	0.62
Third Quarter	1.38	0.65
Fourth Quarter	1.20	0.69
2011		
First Quarter	4.29	3.00
Second Quarter	3.50	2.31
Third Quarter	3.39	1.85
Fourth Quarter	2.10	0.88

Stockholders

Our transfer Agent is American Stock Transfer and Trust Company. On March 21, 2013, the last reported sale price of our common stock on The Nasdaq Capital Market was \$1.05 per share. On March 21, 2013, there were approximately 172 holders of record of our common stock.

Dividend Policy

We have not declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. We expect to retain future earnings, if any, to fund the development and growth of our business. Our board of directors will determine future dividends, if any.

Item 6. Selected Financial Data.

Not applicable.

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

The following discussion and analysis should be read in conjunction with our Consolidated Financial Statements and related Notes included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report includes forward-looking statements based on our current management's expectations. There can be no assurance that actual results, outcomes or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors, including, among others, our limited operating history, unpredictability of future operating results, competitive pressures and the other potential risks and uncertainties discussed in the Risk Factors section of this Form 10-K.

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of oncology treatment and supportive care pharmaceutical products. Through our acquisition of Oncogenex, Inc., which occurred on January 17, 2012, we acquired exclusive U.S. marketing rights to our first commercial proprietary

product, Soltamox (tamoxifen citrate) oral solution. Soltamox has been approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of breast cancer and is currently sold in the UK and Ireland by Rosemont Pharmaceuticals, Ltd. We have an exclusive license with Helsinn Healthcare SA (“Helsinn”), to distribute, promote, market and sell Gelclair, a unique oral gel whose key ingredients are polyvinylpyrrolidone (PVP) and sodium hyaluronate (hyaluronic acid) for treatment of certain approved indications in the United States. Gelclair is an FDA-cleared product indicated for the treatment of oral mucositis. In addition, we have a marketing agreement with Innocutis Holdings, LLC pursuant to which we will promote Bionect (hyaluronic acid sodium salt, 0.2%) within the oncology and radiation oncology marketplace. Bionect has been cleared by the FDA for the management of irritation of the skin as well as first and second degree burns. Additionally, we continue to have an internal clinical development program focused on our drug candidate KRN5500 for the treatment of painful chronic chemotherapy induced peripheral neuropathy in cancer patients.

Our recognized net revenue for 2012 is \$53,629 (deferred net revenue - \$149,848) primarily from the launch of Soltamox in the fourth quarter of 2012. We have liquidated or distributed to our stockholders substantially all of our investments made in other companies. Our primary sources of working capital have been proceeds from the sale of our securities and proceeds from the sale of securities held in subsidiary companies and marketable securities. From inception through December 31, 2012, we raised a total of \$48,402,280 in proceeds from issuance of preferred and common stock, net of issuance costs. From inception through December 31, 2012, we received net proceeds from the sale of investments of \$7,103,599.

We expect to continue to incur operating losses in the near-term. Our results may vary depending on many factors, including the success of our product marketing efforts, the progress of licensing activities with pharmaceutical partners and clinical test results.

Product Commercialization

Our primary focus is on the commercialization and development of the following types of oncology treatment and oncology supportive care pharmaceutical products:

- Soltamox (tamoxifen citrate) oral solution, an FDA-approved liquid formulation of tamoxifen and other liquid formulation products; and
- Cancer support therapeutics, including Gelclair, an FDA-cleared product indicated for the treatment of oral mucositis and Bionect, an FDA-cleared product for the management of irritation of the skin as well as first and second degree burns
- KRN5500 is a novel, non-narcotic/non-opioid intravenous product for the treatment of painful chronic chemotherapy induced peripheral neuropathy in patients with cancer. Since KRN5500 would complement our portfolio of oncology treatment and supportive care pharmaceuticals, we are looking to advance clinical development with a partner who has the pain/oncology expertise and resources to fund the Phase 2b trial.

We currently have an exclusive license to a FDA approved product, Soltamox, an exclusive license to distribute, promote and market a FDA cleared product, Gelclair, and a marketing agreement to promote Bionect within the oncology and radiation oncology marketplace. We are working to build a portfolio of additional products through licenses and other collaborative arrangements.

Soltamox (tamoxifen citrate) oral solution, our first proprietary, FDA approved product, is a drug primarily used to treat breast cancer. Soltamox is the only liquid formulation of tamoxifen available for sale in the United States. As a result of our acquisition of Oncogenerix, we became party to an exclusive license and distribution agreement with Rosemont Pharmaceuticals, Ltd., a U.K. based manufacturer, for rights to market Soltamox in the United States. Previously, Soltamox was marketed only in the U.K. and Ireland. Soltamox is the subject of a U.S. issued patent which expires in June, 2018. We launched Soltamox in the U.S. in the fourth quarter of 2012.

In February 2012, we entered into an Exclusive Distribution Agreement with Uman Pharma Inc. pursuant to which we received an exclusive license to import, sell, market and distribute Uman's gemcitabine lyophilized powder product in 200mg and 1g dosage sizes in the U.S. Gemcitabine went off patent in 2011 in the U.S. and is widely prescribed as first-line therapy for ovarian, breast, lung and pancreatic cancers. Uman intended to file an Abbreviated New Drug Application for Gemcitabine with the FDA in the second half of 2012.

However, due to the current U.S. market conditions for gemcitabine lyophilized powder, Uman did not file an Abbreviated New Drug Application for gemcitabine with the FDA in 2012. In fact, downward pricing pressure on gemcitabine makes it unlikely that Uman will be able to manufacture it. Therefore we will not be able to launch gemcitabine in the U.S. at prices competitive enough to be commercially viable. As a result, we believe it is unlikely we will ever commercialize gemcitabine in the U.S. under our Exclusive Distribution Agreement with Uman.

On March 23, 2012, we entered into an Exclusive Marketing Agreement with Innocutis Holdings, LLC pursuant to which we are promoting Bionect (hyaluronic acid sodium salt, 0.2%) within the oncology and radiation oncology marketplace. Bionect has been approved by the FDA for the management of irritation of the skin as well as first and second degree burns. Bionect is currently being promoted and sold by Innocutis in the dermatology market. The Company will be compensated by Innocutis for each unit sold in the oncology and radiation oncology market. The Company began marketing and promoting Bionect in the U.S. in the second quarter of 2012.

We have two lead drug candidates in clinical development with cleared Investigational New Drug applications from the FDA:

- KRN5500, a cancer support product for the treatment of chronic chemotherapy-induced neuropathic pain in cancer patients; and
- DB959, a first-in-class drug candidate for the treatment of type 2 diabetes and dyslipidemia.

We are actively pursuing partnering opportunities for KRN5500 and out-licensing opportunities for DB959.

Status of our Drug Candidates

KRN5500

KRN5500 is a novel, non-narcotic/non-opioid intravenous product for the treatment of chronic chemotherapy-induced neuropathic pain in patients with cancer. The drug has successfully completed a Phase 2a proof of concept study in patients with end-stage cancer and analgesia-resistant neuropathic pain where it showed statistically-significant pain reduction versus placebo ($p = 0.03$) using standardized pain test scores. There were no major safety concerns. The FDA has designated KRN5500 a Fast Track drug, based on its potential usefulness in treating a serious medical condition and in fulfilling an unmet medical need. We are working with the National Cancer Institute (NCI) to design an additional clinical trial under joint DARA-NCI auspices. Since KRN5500 would complement our portfolio of oncology treatment and supportive care pharmaceuticals, we are looking to partner the drug with an established oncology development company to undertake and support the cost for the Phase 2b program. We incurred \$598,257 in costs associated with the development of KRN5500 during 2012, and we have incurred third party costs of \$5,371,472 from inception to date.

DB959

DB959 is a first-in-class small molecule drug candidate for the treatment of type 2 diabetes and dyslipidemia and has successfully completed Phase 1a and 1b studies. This compound activates genes involved in the metabolism of sugars and fats thereby improving the body's ability to regulate both aspects of diabetes. Phase 1 clinical data demonstrated a good safety profile even when dosed at approximately 10 times the anticipated human dose and a pharmacokinetic profile supporting a once-a-day oral dose. Our review of non-clinical studies in models

predictive of human disease indicates that this drug candidate provides glucose control and increases good HDL cholesterol and lowers triglycerides better than rosiglitazone (Avandia) with less weight gain. DB959 is targeted for out-licensing to partners more able to sustain the prolonged time-lines and significant costs involved in diabetes drug development.

We incurred \$383,342 in direct outside development costs associated with the development of DB959 during 2012, and we have incurred costs of \$7,830,020 from inception to date.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to clinical trial expenses, stock-based compensation and asset impairment and significant judgments and estimates. We base our estimates on historical experience and on various other factors that are believed to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included in this report, we believe the following accounting policies are most critical to aid in fully understanding and evaluating our reported financial results.

Revenue Recognition

We recognize revenue when there is persuasive evidence that an arrangement exists, title has passed, collection is reasonably assured and the price is fixed or determinable. We sell mostly to wholesalers who, in-turn, sell the product to hospitals and other end-user customers. Sales to wholesalers provide for selling prices that are fixed on the date of sale, although we offer certain discounts to group purchasing organizations and governmental programs. The wholesalers take title to the product, bear the risk of loss of ownership, and have economic substance to the inventory.

We allow for product to be returned beginning prior to and following product expiration. We do not believe that we have sufficient sales and returns history at this time to reasonably estimate product returns from our wholesaler distribution channel. Therefore, we are deferring the recognition of revenue until the wholesalers sells its product to hospitals or other end-user customers. We will continue to defer revenue recognition until the point at which we have obtained sufficient sales history to reasonably estimate returns from the wholesalers and inventory levels are reduced to normalized amounts. Shipments of product that are not recognized as revenue are treated as deferred revenue until evidence exists to confirm that pull through sales to hospitals or other end-user customers have occurred. Revenue is recognized from products sales directly to hospitals, clinics, and pharmacies when the merchandised is shipped.

We recognize sales allowances as a reduction of revenues in the same period the related revenue is recognized. Sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with wholesale distributors and the levels of inventory within the distribution channels that may result in future discounts taken. We must make significant judgments in determining these allowances. If actual results differ from our estimates, we will be required to make adjustments to these allowances in the future, which could have an effect on revenue in the period of adjustment. The following briefly describes the nature of each provision and how such provisions are estimated

- Payment discounts are reductions to invoiced amounts offered to customers for payment within a specified period and are estimated upon shipment utilizing historical customer payment experience.

- The returns reserve is based on management's best estimate of the product sales recognized as revenue during the period that are anticipated to be returned. The returns reserve is recorded as a reduction of revenue in the same period the related product sales revenue is recognized and is included in accrued expenses.
- Generally, credits may be issued to wholesalers for decreases that are made to selling prices for the value of inventory that is owned by the wholesaler at the date of the price reduction. Price adjustment credits are estimated at the time the price reduction occurs and the amount is calculated based on the level of the wholesaler inventory at the time of the reduction.
- There are arrangements with certain parties establishing prices for products for which the parties independently select a wholesaler from which to purchase. Such parties are referred to as indirect customers. A chargeback represents the difference between the sales invoice price to the wholesaler and the indirect customer's contract price, which is lower. Provisions for estimating chargebacks are calculated primarily using historical chargeback experience, contract pricing and sales information provided by wholesalers and chains, among other factors. The Company recognizes chargebacks in the same period the related revenue is recognized.

Income Taxes

The Company uses the liability method in accounting for income taxes as required by FASB ASC 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are recognized for operating loss and tax credit carry forwards and for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is recorded to reduce the carrying amounts of deferred tax assets unless it is more likely than not that such assets will be realized. At December 31, 2012 and December 31, 2011 a valuation allowance has been recorded to reduce the net deferred tax asset to zero.

The Company's policy for recording interest and penalties is to record them as a component of interest income (expense), net.

As of December 31, 2012 and 2011, respectively, the Company had an estimated \$203,122,000 and \$203,893,300 of U.S. Federal net operating loss carryforwards that have started to expire. The Company also has an estimated \$37,716,000 and \$41,459,200 of state net economic loss carryforwards that have started to expire. Additionally, the Company has research and development credits of approximately \$2,830,000 and \$922,000 for federal and state tax purposes that have started to expire.

The Internal Revenue Code provides limitations on utilization of existing net operating losses and tax credit carryforwards against future taxable income based upon changes in share ownership. If these changes have occurred, the ultimate realization of the net operating loss and R&D credit carryforwards could be permanently impaired.

Sales and Marketing Costs

Sales and marketing costs consist of salaries, commissions, and benefits to sales and marketing personnel, sales personnel travel and operating costs marketing programs, certain promotional allowances to customers, co-pay assistance and administration costs and advertising costs.

Research and Development Expenses

We expense research and development costs as incurred. Research and development costs include personnel and personnel related costs, costs associated with clinical trials, including amounts paid to contract research

organizations and clinical investigators, clinical material manufacturing costs, process development and clinical supply costs, research costs and other consulting and professional services.

Accrued Expenses

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

- fees paid to CROs in connection with preclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of raw materials, drug substance and drug products; and
- professional service fees.

Share-Based Compensation

Share-based compensation is accounted for using the fair value based method prescribed by Financial Accounting Standards Board Accounting Standards Codification 718 (“ASC 718, *Compensation-Stock Compensation*”). For stock and stock-based awards issued to employees, a compensation charge is recorded against earnings based on the fair value of the award. For transactions with non-employees in which services are performed in exchange for our common stock or other equity instruments, the transactions are recorded on the basis of the fair value of the service received or the fair value of the equity instruments issued, whichever is more readily measurable at the date of issuance. Please refer to Note 10 - Share Based Compensation, included in the condensed consolidated financial statements appearing elsewhere in this report, for additional information regarding our adoption of ASC 718.

Significant Judgments and Estimates

The preparation of our consolidated financial statements in conformity with U.S. generally accepted accounting principles requires that we make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at our balance sheet date. Such estimates include the carrying value of property and equipment and the value of certain liabilities. Actual results may differ from such estimates.

Results of Operations

We incurred sales and marketing expense of \$1,609,601, for the year ended December 31, 2012 as a result of its merger with Oncogenex and the costs incurred in establishment of a sales and marketing infrastructure to support the promotion of Bionect and to prepare for the launch of Soltamox in the fourth quarter of the year. As of December 31, 2012 sales and marketing costs consist of salaries, and benefits to sales and marketing personnel, marketing programs, and distribution establishment costs. Prior to the merger we had no commercial activities.

Research and development expenses increased from \$2,633,449 for the year ended December 31, 2011 to \$2,734,517 for the year ended December 31, 2012. While costs related to DB959 in the 2012 period were reduced by approximately \$1 million as compared to the 2011 period due to a decision to cease development and pursue out-licensing opportunities, the Company incurred additional costs of \$125,000 related to gemcitabine licensing and development, additional costs of approximately \$650,000 related to Soltamox regulatory FDA fees

and also incurred greater research and development infrastructure costs as well as stock based compensation expense for the year ended December 31, 2012.

General and administrative expenses consist primarily of salaries and benefits, professional fees related to administrative, finance, human resource, legal and information technology functions. In addition, general and administrative expenses include allocated facility, basic operational and support costs and insurance costs. General and administrative expenses increased from \$3,989,054 in 2011 to \$4,663,359 in 2012, primarily as a result of expenses associated with our increase in investor relations activities and additional compensation expense. Depreciation and amortization expense increased from \$139,392 in 2011 to \$659,441 in 2012 primarily related to amortization on the Rosemont, Bayer, and Helsinn licenses for the year ended December 31, 2012. Other income (expense), net reflects non-operating activities associated with investments and dispositions of investments made in collaborations with other companies, as well as interest earned and expensed and other revenues not related to normal basic operations. Other income, net increased from income of \$90,200 in 2011 to \$596,885 in 2012. The increase is due to the gain on the net sale of our marketable securities of \$608,601 and an increase in other income of \$1,510, offset by a decrease in interest income of \$103,426. The income of \$90,200 for the corresponding 2011 period was primarily as a result of the \$85,277 benefit to accrued interest from the recognition of previously unrecognized state tax benefits of \$194,445.

Liquidity and Capital Resources

Overview

From inception through December 31, 2012, we have financed our operations primarily from the net proceeds of (1) registered direct offerings and private placements of equity securities, through which we raised \$48,402,280 in net proceeds and (2) the sale of marketable securities and securities held in subsidiary companies, through which we raised \$1,951,211 and \$5,152,388, respectively.

Working Capital

	December 31, 2012	December 31, 2011
Current assets	\$ 7,044,827	\$ 1,462,866
Current liabilities	2,038,862	867,995
Working capital	\$ 5,005,965	\$ 594,871

At December 31, 2012, our principal sources of liquidity were our cash and cash equivalents which totaled \$6,496,457. As of December 31, 2012, we had working capital of \$5,005,965. Our cash resources have been used to acquire licenses, and to fund research and development activities, capital expenditures, sales and marketing and general and administrative expenses. From December 31, 2011 to December 31, 2012, our working capital increased by \$4,411,094 due primarily to the Series B-1 and Series B-2 equity financings totaling approximately \$10,698,000, exercises of Series B-2 \$1.00 warrants totaling approximately \$1,170,000 and cash received from the sale of available for sale securities totaling approximately \$747,000, offset by purchases of license rights of approximately \$250,000, cash used in operating activities of approximately \$7,021,000 and other increases in other current assets and liabilities of approximately \$933,000, primarily made up of the 2012 accrual for FDA fees related to Soltamox of \$620,000 as well as a year-end accrual of license fees of \$250,000.

We have incurred significant net losses and have had negative cash flows from operations during each period from inception through December 31, 2012 and have a deficit accumulated during the development stage of \$47,027,581 at December 31, 2012. Management expects operating losses and negative cash flows to continue through 2013 and the foreseeable future.

Cash Flows

	2012	2011
Cash used in operating activities	\$ (7,021,194)	\$ (4,860,806)
Cash provided by investing activities	459,346	-
Cash provided by financing activities	11,879,148	561,549
Net increase (decrease) in cash and cash equivalents	\$ 5,317,300	\$ (4,299,257)

Our cash used in operating activities for the year ended December 31, 2012 compared to our cash used in operating activities for the year ended December 31, 2011 increased by \$2,160,388 primarily due to the increase in consolidated net loss of \$1,263,121, which was driven primarily by the increase in sales and marketing expenses of \$1,609,601, an increase in general and administrative expenses of \$674,305, an increase in research and development expenses of \$101,068, and an increase in depreciation and amortization expense of \$520,049 as explained above.

Our net cash provided by investing activities during the year ended December 31, 2012 was \$459,346 which consisted of proceeds received from sale of its marketable securities of \$746,696 and cash from the Oncogenex merger of \$10,632 offset by purchases of license rights of \$250,000, purchases of furniture and fixtures of \$18,063, as well as an investment in MRI Interventions Inc. of \$29,919. There was no cash provided by investing activities during the same period in 2011.

Our net cash provided by financing activities for the year ended December 31, 2012 compared to our net cash provided by financing activities for the year ended December 31, 2011 increased by \$11,317,599 primarily due to (i) the issuances of preferred stock which generated net proceeds of \$10,698,197 and (ii) net proceeds of \$1,170,200 from the exercise of 1,170,000 Series B-2 warrants while during the same period in 2011, we had only \$562,500 in receipts from the exercise of options and warrants.

Financial Condition

In addition to working capital on hand at December 31, 2012, we received approximately \$2,500,000 in net proceeds from issuance of Series B-3 and B-4 convertible preferred stock in January 2013. Also, during the period from January 1, 2013 through March 21, 2013, investors in the B-2 preferred stock have exercised 1,213,874 warrants at \$.80 per share for proceeds of approximately \$971,000 and 250,000 warrants at \$1.00 per share for proceeds of approximately \$250,000.

We believe we have sufficient working capital to continue our operations through 2013. We expect to require additional investment capital to pursue our long-term business plan. Our working capital requirements will depend upon numerous factors including the costs we may incur building a portfolio of pharmaceutical products and a sales force to commercialize such products, and our ability to sell or license these technologies to third parties. In any event, we may require substantial funds in addition to those presently available to meet our business objectives. To ensure the continued level of development and funding of our operations, we expect to continue to explore various possible financing options that may be available to us, which may include a sale of our securities, the sale of certain of our investments or out-licensing of one or more of our drug programs. We have no commitments to obtain any additional funds, and there can be no assurance such funds will be available on acceptable terms or at all. If we need to raise funds and are unable to secure them, we may not be able to:

- continue marketing and sales efforts with respect to Soltamox or begin such efforts for other products;
- successfully build a portfolio of additional products for commercialization;

- continue the development of our active drug development programs;
- successfully out-license, otherwise monetize or commercialize any of our programs; or
- continue operations.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of December 31, 2012.

Recently Issued Accounting Pronouncements

In accordance with the guidance of FASB issued in Accounting Standards Update (ASU) 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* (“ASU 2011-05”), the Company adopted the requirement to separately report its comprehensive income. Other comprehensive income refers to revenue, expenses, gains, and losses that are recorded directly as an adjustment to shareholders’ equity. These changes became effective for the Company in the first quarter of 2012 and are reflected in the consolidated statement of operations and comprehensive income/loss. The adoption of ASU 2011-05 did not have a material impact on the Company’s financial statements.

In May 2011, FASB amended the fair value measurement and disclosure guidance in ASC 820, *Fair Value Measurement*, to converge US GAAP and IFRS requirements for measuring amounts at fair value as well as disclosures about these measurements. FASB ASC 820 is effective for interim and annual periods beginning after December 15, 2011. The Company’s application of FASB ASC 820 did not have a material effect on the Company’s consolidated results of operations and financial position.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

**DARA BioSciences, Inc.
(A Development Stage Company)**

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

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders
DARA BioSciences, Inc.

We have audited the accompanying consolidated balance sheet of DARA BioSciences, Inc. and subsidiaries (a development stage enterprise) (the "Company") as of December 31, 2012, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year then ended, and for the period from inception (June 22, 2002) to December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The financial statements for the period from inception (June 22, 2002) to December 31, 2011 were audited by other auditors and our opinion, insofar as it relates to cumulative amounts included for such prior periods, is based solely on the report of other such auditors.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit 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 audit included 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 also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, based on our audit and the report of other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2012, and the results of its operations and its cash flows for the year then ended, and for the period from inception (June 22, 2002) to December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

/s/ HORNE LLP

Ridgeland, Mississippi
March 28, 2013

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of DARA BioSciences, Inc.

We have audited the accompanying consolidated balance sheet of DARA BioSciences, Inc. and subsidiaries, as of December 31, 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for the period ended December 31, 2011 and for the period from June 22, 2002 (date of inception) through December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included 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 also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of DARA BioSciences, Inc. and subsidiaries, at December 31, 2011, and the consolidated results of their operations and their cash flows for the period ended December 31, 2011 and for the period from June 22, 2002 (date of inception) through December 31, 2011, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that DARA BioSciences, Inc. will continue as a going concern. As more fully described in Note 1, DARA has incurred recurring operating losses since inception which has resulted in insufficient working capital. These conditions raise substantial doubt about DARA's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The December 31, 2011 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Raleigh, North Carolina
February 17, 2012

DARA BIOSCIENCES, INC. AND SUBSIDIARIES
(A Development Stage Company)
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2012	2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 6,496,457	\$ 1,179,157
Investment-available-for-sale, at fair value	96,346	-
Accounts receivable	173,382	-
Inventory	125,275	-
Prepaid expenses and other assets, current portion	153,367	283,709
Total current assets	7,044,827	1,462,866
Furniture, fixtures and equipment, net	50,190	42,455
Restricted cash	12,875	38,554
Prepaid expenses and other assets, net of current portion	54,439	77,999
Intangible assets, net	3,708,569	100,000
Goodwill	821,210	-
Investments	-	130,468
Total assets	\$ 11,692,110	\$ 1,852,342
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,382,881	\$ 640,817
Accrued liabilities	326,713	140,673
Accrued compensation	172,250	71,193
Deferred revenue	149,848	-
Capital lease obligation, current portion	7,170	15,312
Total current liabilities	2,038,862	867,995
Deferred lease obligation	40,865	9,099
License milestone liability, non-current	599,446	-
Capital lease obligation, net of current portion	19,962	16,100
Total liabilities	2,699,135	893,194
Stockholders' equity:		
Preferred stock, Series A, \$0.01 par value, 1,000,000 shares authorized, 828 shares issued and outstanding at December 31, 2012, and 2011.	8	8
Preferred stock, Series B2, \$0.01 par value, 1,250,000 shares authorized, 1,110 shares issued and outstanding at December 31, 2012.	11	-
Common stock, \$0.01 par value, 75,000,000 shares authorized, 18,947,094 shares issued and outstanding at December 31, 2012, 5,600,804 issued and outstanding as of December 31, 2011.	189,471	56,008
Accumulated other comprehensive income, net of taxes	45,469	-
Additional paid-in capital	56,430,227	40,834,972
Deficit accumulated during the development stage	(47,027,581)	(39,716,548)
Total stockholders' equity before noncontrolling interest	9,637,605	1,174,440
Noncontrolling interest	(644,630)	(215,292)
Total stockholders' equity	8,992,975	959,148
Total liabilities and stockholders' equity	\$ 11,692,110	\$ 1,852,342

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

DARA BIOSCIENCES, INC. AND SUBSIDIARIES
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	<u>Year Ended December 31,</u>		<u>Period from</u>
	<u>2012</u>	<u>2011</u>	<u>June 22, 2002</u>
			<u>(inception)</u>
			<u>through</u>
			<u>December 31,</u>
			<u>2012</u>
Net revenues	\$ 53,629	\$ -	\$ 53,629
Cost of Goods Sold	23,804	-	23,804
Gross Margin	<u>29,825</u>	<u>-</u>	<u>29,825</u>
Operating expenses:			
Sales and marketing	1,609,601	-	1,609,601
Research and development	2,734,517	2,633,449	27,969,018
General and administrative	4,663,359	3,989,054	30,042,566
Depreciation and amortization of intangibles	659,441	139,392	2,006,353
Total operating expenses	<u>9,666,918</u>	<u>6,761,895</u>	<u>61,627,538</u>
Loss from operations	<u>(9,637,093)</u>	<u>(6,761,895)</u>	<u>(61,597,713)</u>
Other income (expense):			
Gain on distribution of nonmonetary asset	-	-	4,760,953
Gain on sale of marketable securities and nonmonetary assets	608,601	-	7,388,748
Other (expense) income, net	-	(1,510)	605,462
Interest (expense) income, net	<u>(11,716)</u>	<u>91,710</u>	<u>827,877</u>
Other income	<u>596,885</u>	<u>90,200</u>	<u>13,583,040</u>
Loss before undistributed loss in equity method investments	<u>(9,040,208)</u>	<u>(6,671,695)</u>	<u>(48,014,673)</u>
Undistributed loss in equity method investments	<u>-</u>	<u>-</u>	<u>(2,374,422)</u>
Net loss before benefit from income taxes	<u>(9,040,208)</u>	<u>(6,671,695)</u>	<u>(50,389,095)</u>
Income tax benefit	<u>1,299,837</u>	<u>194,445</u>	<u>1,494,282</u>
Consolidated net loss	<u>(7,740,371)</u>	<u>(6,477,250)</u>	<u>(48,894,813)</u>
Loss attributable to noncontrolling interest	<u>429,338</u>	<u>306,662</u>	<u>2,086,579</u>
Loss attributable to controlling interest	<u>\$ (7,311,033)</u>	<u>\$ (6,170,588)</u>	<u>\$ (46,808,234)</u>
Basic and diluted net loss per common share attributable to controlling interest	<u>\$ (0.60)</u>	<u>\$ (1.20)</u>	
Shares used in computing basic and diluted net loss per common share	<u>12,110,386</u>	<u>5,151,017</u>	
Comprehensive Loss:			
Consolidated net loss	\$ (7,740,371)	\$ (6,477,250)	\$ (48,894,813)
Other comprehensive income			
Unrealized gain on investments available for sale	682,654	-	7,786,198
Reclassification adjustments for gains included in net loss	(608,601)	-	(7,712,145)
Income taxes related to other comprehensive income	<u>(28,584)</u>	<u>-</u>	<u>(28,584)</u>
Other comprehensive income, net of tax	<u>45,469</u>	<u>-</u>	<u>45,469</u>
Comprehensive Loss	<u>(7,694,902)</u>	<u>(6,477,250)</u>	<u>(48,849,344)</u>
Comprehensive loss attributable to noncontrolling interest	<u>429,338</u>	<u>306,662</u>	<u>2,086,579</u>
Comprehensive loss attributable to controlling interest	<u>\$ (7,265,564)</u>	<u>\$ (6,170,588)</u>	<u>\$ (46,762,765)</u>

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

DARA BIOSCIENCES, INC. AND SUBSIDIARIES
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Series A		Series B		Common Stock		Additional Paid-In Capital	Stock Subscription Receivable	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income	Stockholders' Equity (Deficit)		Total Stockholders' Equity
	Convertible Preferred Stock		Convertible Preferred Stock								Noncontrolling Interest	Noncontrolling Interest	
	Shares	Amount	Shares	Amount	Shares	Amount							
Issuance of common stock to founders	-	\$ -	-	\$ -	65,000	\$ 65	\$ 975	\$ -	\$ -	\$ -	\$ 1,040	\$ -	\$ 1,040
Net loss	-	-	-	-	-	-	-	-	(111,563)	-	(111,563)	-	(111,563)
Balance at December 31, 2002	-	-	-	-	65,000	65	975	-	(111,563)	-	(110,523)	-	(110,523)
Issuance of common stock	-	-	-	-	310,000	310	4,650	-	-	-	4,960	-	4,960
Issuance of preferred stock, net of issuance costs of \$176,959	208,437	208	-	-	-	-	3,161,168	-	-	-	3,161,376	-	3,161,376
Share-based compensation	-	-	-	-	-	-	57,000	-	-	-	57,000	-	57,000
Net loss and comprehensive loss	-	-	-	-	-	-	-	-	(589,010)	-	(589,010)	-	(589,010)
Balance at December 31, 2003	208,437	208	-	-	375,000	375	3,223,793	-	(700,573)	-	2,523,803	-	2,523,803
Issuance of common stock	-	-	-	-	18,275	18	174,982	-	-	-	175,000	-	175,000
Issuance of preferred stock, net of issuance costs of \$155,948	104,063	104	22,500	23	-	-	2,590,950	-	-	-	2,591,077	-	2,591,077
Stock subscription receivable	-	-	-	-	16,406	16	242,484	(242,500)	-	-	-	-	-
Issuance of options for services	-	-	-	-	-	-	12,254	-	-	-	12,254	-	12,254
Share-based compensation	-	-	-	-	-	-	94,219	-	-	-	94,219	-	94,219
Net loss and comprehensive loss	-	-	-	-	-	-	-	-	(3,949,039)	-	(3,949,039)	-	(3,949,039)
Balance at December 31, 2004	312,500	\$ 312	22,500	\$ 23	409,681	\$ 409	\$ 6,338,682	\$ (242,500)	\$ (4,649,612)	\$ -	\$ 1,447,314	\$ -	\$ 1,447,314

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

DARA BIOSCIENCES, INC. AND SUBSIDIARIES
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Stock Subscription Receivable	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income	Stockholders' Equity (Deficit) Before Noncontrolling Interest	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount							
Balance at December 31, 2004	312,500	\$ 312	22,500	\$ 23	409,681	\$ 409	\$ 6,338,682	\$ (242,500)	\$ (4,649,612)	\$ -	\$ 1,447,314	\$ -	\$ 1,447,314
Common stock dividend	-	-	-	-	429,891	430	(430)	-	-	-	-	-	-
Issuance of common stock	-	-	-	-	7,804	8	67,592	-	-	-	67,600	-	67,600
Issuance of preferred stock, net of issuance costs of \$88,877	-	-	107,208	107	-	-	4,795,233	-	-	-	4,795,340	-	4,795,340
Issuance of options for services	-	-	-	-	-	-	16,304	-	-	-	16,304	-	16,304
Share-based compensation	-	-	-	-	-	-	1,224,805	-	-	-	1,224,805	-	1,224,805
Dividend of Medivation, Inc. stock	-	-	-	-	-	-	(2,532,600)	-	-	-	(2,532,600)	-	(2,532,600)
Comprehensive loss:													
Net loss	-	-	-	-	-	-	-	-	(4,618,654)	-	(4,618,654)	-	(4,618,654)
Unrealized gain on investments	-	-	-	-	-	-	-	-	-	647,572	647,572	-	647,572
Comprehensive loss											(3,971,082)	-	(3,971,082)
Balance at December 31, 2005	312,500	\$ 312	129,708	\$ 130	847,466	\$ 847	\$ 9,909,586	\$ (242,500)	\$ (9,268,266)	\$ 647,572	\$ 1,047,681	\$ -	\$ 1,047,681
Issuance of common stock	-	-	-	-	3	-	50	-	-	-	50	-	50
Non-cash exercise of options	-	-	-	-	10,052	10	(10)	-	-	-	-	-	-
Issuance of preferred stock, net of issuance costs of \$487,987	-	-	267,187	267	-	-	12,336,747	-	-	-	12,337,014	-	12,337,014
Non-cash exercise of warrants	-	-	-	-	20,883	21	(21)	-	-	-	-	-	-
Issuance of common stock warrants	-	-	-	-	1,666	2	79,999	-	-	-	80,001	-	80,001
Share-based compensation	-	-	-	-	-	-	339,505	-	-	-	339,505	-	339,505
Distribution of Surgi-vision, Inc. stock	-	-	-	-	-	-	(3,083,156)	-	-	-	(3,083,156)	-	(3,083,156)
Comprehensive loss:													
Net loss	-	-	-	-	-	-	-	-	(1,965,290)	-	(1,965,290)	-	(1,965,290)
Unrealized gain on investments	-	-	-	-	-	-	-	-	-	4,799,964	4,799,964	-	4,799,964
Comprehensive loss											2,834,674	-	2,834,674
Balance at December 31, 2006	312,500	\$ 312	396,895	\$ 397	880,070	\$ 880	\$ 19,582,700	\$ (242,500)	\$ (11,233,556)	\$ 5,447,536	\$ 13,555,769	\$ -	\$ 13,555,769

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

DARA BIOSCIENCES, INC. AND SUBSIDIARIES
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Stock Subscription Receivable	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income	Stockholders' Equity (Deficit) Before Noncontrolling Interest		Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount					Noncontrolling Interest	Noncontrolling Interest	
Balance at December 31, 2006	312,500	\$ 312	396,895	\$ 397	880,070	\$ 880	\$ 19,582,700	\$ (242,500)	\$ (11,233,556)	\$ 5,447,536	\$ 13,555,769	\$ -	\$ 13,555,769
Increase in reserves for uncertain tax positions per FIN 48 adoption	-	-	-	-	-	-	-	-	(219,348)	-	(219,348)	-	(219,348)
Noncontrolling interest upon consolidation	-	-	-	-	-	-	-	-	-	-	-	1,441,949	1,441,949
Issuance of common stock	-	-	-	-	416	1	15,999	-	-	-	16,000	-	16,000
Share-based compensation	-	-	-	-	-	-	590,125	-	-	-	590,125	-	590,125
Cancellation of subscription receivable	-	-	-	-	-	-	-	242,500	-	-	242,500	-	242,500
Comprehensive loss:													
Net loss	-	-	-	-	-	-	-	-	(1,527,691)	-	(1,527,691)	(463,774)	(1,991,465)
Reversal of unrealized gain on investment and marketable securities	-	-	-	-	-	-	-	-	-	(5,447,536)	(5,447,536)	-	(5,447,536)
Comprehensive loss												(6,975,227)	(7,439,001)
Balance at December 31, 2007	312,500	312	396,895	397	880,486	881	20,188,824	-	(12,980,595)	-	7,209,819	978,175	8,187,994
Conversion of DARA Shares	(312,500)	(312)	(396,895)	(397)	(880,486)	(881)	1,590	-	-	-	-	-	-
Exchange of common stock	-	-	-	-	908,161	9,081	(9,081)	-	-	-	-	-	-
Exchange of preferred stock	-	-	-	-	731,675	7,317	(7,317)	-	-	-	-	-	-
Merger/Reverse stock split Point Therapeutics	-	-	-	-	61,360	614	440,089	-	-	-	440,703	-	440,703
Shares issued to directors	-	-	-	-	7,976	80	120,460	-	-	-	120,540	-	120,540
Share-based compensation	-	-	-	-	13,750	138	1,540,588	-	-	-	1,540,726	-	1,540,726
Issuance of common stock	-	-	-	-	18,130	181	188,373	-	-	-	188,554	-	188,554
Shares issued for deferred payment	-	-	-	-	55	1	1,063	-	-	-	1,064	-	1,064
Shares issued to placement agent	-	-	-	-	140,936	1,409	1,931,448	-	-	-	1,932,857	-	1,932,857
Warrants issued	-	-	-	-	-	-	183,214	-	-	-	183,214	-	183,214
Comprehensive loss:													
Net loss	-	-	-	-	-	-	-	-	(11,569,342)	-	(11,569,342)	(328,975)	(11,898,317)
Unrealized gain on marketable securities	-	-	-	-	-	-	-	-	-	1,656,008	1,656,008	-	1,656,008
Comprehensive loss												(9,913,334)	(10,242,309)
Balance at December 31, 2008	-	\$ -	-	\$ -	1,882,043	\$ 18,820	\$ 24,579,252	\$ -	\$ (24,549,937)	\$ 1,656,008	\$ 1,704,143	\$ 649,200	\$ 2,353,343

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

DARA BIOSCIENCES, INC. AND SUBSIDIARIES
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Stock Subscription Receivable	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income	Stockholders' Equity (Deficit) Before		Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount					Noncontrolling Interest	Noncontrolling Interest		
Balance at December 31, 2008	-	\$ -	-	\$ -	1,882,043	\$ 18,820	\$ 24,579,252	\$ -	\$ (24,549,937)	\$ 1,656,008	\$ 1,704,143	\$ 649,200	\$ 2,353,343	
Shares issued to directors	-	-	-	-	(1,900)	(19)	32,721	-	-	-	32,702	-	32,702	
Share-based compensation	-	-	-	-	32,012	320	470,040	-	-	-	470,360	-	470,360	
Issuance of common stock	-	-	-	-	877,371	8,774	5,458,557	-	-	-	5,467,331	-	5,467,331	
Warrants issued to placement agent	-	-	-	-	-	-	47,706	-	-	-	47,706	-	47,706	
Comprehensive loss														
Net loss	-	-	-	-	-	-	-	-	(3,343,615)	-	(3,343,615)	(218,339)	(3,561,954)	
Unrealized gain on marketable securities	-	-	-	-	-	-	-	-	-	(1,656,008)	(1,656,008)	-	(1,656,008)	
Comprehensive loss											(4,999,623)	(218,339)	(5,217,962)	
Balance at December 31, 2009	-	-	-	-	2,789,526	27,895	30,588,276	-	(27,893,552)	-	2,722,619	430,861	3,153,480	
Shares issued to directors	-	-	-	-	1,420	14	48,464	-	-	-	48,478	-	48,478	
Share-based compensation	-	-	-	-	12,500	125	578,329	-	-	-	578,454	-	578,454	
Issuance of common stock	-	-	-	-	872,558	8,726	3,112,985	-	-	-	3,121,711	-	3,121,711	
Issuance of preferred stock, net of issuance costs of \$513,062	4,800	48	-	-	-	-	4,286,892	-	-	-	4,286,940	-	4,286,940	
Conversion of preferred stock to common stock	(1,125)	(11)	-	-	450,000	4,500	(4,489)	-	-	-	-	-	-	
Net loss and comprehensive loss	-	-	-	-	-	-	-	-	(5,652,408)	-	(5,652,408)	(339,491)	(5,991,899)	
Balance at December 31, 2010	3,675	\$ 37	-	\$ -	4,126,004	\$ 41,260	\$ 38,610,457	\$ -	\$ (33,545,960)	\$ -	\$ 5,105,794	\$ 91,370	\$ 5,197,164	

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

DARA BIOSCIENCES, INC. AND SUBSIDIARIES
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)

	Series A Convertible Preferred Stock		Series B-1 Convertible Preferred Stock		Series B-2 Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income	Stockholders' Equity (Deficit) Before Noncontrolling Interest	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount						
Balance at December 31, 2010	3,675	\$ 37	-	\$ -	-	\$ -	4,126,004	\$ 41,260	\$ 38,610,457	\$ (33,545,960)	\$ -	\$ 5,105,794	\$ 91,370	\$ 5,197,164
Share-based compensation	-	-	-	-	-	-	111,000	1,110	1,444,663	-	-	1,445,773	-	1,445,773
Issuance of common stock	-	-	-	-	-	-	225,000	2,250	560,250	-	-	562,500	-	562,500
Warrants issued	-	-	-	-	-	-	-	-	230,961	-	-	230,961	-	230,961
Conversion of preferred stock to common stock	(2,847)	(28)	-	-	-	-	1,138,800	11,388	(11,359)	-	-	-	-	-
Net loss and comprehensive loss	-	-	-	-	-	-	-	-	-	(6,170,588)	-	(6,170,588)	(306,662)	(6,477,250)
Balance at December 31, 2011	828	\$ 8	-	\$ -	-	\$ -	5,600,804	\$ 56,008	\$ 40,834,972	\$ (39,716,548)	\$ -	\$ 1,174,440	\$ (215,292)	\$ 959,148
Share-based compensation	-	-	-	-	-	-	400,000	4,000	807,858	-	-	811,858	-	811,858
Issuance of common stock Oncogenex merger	-	-	-	-	-	-	1,337,471	13,375	2,750,734	-	-	2,764,109	-	2,764,109
Issuance of common stock from exercise of warrants	-	-	-	-	-	-	1,170,200	11,702	1,158,498	-	-	1,170,200	-	1,170,200
Issuance of B-1 preferred stock, net of issuance costs of \$139,500	-	-	1,700	17	-	-	-	-	1,174,043	-	-	1,174,060	-	1,174,060
Issuance of B-1 warrants	-	-	-	-	-	-	-	-	386,440	-	-	386,440	-	386,440
Issuance of B-2 preferred stock, net of issuance costs of \$1,066,532	-	-	-	-	10,250	103	-	-	5,014,670	-	-	5,014,773	-	5,014,773
Issuance of B-2 warrants @ \$1.00	-	-	-	-	-	-	-	-	2,107,551	-	-	2,107,551	-	2,107,551
Issuance of B-2 warrants @ \$1.25	-	-	-	-	-	-	-	-	2,061,145	-	-	2,061,145	-	2,061,145
Modification of B-2 warrants	-	-	-	-	-	-	-	-	238,593	-	-	238,593	-	238,593
Conversion of preferred stock to common stock	-	-	(1,700)	(17)	(9,140)	(92)	10,438,619	104,386	(104,277)	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	-	(7,311,033)	-	(7,311,033)	\$ (429,338)	(7,740,371)
Net change in unrealized gain on investments available-for-sale, net of taxes	-	-	-	-	-	-	-	-	-	-	45,469	45,469	-	45,469
Balance at December 31, 2012	828	\$ 8	-	\$ -	1,110	\$ 11	18,947,094	\$ 189,471	\$ 56,430,227	\$ (47,027,581)	\$ 45,469	\$ 9,637,605	\$ (644,630)	\$ 8,992,975

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

DARA BIOSCIENCES, INC. AND SUBSIDIARIES
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF CASH
FLows

	Year Ended December 31,		Period From
	2012	2011	June 22,
			2002
			(inception)
			through
			December 31,
			2012
Operating activities			
Consolidated net loss	\$ (7,740,371)	\$ (6,477,250)	\$ (48,894,813)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	659,441	139,392	1,359,963
Deferred income tax benefit	(1,299,837)	-	(1,299,837)
Forgiveness of stock subscription receivable	-	-	242,500
Recognition of expense related to nonmonetary asset	-	-	1,035,589
Loss from equity investment	-	-	2,374,422
Accretion of debt discount and other	17,738	-	424,097
Share-based compensation	811,858	1,676,734	7,631,129
Expense of warrants issued with convertible notes	-	-	4,860
Expense of warrants issued to placement agent	-	-	230,920
Expense of B-2 warrant modification	238,593	-	238,593
Loss on disposal of capital assets	-	1,510	21,440
Gain on extinguishment of capital lease obligation	-	-	(12,240)
Loss on disposal of furniture, fixtures and equipment, net	-	-	36,065
Sale of investment as payment of interest expense	-	-	36,712
Distribution of investment for compensation	-	-	100,000
Gain on distribution of nonmonetary asset	-	-	(4,760,953)
Gain on sale of investments	(608,601)	-	(7,388,748)
Deferred lease obligation	31,766	(2,955)	40,866
Changes in operating assets and liabilities, net of effect of acquisitions:			
Accounts receivable	(173,382)	-	(173,382)
Inventory	(125,275)	-	(125,275)
Prepaid expenses and other assets	200,224	137,699	(280,847)
Accounts payable and accrued liabilities	966,652	(56,214)	755,323
Other liability	-	(279,722)	(237,548)
Net cash used in operating activities	(7,021,194)	(4,860,806)	(48,641,164)
Investing activities			
Purchases of furniture, fixtures and equipment	(18,063)	-	(217,975)
Purchases of license rights	(250,000)	-	(250,000)
Proceeds from sale of furniture, fixtures and equipment	-	-	5,716
Issuance of notes receivable	-	-	(1,400,000)
Payments on notes receivable	-	-	711,045
Cash received in the Point merger	-	-	771,671
Cash received in the Oncogenerix merger	10,632	-	10,632
Purchase of investments in affiliates	(29,919)	-	(2,501,319)
Proceeds from sale of investments	746,696	-	7,103,599
Net cash provided by investing activities	459,346	-	4,233,369

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

DARA BIOSCIENCES, INC. AND SUBSIDIARIES
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

	Year Ended December 31,		Period From
	2012	2011	June 22,
			2002
			(inception)
			through
			December 31,
			2012
Financing activities			
Proceeds from issuance of notes payable	\$ —	\$ —	\$ 605,000
Principal payments on notes payable	—	—	(255,000)
Repayments of capital lease obligation	(14,928)	(13,217)	(55,582)
Establishment of other financing	—	114,768	254,844
Repayments on other financing	—	(115,349)	(246,470)
Proceeds from exercise of options and warrants	1,170,200	562,500	2,212,055
Proceeds from issuance of preferred stock, common stock, and warrants, net of issuance costs	10,698,197	—	48,402,280
Change in restricted cash	25,679	12,847	(12,875)
Net cash provided by financing activities	<u>11,879,148</u>	<u>561,549</u>	<u>50,904,252</u>
Net increase (decrease) in cash and cash equivalents	5,317,300	(4,299,257)	6,496,457
Cash and cash equivalents at beginning of period	1,179,157	5,478,414	—
Cash and cash equivalents at end of period	<u>\$ 6,496,457</u>	<u>\$ 1,179,157</u>	<u>\$ 6,496,457</u>
Supplemental disclosure of non-cash investing and financing activity			
Equipment purchased through financing	\$ —	\$ —	\$ 91,676
License milestone liability	703,634	—	703,634
Advances to stockholders for stock issued	—	—	1,040
Payable accrued for stock issuance	—	—	350,000
Note issued for stock issuance	—	—	150,000
Note issued for prepaid license fee	—	—	1,000,000
Note received for stock issuance	—	—	(242,500)
Stock received for consideration of outstanding loans	—	—	(427,280)
Forgiveness of stock subscription receivable	—	—	242,500
Common stock and contingent consideration issued in Oncogener	2,764,109	—	2,764,109
B-2 warrant modification	238,593	—	238,593
Shares issued to employees & non-employee directors	—	232,768	736,737
Shares issued to third party for services	248,800	98,613	805,749
Exchange of investment for cancellation of accrued interest	—	—	36,712
Exchange of investment for cancellation of note payable	—	—	500,000
Conversion of note into equity of subsidiary	—	—	1,441,948

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

DARA BIOSCIENCES, INC. AND SUBSIDIARIES
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Basis of Presentation

The Company

DARA BioSciences, Inc. (the “Company”), headquartered in Raleigh, North Carolina is a specialty pharmaceutical company focused on the development and commercialization of oncology treatment and oncology supportive care pharmaceutical products. Through its acquisition of Oncogenerix, Inc., which occurred on January 17, 2012, the Company acquired its first commercial, FDA-approved proprietary product license Soltamox® (tamoxifen citrate) oral solution. Soltamox has been approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of breast cancer. On September 12, 2012 the Company entered into a license agreement with Helsinn Healthcare SA (“Helsinn”) to distribute, promote, market and sell Gelclair®, a unique oral gel whose key ingredients are polyvinylpyrrolidone (PV) and sodium hyaluronate (hyaluronic acid) for the treatment of certain approved indications in the United States and the right to subcontract certain of those licensed rights to subcontractors. Gelclair is an FDA-cleared product indicated for the treatment of oral mucositis. In addition, the Company has a marketing agreement with Innocutis Holdings, LLC pursuant to which it promotes Bionect® (hyaluronic acid sodium salt, 0.2%) within the oncology and radiation oncology marketplace. Bionect has been cleared by the FDA for the management of irritation of the skin as well as first and second degree burns. The Company also continues to have two internal clinical development programs, consisting of KRN5500 and DB959 for which we are pursuing out-licensing opportunities. The Company continues to pursue other in-licensing opportunities for approved products.

The activities of the Company have historically consisted of establishing offices, recruiting personnel, conducting research and development, performing business and financial planning and raising capital. Since its acquisition of Oncogenerix and a refocus on commercial activities, the Company is now primarily focused on the sales and marketing of approved products targeting the oncology treatment and oncology supportive care markets. Since the Company has only recently commenced its commercial focus, it is still considered to be a development stage company. The Company has incurred losses since inception through December 31, 2012 of \$46,808,234 and expects to continue to incur losses and require additional financial resources to achieve monetization of its product candidates.

On February 12, 2008, the Company, formerly known as Point Therapeutics, Inc. (the “Company”), completed the merger transaction (the “Merger”) contemplated by the Agreement and Plan of Merger dated October 9, 2007, as amended December 19, 2007 (the “Merger Agreement”), among the Company, DP Acquisition Corp., a wholly-owned subsidiary of the Company (“Merger Sub”), and DARA BioSciences, Inc., a privately held development stage pharmaceutical company based in Raleigh, North Carolina (“DARA”). Pursuant to the Merger, each share of DARA common stock and preferred stock issued and outstanding immediately prior to the effective time of the Merger ceased to be outstanding and was converted into the right to receive 1.031406 shares of Company common stock, plus cash in lieu of any fractional shares. As a result of the transaction, the former DARA stockholders received 96.4% of the Company’s outstanding shares of common stock on a fully-diluted basis and Merger Sub merged with and into DARA, with DARA surviving as a wholly-owned subsidiary of the Company. Upon consummation of the Merger, the Company changed its name to DARA BioSciences, Inc.

For accounting purposes, the Merger was treated as a reverse acquisition with DARA being the accounting acquirer. Accordingly, the historical financial information in these financial statements prior to the Merger is that of DARA and its consolidated subsidiaries and all references to the “Company” in these financial statements relating to periods prior to the Merger refer to DARA (see Note 3).

On January 17, 2012, the Company merged with Oncogenerix, Inc. (“Oncogenerix”) as a result of which Oncogenerix became a wholly-owned subsidiary of DARA. Oncogenerix was a specialty pharmaceutical company which was focused on the identification, development and commercialization of branded and generic oncology pharmaceutical products. The Directors of DARA believed the acquisition of Oncogenerix and the

rights to Soltamox leveraged DARA's existing cancer drug development program and provided DARA with the possibility of generating near term revenue, as well as establishing a commercial platform whereby other cancer and cancer-support products may be accessed in the future through licensing efforts. Oncology treatment and oncology supportive care products and other product licensing opportunities, along with DARA's existing proprietary development pipeline, will be the basis of the Company's long-term product portfolio.

For accounting purposes, the merger with Oncogenex was accounted for under the acquisition method of accounting for business combinations in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC 805), *Business Combinations*.

Going Concern Considerations

The accompanying consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplated the realization of assets and the settlement of liabilities and commitments in the normal course of business.

The Company has incurred significant net losses and has had negative cash flows from operations during each period from inception through December 31, 2012 and had a deficit accumulated during the development stage of approximately \$47,027,581 at December 31, 2012. Management expects operating losses and negative cash flows to continue into 2013.

At December 31, 2011, management believed that currently available cash and cash equivalents together with existing financing agreements would provide sufficient funds to enable the Company to meet its obligations through June of 2012. The Company expected to begin generating revenues from the sale of Soltamox in the second half of 2012. Delays in final approval for packaging and other matters resulted in the commercial launch occurring in the fourth quarter of 2012.

As presented in the consolidated financial statements, at December 31, 2011, the Company had unrestricted cash of \$1,179,157 and an accumulated deficit of \$39,716,548. The Company also incurred a net loss of \$6,170,588 and negative cash flows from operations of \$4,860,806 in 2011. As a result, there existed substantial doubt about the Company's ability to continue as a going concern as of December 31, 2011. The 2011 consolidated financial statements did not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may have resulted from uncertainty related to the Company's ability to continue as a going concern.

The Company funded its 2012 operations primarily from net proceeds from equity securities issued totaling approximately \$11,868,000 in 2012. The Company ended 2012 with cash and cash equivalents and investments totaling approximately \$6,593,000. Through March 28, 2013, the Company also received approximately \$2,516,000 in net proceeds from the issuance of convertible preferred stock and approximately \$1,221,000 in net proceeds from the exercise of warrants. Management believes that such currently available funds, together with projected sales of Soltamox and Gelclair in 2013 will enable the Company to fund its planned operations and to meet its obligations through at least December 31, 2013. If revenues from product sales are substantially less than projected, the Company may be required to delay planned expenditures, reduce the scope of, or eliminate one or more of its development programs or obtain funds through collaborative arrangements with others that may require the Company to relinquish rights to certain of its technologies, product candidates or products that it would otherwise seek to develop itself.

2. Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of DARA BioSciences, Inc. and its majority-owned subsidiaries: DARA Pharmaceuticals, Inc., Point Therapeutics Massachusetts, Inc., and Oncogenex, Inc. (which are each wholly owned by the Company), and DARA Therapeutics, Inc. (which holds the Company's assets related to its KRN5500 program and is owned 75% by the Company). The Company has control of all subsidiaries, and as such, they are all consolidated in the presentation of the consolidated financial statements. All significant intercompany transactions have been eliminated in the consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual amounts could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents approximate their fair value.

Investments

The Company accounts for its investment in marketable securities in accordance with FASB ASC 320, *Investments – Debt and Equity Securities*. See Note 3 for further information. This statement requires certain securities to be classified into three categories:

Held-to-maturity – Debt securities that the entity has the positive intent and ability to hold to maturity are reported at amortized cost.

Trading Securities – Debt and equity securities that are bought and held primarily for the purpose of selling in the near term are reported at fair value, with unrealized gains and losses included in earnings.

Available-for-Sale – Debt and equity securities not classified as either securities held-to-maturity or trading securities are reported at fair value with unrealized gains or losses excluded from earnings and reported as a separate component of shareholders' equity.

In accordance with FASB ASC 320, the Company reassesses the appropriateness of the classification of its investment as of the end of each reporting period. Beginning with the three month period ended June 30, 2012, the Company's investments have been classified as available-for-sale, and are carried at fair value with unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity.

Fair Value Measures

The Company utilizes FASB ASC 820, *Fair Value Measurements and Disclosures*, to value its financial assets and liabilities. FASB ASC 820's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect our market assumptions. FASB ASC 820 classifies these inputs into the following hierarchy:

Level 1 Inputs – Quoted prices for identical instruments in active markets.

Level 2 Inputs – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 Inputs – Instruments with primarily unobservable value drivers.

In determining fair value, the Company utilizes techniques to optimize the use of observable inputs, when available, and minimize the use of unobservable inputs to the extent possible. As such, the Company has utilized Level 1 for the valuation of its available-for-sale investment.

The Company's investments at December 31, 2011 included investments in privately-held companies. Pursuant to FASB ASC 323, *Investments – Equity Method and Joint Ventures*, the Company accounted for these investments either at historical cost, or if the Company has significant influence over the investee, the Company accounts for

these investments using the equity method of accounting. The Company reviews all investments for indicators of impairment at least annually, or whenever events or changes in circumstances indicate the carrying amount of the assets may not be recoverable. In making impairment determinations for investments in privately-held companies, the Company considers certain factors, including each company's cash position, financing needs, earnings, revenue outlook, operational performance, management or ownership changes as well as competition.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. The Company maintains cash deposits with a federally insured bank that may at times exceed federally insured limits. The majority of funds in excess of the federally insured limits are held in sweep investment accounts collateralized by the securities in which the funds are invested. As of December 31, 2012 and 2011, the Company had bank balances of \$6,290,795 and \$990,861, respectively, in excess of federally insured limits of \$250,000 held in non-investment accounts. In addition, our top three customers, Cardinal Health, McKesson Corporation, and Amerisource Bergen Corporation represented 95% of our gross trade accounts receivable as of December 31, 2012.

Furniture, Fixtures and Equipment, net

Furniture, fixtures and equipment, net are recorded at cost and depreciated over the estimated useful lives of the assets (three to five years) using the straight-line method.

Sales and Marketing Costs

Sales and marketing costs consist of salaries, commissions, and benefits to sales and marketing personnel, marketing programs, certain promotional allowances to customers, advertising, distribution and shipping costs.

Research and Development Costs

The Company expenses research and development costs as incurred. Research and development costs include personnel and personnel related costs, costs associated with clinical trials, including amounts paid to contract research organizations and clinical investigators, clinical material manufacturing costs, process development and clinical supply costs, research costs, and other consulting and professional services.

Goodwill and Intangible Assets

Acquired businesses are accounted for using the acquisition method of accounting, which requires that assets acquired, including identifiable intangible assets, and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. If the acquired net assets do not constitute a business, the transaction is accounted for as an asset acquisition and no goodwill is recognized. Other purchases of intangible assets, including product rights are recorded at cost.

Product rights are amortized over the estimated useful life of the product or the license agreement term on a straight-line or other basis to match the economic benefit received. Amortization begins once product rights are secured. The Company evaluates its product rights on an ongoing basis to determine whether a revision to their useful lives should be made. This evaluation is based on its projection of the future cash flows associated with the products. As of December 31, 2012, the Company had an aggregate of \$3.7 million in capitalized product rights, which it expects to amortize over remaining periods of approximately 5.5 to 9.8 years. As of December 31, 2011 the Company had an aggregate of \$100,000 in capitalized product rights (See Notes 3 and 7).

Goodwill is reviewed for impairment on an annual basis or more frequently if events or circumstances indicate potential impairment. The Company's goodwill evaluation is based on both qualitative and quantitative assessments regarding the fair value of goodwill relative to its carrying value. The Company assesses qualitative factors to determine if its sole reporting unit's fair value is more likely than not to exceed its carrying value, including goodwill. In the event the Company determines that it is more likely than not that its reporting unit's fair value is less than its carrying amount, quantitative testing is performed comparing recorded values to

estimated fair values. If the fair value exceeds the carrying value, goodwill is not impaired. If the carrying value exceeds the fair value, an impairment charge is recognized through a charge to operations based upon the excess of the carrying value of goodwill over the implied fair value. The Company performs its evaluation of goodwill annually. There was no impairment to goodwill recognized during 2012.

The Company evaluates the recoverability of its intangible assets subject to amortization and other long-lived assets whenever events or changes in circumstances suggest that the carrying value of the asset or group of assets is not recoverable. The Company measures the recoverability of assets by comparing the carrying amount to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment charge equals the amount by which the carrying amount of the assets exceeds the fair value. Any write-downs are recorded as permanent reductions in the carrying amount of the assets.

Revenue Recognition

The Company recognizes revenue when there is persuasive evidence that an arrangement exists, title has passed, collection is reasonably assured and the price is fixed or determinable. The Company sells mostly to wholesalers who, in-turn, sell the product to hospitals and other end-user customers. Sales to wholesalers provide for selling prices that are fixed on the date of sale, although the Company offers certain discounts to group purchasing organizations and governmental programs. The wholesalers take title to the product, bear the risk of loss of ownership, and have economic substance to the inventory.

The Company allows for product to be returned beginning prior to and following product expiration. The Company does not believe it has sufficient sales and returns history at this time to reasonably estimate product returns from its wholesaler distribution channel. Therefore, the Company is deferring the recognition of revenue until the wholesalers sells its product to hospitals or other end-user customers. It will continue to defer revenue recognition until the point at which it has obtained sufficient sales history to reasonably estimate returns from the wholesalers and inventory levels are reduced to normalized amounts. Shipments of product that are not recognized as revenue are treated as deferred revenue until evidence exists to confirm that pull through sales to hospitals or other end-user customers have occurred. Revenue is recognized from products sales directly to hospitals, clinics, and pharmacies when the merchandise is shipped.

The Company recognizes sales allowances as a reduction of revenues in the same period the related revenue is recognized. Sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with wholesale distributors and the levels of inventory within the distribution channels that may result in future discounts taken. The Company must make significant judgments in determining these allowances. If actual results differ from our estimates, we will be required to make adjustments to these allowances in the future, which could have an effect on revenue in the period of adjustment. The following briefly describes the nature of each provision and how such provisions are estimated

- Payment discounts are reductions to invoiced amounts offered to customers for payment within a specified period and are estimated upon shipment utilizing historical customer payment experience.
- The returns reserve is based on management's best estimate of the product sales recognized as revenue during the period that are anticipated to be returned. The returns reserve is recorded as a reduction of revenue in the same period the related product sales revenue is recognized and is included in accrued expenses.
- Generally, credits may be issued to wholesalers for decreases that are made to selling prices for the value of inventory that is owned by the wholesaler at the date of the price reduction. Price adjustment credits are estimated at the time the price reduction occurs and the amount is calculated based on the level of the wholesaler inventory at the time of the reduction.
- There are arrangements with certain parties establishing prices for products for which the parties independently select a wholesaler from which to purchase. Such parties are referred to as indirect customers. A chargeback represents the difference between the sales invoice price to the wholesaler and the indirect customer's contract price, which is lower. Provisions for estimating chargebacks are

calculated primarily using historical chargeback experience, contract pricing and sales information provided by wholesalers and chains, among other factors. The Company recognizes chargebacks in the same period the related revenue is recognized.

Share-Based Compensation Valuation and Expense

Share-based compensation for stock and stock-based awards issued to employees and non-employee directors, is accounted for using the fair value method prescribed by FASB ASC 718, *Stock Compensation*, and, is recorded as a compensation charge based on the fair value of the award on the date of grant. Share based compensation for stock and stock-based awards issued to non-employees in which services are performed in exchange for the Company's common stock or other equity instruments is accounted for using the fair value method prescribed by FASB ASC 505-50, *Equity-Based Payment to Non-Employees*, and is recorded on the basis of the fair value of the service received or the fair value of the equity instruments issued, whichever is more readily measurable at the date of issuance. See Note 10 for further information.

Comprehensive Loss

The Company's comprehensive loss consists of net loss and other comprehensive income unrealized gains and losses on available-for-sale investments. The Company displays comprehensive income and its components as part of the consolidated statements of net loss and comprehensive loss and in its consolidated statements of shareholder equity.

Income Taxes

The Company uses the liability method in accounting for income taxes as required by FASB ASC 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are recognized for operating loss and tax credit carry forwards and for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is recorded to reduce the carrying amounts of deferred tax assets unless it is more likely than not that such assets will be realized. At December 31, 2012 and December 31, 2011 a valuation allowance has been recorded to reduce the net deferred tax asset to zero.

The Company's policy for recording interest and penalties is to record them as a component of interest income (expense), net.

Net Loss Per Common Share

The Company calculates its basic loss per share in accordance with FASB ASC 260, *Earnings Per Share*, by dividing the earnings or loss applicable to common stockholders by the weighted-average number of common shares outstanding for the period less the weighted average unvested common shares subject to forfeiture and without consideration for common stock equivalents. Diluted loss per share is computed by dividing the loss applicable to common stockholders by the weighted-average number of common share equivalents outstanding for the period less the weighted average unvested common shares subject to forfeiture and dilutive common stock equivalents for the period determined using the treasury-stock method. For purposes of this calculation, in-the-money options and warrants to purchase common stock and convertible preferred stock are considered to be common stock equivalents but are not included in the calculation of diluted net loss per share for the years ended December 31, 2012 and 2011 as their effect is anti-dilutive. For the year ended December 31, 2012, the following in-the-money common equivalents have been excluded from the calculation because their inclusion would be anti-dilutive: 1,460,526 common equivalents from the Series B-2 convertible preferred stock and 125,000 options. For the year ended December 31, 2011 there were no in-the-money common stock equivalents.

	Year ended December 31,	
	<u>2012</u>	<u>2011</u>
Net loss attributable to controlling interest	<u>\$ (7,311,033)</u>	<u>\$ (6,170,588)</u>
Basic and diluted net loss per common share attributable to controlling interest:		
Weighted-average shares used in computing basic and diluted net loss per common share	<u>12,110,386</u>	<u>5,151,017</u>
Basic and diluted net loss per common share attributable to controlling interest	<u>\$ (0.60)</u>	<u>\$ (1.20)</u>

Recently Issued Accounting Pronouncements

In accordance with the guidance of FASB issued in Accounting Standards Update (ASU) 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* (“ASU 2011-05”), the Company adopted the requirement to separately report its comprehensive income. Other comprehensive income refers to revenue, expenses, gains, and losses that are recorded directly as an adjustment to shareholders’ equity. These changes became effective for the Company in the first quarter of 2012 and are reflected in the consolidated statement of operations and comprehensive income/loss. The adoption of ASU 2011-05 did not have a material impact on the Company’s financial statements.

In May 2011, the FASB issued ASU No. 2011-04, *Fair Value Measurements (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (“ASU 2011-04”). This guidance contains certain updates to the fair value measurement guidance as well as enhanced disclosure requirements. The most significant change in disclosures is an expansion of the information required for “Level 3” measurements, including enhanced disclosure for: (1) the valuation processes used by the reporting entity; and (2) the sensitivity of the fair value measurement to changes in unobservable inputs and the interrelationships between those unobservable inputs, if any. The provisions of this update are effective for interim and annual periods beginning on or after December 15, 2011, with early adoption prohibited. The Company’s adoption of this standard did not have a significant impact on the Company’s fair value measurements, financial condition, results of operations or cash flows.

3. Mergers

On February 12, 2008, DARA and Point Therapeutics, Inc. (Point) completed the Merger as described in Note 1. The Directors of Point and DARA, respectively, believed that by combining Point and DARA, the combined company would generate improved long-term operating and financial results and establish a stronger competitive position in the industry by gaining access to greater resources, diversification and increased access to capital. In merging with Point, the DARA board also considered the potential for increased liquidity for its stockholders expected as the result of the Merger.

Following the effectiveness of the Merger, Point changed its corporate name to DARA BioSciences, Inc. and changed its ticker symbol on the NASDAQ Capital Market to “DARA”. The Merger was intended, among other things, to allow the business of privately-held DARA to be conducted by the Company given that DARA’s business became the primary business of the Company following the Merger.

The Merger was accounted for as a reverse acquisition under the purchase method of accounting for business combinations in accordance with GAAP. Under this method of accounting, Point is treated as the acquired company for financial reporting purposes. On February 12, 2008, Point had \$761,671 in cash. Under the terms of the Merger Agreement, as of the closing of the Merger, the former holders of DARA equity securities acquired 96.4% of the capital stock of the Company (on a fully diluted basis). Immediately following the Merger, the Board of Directors of the Company consisted of six directors, all of whom were former directors of DARA. In

addition, the senior management team of DARA manages the operations of the Company. In accordance with guidance applicable to these circumstances, the Merger was considered to be a capital transaction in substance. Accordingly, for accounting purposes, the Merger was treated as the equivalent of the Company issuing stock for the net assets of Point. The net assets of Point were stated at fair value, which approximates historical cost, with no goodwill or other intangible assets recorded. The Company's deficit accumulated in the development stage was carried forward after the Merger.

On January 17, 2012, the Company merged with Oncogenex, Inc., as a result of which Oncogenex became a wholly-owned subsidiary of DARA. Oncogenex is a specialty pharmaceutical company which is focused on the identification, development and commercialization of branded and generic oncology pharmaceutical products. The Directors of DARA believed the acquisition of Oncogenex and the rights to Soltamox leveraged DARA's existing cancer drug development program and provided DARA with the possibility of generating near term revenue, as well as establishing a commercial platform whereby other cancer and cancer-support products may be accessed in the future through pending Oncogenex licensing efforts. As part of its strategy, the Company also planned to target generic injectable cytotoxics, where products are losing patent protection. Going forward, cancer-support products and other product licensing opportunities, along with DARA's existing proprietary development pipeline, will be the basis of the Company's long-term product portfolio.

The merger was accounted for under the acquisition method of accounting for business combinations in accordance with FASB ASC 805, *Business Combinations*, which requires, among other things that the assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date. The results of operations of Oncogenex were consolidated beginning on the date of the merger. Acquisition-related costs are not included as a component of the acquisition accounting, but are recognized as expenses in the periods in which the costs are incurred. Any changes within the measurement period resulting from facts and circumstances that existed as of the acquisition date may result in retrospective adjustments to the provisional amounts recorded at the acquisition date.

DARA agreed to acquire Oncogenex for consideration consisting of 1,114,559 shares of restricted stock issued at closing with a value of \$1,727,568 determined based on the closing price of the stock at closing on January 17, 2012 and up to 1,114,559 in additional shares of stock to be issued in the future if certain contingent milestones are achieved ("contingent merger consideration shares") with a discounted value of \$1,036,541 determined as of the closing date based upon a probability-weighted assessment of the occurrence of triggering events outlined in the merger agreement. The fair value of the contingent shares issuable is recorded in additional-paid in capital.

Of the 1,114,559 restricted shares of common stock (equal to 19.9 percent of DARA's common stock outstanding) issued to the Oncogenex stockholders as of the closing date of January 17, 2012, 167,184 of these shares were deposited into an escrow account and held for offset against possible indemnification claims against the sellers. Up to an additional 1,114,559 shares could be issued over a period of up to 60 months following the closing date ("contingent merger consideration shares"). The issuance of the contingent merger consideration shares is based on the achievement of certain financial milestones related to sales or market capitalization or upon a change of control during the contingent earn out period. On May 15, 2012 the Company's Board of Directors determined the Company had achieved one of the specified milestones and 222,912 of these shares were issued.

On January 17, 2012, the Company estimated the fair value of the upfront consideration based upon the closing price of the stock on the date of the merger for the upfront shares and determined a value of \$1,727,568 and estimated the fair value of the contingent consideration shares using a probability-weighted assessment of the occurrence of the triggering events related to those shares and determined a value of \$1,560,384 resulting in a total fair value for all consideration of \$3,287,952.

As of December 31, 2012, the Company has revised the probability-weighted assessment of the contingent consideration shares based upon a better understanding of the future outlook for certain products acquired and has reduced the value of those shares to \$1,036,541 for a total revised fair value of \$2,764,109. In accordance with the provisions of FASB ASC 805, the following table presents the preliminary allocation of the total fair value of consideration transferred, as discussed above, to the acquired tangible and intangible assets and assumed

liabilities of Oncogenex based on their estimated fair values as of the closing date of the transaction, measurement period adjustments recorded since that date and the adjusted allocation of the total fair value:

	January 17, 2012 (As initially reported)	Measurement Period Adjustments (1)	January 17, 2012 (As adjusted)
Cash	\$ 10,632	\$ -	\$ 10,632
Other assets	550	-	550
Soltamox license	3,367,201	(73,801)	3,293,400
Accounts payable and accrued liabilities	(90,431)	-	(90,431)
Deferred tax liability related to intangibles acquired	-	(1,271,252)	(1,271,252)
Total identifiable net assets	3,287,952	(1,345,053)	1,942,899
Goodwill	-	821,210	821,210
Total fair value of consideration	<u>\$ 3,287,952</u>	<u>\$ (523,843)</u>	<u>2,764,109</u>

- (1) The measurement period adjustments primarily reflect changes in the fair value of the consideration transferred and the recording of a deferred tax liability and resulting goodwill. The measurement period adjustments were made to reflect facts and circumstances existing as of the merger date and did not result from intervening events subsequent to the merger date.

Subsequent to the final allocation, the Company reduced its valuation allowance for the amount of the deferred tax liability resulting in a tax benefit of \$1,271,253 for the period ended December 31, 2012. The Company is amortizing the Soltamox license over the estimated useful life of seventy-eight months on a straight line basis, beginning with January 2012.

Pro Forma Impact of the Oncogenex Merger (Unaudited)

The results of operations of Oncogenex are included in the Company's consolidated financial statements from the closing date of January 17, 2012. The following table presents pro forma consolidated results of operations as if the Oncogenex transaction had been consummated on January 1, 2011. The unaudited pro forma results of operations are not necessarily indicative of what would have occurred had the business combination been completed at the beginning of the period or of the results that may occur in the future. Furthermore, the pro forma financial information does not reflect the impact of any reorganization or restructuring expenses or operating efficiencies resulting from the combining the two companies.

	Year Ended December 31,	
	2012	2011
Net revenues	<u>\$ 53,629</u>	<u>\$ -</u>
Loss attributable to controlling interest	<u>\$ (7,311,033)</u>	<u>\$ (7,897,482)</u>
Basic and diluted net loss per common share attributable to controlling interest	<u>\$ (0.60)</u>	<u>\$ (1.26)</u>

4. Investments

MRI Interventions, Inc.

The Company's marketable securities classified as available-for-sale consist of equity securities in MRI Interventions, Inc. ("MRI"), (OTBB: MRIC), formerly SurgiVision, Inc. MRI Interventions became a publicly traded company on May 18, 2012. The Company carried the investment at cost totaling \$160,387 at May 18, 2012 and \$130,468 at December 31, 2011.

During the year ended December 31, 2012, the Company recognized a gain of \$608,601 on the sale of MRI shares. There were no sales of MRI shares and no gain or loss recognized during the year ended December 31, 2011.

As of December 31, 2012, the fair value of the Company's investment in MRI was \$96,346. Unrealized holding gains, net of tax, on available-for-sale securities were \$45,469 as of December 31, 2012. There was no unrealized gain or loss for the year ended December 31, 2011.

5. Fair Value

Assets measured at fair value on a recurring basis consisted of the following instrument as of December 31, 2012:

	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Assets:				
Investment in MRI Interventions, Inc.	\$ 96,346	\$ 96,346	\$ -	\$ -
Total	<u>\$ 96,346</u>	<u>\$ 96,346</u>	<u>\$ -</u>	<u>\$ -</u>

There were no assets measured at fair value on a recurring basis as of December 31, 2011.

6. Furniture, Fixtures and Equipment, net

Furniture fixtures and equipment consisted of the following at December 31, 2012 and 2011:

	<u>2012</u>	<u>2011</u>
Furniture and fixtures	\$ 87,009	\$ 87,009
Equipment	89,184	78,078
Computer software	15,659	11,104
Leasehold improvements	<u>11,634</u>	<u>11,634</u>
Total	<u>203,486</u>	187,825
Less accumulated depreciation	<u>(153,296)</u>	<u>(145,370)</u>
Furniture, fixtures, and equipment	<u>\$ 50,190</u>	<u>\$ 42,455</u>

The Company recognized a loss of \$1,510 from disposals of fixed assets in 2011. No loss was recognized in 2012.

Depreciation expense, including depreciation related to assets held under capital leases, was \$20,976 and \$19,392 for the years ended December 31, 2012 and 2011, respectively.

7. Intangible Assets

The Company holds an exclusive license for the U.S. marketing rights to Soltamox from Rosemont Pharmaceuticals, Ltd., a U.K. based oral liquids specialty pharmaceutical company. The Company acquired this license on January 17, 2012 in connection with its acquisition of Oncogenerix as described in Note 3.

On February 9, 2012, the Company entered into an Exclusive Distribution Agreement with Uman Pharma Inc. in which the Company received an exclusive license to import, sell, market, and distribute Uman's gemcitabine lyophilized powder product in 200mg and 1g dosage sizes in the U.S. The Company made a \$125,000 license fee payment in February 2012 which it capitalized and has been amortizing the amount over the term of the license of 49 months.

Due to the current U.S. market conditions for gemcitabine lyophilized powder, Uman did not file an Abbreviated New Drug Application for gemcitabine with the FDA in 2012. In fact, pricing pressure on gemcitabine makes it unlikely that Uman will be able to manufacture and the Company does not believe it will be able to

commercialize gemcitabine in the U.S. at prices competitive enough to establish any significant market share. As a result, the Company has written off the license fee with a charge in the amount of \$125,000 being recorded to research and development expense.

On September 12, 2012, the Company acquired an exclusive license with Helsinn Healthcare SA (“Helsinn”), to distribute, promote, market and sell Gelclair, a unique oral gel whose key ingredients are polyvinylpyrrolidone (PVP) and sodium hyaluronate (hyaluronic acid) for treatment of certain approved indications in the United States and the right to subcontract certain of those licensed rights to subcontractors. Gelclair is an FDA-cleared product indicated for the treatment of oral mucositis. The Company has determined there is a strong likelihood that certain milestones under its license agreements will be reached and that the additional consideration will be paid when due. This liability has been recorded in the Company’s financial statements at the initial discounted value of approximately \$703,000. The discounted value of the additional consideration has been recorded by the Company as a non-current asset with a portion recorded as a current liability and the balance recorded as a long-term liability on its December, 2012 balance sheet. The liability was discounted at the Company’s estimated long-term borrowing rate. The Company is amortizing these prepaid license fees over the estimated useful life of one hundred twenty months on a straight line basis, beginning with September, 2012.

On March 23, 2012, the Company entered into an Exclusive Marketing Agreement with Innocutis Holdings, LLC pursuant to which the Company will promote Bionect (hyaluronic acid sodium salt, 0.2%) within the oncology and radiation oncology marketplace. The Company will be compensated by Innocutis for each unit sold in the oncology and radiation oncology market.

On May 4, 2004, the Company entered into a license agreement with a third party in which the Company received a worldwide non-exclusive license to develop and commercialize licensed products based on patents and technological information in exchange for a promissory note and a royalty agreement related to future products and processes resulting from the technology as defined in the agreement. The Company recorded \$1,035,000 in research and development expense during 2004 related to the license.

On July 1, 2004 the Company entered into a license agreement for a compound for the treatment of pain and central and peripheral nervous system conditions or diseases. The Company made a \$100,000 license fee payment in 2004 which was recorded in research and development expense. In addition, the Company will be obligated to make future payments upon achievement of certain milestones.

On October 8, 2007, the Company entered into an exclusive license agreement under which the Company received certain intellectual property rights. The Company made a \$600,000 license fee payment in October 2007. The Company has capitalized this asset and is amortizing the license over a 5 year period. The Company amortized \$100,000 and \$120,000 for the years ended December 31, 2012 and 2011, respectively. The license was fully amortized as of October 2012. In addition, the Company will be obligated to make future payments upon achievement of certain milestones as well as royalty payments as defined in the agreement.

Gross cost and accumulated amortization of intangible assets at December 31, 2012 totaled \$4,847,033 and \$1,138,464, respectively. Amortization of these intangible assets is expected to be approximately \$604,000 each year for the next five years.

8. Noncontrolling Interest

On May 4, 2004, the Company issued a promissory note (the 2004 Note) to a third party organization in consideration for the license of the patents and technological information related to the therapeutic application of a certain compound for neuropathic pain. The principal amount of the 2004 Note was \$1,000,000 payable through issuance of \$1,000,000 in common stock of DARA Therapeutics, Inc. (formerly DARA Pharmaceuticals, Inc.), a wholly owned subsidiary of the Company at the maturity date, or through cash payments of \$500,000 and \$1,000,000 at May 3, 2006 and May 3, 2007, respectively. The original 2004 Note had no stated interest rate.

The Company accounted for the 2004 Note in accordance with APB 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants* (APB 14), and utilized a discounted cash flow model with an

incremental borrowing rate of 15% to determine the fair value of the 2004 Note. At May 3, 2004, the Company determined that the fair value of the 2004 Note was approximately \$1,035,000 and recorded a discount of \$465,000. Also, as part of the original agreement, if the Company elected to settle the debt through issuance of shares of common stock DARA Therapeutics common stock (at a price per share as defined in the agreement), a repurchase put feature would be triggered. Under this repurchase feature, if DARA Therapeutics completed a sub-licensing or commercialization agreement with a third party using the compound technology, the third party would have the ability to require DARA Therapeutics to repurchase its shares of common stock at a price based upon the third party's percentage of equity ownership in DARA Therapeutics as defined in the agreement.

On March 3, 2006, the promissory note was amended to extend the payment dates to March 3, 2007 and September 3, 2007 and accrue interest at 5% annually on \$500,000 beginning March 3, 2006 and 5% annually on the remaining \$500,000 beginning March 3, 2007.

Interest expense of \$0 for the years ended December 31, 2012 and 2011, and \$411,660 for the period from June 22, 2002 (inception) through December 31, 2012 was attributable to the amortization of the debt discount and accrued interest on the 2004 Note.

On March 1, 2007, DARA Therapeutics settled the 2004 note through the issuance of 333,334 shares of common stock of DARA Therapeutics representing 25% of the then outstanding stock of DARA Therapeutics. The Company recorded the issuance of DARA Therapeutics shares as a noncontrolling interest in the subsidiary in the amount of \$1,441,948. Net loss attributable to the third party's noncontrolling interest was \$429,338 and \$306,662 for the years ended December 31, 2012 and 2011, respectively, and \$2,086,579 for the period from June 22, 2002 (inception) through December 31, 2012; which has reduced the noncontrolling interest in the subsidiary to (\$644,630) at December 31, 2012.

9. Leases and Other Financing Arrangements

Operating leases

On November 30, 2007, the Company entered into a lease agreement for 7,520 square feet of office space at 8601 Six Forks Road, Raleigh, North Carolina, known as Forum I. The Company relocated its corporate headquarters from 4505 Falls of the Neuse Road, Raleigh, North Carolina to Forum I in April 2008. The lease term began on April 1, 2008 and was to expire on March 31, 2013 with the option to terminate earlier for cause or to extend. Effective April 1, 2012 the Company amended the lease to extend the expiration date through March 31, 2018. DARA is recording expenses related to the lease ratably over the term of the lease and as a result has recorded a liability at December 31, 2012 for the deferred lease obligation of \$40,865.

In connection with this lease, the Company issued a letter of credit in the amount of \$77,080 on December 11, 2007. The letter of credit is renewable annually for the term of the lease with the landlord and is collateralized by cash held in an interest-bearing time deposit at a bank. The security deposit balance, shown as restricted cash on the balance sheet, has been reduced to \$12,875 at December 31, 2012. Total rent expense was \$149,653 and \$162,071 for the years ended December 31, 2012 and 2011, respectively.

DARA also has in place various operating leases related to office equipment.

At December 31, 2012, future minimum commitments under leases with non-cancelable terms of more than one year are as follows:

Year:	Operating Leases
2013	\$ 127,535
2014	161,058
2015	173,391
2016	177,058
2017	181,476
Thereafter	<u>45,646</u>
Total	<u>\$866,164</u>

Capital Leases

As part of the merger with Point during 2008, the Company acquired office equipment under a capital lease agreement of \$34,328. This capital lease agreement was terminated in 2009 and the Company recorded a net loss of \$19,930 on the capital lease assets and a gain on the extinguishment of the capital lease obligation of \$12,240 in connection therewith which is recorded as other income (expense), net on the consolidated statements of operations for the year ended December 31, 2009. Additionally during 2008, the Company entered into a capital lease agreement of \$35,801 for additional office equipment. During 2012, the Company entered into a capital lease agreement of \$36,751 for additional office equipment. The cost of capital lease assets is included under property and equipment in the balance sheet at December 31, 2012 and 2011, respectively. Accumulated depreciation of the leased equipment was \$27,047 and \$29,736 at December 31, 2012 and 2011, respectively.

The future minimum lease payments required under capital leases and the present values of the net minimum lease payments as of December 31, 2012 are as follows:

Year:	Capital Leases
2013	\$ 15,130
2014	11,016
2015	11,016
2016	11,016
2017	<u>9,180</u>
Total	57,358
Less amount representing interest and maintenance	<u>(30,226)</u>
Present value of minimum lease payment	<u>\$ 27,132</u>

10. Stockholders' Equity

Pursuant to the Point Therapeutics Merger Agreement, each share of DARA common stock and preferred stock issued and outstanding immediately prior to the effective time of the merger ceased to be outstanding and was converted into the right to receive 1.031406 shares of the post-merger Company common stock, plus cash in lieu of any fractional shares. Additionally, outstanding options and warrants to purchase shares of DARA common stock became options and warrants to purchase shares of the post-merger Company common stock adjusted as follows: the number of shares acquirable upon exercise was multiplied by 1.031406 and the exercise price per share was divided by 1.031406. As a result of the transaction, the former DARA stockholders received 96.4% of the Company's outstanding shares of common stock on a fully-diluted basis and Merger Sub merged with and into DARA, with DARA surviving as a wholly-owned subsidiary of the Company.

Common Stock

As a result of the merger with Oncogenex on January 17, 2012, 1,114,559 shares of DARA common stock were issued to former Oncogenex stockholders. In addition to the initial shares the Oncogenex stockholders will be entitled to receive up to an additional 1,114,559 shares of DARA common stock based upon the combined company's achievement of certain revenue or market capitalization milestones during the 60 months following the Closing Date. On May 15, 2012, 222,912 of these contingent shares were issued.

On February 26, 2010 and March 5, 2010, the Company entered into two securities purchase agreements with certain accredited investors in connection with the private issuance and sale to such investors of a total of 234,896 shares of the Company's common stock and 117,456 warrants to purchase shares of common stock. The common stock and warrants were sold in units for \$7.52 per unit, with each unit consisting of one share of common stock and one-half of a warrant to purchase one share of common stock for each unit purchased. The closings of the sale of the units under these securities purchase agreements took place on February 26, 2010 and March 5, 2010 for proceeds of \$1,759,545, net of issuance costs of \$6,959. Each warrant entitles the holder to purchase shares of common stock for an exercise price per share equal to \$7.52. Of these warrants, 114,131 expire on August 26, 2015 and 3,325 expire on September 5, 2015.

On October 22, 2010, the Company entered into a securities purchase agreement with certain accredited investors in connection with a registered direct offering by the Company of 612,667 shares of the Company's common stock and 306,334 warrants to purchase shares of common stock. The common stock and warrants were sold in units for \$2.25 per unit, with each unit consisting of one share of common stock and one-half of a warrant to purchase one share of common stock for each unit purchased. The closing of the sale of these units took place on October 26, 2010 for gross proceeds of \$1,378,500 and net proceeds after placement agent fees of \$1,262,166. Each warrant entitles the holder to purchase shares of common stock for an exercise price per share equal to \$2.79, becomes exercisable on April 26, 2011 and expires April 26, 2016.

Preferred Stock

On December 28, 2012, the Company entered into a securities purchase agreement with certain institutional investors providing for the issuance and sale by the Company of \$2,800,000 of shares of Series B-3 and Series B-4 convertible preferred stock (convertible into a combined total of 3,684,210 shares of common stock). In connection with the purchase of shares of Series B-3 and B-4 convertible preferred stock, each investor received warrants to purchase a number of shares of common stock equal to the number of shares of common stock into which such investor's shares of Series B-3 and B-4 convertible preferred stock are convertible, at an exercise price equal to \$1.05. Each warrant is exercisable at any time on or after the six-month anniversary of date of issuance (the "Initial Exercise Date"). One-half of the warrants are exercisable for two years from the Initial Exercise Date, but not thereafter, and the other half are exercisable for five years from the Initial Exercise Date, but not thereafter.

The closing date for the sale of these securities took place on December 31, 2012 for net proceeds of \$2,515,728 with the cash being received by the Company in January 2013. Because the proceeds from the offering were not received until January 2013, the transaction has not been accounted for as of December 31, 2012. The offering required and received the approval of at least 67% of the then outstanding Series B-2 warrants holders.

The Series B-3 convertible preferred stock is issued pursuant to an effective shelf registration statement. The Series B-4 convertible preferred stock and the warrants are issued without registration. Accordingly, the investor may exercise those warrants and sell the underlying shares only pursuant to an effective registration statement under the Securities Act covering the resale of those shares, an exemption under Rule 144 under the Securities Act or another applicable exemption under the Securities Act. The Company has filed a registration statement with the SEC covering the resale of the shares of common stock issuable upon conversion of or in connection with the Series B-4 convertible preferred stock and upon exercise of the warrants which is pending effectiveness.

In connection with the Series B-3 and B-4 transaction, on December 28, 2012, the Company entered into an Amendment to Series B-2 Securities Purchase Agreement and Warrants with all of the current holders of warrants

issued by the Company pursuant to the securities purchase agreement, dated April 6, 2012. Pursuant to the amendment, the warrant holders agreed to amend the April Purchase Agreement to permit the Company to conduct a financing below \$1.00 and the Company agreed to amend the exercise price of the warrants issued to such warrant holders. In connection with the amendment, the exercise price of a total of 5,125,000 of \$1.25 warrants was reduced to \$1.00 and the exercise price of a total of 3,954,800 of \$1.00 warrants was reduced to \$0.80. Additionally, pursuant to the certificate of designations for Series B-2 preferred stock, the conversion price of the Company's then outstanding shares of Series B-2 convertible preferred stock was adjusted from \$1.00 to \$0.76. The fair value of the warrant modifications was determined to be \$238,593 and was recorded as an expense to general and administrative expense as of December 31, 2012.

On April 6, 2012, the Company entered into a securities purchase agreement with certain investors in connection with a registered public offering by the Company of 10,250 shares of the Company's Series B-2 convertible preferred stock (which are convertible into a total of 10,250,000 shares of common stock) and warrants to purchase up to 5,125,000 shares of the Company's common stock at an exercise price of \$1.00 per share and warrants to purchase up to 5,125,000 shares of the Company's common stock at an exercise price of \$1.25 per share, for gross proceeds of \$10,250,000. The closing of the sale of these securities took place on April 12, 2012 for net proceeds of \$9,183,468.

Shares of Series B-2 preferred stock have a liquidation preference equal to \$1,000 per share and, subject to certain ownership limitations, are convertible at any time at the option of the holder into shares of the Company's common stock at a conversion price of \$1.00 per share. The Series B-2 warrants represent the right to acquire shares of common stock at an exercise price of \$1.00 per share and \$1.25 per share and will expire on April 12, 2017. During the year ended December 31, 2012, 9,140 Series B-2 Preferred shares were converted into 9,200,000 shares of common stock. During the year ended December 31, 2012, 1,170,200 of the \$1.00 Series B-2 warrants were exercised.

Management evaluated the terms and conditions of the embedded conversion features based on the guidance of FASB ASC 815 to determine if there was an embedded derivative requiring bifurcation. Management concluded that the embedded conversion feature of the preferred stock was not required to be bifurcated because the conversion feature is clearly and closely related to the host instrument.

Management determined that there were no beneficial conversion features for the Series B-2 convertible preferred stock because the effective conversion price was equal to or higher than the fair value at the date of issuance.

On January 17, 2012, the Company entered into a securities purchase agreement with an institutional investor in connection with a registered direct offering by the Company of 1,700 shares of the Company's Series B-1 convertible preferred stock (which are convertible into a total of 1,238,616 shares of common stock) and warrants to purchase 619,308 shares of the Company's common stock, for gross proceeds of \$1,700,000. The closing of the sale of these securities took place on January 20, 2012 for net proceeds of \$1,560,500.

Shares of Series B-1 preferred stock have a liquidation preference equal to \$1,000 per share and, subject to certain ownership limitations, are convertible at any time at the option of the holder into shares of the Company's common stock at a conversion price of \$1.3725 per share. The B-1 warrants represent the right to acquire shares of common stock at an exercise price of \$1.31 per share and will expire on January 20, 2017. During the year ended December 31, 2012, 1,700 Series B-1 Preferred shares were converted into 1,238,616 shares of common stock. All Series B-1 Preferred shares have been converted as of December 31, 2012. No Series B-1 warrants were exercised during the year ended December 31, 2012.

On December 30, 2010, the Company entered into a securities purchase agreement with certain accredited investors in connection with a registered direct offering by the Company of units comprised of 4,800 shares of Series A convertible preferred stock (which are convertible into a total of 1,920,000 shares of common stock), Class A warrants to purchase 960,000 shares of common stock and Class B warrants to purchase a total of 960,000 shares of common stock, for net proceeds of \$4,286,40.

Shares of Series A preferred stock have a liquidation preference equal to \$1,000 per share and, subject to certain ownership limitations, are convertible at any time at the option of the holder into shares of Company common stock at a conversion price of \$2.50 per share.

Class A warrants entitle the holder to purchase shares of common stock for an exercise price equal to \$2.50 and expire December 30, 2015. Class B warrants will entitle the holder to purchase shares of common stock for an exercise price equal to \$2.50 and expire December 30, 2011.

No Series A convertible preferred shares were converted and no Series A warrants were exercised for the year ended December 31, 2012. For the year ended December 31, 2011, 2,847 Series A convertible preferred shares were converted into 1,138,800 shares of common stock and 225,000 warrants were exercised at \$2.50 per warrant.

Stock Dividend

On April 28, 2005, the board of directors approved a three for two (3:2) stock split in the form of a stock dividend. Stockholders of record on April 28, 2005 received a stock dividend of one share of common stock for every two shares of capital stock (preferred or common) owned on that date.

Warrants

In 2012, the Company recognized share-based compensation in accordance with the provisions of ASC 505, *Equity*, using a fair-value approach related to issuance of 150,000 warrants at an exercise price of \$1.50 per share to a third party provider in the amount of \$163,263. In 2011, the Company recognized share-based compensation related to issuance of 200,000 warrants at an exercise price of \$1.31 per share to two nonemployees totaling \$230,961.

The Company has a total of 12,274,239 warrants at a weighted-average price of \$2.02 to purchase its common stock outstanding as of December 31, 2012, all of which are fully vested and exercisable. These warrants are summarized as follows:

<u>Date</u>	<u>Price</u>	<u>Number of Shares</u>	<u>Life</u>
October 21, 2008	\$ 16.00	14,094	5 year
October 21, 2008	\$ 20.80	140,938	5 year
October 21, 2008	\$ 36.00	70,471	5 year
June 15, 2009	\$ 7.36	224,109	5 year
September 14, 2009	\$ 8.96	339,227	5 year
September 18, 2009	\$ 7.84	68,750	5 year
October 13, 2009	\$ 7.57	43,752	5 year
February 26, 2010	\$ 7.52	114,131	5 year
March 5, 2010	\$ 7.52	3,325	5 year
October 26, 2010	\$ 2.79	306,334	5 year
December 29, 2010	\$ 2.50	900,000	5 year
December 27, 2011	\$ 1.31	150,000	10 year
December 27, 2011	\$ 1.31	50,000	10 year
January 20, 2012	\$ 1.31	619,308	5 year
February 6, 2012	\$ 1.50	150,000	5 year
April 16, 2012	\$ 0.80	3,954,800	5 year
April 16, 2012	\$ 1.00	5,125,000	5 year

Common Stock Reserved for Future Issuance

The Company has reserved authorized shares of common stock for future issuance at December 31, 2012 as follows:

Outstanding stock options	1,331,887
Possible future issuance under stock option plan	459,033
Oncogenex contingent consideration	891,648
Possible conversion of preferred shares	1,791,726
Outstanding warrants	<u>12,274,239</u>
	<u>16,748,533</u>

The tables above exclude 3,684,210 Series B-3 and B-4 preferred shares and 3,684,210 related warrants which were recorded in January of 2013. The table above also excludes 4,261,907 new stock options authorized for the issuance under the evergreen provision of the 2008 Plan.

11. Share-Based Compensation

The Company has two share-based compensation plans, the 2008 Employee, Director, and Consultant Plan (the “2008 Plan”), and the 2003 Amended and Restated Employee, Director, and Consultant Plan (the “2003 Plan”), together referred to herein as the “Stock Plans”.

The 2008 Plan provides for the granting of incentive stock options, non-qualified stock options, stock appreciation rights, and restricted stock and other stock awards. Options granted and shares underlying stock awards issued under the 2008 Plan vest over periods determined by the compensation committee of the board of directors.

The 2003 Plan provided for the granting of incentive stock options to employees and non-qualified stock options to employees, directors, and consultants of the Company or its subsidiaries. In connection with the adoption of the 2008 Plan, the 2003 Plan was frozen. As a result there were no shares of common stock available for future grants under the 2003 Plan at December 31, 2012 and 2011.

Incentive stock options and non-qualified stock options were granted under the Stock Plans through December 31, 2012. The options are exercisable for a period not to exceed ten years and vesting for the options and restricted shares granted to date range from being 100% fully vested at grant to 20% immediately vested and the remainder vesting over a three to five year period.

As of December 31, 2012, a total of 2,167,586 shares were authorized for grants under the Stock Plans, of which 459,033 were available for future grant. As of December 31, 2012 there were no restricted stock awards outstanding under the 2008 and 2003 Plans. As of December 31, 2012, a total of 1,322,088 and 9,799 stock options were outstanding under the 2008 Plan and 2003 Plans, respectively. As of January 1, 2013, the authorized options under the 2008 Plan increased by 4,261,907 pursuant to the evergreen provision contained in the 2008 Plan.

The following table summarizes the Company’s stock plan activity under all of the Company’s stock based compensation plans from March 12, 2003 (plan inception) through December 31, 2012:

	Shares Available for Grant	Shares Subject to Outstanding Options	Weighted Average Exercise Price
Shares authorized at March 12, 2003	62,500	-	\$ -
Options granted	(6,250)	6,250	8.48
Balance at December 31, 2003	56,250	6,250	8.48
Options granted	(37,813)	37,813	10.24
Options exercised	-	(24,609)	9.92
Balance at December 31, 2004	18,437	19,454	10.08
Shares authorized on January 25, 2005	62,500	-	-
Options granted through April 28, 2005	(24,375)	24,375	30.88
Additional authorized shares due to stock dividend on April 28, 2005	62,500	-	-
Options granted as result of stock dividend on April 28, 2005	(34,219)	34,219	30.88
Options granted after April 28, 2005	(25,625)	25,625	30.88
Options exercised	-	(2,063)	8.48
Options forfeited	11,219	(11,219)	22.08
Balance at December 31, 2005	70,437	90,391	22.88
Options granted	(28,750)	28,750	38.40
Options exercised	-	(15,003)	12.00
Options forfeited	6,094	(6,094)	17.44
Balance at December 31, 2006	47,781	98,044	29.44
Shares authorized on January 16, 2007	62,500	-	-
Options granted	(72,471)	72,471	41.60
Options forfeited	3,841	(3,841)	36.80
Balance at December 31, 2007	41,651	166,674	34.24
Adjustment to beginning balance from merger ratio	1,309	4,943	-
Balance at February 12, 2008	42,960	171,617	-
Options authorized under the 2008 plan	287,890	-	-
Reduction to options available to be issued under the 2003 plan	(41,993)	-	-
Options granted	(29,707)	29,707	23.30
Shares issued to directors	(6,563)	-	-
Options exercised	-	(18,131)	10.40
Shares cancelled and forfeited	-	(48,363)	33.96
Balance at December 31, 2008	252,587	134,830	34.23
Options granted	(71,877)	71,877	4.43
Shares issued to directors	(703)	-	-
Shares issued as compensation	(32,012)	-	-
Options exercised	-	(26,563)	4.17
Shares cancelled and forfeited	20,053	(90,671)	35.04
Balance at December 31, 2009	168,048	89,473	18.40
Options authorized under the 2008 plan	284,347	-	-
Options granted	(80,625)	80,625	7.35
Options exercised	-	(25,000)	4.00
Shares issued to directors	(1,458)	-	-
Shares issued as compensation	(12,500)	-	6.25
Balance at December 31, 2010	357,812	145,098	14.63
Options authorized under the 2008 plan	723,359	-	-
Options granted	(915,000)	915,000	1.36
Options forfeited	31,250	(31,250)	7.36
Shares issued as compensation	(111,000)	-	3.43
Balance at December 31, 2011	86,421	1,028,848	3.05
Options authorized under the 2008 plan	699,502	-	-
Options granted	(870,000)	870,000	0.99
Options forfeited	543,110	(566,961)	3.23
Balance at December 31, 2012	<u>459,033</u>	<u>1,331,887</u>	<u>\$ 1.63</u>

Effective with the adoption of FASB ASC 718, *Compensation-Stock Compensation*, as of January 1, 2006, the Company has elected to use the Black-Scholes option pricing model to determine the fair value of options granted. The Company has not paid and does not anticipate paying cash dividends; therefore the expected dividend rate is assumed to be 0%. Stock price volatility is based on an analysis of historical stock price data reported for a peer group of public companies and the Company. The expected life is the length of time options are expected to be outstanding before being exercised. The Company estimates expected life using the “simplified method” as allowed under the provision of the Securities and Exchange Commission’s Staff Accounting Bulletin No. 107, *Share-Based Payment*. The simplified method uses an average of the option vesting period and the option’s original contractual term. The Company uses the implied yield of U. S. Treasury instruments with terms consistent with the expected life of options as the risk-free interest rate. FASB ASC 718 requires companies to estimate a forfeiture rate for options and accordingly reduce the compensation expense reported. The Company used historical data among other factors to estimate the forfeiture rate.

The fair value of stock options granted to employees and non-employee directors was estimated using a Black-Scholes option-pricing model and the following weighted-average assumptions:

	<u>2012</u>	<u>2011</u>
Estimated dividend yield.....	-	-
Expected stock price volatility	105.53%	95.27%
Expected life of option (in years).....	5.85	9.77
Risk-free interest rate	0.97%	1.99%

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of ASC 505, *Equity*, using a fair-value approach. The equity instruments, consisting of shares of restricted stock, stock options and warrants granted to lenders and consultants, are valued using the Black-Scholes valuation model. Measurement of share-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the term of the related financing or the period over which services are received.

The weighted average grant-date fair value of options granted during the years ended December 31, 2012 and 2011 were \$0.72 and \$1.18, respectively. There were no stock options exercised during the years ended December 31, 2012 and 2011. The Company did not realize a tax benefit from stock options exercised during the years ended December 31, 2012 and 2011.

The following summarizes certain information about fully vested stock options and stock options expected to vest as of December 31, 2012:

	Number of Options	Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding	1,331,887	9.12	\$ 1.63	\$ 6,250
Exercisable	779,791	8.93	\$ 2.08	\$ 1,338

The following table summarizes certain information about the Company's stock options outstanding as of December 31, 2012:

Exercise Price	Number of Shares Outstanding	Weighted Average Remaining Contractual Life (in	Number of Options Exercisable
\$ 0.70	75,000	9.73	16,250
\$ 0.75	50,000	9.53	10,000
\$ 1.00	570,000	9.34	164,000
\$ 1.29	60,000	9.24	15,000
\$ 1.31	495,000	8.99	495,000
\$ 2.05	30,000	8.71	30,000
\$ 3.03	15,000	8.25	15,000
\$ 6.24	9,375	7.36	7,029
\$ 6.88	6,251	6.34	6,251
\$ 7.20	5,625	7.23	5,625
\$ 22.40	5,212	5.69	5,212
\$ 35.04	625	5.33	625
\$ 37.28	2,708	2.73	2,708
\$ 41.92	7,091	4.83	7,091
	<u>1,331,887</u>	9.12	<u>779,791</u>

The Company recognized stock option compensation expense for employees and non-employee directors as follows:

	Year Ended December 31,		Period from
	2012	2011	June 22, 2002 (inception) to December 31, 2012
Research and development	\$ 25,292	\$ 19,636	\$ 1,230,403
Sales and marketing	103,141	-	103,141
General and administration	271,362	1,092,208	3,696,600
Total stock-based compensation to employees and non-employee directors	<u>\$ 399,795</u>	<u>\$ 1,111,844</u>	<u>\$ 5,030,144</u>

Stock option compensation expense for non-employees in exchange for services during the years ended December 31, 2012 and 2011 was none and \$2,547, respectively, and \$664,300 for the period from June 22, 2002 (inception) through December 31, 2012.

As of December 31, 2012, there was \$449,273 of total unrecognized compensation cost for non-vested share-based stock option compensation arrangements which is expected to be recognized over a weighted average period of 3 years.

Restricted Stock Activity

The Company did not issue shares of restricted stock to employees during the year ended December 31, 2012. In January 2011, the Company issued 66,000 shares of restricted stock to five employees which vested 100% on the one year anniversary of the grant date. The former Chief Executive Officer/President was awarded 50,000 restricted shares and four employees were each awarded 4,000 restricted shares. The shares vested on the anniversary of the grant, January 3, 2012 and the Company recognized \$198,940 and \$27,440 stock-based compensation expense in general and administrative and research and development, respectively, for the year ended December 31, 2011. The Company recognized \$366,455 and \$69,318 stock-based compensation expense in general and administrative and research and development, respectively, for the period from June 22, 2002 (inception) through December 31, 2012.

During 2009 the Company issued 31,250 restricted shares to five employees. The Chief Executive Officer/President was awarded 18,750 restricted shares and four employees each were awarded 3,125 restricted shares. The shares vested on the anniversary of the grant, September 24, 2010 and the Company recognized \$167,515 and \$41,878 stock-based compensation expense in general and administrative and research and development, respectively, for the year ended December 31, 2010.

The Company did not issue shares of restricted stock to members of the board during the year ended December 31, 2012. The Company recognized share-based compensation expense related to issuance of restricted stock to certain members of the board of directors in general and administrative expense of \$6,388 for the year ended December 31, 2011, and \$224,109 for the period from June 22, 2002 (inception) through December 31, 2012.

The Company recognized share-based compensation related to issuance of restricted stock to nonemployees in exchange for services totaling \$248,800 and \$98,613 for the years ended December 31, 2012 and 2011, respectively, and \$805,749 for the period from June 22, 2002 (inception) through December 31, 2012.

	Outstanding Shares	Weighted Average Grant Date Fair Value
Nonvested restricted stock at December 31, 2008	4,920	\$ 31.57
Restricted stock granted	33,650	9.04
Restricted stock vested	(10,246)	11.73
Restricted stock cancelled (forfeited)	(2,758)	17.89
Nonvested restricted stock at December 31, 2009	25,566	10.53
Restricted stock granted	13,958	6.12
Restricted stock vested	(36,972)	8.85
Nonvested restricted stock at December 31, 2010	2,552	18.98
Restricted stock granted	111,000	3.43
Restricted stock vested	(113,552)	3.78
Nonvested restricted stock at December 31, 2011	-	-
Restricted stock granted	400,000	1.09
Restricted stock vested	(240,000)	-
Nonvested restricted stock at December 31, 2012	160,000	\$ 1.09

In September 2012, the Company issued 400,000 shares of restricted stock to non-employees (i.e. consultants) in exchange for services pursuant to a consulting agreement with a vendor ("the Consulting Agreement"). The Company terminated this Consulting Agreement on January 29, 2013 and pursuant to the terms of the agreement, 200,000 of the original 400,000 shares were returned to the Company and cancelled. In January 2013, the Company issued 40,000 additional restricted shares to these non-employees for services provided in 2012. Although the shares were not issued until 2013, the compensation was recognized in 2012. As of December 31,

2012, there was unrecognized compensation cost related to 200,000 nonvested restricted shares which were subsequently forfeited.

12. Employee Benefit Plan

During 2005, the Company adopted a defined contribution employee benefit plan that covers all qualifying employees. The plan provides for voluntary employee contributions and a discretionary matching employer contribution equal to amounts that do not exceed the maximum amounts allowed by the Internal Revenue Service. As part of the Company's cost reduction program, effective April 1, 2009 the Company amended its contribution to the employee benefit plan to remove the Safe Harbor Cash or Deferred Arrangement provisions.

Defined contribution plan expense prior to the effective date of the amendment was \$179,359 for the period from June 22, 2002 (inception) through December 31, 2010. There was no discretionary employer match and therefore no expense was recognized in 2012 and 2011.

13. Subsidiaries

During 2004, the Company organized several subsidiaries: Signum Pharmaceuticals, OnsetThera, Inc., and MIKKO Pharmaceuticals. Upon formation, the Company acquired 1,000,000 shares of each of the subsidiaries which represented 100% equity ownership. OnsetThera, Inc. and Signum Pharmaceuticals obtained licensing rights for certain patents and technologies during 2004 in exchange for certain payments and the sale to the licensors of a 40% and 25% equity ownership in the respective entities. These transactions reduced the Company's ownership in OnsetThera, Inc. to 60% and its ownership in Signum Pharmaceuticals to 75%.

As a result of the Company's merger with Point Therapeutics, Inc. on February 12, 2008, the Company acquired Point Therapeutics' wholly owned subsidiary, Point Massachusetts, Inc.

Effective December 18, 2006, the Company filed certificates of dissolution for both Onset Thera, Inc. and NYVARA Pharmaceuticals, Inc. Effective December 16, 2008, the company filed a certificate of dissolution for Mikko Pharmaceuticals, Inc. Effective December 8, 2009, the company filed a certificate of dissolution for Signum Pharmaceuticals, Inc. Effective June 18, 2012 the Commonwealth of Massachusetts filed a dissolution of Point Therapeutics Massachusetts, Inc.

14. Income Taxes

The benefit from income taxes for the years ended December 31, 2012 and 2011 are as follows:

	<u>2012</u>	<u>2011</u>
Current	\$ -	\$ (194,445)
Deferred	<u>(1,299,837)</u>	<u>-</u>
Benefit from income taxes	<u>\$ (1,299,837)</u>	<u>\$ (194,445)</u>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities for federal income tax purposes are as follows at December 31:

	<u>2012</u>	<u>2011</u>
Deferred tax assets:		
Net operating loss carryforwards	<u>\$ 70,777,633</u>	\$ 71,415,531
Tax credits	<u>3,752,120</u>	4,035,576
Investments and other	<u>2,405,642</u>	2,282,404
Total deferred tax assets	<u>76,935,395</u>	77,733,511
Valuation allowance	<u>(76,935,395)</u>	(77,733,511)
Net deferred tax assets	<u>\$ -</u>	<u>\$ -</u>

The Company has provided a valuation allowance against the deferred tax assets recorded as of December 31, 2012 and 2011, due to uncertainties as to their ultimate realization. The increase in the valuation allowance in each period resulted primarily from the additional net operating loss carryforward generated.

For the years ended December 31, 2012 and 2011, the Company recorded a tax benefit of \$1,299,837 and \$194,445, respectively. For the year ended December 31, 2012, the Company recorded unrealized gains on its investments in available-for-sale securities in other comprehensive income. The benefit of \$28,584 for the year ended December 31, 2012 is due to the recognition of corresponding income tax expense associated with the increase in the value of the Company's investment in MRI Interventions that the Company carried at fair market value during the same period. The corresponding income tax expense has been recorded in other comprehensive income. Intraproduct tax allocation rules require the Company to allocate its provision for income taxes between continuing operations and other categories of earnings, such as other comprehensive income. In periods in which the Company has a year-to-date pre-tax loss from continuing operations and pre-tax income in other categories of earnings, such as other comprehensive income, the Company must allocate the tax provision to the other categories of earnings. The Company then records a related tax benefit in continuing operations. In addition, the Company recorded a tax benefit of \$1,271,253 related to the acquisition of Oncogenex. As a result of the acquisition, the Company determined that some of the existing deferred tax assets would more likely than not be realized by the combined entities through the reversal of the deferred tax liability. Under ASC 805-740, a change in an acquirer's valuation allowances that stem from a business combination should be recognized as an element of the acquirer's deferred income tax expense (benefit) in the reporting period that includes the business combination.

As of December 31, 2012 and 2011, respectively, the Company had approximately \$203 million and \$204 million of U.S. Federal net operating loss carryforwards that have started to expire. These carryforwards will expire at various dates through 2032. As of December 31, 2012 and 2011, respectively, the Company also has approximately \$38 million and \$41 million of state net economic loss carryforwards that have started to expire. Additionally, as of December 31, 2012 and 2011, respectively, the Company has research and development credits of approximately \$2.8 million and \$900 thousand for federal and state tax purposes that have started to expire.

The Internal Revenue Code provides limitations on utilization of existing net operating losses and tax credit carryforwards against future taxable income based upon changes in share ownership. If these changes have occurred, the ultimate realization of the net operating loss and R&D credit carryforwards could be permanently impaired.

Income taxes computed at the statutory federal income tax rate of 34% are reconciled to the provision (benefit) for income taxes as follows:

	<u>2012</u>	<u>2011</u>
Expected federal tax benefit	\$ (2,927,700)	\$ (2,164,111)
State income taxes, net of federal benefit	(391,800)	(289,609)
Other permanent differences	39,300	(73,249)
Tax credits	-	(284,915)
Expired federal NOLs	3,051,800	2,446,332
Expired tax credits and state NOLs	807,600	1,818,770
Deferred tax liability related to Onco acquisition	(1,271,253)	-
Other	190,316	(74,758)
Change in valuation allowance	<u>(798,100)</u>	<u>(1,572,905)</u>
Income tax benefit	<u>\$ (1,299,837)</u>	<u>\$ (194,445)</u>

On January 1, 2007, the Company adopted ASC 740-10 (formerly FIN 48). There was a cumulative effect adjustment of \$219,338 upon adoption and included in this amount was \$24,893 related to penalties and interest. An additional \$11,100 of penalties and interest on these liabilities was accrued in 2010 and the Company had recorded total interest and penalties related to these liabilities of \$85,277 as of December 31, 2010. During 2011, the Company recognized a decrease in its liability for unrecognized tax benefits. The decrease of \$194,445 in the

liability for unrecognized tax benefits was due to the Company no longer being subject to examination for tax periods prior to 2007 in the state jurisdictions to which the liability for unrecognized tax benefits related. No unrecognized tax benefits exist as of December 31, 2012.

15. Subsequent Events

During the period from January 1, 2013 through March 21, 2013, investors in the B-2 preferred stock have exercised 1,182,000 warrants at \$.80 per share for proceeds of \$873,600 and 250,000 warrants at \$1.00 per share for proceeds of \$250,000. In addition, during the same period, investors in the B-2 preferred stock have converted 860 shares into 1,131,578 shares of common stock and investors in the B-3 preferred stock have converted all 2,550 shares into 3,355,258 shares of common stock.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Disclosure controls and procedures

We maintain "disclosure controls and procedures", as that term is defined in Rule 13a-15(e), promulgated by the Securities and Exchange Commission pursuant to the *Securities Exchange Act of 1934*, as amended. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our company's reports filed under the *Securities Exchange Act of 1934* is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer to allow timely decisions regarding required disclosure.

As required by paragraph (b) of Rules 13a-15 under the *Securities Exchange Act of 1934*, our management, with the participation of our principal executive officer and principal financial officer, evaluated our company's disclosure controls and procedures as of the end of the period covered by this annual report on Form 10-K. Based on this evaluation, our management concluded that as of the end of the period covered by this annual report on Form 10-K, our disclosure controls and procedures were effective.

Internal control over financial reporting

Management's annual report on internal control over financial reporting

Our management, including our principal executive officer and principal financial officer, is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934).

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our internal control over financial reporting as of December 31, 2012. Our management's evaluation of our internal control over financial reporting was based on the framework in Internal Control—Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2012 and that there were no material weaknesses in our internal control over financial reporting.

A material weakness is a deficiency or a combination of control deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Limitations on Effectiveness of Controls

Our principal executive officer and principal financial officer do not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additional controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting during the fourth quarter of 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

For information with respect to the directors and executive officers of DARA, see the “Proposal 1 – Election of Directors”, “Information Concerning Executive Officers Who Are Not Directors” and “Executive Officers” sections of the Proxy Statement for the 2013 Annual Meeting of Stockholders, which is incorporated herein by reference. For information with respect to Section 16 reports, see the “Section 16(a) Beneficial Ownership Reporting Compliance” section of the Proxy Statement for the 2013 Annual Meeting of Stockholders, which is incorporated herein by reference. For information with respect to the Audit Committee of the board of directors, see the “The Board and Board Committees” and “Audit Committee Matters” sections of the Proxy Statement for the 2013 Annual Meeting of Stockholders, which is incorporated herein by reference.

Code of Ethics and Conduct

Our board of directors has adopted a code of business ethics and conduct (the “Code of Ethics”), applicable to all of our executives, directors and employees. The Code of Ethics is available in print to any shareholder that requests a copy. Copies may be obtained by contacting Investor Relations at our corporate headquarters. Our Code of Ethics is also available in the Investor Relations section of our website at <http://www.darabiosciences.com>. We intend to make any disclosures regarding amendments to, or waivers from, the Code of Ethics required under Form 8-K by posting such information on our website.

Item 11. Executive Compensation.

Executive Officer Compensation

For information with respect to executive and director compensation, see the “Executive Compensation” and “Corporate Governance” sections of the Proxy Statement for the 2013 Annual Meeting of Stockholders, which are incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

For information with respect to security ownership of certain beneficial owners and management, see the “Security Ownership of Certain Beneficial Owners and Management” section of the Proxy Statement for the 2013 Annual Meeting of Stockholders, which is incorporated herein by reference. For information with respect to securities authorized for issuance under equity compensation plans, see the “Equity Compensation Plan Information” section of the Proxy Statement for the 2013 Annual Meeting of Stockholders, which is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions and Director Independence.

For information with respect to certain relationships and related transactions, see the “Transactions With Related Persons” section of the Proxy Statement for the 2013 Annual Meeting of Stockholders, which is incorporated herein by reference. For certain information with respect to director independence, see the disclosures in the “Proposal 1 – Election of Directors” section of the Proxy Statement for the 2013 Annual Meeting of Stockholders, which is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

For information with respect to principal accountant fees and services, see “Proposal 5: Ratification of Appointment of Independent Registered Public Accounting Firm” section of the Proxy Statement for the 2013 Annual Meeting of Stockholders, which is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

The following documents are included as part of this Annual Report on Form 10-K.

(a)(1) The Consolidated Financial Statements and related Notes filed as part of this Report are listed and indexed on Page 29.

(a)(2) Financial Statement Schedules:

All schedules are omitted because they are inapplicable, not required or the information is included in the Consolidated Financial Statements or the related Notes.

(a)(3) Exhibits:

The Exhibits listed in the Exhibit Index immediately preceding the Exhibits are filed as part of this Annual Report on Form 10-K.

(b) The Exhibits are set forth on the following exhibit index. Management contracts, compensatory plans and arrangements are identified in the exhibit index with an asterisk “*.”

(c) Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 28, 2013.

DARA BIOSCIENCES, INC.

By: /s/ David J. Drutz, M.D.
 David J. Drutz, M.D.,
 Chief Executive Officer/Chief Medical Officer

POWER OF ATTORNEY

We, the undersigned directors and executive officers of DARA BioSciences, Inc., hereby severally constitute and appoint David L. Tousley our true and lawful attorney and agent, with full power to him to sign for us, and in our names in the capacities indicated below, any and all amendments to the Annual Report on Form 10-K of DARA BioSciences, Inc. filed with the Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorney to any and all amendments to said Annual Report on Form 10-K.

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ David J. Drutz, M.D.</u> David J. Drutz, M.D.	Chief Executive Officer/Chief Medical Officer (Principal Executive Officer and Director)	March 28, 2013
<u>/s/ David L. Tousley</u> David L. Tousley	Acting Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 28, 2013
<u>/s/ Christopher G. Clement</u> Christopher G. Clement	Chief Operating Officer, President and Director	March 28, 2013
<u>/s/ Haywood D. Cochrane, Jr.</u> Haywood D. Cochrane, Jr.	Chairman of the Board Director	March 28, 2013
<u>/s/ Timothy J. Heady</u> Timothy J. Heady	Director	March 28, 2013
<u>/s/ Gail F. Lieberman</u> Gail F. Lieberman	Director	March 28, 2013
<u>/s/ Stephen O. Jaeger</u> Stephen O. Jaeger	Director	March 28, 2013
<u>/s/ Paul J. Richardson</u> Paul J. Richardson	Director	March 28, 2013

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference to
3.1	Restated Certificate of Incorporation of DARA BioSciences, Inc.	Incorporated by reference to the Company's Report on Form 8-K filed on February 12, 2008
3.2	Certificate of Amendment to Restated Certificate of Incorporation of DARA BioSciences, Inc.	Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010
3.3	Certificate of Designation of Preferences, Rights, and Limitations of Series A Convertible Preferred Stock	Incorporated by reference to the Company's Report on Form 8-K filed on December 29, 2010
3.4	Certificate of Designation of Preferences, Rights, and Limitations of Series B Convertible Preferred Stock	Incorporated by reference to the Company's Report on Form 8-K filed on January 18, 2012
3.5	Certificate of Designation of Preferences, Rights, and Limitations of Series B-2 Convertible Preferred Stock	Incorporated by reference to the Company's Report on Form 8-K filed on April 9, 2012
3.6	Certificate of Designation of Preferences, Rights, and Limitations of Series B-3 Convertible Preferred Stock	Incorporated by reference to the Company's Report on Form 8-K filed on December 31, 2012
3.7	Certificate of Designation of Preferences, Rights, and Limitations of Series B-4 Convertible Preferred Stock	Incorporated by reference to the Company's Report on Form 8-K filed on December 31, 2012
3.8	Amended and Restated By-Laws of DARA BioSciences, Inc.	Incorporated by reference to the Company's Report on Form 8-K filed on February 12, 2008
4.1	Specimen stock certificate for common stock	Incorporated by reference to the Company's Report on Form 8-K filed on February 12, 2008
4.2	Form of Warrant for Point Therapeutics, Inc.	Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002
4.3	Form of Investor Warrant for Point Therapeutics, Inc. dated as of September 24, 2003	Incorporated by reference to the Company's Registration Statement on Form S-1 filed on November 18, 2003
4.4	Form of Paramount Warrant for Point Therapeutics, Inc. dated as of September 24, 2003	Incorporated by reference to the Company's Registration Statement on Form S-1 filed on November 18, 2003
4.5	Form of Investor Warrant for Point Therapeutics, Inc. dated as of March 24, 2004	Incorporated by reference to the Company's Report on Form 8-K filed on April 1, 2004
4.6	Form of Investor Securities Purchase Agreement dated as of March 24, 2004	Incorporated by reference to the Company's Report on Form 8-K filed on April 1, 2004
4.7	Form of Class A Common Stock Purchase Warrant	Incorporated by reference to the Company's Report on Form 8-K filed on October 21, 2008
4.8	Form of Class B Common Stock Purchase	Incorporated by reference to the Company's Report

	Warrant	on Form 8-K filed on October 21, 2008
4.9	Form of Common Stock Purchase Warrant	Incorporated by reference to the Company's Report on Form 8-K filed on June 16, 2009
4.10	Form of Common Stock Purchase Warrant	Incorporated by reference to the Company's Report on Form 8-K filed on September 14, 2009
4.11	Form of Common Stock Purchase Warrant	Incorporated by reference to the Company's Report on Form 8-K filed on September 18, 2009
4.12	Form of Common Stock Purchase Warrant	Incorporated by reference to the Company's Report on Form 8-K filed on October 15, 2009
4.13	Form of Common Stock Purchase Warrant	Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010
4.14	Form of Class A Common Stock Purchase Warrant	Incorporated by reference to the Company's Report on Form 8-K filed on December 29, 2010
4.15	Form of Class B Common Stock Purchase Warrant	Incorporated by reference to the Company's Report on Form 8-K filed on December 29, 2010
4.16	Form of Indenture	Incorporated by reference to the Company's Registration Statement on Form S-3 filed on March 25, 2011
4.17	Form of Common Stock Purchase Warrant	Incorporated by reference to the Company's Report on Form 8-K filed on January 18, 2012
4.18	Form of Common Stock Purchase Warrant	Incorporated by reference to the Company's Report on Form 8-K filed on April 9, 2012
4.19	Form of Common Stock Purchase Warrant	Incorporated by reference to the Company's Report on Form 8-K filed on December 31, 2012
10.1	DARA BioSciences, Inc. Amended and Restated 2003 Employee, Director and Consultant Stock Plan *	Incorporated by reference to the Company's Report on Form 8-K filed on February 12, 2008
10.2	DARA BioSciences, Inc. 2008 Employee, Director and Consultant Stock Plan *	Incorporated by reference to the Company's Report on Form 8-K filed on February 12, 2008
10.3	Amendment No. 1 to DARA BioSciences, Inc. 2008 Employee, Director and Consultant Stock Plan *	Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012
10.4	Lease Agreement dated November 30, 2007, by and between DARA BioSciences, Inc. and The Prudential Insurance Company of America ("Prudential") (assigned from Prudential to Highwoods DLF Forum, LLC in 2008)	Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008
10.5	Form of Stock Option Award for 2008 Employee, Director and Consultant Stock Plan (Incentive Stock Options) *	Incorporated by reference to the Company's Registration Statement on Form S-8 filed on April 8, 2008
10.6	Form of Stock Option Award for 2008 Employee, Director and Consultant Stock Plan (Non-Qualified Options) *	Incorporated by reference to the Company's Registration Statement on Form S-8 filed on April 8, 2008

10.7	Form of Restricted Stock Award Agreement for 2008 Employee, Director and Consultant Stock Plan *	Incorporated by reference to the Company's Registration Statement on Form S-8 filed on April 8, 2008
10.8	Form of Restricted Stock Unit Award Agreement for 2008 Employee, Director and Consultant Stock Plan *	Incorporated by reference to the Company's Registration Statement on Form S-8 filed on April 8, 2008
10.9	License Agreement dated May 3, 2004, by and between The General Hospital Corporation d/b/a Massachusetts General Hospital and DARA Pharmaceuticals, Inc.**	Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008
10.10	Exclusive License Agreement effective July 1, 2004, by and between Kirin Brewery Company, Limited and DARA Therapeutics, Inc.**	Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008
10.11	Exclusive License Agreement dated October 8, 2007, by and between Bayer Pharmaceuticals Corporation and DARA BioSciences, Inc.**	Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008
10.12	Stock Purchase and Loan Agreement dated January 30, 2009, by and between DARA BioSciences, Inc. and SurgiVision, Inc.	Incorporated by reference to the Company's Report on Form 8-K filed on January 30, 2009
10.13	Stock Purchase Agreement, dated December 31, 2009, by and between DARA Pharmaceuticals, Inc. and SurgiVision, Inc.	Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2009
10.14	First Amendment to License Agreement dated July 7, 2009 by and between The General Hospital Corporation d/b/a Massachusetts General Hospital and DARA Pharmaceuticals, Inc.	Incorporated by reference to the Company's Registration Statement on Form S-1/A filed on May 17, 2010
10.15	Agreement between DARA Therapeutics, Inc., a Subsidiary of DARA BioSciences, Inc., and the Division of Cancer Prevention, National Cancer Institute for the Clinical Development of KRN5500 dated April 26, 2010	Incorporated by reference to the Company's Report on Form 8-K filed on April 30, 2010
10.16	Employment Agreement, dated January 17, 2012, by and between DARA BioSciences, Inc. and David J. Drutz *	Incorporated by reference to the Company's Report on Form 8-K filed on January 17, 2012
10.17	Employment Agreement, dated January 17, 2012, by and between DARA BioSciences, Inc. and Christopher Clement *	Incorporated by reference to the Company's Report on Form 8-K filed on January 17, 2012
10.18	Agreement and Plan of Merger, dated January 17, 2012, by and among DARA BioSciences, Inc., Oncogenex, Inc. and certain other parties thereto	Incorporated by reference to the Company's Report on Form 8-K filed on January 17, 2012
10.19	Form of Securities Purchase Agreement	Incorporated by reference to the Company's Report on Form 8-K filed on January 18, 2012
10.20	Placement Agent Agreement, dated January	Incorporated by reference to the Company's Report

	17, 2012, by and between DARA BioSciences, Inc. and Ladenburg Thalman & Co., Inc.	on Form 8-K filed on January 18, 2012
10.21	Form of Securities Purchase Agreement	Incorporated by reference to the Company's Report on Form 8-K filed on April 9, 2012
10.22	Placement Agent Agreement, dated April 6, 2012, by and between DARA BioSciences, Inc. and Ladenburg Thalman & Co., Inc.	Incorporated by reference to the Company's Report on Form 8-K filed on April 9, 2012
10.23	Form of Securities Purchase Agreement	Incorporated by reference to the Company's Report on Form 8-K filed on December 31, 2012
10.24	Placement Agent Agreement, dated December 28, 2012, by and between DARA BioSciences, Inc. and Ladenburg Thalman & Co., Inc.	Incorporated by reference to the Company's Report on Form 8-K filed on December 31, 2012
10.25	Employment Agreement, dated March 1, 2013, by and between DARA BioSciences, Inc. and David L. Tousley *	Incorporated by reference to the Company's Report on Form 8-K filed on March 5, 2013
21	Subsidiaries of DARA BioSciences, Inc.	
23.1	Consent of Horne LLP	
23.2	Consent of Ernst & Young LLP	
24	Power of Attorney	Included on signature page
31.1	Certification of David J. Drutz, M.D. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 28, 2013	
31.2	Certification of David L. Tousley pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 28, 2013	
32	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 28, 2013	
101	Interactive Data Files	

* Management Contract or Compensatory Plan or Arrangement.

** Confidential Treatment requested for certain portions of this Agreement.