

# TALON THERAPEUTICS, INC.

## FORM 10-K (Annual Report)

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

FORM 10-K

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

For the fiscal year ended: December 31, 2010

or

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

For the transition period from: \_\_\_\_\_ to \_\_\_\_\_

**Talon Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation or Organization)

**1-32626**  
(Commission  
File Number)

**32-0064979**  
(I.R.S. Employer  
Identification No.)

**2207 Bridgepointe Parkway Suite 250, San Mateo, California 94404**

(Address of Principal Executive Office) (Zip Code)

**(650) 588-6404**

(Registrant's telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:** None

**Securities registered pursuant to Section 12(g) of the Act:** Common stock, \$0.001 par value

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 (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of 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, or a smaller reporting company.

Large accelerated filer  Accelerated filer  Non-accelerated filer  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 approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was \$11.4 million as of June 30, 2010, based on the last sale price of the registrant's common stock as reported on the OTC Bulletin Board on such date.

As of March 28, 2011, there were 21,242,772 shares of the registrant's common stock outstanding.

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## FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These forward-looking statements include, but are not limited to, statements about:

- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- our ability to secure funding for our planned future operations;
- the regulatory approval of our drug candidates;
- our use of clinical research centers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- acceptance of our products by doctors, patients or payors and the availability of reimbursement for our product candidates;
- our ability to market any of our products;
- our history of operating losses;
- our ability to secure adequate protection for our intellectual property;
- our ability to compete against other companies and research institutions;
- the effect of potential strategic transactions on our business;
- our ability to attract and retain key personnel;
- the volatility of our stock price; and
- other risks and uncertainties detailed in “Risk Factors” in this Form 10-K.

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe” “intend” and similar words or phrases. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Annual Report on Form 10-K are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Annual Report on Form 10-K was filed with the Securities and Exchange Commission, or SEC. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Discussions containing these forward-looking statements may be found throughout this Form 10-K, including Part I, the sections entitled “Item 1: Description of Business” as well as “Item 1A: Risk Factors” and Part II, the sections entitled “Item 7: Management’s Discussion and Analysis of Financial Condition and Results of Operations or Plan of Operations.” These forward-looking statements involve risks and uncertainties, including the risks discussed in Part I of this form in the section entitled “Item 1A: Risk Factors,” that could cause our actual results to differ materially from those in the forward-looking statements. Except as required by law, we undertake no obligation to publicly revise our forward-looking statements to reflect events or circumstances that arise after the filing of this Annual Report on Form 10-K or documents incorporated by reference herein that include forward-looking statements. The risks discussed in this report should be considered in evaluating our prospects and future financial performance.

In addition, past financial or operating performance is not necessarily a reliable indicator of future performance and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition.

References to the “Company,” “Talon,” the “Registrant,” “we,” “us,” or “our” in this Annual Report on Form 10-K refer to Talon Therapeutics, Inc., a Delaware corporation, unless the context indicates otherwise. Marqibo® is our U.S. registered trademark for our vincristine sulfate liposomes injections product candidate. Alocrest™ and Brakiva™ are our trademarks for our vinorelbine liposome injection and topotecan liposome injection product candidates, respectively. Optisome™ is our trademark for our liposome encapsulation technology, which we currently utilize with respect to our Marqibo, Alocrest and Brakiva product candidates. We have applied for registration for our Alocrest, Brakiva and Optisome trademarks, and for our Talon Therapeutics logo, in the United States. All other trademarks and trade names mentioned in this Annual Report on Form 10-K are the properties of their respective owners.

## PART I

### ITEM 1. BUSINESS

#### Overview

We are a San Mateo, California-based biopharmaceutical company dedicated to developing and commercializing new and differentiated cancer therapies designed to improve and enable current standards of care. Our two lead product candidates target large markets. We are developing Marqibo for the treatment of acute lymphoblastic leukemia and other blood cancers including lymphoma. Menadione topical lotion is a first-in-class compound that we are developing for the potential prevention and/or treatment of skin toxicity associated with epidermal growth factor receptor inhibitors. We have additional pipeline opportunities that, like Marqibo, we believe may improve delivery and enhance the therapeutic benefits of well-characterized, proven chemotherapies and enable high potency dosing without increased toxicity.

Our executive offices are located at 2207 Bridgepointe Parkway Suite 250, San Mateo, California 94404. Our telephone number is (650) 588-6404 and our Internet address is [www.talontx.com](http://www.talontx.com). We were originally incorporated under Delaware law in 2002 under the name Hudson Health Sciences, Inc. In July 2004, we acquired Email Real Estate.com, Inc., a Colorado corporation and public shell company in a reverse acquisition. In September 2004, we reincorporated under Delaware law under the name Hana Biosciences, Inc. In December 2010, we changed our name to Talon Therapeutics, Inc.

#### Our Research and Development Programs

We currently have rights to the following product candidates in various stages of development:

- Marqibo® (vincristine sulfate liposomes injection), our lead product candidate, is a novel, targeted Optisome™ encapsulated formulation product candidate of the Food and Drug Administration (FDA)-approved anticancer drug vincristine, currently in development primarily for the treatment of adult acute lymphoblastic leukemia, or ALL, in second or greater relapse or that has progressed following two or more prior lines of anti-leukemia therapy.
- Menadione Topical Lotion, a novel supportive care product candidate being developed for the prevention and/or treatment of the skin toxicities associated with the use of epidermal growth factor receptor inhibitors, or EGFRIs, a type of anti-cancer agent used in the treatment of lung, colon, head and neck, pancreatic and breast cancer.
- Brakiva™ (topotecan liposome injection), a novel targeted™ Optisome™ encapsulated formulation product candidate of the FDA-approved anticancer drug topotecan.
- Alocrest™ (vinorelbine liposome injection), a novel, targeted Optisome™ encapsulated formulation product candidate of the FDA-approved anticancer drug vinorelbine.

#### Industry Background and Market Opportunity

Cancer is a group of diseases characterized by either the uncontrolled growth of cells or the failure of cells to function normally. Cancer is caused by a series of mutations, or alterations, in genes that control cells' ability to grow and divide. These mutations cause cells to rapidly and continuously divide or lose their normal ability to die. There are more than 100 different varieties of cancer, which can be divided into six major categories. Carcinomas, the most common category, include breast, lung, colorectal and prostate cancer. Sarcomas begin in tissue that connects, supports or surrounds other tissues and organs. Lymphomas are cancers of the lymphatic system, a part of the body's immune system. Leukemias are cancers of blood cells, which originate in the bone marrow. Brain tumors are cancers that begin in the brain, and skin cancers, including melanomas, originate in the skin. Cancers are considered metastatic if they spread via the blood or lymphatic system to other parts of the body to form secondary tumors.

According to the American Cancer Society, over 1.5 million new cases of cancer were expected to be diagnosed in 2010 in the United States alone. Cancer is the second leading cause of death, after heart disease, in the United States, and was expected to account for more than 569,000 deaths in 2010. Major cancer treatments include surgery, radiotherapy and chemotherapy. Supportive care, such as blood cell growth factors, represents another major segment of the cancer treatment market. There are many different drugs that are used to offer supportive care and to treat cancer, including cytotoxics or antineoplastics, hormones and biologics. Major categories include:

- *Chemotherapy* . Cytotoxic chemotherapy refers to anticancer drugs that destroy cancer cells by stopping them from multiplying. Healthy cells can also be harmed with the use of cytotoxic chemotherapy, especially those that divide quickly. Cytotoxic agents act primarily on macromolecular synthesis, repair or activity, which affects the production or function of DNA, RNA or proteins. Our product candidates Marqibo, Alocrest and Brakiva are liposome encapsulated cytotoxic agents that we are currently evaluating for the treatment of solid tumor and hematological malignancies.
- *Supportive care* . Cancer treatment can include the use of chemotherapy, radiation therapy, biologic response modifiers, surgery or some combination of these or other therapeutic options. All of these treatment options are directed at killing or eradicating the cancer that exists in the patient's body. Unfortunately, the delivery of many cancer therapies adversely affects the body's normal organs. These complications of treatment or side effects not only cause discomfort, but may also prevent the optimal delivery of therapy to a patient at its maximal dose and time. Our product candidate Menadione Topical Lotion is a supportive care product candidate designed to treat and prevent skin toxicities associated with the use of EGFRIs, a class of anti-cancer agents.

## **Our Strategy**

We are committed to developing and commercializing new, differentiated cancer therapies designed to improve and enable current standards of care. Key aspects of our strategy include:

- *Focus on developing innovative cancer therapies* . We focus on oncology product candidates in order to capture efficiencies and economies of scale. We believe that drug development for cancer markets is particularly attractive because relatively small clinical trials can provide meaningful information regarding patient response and safety. Our main focus is the development of Marqibo, our lead product candidate.
- *Build a sustainable pipeline by employing multiple therapeutic approaches and disciplined decision criteria based on clearly defined proof of principle goals* . We seek to build a sustainable product pipeline by employing multiple therapeutic approaches and by acquiring product candidates belonging to known drug classes. In addition, we employ disciplined decision criteria to assess product candidates. By pursuing this strategy, we seek to minimize our clinical development risk and accelerate the potential commercialization of current and future product candidates. For a majority of our product candidates, we intend to pursue regulatory approval in multiple indications.

## **Product Pipeline**

### ***Background of Optisomal Targeted Drug Delivery***

Optisomal encapsulation is a novel method of liposomal drug delivery, which is designed to significantly increase tumor targeting and duration of exposure for cell-cycle specific anticancer agents, such as vincristine sulfate, an FDA-approved chemotherapy drug. Optisomal drug delivery involves the encapsulation of an appropriate drug in a lipid envelope composed of sphingomyelin and cholesterol. The encapsulated agent is carried through the bloodstream and delivered to disease sites where it is released to carry out its therapeutic action. When used in unencapsulated form, chemotherapeutic drugs mostly diffuse indiscriminately throughout the body, diluting drug effectiveness and potentially causing toxic side effects in the patient's healthy tissues. Our proprietary Optisomal formulation technology is designed to permit loading high concentrations of therapeutic agent inside the lipid envelope, which promotes accumulation of the drug in tumors and prolongs the drug's release at disease sites. Non-clinical studies have demonstrated the Optisomal formulation technology's ability to deliver dose intensification to the tumor, which we believe has the potential to increase the therapeutic benefit of the drug.

- *Targeted delivery with improved pharmacokinetics* . In normal tissues, a continuous endothelial (blood vessel) lining constrains liposomes within capillaries, limiting accumulation of the drug in the healthy tissues. In contrast, the immature blood vessel system within tumors is created during tumor growth and has numerous gaps up to 800 nanometers in size. With an average diameter of approximately 100 nanometers, Optisomes can pass through these gaps. Once lodged within the tumor interstitial space, these Optisomes gradually release the encapsulated drug. We believe that gradual release of the drug from Optisomes increases drug levels within the tumor, extends drug exposure through multiple cell cycles, and increases tumor cell killing. A limited fraction of a patient's tumor cells are in a particular drug-sensitive phase at any point in time, which we believe indicates that duration of drug exposure is critical to increased drug efficacy.
- *Increased drug concentration* . The link between drug exposure and anti-tumor efficacy is especially pronounced for cell cycle-specific agents such as vincristine, vinorelbine and topotecan, which destroy tumor cells by interfering in one specific phase in cell division (e.g., the mitosis, synthesis and/or rapid growth phases).
- *Prolonged exposure* . The advanced liposomal technology of the capsule which protects the active drug increases the circulating half-life and is designed to extend the duration of drug release within cancerous tissues.

## ***Unmet Medical Needs in ALL***

ALL is a type of cancer of the blood and bone marrow, the spongy tissue inside bones where blood cells are made. Acute leukemias progress rapidly and are characterized by the accumulation of immature blood cells. ALL affects a group of white blood cells, called lymphocytes, which fight infection and constitute our immune systems. Normally, bone marrow produces immature cells or stem cells, in a controlled way, and they mature and specialize into the various types of blood cells, as needed. In people with ALL, this production process breaks down. Abnormally large numbers of immature, abnormal lymphocytes called lymphoblasts are produced and released into the bloodstream. These abnormal cells are not able to mature and perform their usual functions. Furthermore, they multiply rapidly and can crowd out healthy blood cells like neutrophils and platelets, leaving an adult or child with ALL vulnerable to infection or bleeding. Leukemic cells can also collect in certain areas of the body, including the central nervous system and spinal cord, which can cause serious problems. According to the American Cancer Society, over 5,000 people in the United States over the age of 15 were expected to be diagnosed with ALL in 2010, and over 1,400 people were expected to die from the disease. Multiple clinical trials have suggested the overall 5-year survival rate for adults diagnosed with ALL is approximately 20% to 50%, underscoring the need for new therapeutic options.

### ***Marqibo® (vincristine sulfate liposomes injection)***

Marqibo is a novel, targeted Optisome™ encapsulated formulation product candidate of the FDA-approved anticancer drug vincristine. We are primarily developing Marqibo for the treatment of adult ALL. Vincristine, a microtubule inhibitor, is FDA-approved for ALL and is widely used as a single agent and in combination regimens for treatment for hematologic malignancies such as lymphomas and leukemias. Our encapsulation formulation is designed to provide prolonged circulation of the drug in the blood and accumulation at the tumor site. These characteristics are intended to increase the effectiveness and potentially reduce the side effects of the encapsulated drug.

Marqibo has been evaluated in 18 clinical trials with over 700 patients, including Phase 2 clinical trials in patients with non-Hodgkin's lymphoma, or NHL and ALL. Based on the results from these studies, in 2007 we initiated a global, Phase 2 clinical trial of Marqibo in adult Philadelphia chromosome negative ALL patients in second relapse, or those who have progressed following two or greater prior lines of anti-leukemia therapy. We refer to this clinical trial as the rALLY study. The primary outcome measure was complete remission, or CR, or complete remission without full hematologic recovery, which we refer to as CRi.

We completed the rALLY study in 2010 and announced data at the 2010 Annual Meeting of the American Society of Clinical Oncology. The sample size from the study consisted of 65 evaluable subjects. The analysis of the study data demonstrated an overall response rate (measured by CR, CRi, partial remission and bone marrow blast count normalization without blood count recovery) reported by study investigators in 23 of the 65 evaluable subjects, or 35 percent. Thirteen subjects, or 20 percent, experienced a CR or CRi. As of the announcement of the study results, the estimated median overall survival in complete responders was 7.7 months, with five subjects having an overall survival of more than one year. The estimated median duration of CR/CRi was 5.4 months. Eleven subjects participating in the rALLY study went on to receive a potentially life-saving stem cell transplant. The data also showed that the safety profile of Marqibo was predictable, manageable and similar to standard vincristine sulfate.

Based on the data from the rALLY study, in the first half of 2011, we plan to submit to the FDA a New Drug Application, or NDA, seeking accelerated approval of Marqibo in Ph- adult ALL, in second or greater relapse or that has progressed following two or more prior lines of anti-leukemia therapy. At a February 8, 2011 meeting of the FDA's Oncology Drug Advisory Committee, or ODAC, the FDA indicated that a drug sponsor and the FDA must agree on the feasibility and design of Phase 3 confirmatory studies as a necessary element in the NDA submission process for those sponsors seeking accelerated approval. According to the FDA, a sponsor seeking accelerated approval should not submit its NDA until such agreement on Phase 3 confirmatory studies has been finalized. Our NDA submission may be delayed if the FDA does not accept our proposed confirmatory Phase 3 study.

In addition, we are conducting a Phase 2 study to assess the efficacy of Marqibo in patients with metastatic malignant uveal melanoma as determined by Disease Control Rate (CR, partial response or durable stable disease). Secondary objectives are to assess the safety and antitumor activity of Marqibo as determined by response rate, progression free survival and overall survival. In addition, patients undergo continuous electrocardiographic evaluation during the first dose of Marqibo exposure. The patient population is defined as adults with uveal melanoma and confirmed metastatic disease that is untreated. We have enrolled 49 subjects to date and plan to enroll up to a total of approximately 59 subjects in this clinical trial.

Marqibo received a U.S. orphan drug designation in January 2007 as well as a European Commission orphan drug designation in June 2008 for the ALL indication. Marqibo also received a U.S. orphan drug designation in July 2008 for metastatic uveal melanoma. Marqibo received a fast track designation from the FDA in August 2007 for the treatment of adult ALL in second or greater relapse or that has progressed following two or more prior lines of anti-leukemia therapy.

### ***Menadione Topical Lotion (Supportive Care Product)***

Menadione Topical Lotion, or MTL, which we licensed from the Albert Einstein College of Medicine, or AECOM, in October 2006, is a novel, product candidate under development for the treatment and/or prevention of skin rash associated with the use of EGFR inhibitors in the treatment of certain cancers. EGFR inhibitors, which include Tarceva, Erbitux, Iressa, Tykerb and Vectibix, are currently approved to treat non-small cell lung cancer, pancreatic, colorectal, breast and head and neck cancer. EGFR inhibitors are associated with significant skin toxicities presenting as acne-like rash on the face, neck and upper-torso of the body in approximately 75% of patients. Fifty percent of patients who manifest skin toxicity experience significant discomfort. This results in discontinuation or dose reduction in at least 10% and up to 30% of patients that receive the EGFR inhibitor. Menadione, a small organic molecule, has been shown to activate the EGFR signaling pathway by inhibiting phosphatase activity which is an important enzyme in the EGFR pathway. In vivo studies have suggested that topically-applied menadione may restore EGFR signaling specifically in the skin of patients treated systemically with EGFR inhibitors. Currently, there are no FDA-approved products or therapies available to treat these skin toxicities.

We completed enrollment of a Phase 1 clinical trial in cancer patients. The primary endpoints for the Phase 1 study included safety, tolerability and identification of a maximum tolerated dose. The results of the Phase 1 study demonstrated that MTL is generally safe and well-tolerated. A dose limiting toxicity of skin irritation and redness was observed primarily at the 0.2% lotion strength. The apparent maximum tolerated lotion strength is 0.1%. MTL applied twice daily at all strengths, including the highest lotion strength tested (0.2%) resulted in no appreciable systemic exposure.

Following the completion of the Phase 1 study, we are continuing to evaluate the development plan for MTL. However, our immediate strategy is to seek a partner to enhance and accelerate the future development of MTL.

### ***Brakiva™ (topotecan liposome injection)***

Brakiva is our proprietary product candidate comprised of the anti-cancer drug topotecan encapsulated in Optisomes. Topotecan is FDA-approved for the treatment of metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy, and small cell lung cancer sensitive disease after failure of first-line chemotherapy. In November 2008, we initiated a Phase 1 dose-escalation clinical trial of Brakiva, which is primarily designed to assess the safety, tolerability and maximum tolerated dose.

### ***Alocrest™ (vinorelbine liposome injection)***

Alocrest is a novel Optosomal encapsulated formulation product candidate of the FDA-approved drug vinorelbine, a microtubule inhibitor for use as a single agent or in combination with cisplatin for the first-line treatment of unresectable, advanced non-small cell lung cancer. In February 2008, we completed enrollment in a Phase 1 study of Alocrest. The trial enrolled 30 adult subjects with confirmed solid tumors refractory to standard therapy or for which no standard therapy was known to exist. The objectives of the Phase 1 clinical trial were: (1) to assess the safety and tolerability of Alocrest; (2) to determine the maximum tolerated dose of Alocrest; (3) to characterize the pharmacokinetic profile of Alocrest; and (4) to explore preliminary efficacy of Alocrest. The study was conducted at the Cancer Therapy and Research Center and South Texas Accelerated Research Therapeutics (START), both located in San Antonio, Texas and at McGill University in Montreal. Reversible neutropenia, a low white blood cell count, was the dose-limiting toxicity. The results of this study revealed expected toxicity, and a 50% disease control rate was achieved across a range of doses in patients with previously treated, advanced cancers.

## **License Agreements**

### ***Marqibo, Alocrest and Brakiva***

In May 2006, we completed a transaction with Tekmira Pharmaceuticals Corporation, formerly Inex Pharmaceuticals Corporation, pursuant to which we acquired exclusive, worldwide rights to develop and commercialize Marqibo, Alocrest and Brakiva, which we collectively refer to as the Optisome products. The following is a summary of the various agreements entered into to consummate the transaction.

#### *Tekmira License Agreement*

Pursuant to the terms of a license agreement between us and Tekmira dated May 6, 2006, which was amended and restated on April 30, 2007, and further amended in June 2009 and September 2010, Tekmira granted us:

- an exclusive license under certain patents held by Tekmira to commercialize the Optisome products for all uses throughout the world;
- an exclusive license under certain patents held by Tekmira to commercialize the Optisome products for all uses throughout the world under the terms of certain research agreements between Tekmira and the British Columbia Cancer Agency, or BCCA; and
- an exclusive license to all technical information and know-how relating to the technology claimed in the patents held exclusively by Tekmira and to all confidential information possessed by Tekmira relating to the Optisome products, including all data, know-how, manufacturing information, specifications and trade secrets, collectively called the Tekmira Technology, to commercialize the Optisome products for all uses throughout the world.

We have the right to grant sublicenses to third parties and in such event we and Tekmira will share sublicensing revenue received by us at varying rates for each Optisome product depending on such Optisome product's stage of clinical development. Under the license agreement, we also granted back to Tekmira a limited, royalty-free, non-exclusive license in certain patents and technology owned or licensed to us solely for use in developing and commercializing liposomes having an active agent encapsulated, intercalated or entrapped therein.

We and Tekmira amended the terms of the license agreement in June 2009, which is summarized as follows:

- As amended, the amount of the milestone payment that we are required to make to Tekmira upon the FDA's approval of a Marqibo NDA was increased.
- The original license agreement previously required us to make milestone payments upon the dosing of the first patient in any clinical trial of each of Alocrest and Brakiva. Following the June 2009 amendment, such milestones are payable following the FDA's acceptance for review of an NDA for such product candidates. In addition, the milestone payments payable under the license agreement upon the FDA's approval of an NDA for Alocrest and Brakiva were both increased in amount.
- Tekmira's share of any payments received by us from third parties in consideration of sublicenses granted to such third parties or for royalties received by us from such third parties was reduced.
- The maximum aggregate amount of milestone payments for all product candidates was increased from \$30.5 million to \$37.0 million.

As a result of the June 2009 amendment, we reversed recognition of a previously accrued milestone payment to Tekmira which was achieved upon the enrollment of the first patient in our Phase 1 clinical trial in Brakiva.

In September 2010, we and Tekmira further amended the terms of the license agreement, as follows:

- Our maximum aggregate obligation for milestone payments to Tekmira for all three product candidates was decreased from \$37.0 million to \$19.0 million. All of the affected milestone payment obligations relate to amounts triggered by the achievement of regulatory milestones for Marqibo.
- The royalty rates payable by us for net sales of Marqibo were modified by eliminating a tiered royalty rate structure based upon the amount of net sales and instead now provide for a single royalty rate without regard to the amount of net sales. With respect to Alocrest and Brakiva, the license agreement continues to provide that we will pay royalties to Tekmira in the range of 5% to 10% of net sales, against which we may offset a portion of the research and development expenses we incur in connection with the development of those product candidates.
- In consideration of the foregoing, we made a one-time payment to Tekmira of \$5.75 million.

Pursuant to the terms of the Tekmira license, including all amendments, at our option the milestones may be paid in cash or, subject to certain restrictions, shares of our common stock. In addition to our obligations to make milestone payments and pay royalties to Tekmira, we also assumed all of Tekmira's obligations to its licensors and collaborators relating to the Optisome products, which include aggregate milestone payments of up to \$2.5 million, annual license fees and additional royalties.

The license agreement also provides that we will use our commercially reasonable efforts to develop each Optisome product, including causing the necessary and appropriate clinical trials to be conducted in order to obtain and maintain regulatory approval for each Optisome product and preparing and filing the necessary regulatory submissions for each Optisome product. We also agreed to provide Tekmira with periodic reports concerning the status of each Optisome product.

We are required to use commercially reasonable efforts to commercialize each Optisome product in each jurisdiction where an Optisome product has received regulatory approval. We will be deemed to have breached our commercialization obligations in the United States, or in Germany, the United Kingdom, France, Italy or Spain, if for a continuous period of 180 days at any time following commercial sales of an Optisome product in any such country, no sales of an Optisome product are made in the ordinary course of business in such country by us (or a sublicensee), unless the parties agree to such delay or unless we are prohibited from making sales by a reason beyond our control. If we breach this obligation, then Tekmira is entitled to terminate the license with respect to such Optisome product and for such country.

Under the license agreement, Tekmira will be the owner of patents and patent applications claiming priority to certain patents licensed to us, and we have an obligation to assign to Tekmira our rights to inventions covered by such patents or patent applications, and, when negotiating any joint venture, collaborative research, development, commercialization or other agreement with a third party, to require such third party to do the same.

The prosecution and maintenance of the licensed patents will be overseen by an IP committee having equal representation from us and Tekmira. We will have the right and obligation to file, prosecute and maintain most of the licensed patents, although Tekmira maintained primary responsibility to prosecute certain of the licensed patents. The parties agreed to share the expenses of prosecution at varying rates. We also have the first right, but not the obligation, to enforce such licensed patents against third party infringers, or to defend against any infringement action brought by any third party.

We agreed to indemnify Tekmira for all losses resulting from our breach of our representations and warranties, or other default under the license agreement, our breach of any regulatory requirements, regulations and guidelines in connection with the Optisome products, complaints alleging infringement against Tekmira with respect to our manufacture, use or sale of an Optisome product, and any injury or death to any person or damage to property caused by any Optisome product provided by us or our sublicensee, except to the extent such losses are due to Tekmira's breach of a representation or warranty, Tekmira's default under the agreement, and the breach by Tekmira of any regulatory requirements, regulations and guidelines in connection with licensed patent and related know-how. Tekmira has agreed to indemnify us for losses arising from Tekmira's breach of representation or warranty, Tekmira's default under the agreement, and the breach by Tekmira of any regulatory requirements, regulations and guidelines in connection with licensed patent and related know-how, except to the extent such losses are due to our breach of our representations and warranties, our default under the agreement, our breach of any regulatory requirements, regulations and guidelines in connection with the Optisome products, complaints alleging infringement against Tekmira with respect to our manufacture, use or sale of an Optisome product, and any injury or death to any person or damage to property caused by any Optisome product provided by us or our sublicensee.

Unless terminated earlier, the license grants made under the license agreement expire on a country-by-country basis upon the later of (i) the expiration of the last to expire patents covering each Optisome product in a particular country, (ii) the expiration of the last to expire period of product exclusivity covered by an Optisome product under the laws of such country, or (iii) with respect to the Tekmira Technology, on the date that all of the Tekmira Technology ceases to be confidential information. The covered issued patents are scheduled to expire between 2014 and 2021.

Either we or Tekmira may terminate the license agreement in the event that the other has materially breached its obligations thereunder and fails to remedy such breach within 90 days following notice by the non-breaching party. If such breach is not cured, then the non-breaching party may, upon 6 months' notice to the breaching party, terminate the license in respect of the Optisome products or countries to which the breach relates. Tekmira may also terminate the license if we assert or intend to assert any invalidity challenge on any of the patents licensed to us. The license agreement also provides that either party may, upon written notice, terminate the agreement in the event of the other's bankruptcy, insolvency, dissolution or similar proceeding. In the event Tekmira validly terminates the license agreement, all data, materials, regulatory filings and all other documentation reverts to Tekmira.

In April 2007, Tekmira assigned to us its right and interest in and to a Patent and Technology License Agreement dated February 14, 2000 between Tekmira and M.D. Anderson Cancer Center. As assigned to us, this agreement grants to us a royalty-bearing license to certain patents relating to Marqibo that are owned by M.D. Anderson. As consideration for the license, we are required to pay to M.D. Anderson royalties on net sales of Marqibo, as well as an annual maintenance fee. The M.D. Anderson license provides that we have the first right to prosecute and maintain the licensed patents at our expense. In addition, we also have the first right to control any infringement claims against third parties. The M.D. Anderson license will be automatically terminated in the event we become bankrupt or insolvent, and may be terminated by M.D. Anderson in the event we default on our obligations under the agreement.

#### *UBC Sublicense Agreement*

In May 2006, we also entered into a sublicense agreement with Tekmira relating to Tekmira's rights to certain patents it licensed from the University of British Columbia, or UBC. Under the UBC sublicense agreement, Tekmira granted to us an exclusive, worldwide sublicense under several patents relating to Alocrest and Brakiva, together with all knowledge, know-how, and techniques relating to such patents, called the UBC Technology. The UBC Technology is owned by UBC and licensed to Tekmira pursuant to a license agreement dated July 1, 1998. The UBC sublicense agreement provides that we will undertake all of Tekmira's obligations contained in Tekmira's license agreement with UBC, which includes the payment of royalties (in addition to the royalties owing to Tekmira under the license agreement between Tekmira and us) and an annual license fee. The provisions of the UBC sublicense agreement relating to our obligation to develop and commercialize the UBC Technology, termination and other material obligations are substantially similar to the terms of license agreement between Tekmira and us, as discussed above.

#### *Assignment of Agreement with Elan Pharmaceuticals, Inc.*

Pursuant to an Amended and Restated License Agreement dated April 3, 2003, between Tekmira (including two of its wholly-owned subsidiaries) and Elan Pharmaceuticals, Inc., Tekmira held a paid up, exclusive, worldwide license to certain patents, know-how and other intellectual property relating to vincristine sulfate liposomes. In connection with our transaction with Tekmira, Tekmira assigned to us all of its rights under the Elan license agreement pursuant to an Assignment and Novation Agreement dated May 6, 2006 among us, Tekmira and Elan.

As assigned to us, the Elan license agreement provides that Elan will own all improvements to the licensed patents or licensed know-how made by us or our sublicensees, which will in turn be licensed to us as part of the technology we license from Elan. Elan has the first right to file, prosecute and maintain all licensed patents and we have the right to do so if Elan decides that it does not wish to do so only pertaining to certain portions of the technology. Elan also has the first right to enforce such licensed patents and we may do so only if Elan elects not to enforce such patents. In addition, Elan has the right but not the obligation to control any infringement claim brought against Elan.

We have indemnification obligations to Elan for all losses arising from the research, testing, manufacture, transport, packaging, storage, handling, distribution, marketing, advertising, promotion or sale of the products by us, our affiliates or sublicensees, any personal injury suits brought against Elan, any infringement claim, certain third party agreements entered into by Elan, and any acts or omissions of any of our sublicensees.

The Elan license agreement, unless earlier terminated, will expire on a country by country basis, upon the expiration of the life of the last to expire licensed patent in that country. Elan may terminate the Elan license agreement earlier for our material breach upon 60 days' written notice if we do not cure such breach within such 60 day period (we may extend such cure period for up to 90 days if we propose a course of action to cure the breach within the initial 60 day period and act in good faith to cure such breach), for our bankruptcy or going into liquidation upon 10 days' written notice, or immediately if we, or our sublicense, directly or indirectly disputes the ownership, scope or validity of any of the licensed technology or support any such attack by a third party.

### ***Menadione Topical Lotion***

In October 2006, we entered into a license agreement with the Albert Einstein College of Medicine of Yeshiva University, a division of Yeshiva University, or the College. Pursuant to the agreement, we acquired an exclusive, worldwide, royalty-bearing license to certain patent applications, and other intellectual property relating to topical menadione. We are required to make milestone payments in the aggregate amount of \$2.8 million upon the achievement of various clinical and regulatory milestones, as described in the agreement. We also agreed to pay annual maintenance fees, and to make royalty payments to the College on net sales of any products covered by a claim in any licensed patent. We may also grant sublicenses to the licensed patents and the proceeds resulting from such sublicenses will be shared with the College.

## **Intellectual Property**

### ***General***

Patents and other proprietary rights are very important to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. It is our intention to seek and maintain patent and trade secret protection for our product candidates and our proprietary technologies. As part of our business strategy, our policy is to actively file patent applications in the United States and internationally to cover methods of use, new chemical compounds, pharmaceutical compositions and dosing of the compounds and compositions and improvements in each of these. We also rely on trade secret information, technical know-how, innovation and agreements with third parties to continuously expand and protect our competitive position. We own, or license the rights to, a number of patents and patent applications related to our product candidates, but we cannot be certain that issued patents will be enforceable or provide adequate protection or that the pending patent applications will issue as patents.

The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict with certainty the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the United States that claim technology also claimed by us, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our product candidates, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent.

If patents are issued to others containing preclusive or conflicting claims and these claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative technology. Our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. Litigation would create substantial costs. An adverse outcome in litigation could subject us to significant liabilities to third parties and require us to seek licenses of the disputed rights from third parties or to cease using the technology if such licenses are unavailable.

### ***Optisomal Product Candidates***

Pursuant to our license agreement with Tekmira and related sublicense with UBC, we have exclusive rights to 14 issued U.S. patents, 78 issued foreign patents, 4 pending U.S. patent applications and 19 pending foreign applications, covering composition of matter, method of use and treatment, formulation and process. These patents and patent applications cover sphingosine based pharmaceutical compositions including Marqibo, Alocrest and Brakiva, formulation, dosage, process of making the liposome compositions, and methods of use of the compositions in the treatment cancer, relapsed cancer, and solid tumors. The earliest of these issued patents expires in 2014 and the last of the issued patents expires in 2021.

### ***Menadione Topical Lotion***

We have exclusive, worldwide rights to a patent family consisting of one issued U.S. patent; one issued foreign patent and five pending foreign patent applications pursuant to our October 2006 license agreement with AECOM. The issued patent, which expires in 2026, covers a method of using menadione topical lotion in treating skin rash in patients taking biologic and small molecule EGFR inhibitors. The patent applications cover, pharmaceutical compositions and methods of use (e.g., methods of treating and preventing a skin rash secondary to an anti-EGFR therapy). If any foreign patent issues from these applications, such a patent would be scheduled to expire in 2026, excluding any patent term extensions.

In addition, we solely own two pending provisional U.S. patent applications relating to menadione. These applications cover topical formulations and methods of using menadione topical lotion in treating skin rash in patients taking biologic and small molecule EGFR inhibitors. If any patents issue from such applications, they would expire in 2029.

### ***Other Intellectual Property Rights***

We also depend upon trademarks, trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

In addition to patent protection, we may utilize orphan drug regulations to provide market exclusivity for certain of our product candidates. The orphan drug regulations of the FDA provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the United States, or, diseases that affect more than 200,000 individuals in the United States but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product. We believe that certain of the indications for our product candidates will be eligible for orphan drug designation; however, we cannot assure you that our drugs will obtain such orphan drug designation or will be the first to reach the market and provide us with such market exclusivity protection.

### **Government Regulation and Product Approval**

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the testing (preclinical and clinical), manufacturing, labeling, storage, recordkeeping, advertising, promotion, import, export, marketing and distribution, among other things, of drugs and drug product candidates. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted. We and our manufacturers may also be subject to regulations under other United States federal, state, and local laws.

### ***United States Government Regulation***

In the United States, the FDA regulates drugs under the Food, Drug and Cosmetic Act, or FDCA, and implementing regulations. The process required by the FDA before our product candidates may be marketed in the United States generally involves the following (although the FDA is given wide discretion to impose different or more stringent requirements on a case-by-case basis):

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies, all performed in accordance with the FDA’s good laboratory practice regulations and other regulations;
- submission to the FDA of an investigational new drug, or IND, application which must become effective before clinical trials may begin;
- performance of multiple adequate and well-controlled clinical trials meeting FDA requirements to establish the safety and efficacy of the product candidate for each proposed indication;
- submission of an NDA to the FDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product candidate is produced, and potentially other involved facilities as well, to assess compliance with current good manufacturing practice, or cGMP, regulations and other applicable regulations; and
- the FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Risks to us related to these regulations are described under “*Risk Factors – Risks Related to the Clinical Testing, Regulatory Approval and Manufacturing of Our Product Candidates.*”

Preclinical tests may include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity and other effects in animals. The results of preclinical tests, together with manufacturing information and analytical data, among other information, are submitted to the FDA as part of an IND application. Subject to certain exceptions, an IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, issues a clinical hold to delay a proposed clinical investigation due to concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND, or those of our collaboration partners, may not result in the FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. The FDA must also approve changes to an existing IND. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice requirements and regulations for informed consent.

### ***Clinical Trials***

For purposes of NDA submission and approval, clinical trials are typically conducted in the following three sequential phases, which may overlap (although additional or different trials may be required by the FDA as well):

- *Phase 1 clinical trials* are initially conducted in a limited population to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients. In some cases, particularly in cancer trials, a sponsor may decide to conduct what is referred to as a “Phase 1b” evaluation, which is a second safety-focused Phase 1 clinical trial typically designed to evaluate the impact of the drug candidate in combination with currently FDA-approved drugs.
- *Phase 2 clinical trials* are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the drug candidate for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. In some cases, a sponsor may decide to conduct what is referred to as a “Phase 2b” evaluation, which is a second, confirmatory Phase 2 clinical trial that could, if positive and accepted by the FDA, serve as a pivotal clinical trial in the approval of a drug candidate.
- *Phase 3 clinical trials* are commonly referred to as pivotal trials. When Phase 2 clinical trials demonstrate that a dose range of the drug candidate is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

In some cases, the FDA may condition continued approval of an NDA on the sponsor’s agreement to conduct additional clinical trials with due diligence. In other cases, the sponsor and the FDA may agree that additional safety and/or efficacy data should be provided; however, continued approval of the NDA may not always depend on timely submission of such information. Such post-approval studies are typically referred to as Phase IV studies.

## ***New Drug Application***

The results of drug candidate development, preclinical testing and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, and the payment of a user fee, are submitted to the FDA as part of an NDA. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once an NDA is accepted for filing, the FDA begins an in-depth review of the application.

During its review of an NDA, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA may refuse to approve an NDA and issue a not approvable letter if the applicable regulatory criteria are not satisfied, or it may require additional clinical or other data, including one or more additional pivotal Phase III clinical trials. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaboration partners interpret data. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. The FDA may withdraw drug approval if ongoing regulatory requirements are not met or if safety problems occur after the drug reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a drug based on the results of these post-marketing programs. Drugs may be marketed only for the FDA-approved indications and in accordance with the FDA-approved label. Further, if there are any modifications to the drug, including changes in indications, other labeling changes, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require us to develop additional data or conduct additional preclinical studies and clinical trials.

## ***The Hatch-Waxman Act***

Under the Hatch-Waxman Act, newly-approved drugs and new conditions of use may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active entity. The Hatch-Waxman Act prohibits the submission of an abbreviated NDA, or ANDA, or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusive period; however, submission of a Section 505(b)(2) NDA or an ANDA for a generic version of a previously-approved drug containing a paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under the Hatch-Waxman Act does not prevent the submission or approval of another "full" 505(b)(1) NDA; however, the applicant would be required to conduct its own preclinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages, or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. Some of our product candidates may qualify for Hatch-Waxman non-patent marketing exclusivity.

In addition to non-patent marketing exclusivity, the Hatch-Waxman Act amended the FDCA to require each NDA sponsor to submit with its application information on any patent that claims the drug for which the applicant submitted the NDA or that claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. Generic applicants that wish to rely on the approval of a drug listed in the Orange Book must certify to each listed patent, as discussed above. We intend to submit for Orange Book listing all relevant patents for our product candidates.

Finally, the Hatch-Waxman Act amended the patent laws so that certain patents related to products regulated by the FDA are eligible for a patent term extension if patent life was lost during a period when the product was undergoing regulatory review, and if certain criteria are met. We intend to seek patent term extensions, provided our patents and products, if they are approved, meet applicable eligibility requirements.

## ***Orphan Drug Designation and Exclusivity***

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. If the FDA grants orphan drug designation, which it may not, the identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to seven years of orphan drug exclusivity, meaning that the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity (superior efficacy, safety, or a major contribution to patient care). Orphan drug designation does not prevent competitors from developing or marketing different drugs for that indication. We received orphan drug status for Marqibo in January 2007, for the treatment of ALL.

Under European Union medicines laws, the criteria for designating a product as an “orphan medicine” are similar but somewhat different from those in the United States. A drug is designated as an orphan drug if the sponsor can establish that the drug is intended for a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union or that is unlikely to be profitable, and if there is no approved satisfactory treatment or if the drug would be a significant benefit to those persons with the condition. Orphan medicines are entitled to ten years of marketing exclusivity, except under certain limited circumstances comparable to United States law. During this period of marketing exclusivity, no “similar” product, whether or not supported by full safety and efficacy data, will be approved unless a second applicant can establish that its product is safer, more effective or otherwise clinically superior. This period may be reduced to six years if the conditions that originally justified orphan designation change or the sponsor makes excessive profits.

### ***Fast Track Designation***

The FDA’s fast track program is intended to facilitate the development and to expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition and that demonstrate the potential to address unmet medical needs. Under the fast track program, applicants may seek traditional approval for a product based on data demonstrating an effect on a clinically meaningful endpoint, or approval based on a well-established surrogate endpoint. The sponsor of a new drug candidate may request the FDA to designate the drug candidate for a specific indication as a fast track drug at the time of original submission of its IND, or at any time thereafter prior to receiving marketing approval of a marketing application. The FDA will determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor’s request.

If the FDA grants fast track designation, it may initiate review of sections of an NDA before the application is complete. This so-called “rolling review” is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant has paid applicable user fees. The FDA’s PDUFA review clock for both a standard and priority NDA for a fast track product does not begin until the complete application is submitted. Additionally, fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by emerging data, or if the designated drug development program is no longer being pursued.

In some cases, a fast track designated drug candidate may also qualify for one or more of the following programs:

- *Priority Review* . As explained above, a drug candidate may be eligible for a six-month priority review. The FDA assigns priority review status to an application if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast track drug would ordinarily meet the FDA’s criteria for priority review, but may also be assigned a standard review. We do not know whether any of our drug candidates will be assigned priority review status or, if priority review status is assigned, whether that review or approval will be faster than conventional FDA procedures, or that the FDA will ultimately approve the drug.
- *Accelerated Approval* . Under the FDA’s accelerated approval regulations, the FDA is authorized to approve drug candidates that have been studied for their safety and efficacy in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments based upon either a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than patient survival or irreversible morbidity. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies with due diligence, or to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies, may cause the FDA to seek to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

We plan to pursue accelerated approval for our product candidate Marqibo. There is no assurance that the FDA will grant accelerated approval of Marqibo based on the rALLY trial. Instead, the FDA may require us to conduct the Phase 3 confirmatory study of Marqibo to obtain full approval. We intend to seek fast track designation, accelerated approval or priority review for our other product candidates, when appropriate. We cannot predict whether any of our product candidates will obtain fast track, accelerated approval, or priority review designation, or the ultimate impact, if any, of these expedited review mechanisms on the timing or likelihood of the FDA approval of any of our product candidates.

Satisfaction of the FDA regulations and approval requirements or similar requirements of foreign regulatory agencies typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Typically, if a drug candidate is intended to treat a chronic disease, as is the case with some of the product candidates we are developing, safety and efficacy data must be gathered over an extended period of time. Government regulation may delay or prevent marketing of drug candidates for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for changes in dosage form or new indications for our product candidates on a timely basis, or at all. Even if a drug candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a drug may result in restrictions on the drug or even complete withdrawal of the drug from the market. Delays in obtaining, or failures to obtain, regulatory approvals for any of our product candidates would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

### ***Pediatric Studies and Exclusivity***

The FDCA provides an additional six months of non-patent marketing exclusivity and patent protection for any such protections listed in the Orange Book for new or marketed drugs if a sponsor conducts specific pediatric studies at the written request of the FDA. The Pediatric Research Equity Act of 2003, or PREA, authorizes the FDA to require pediatric studies for drugs to ensure the drugs' safety and efficacy in children. PREA requires that certain new NDAs or NDA supplements contain data assessing the safety and effectiveness for the claimed indication in all relevant pediatric subpopulations. Dosing and administration must be supported for each pediatric subpopulation for which the drug is safe and effective. The FDA may also require this data for approved drugs that are used in pediatric patients for the labeled indication, or where there may be therapeutic benefits over existing products. The FDA may grant deferrals for submission of data, or full or partial waivers from PREA. PREA pediatric assessments may qualify for pediatric exclusivity. Unless otherwise required by regulation, PREA does not apply to any drug for an indication with orphan designation. We may also seek pediatric exclusivity for conducting any required pediatric assessments.

### ***Other Regulatory Requirements***

Any drugs manufactured or distributed by us or our collaboration partners pursuant to future FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, sales or use, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a drug from distribution, or withdraw approval of the NDA for that drug.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning and/or untitled letters, corrective advertising and potential civil and criminal penalties.

### ***Foreign Regulation***

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our future products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marking authorization that is valid for all European Union member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marking authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

In addition to regulations in Europe and the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of our future products.

## Reimbursement

In many of the markets where we intend to commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to direct price controls by law and to drug reimbursement programs with varying price control mechanisms.

In the United States, there has been an increased focus on drug pricing in recent years. Although there are currently no direct government price controls over private sector purchases in the United States, federal legislation requires pharmaceutical manufacturers to pay prescribed rebates on certain drugs to enable them to be eligible for reimbursement under certain public health care programs such as Medicaid. Various states have adopted further mechanisms under Medicaid and otherwise that seek to control drug prices, including by disfavoring certain higher priced drugs and by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the market place that increases downward pressure on the prices of pharmaceutical products. Federal legislation, enacted in December 2003, has altered the way in which physician-administered drugs covered by Medicare are reimbursed. Under the new reimbursement methodology, physicians are reimbursed based on a product's "average sales price," or ASP. This new reimbursement methodology has generally led to lower reimbursement levels. The new federal legislation also has added an outpatient prescription drug benefit to Medicare, effective January 2006. In the interim, Congress has established a discount drug card program for Medicare beneficiaries. Both benefits will be provided primarily through private entities, which will attempt to negotiate price concessions from pharmaceutical manufacturers.

Public and private health care payors control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payors limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or that are supported by other appropriate evidence (for example, published medical literature) and appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA. For example, in the case of Medicare coverage for physician-administered oncology drugs, the Omnibus Budget Reconciliation Act of 1993, with certain exceptions, prohibits Medicare carriers from refusing to cover unapproved uses of an FDA-approved drug if the unapproved use is supported by one or more citations in the American Hospital Formulary Service Drug Information, the American Medical Association Drug Evaluations, or the U.S. Pharmacopoeia Drug Information. Another commonly cited compendium, for example under Medicaid, is the DRUGDEX Information System.

Different pricing and reimbursement schemes exist in other countries. For example, in the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive and/or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the National Institute for Clinical Excellence in the UK, which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert a commercial pressure on pricing within a country.

## Manufacturing

We currently rely on a number of third-parties, including contract manufacturing organizations and our collaborative partners, to produce our compounds. Marqibo requires three separate ingredients, sphingomyelin/cholesterol liposomes for injection, or SCLI, Vincristine Sulfate Injection, USP, and sodium phosphate for injection, all of which are handled by separate suppliers. SCLI is manufactured by Cangene Corporation, Vincristine Sulfate Injection, USP is manufactured by Hospira and sodium phosphate for injection is manufactured by Hollister-Stear Laboratories. Alocrest and Brakiva are both manufactured by Gilead. For Menadione, we have contracted with Contract Pharmaceuticals Limited.

## Competition

We compete primarily in the segment of the biopharmaceutical market that addresses cancer and cancer supportive care, which is highly competitive. We face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and selling products designed to address cancer in this market. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large pharmaceutical companies in particular have extensive experience in clinical testing and in obtaining regulatory approvals for drugs. These companies also have significantly greater research capabilities than we do. In addition, many universities and private and public research institutes are active in cancer research. We also compete with commercial biotechnology companies for the rights to product candidates developed by public and private research institutes. Smaller or early-stage companies are also significant competitors, particularly those with collaborative arrangements with large and established companies.

We believe that our ability to successfully compete will depend on, among other things:

- our ability to develop novel compounds with attractive pharmaceutical properties and to secure and protect intellectual property rights based on our innovations;
- the efficacy, safety and reliability of our product candidates;
- the speed at which we develop our product candidates;
- our ability to design and successfully complete appropriate clinical trials;
- our ability to maintain a good relationship with regulatory authorities;
- the timing and scope of regulatory approvals;
- our ability to manufacture and sell commercial quantities of future products to the market or enter into strategic partnership agreements with others; and
- acceptance of future products by physicians and other healthcare providers.

### **Research and Development Expenses**

Research and development expenses, which include salaries and related personnel costs, fees paid to consultants and outside service providers for laboratory development, manufacturing and other expenses relating to the acquiring, design, development, testing, and enhancement of our product candidates, including milestone payments for licensed technology, are the primary source of our overall expenses. Research and development expenses totaled \$20.2 million and \$14.7 million for the years ended December 31, 2010 and December 31, 2009, respectively.

### **Employees**

As of December 31, 2010, we employed 28 full-time employees and no part-time employees. All employees are based at our San Mateo office. None of our employees are covered by a collective bargaining agreement. We believe our relationship with our employees to be good.

### **Additional Information**

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to these reports filed or furnished pursuant to Sections 13(a) or 15(d) of the Exchange Act are available free of charge via our website ([www.talontx.com](http://www.talontx.com)) as soon as reasonably practicable after they are filed with, or furnished to, the SEC.

## ITEM 1A. RISK FACTORS

*Investment in our common stock involves significant risk. You should carefully consider the information described in the following risk factors, together with the other information appearing elsewhere in this Form 10-K, before making an investment decision regarding our common stock. If any of these risks actually occur, our business, financial conditions, results of operation and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or a part of your investment in our common stock. Moreover, the risks described below are not the only ones that we face.*

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

***Our near-term viability is substantially dependent on our ability to obtain accelerated approval from the FDA of Marqibo, our lead product candidate.***

A substantial portion of our current human and financial resources is focused on the development of Marqibo, our lead product candidate. In June 2010, we announced complete data from our global, registration-enabling Phase 2 clinical trial of Marqibo in adult Philadelphia chromosome negative ALL patients in second relapse or those who have progressed following two or greater prior lines of therapy. We refer to this Phase 2 clinical trial as the rALLY study. The primary outcome measure of the rALLY study was complete remission, or CR, or CR without full hematological recovery, or CRi. The complete data indicated that of the 65 evaluable subjects, an overall response was achieved in 23 subjects, or 35%, and a CR or CRi was achieved in 13 subjects, or 20%. The estimated median overall survival in complete responders was 7.7 months, with 5 subjects having an overall survival greater than one year. The estimated median duration of CR/CRi was 5.4 months.

In November 2010, we met with the FDA concerning our plans to initiate a rolling submission new drug application, or NDA, seeking accelerated approval of Marqibo for the treatment of ALL in second relapse or those who have progressed following two or greater prior lines of therapy. At such meeting, we and the FDA agreed that we would simultaneously submit all modules of our proposed NDA as a complete, original, new drug application, as opposed to initiating a partial, rolling submission by the end of 2010. We anticipate submitting the complete NDA during the first half of 2011 and do not anticipate that submitting the NDA as a complete application, as opposed to submitting on a rolling basis, will have any effect on the timing of the complete NDA submission, completion of FDA's review nor a potential accelerated approval. At a February 8, 2011 meeting of the FDA's Oncology Drug Advisory Committee, the FDA indicated that a drug sponsor and FDA must agree on the feasibility and design of Phase 3 confirmatory studies as a necessary element in the NDA submission process for those sponsors seeking accelerated approval. According to the FDA, a sponsor seeking accelerated approval should not submit its NDA until the such agreement on Phase 3 confirmatory studies has been finalized. As such, our NDA submission may be delayed if the FDA does not accept our proposed confirmatory Phase 3 study. Additionally, there can be no guarantee that our submission will be accepted for filing by the FDA and, even if our planned NDA submission is accepted for filing, there is no assurance that the FDA will find that the data and other information relating to Marqibo included in such submission will be sufficient to support accelerated approval of Marqibo. If the final data is insufficient to support the submission of an NDA for accelerated approval, or if the FDA accepts our NDA for review but subsequently denies approval, our business would be substantially and adversely affected and we would be forced to significantly curtail or even cease our operations. If we receive accelerated approval of Marqibo, we will need to conduct a confirmatory Phase 3 trial in order to obtain full approval from the FDA. We anticipate initiating a confirmatory Phase 3 trial of Marqibo in ALL as early as this year. Even if we obtain accelerated approval of Marqibo for the treatment of ALL in second relapse or those who have progressed following two or greater prior lines of therapy, that approval may be revoked if the results of our planned confirmatory trial of Marqibo are insufficient to support continued marketing.

***We need to raise additional capital to fund our planned operations beyond 2011. If we are unable to raise additional capital when needed, we will have to discontinue our product development programs or relinquish our rights to some or all of our product candidates. The manner in which we raise any additional funds may affect the value of your investment in our common stock.***

We believe that our currently available capital is only sufficient to fund our operations through late 2011. Given our desired clinical development plans for the next 12 months, our financial statements reflect an uncertainty about our ability to continue as a going concern, which is reflected in the report from our auditors on the audit of our financial statements as of and for the year ended December 31, 2010. Accordingly, we need additional capital to fund our operations beyond 2011. Further, our available capital may be consumed sooner than we anticipate depending on a variety of factors, including:

- costs associated with conducting our ongoing and planned clinical trials and regulatory development activities;
- costs, timing and outcome of regulatory reviews;
- costs of establishing arrangements for manufacturing our product candidates;

- costs associated with commercializing our lead programs, including establishing sales and marketing functions;
- payments required under our current and any future license agreements and collaborations;
- costs of obtaining, maintaining and defending patents on our product candidates; and
- costs of acquiring any new drug candidates.

Since we do not generate any recurring revenue, the most likely sources of such additional capital include private placements of our equity securities, including our common stock, preferred stock, debt financing or from a potential strategic licensing or collaboration transaction involving the rights to one or more of our product candidates. To the extent that we raise additional capital by issuing equity securities, our stockholders will likely experience significant dilution. We may also grant future investors rights superior to those of our current stockholders. If we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies, product candidates or products, or grant licenses on terms that are not favorable to us. If we raise additional funds by incurring debt, we could incur significant interest expense and become subject to covenants in the related transaction documentation that could affect the manner in which we conduct our business.

In June 2010, we entered into an investment agreement with certain investment funds affiliated with Warburg Pincus, LLC and Deerfield Management pursuant to which we sold an aggregate of 400,000 shares of our Series A-1 Preferred Stock for \$100 per share. Under the Investment Agreement, the investors have the right to invest up to an additional \$20 million prior to the time we have received regulatory approval to market one of our product candidates, and thereafter, up to an additional \$40 million by purchasing shares of our Series A-1 Preferred Stock or Series A-2 Preferred Stock, as applicable. However, the investors have no obligation to make such additional investment. If the investors do not make an additional investment pursuant to the June 2010 investment agreement at times when we are in need of additional capital, then we will need to secure such additional capital from other sources. Beyond the investment agreement, however, we have no committed sources of additional capital and our access to funding is always uncertain. This uncertainty is exacerbated due to the ongoing global economic turmoil, which has continued to restrict access to the U.S. and international capital markets, particularly for small biopharmaceutical and biotechnology companies like us. Accordingly, despite our ability to secure adequate capital in the past, there is no assurance that additional equity or debt financing will be available to us when needed, on acceptable terms or even at all. If we fail to obtain the necessary additional capital when needed, we will be forced to significantly curtail our planned research and development activities, which will cause a delay in our drug development programs. If we do not obtain additional capital before we have consumed our currently available resources, we may be forced to cease our operations altogether, in which case you will lose your entire investment in our company.

***We have a limited operating history and may not be able to commercialize any products, generate significant revenues or attain profitability.***

We do not generate significant recurring revenue and have incurred significant net losses in each year since our inception. We expect to incur substantial losses and negative cash flow from operations for the foreseeable future, and we may never achieve or maintain profitability. For the twelve months ended December 31, 2010 and December 31, 2009, we had a net loss of \$26.0 million and \$24.1 million, respectively. Our net cash used in operations during the twelve months ended December 31, 2010 and December 31, 2009, was approximately \$25.7 million and \$21.1 million, respectively.

We expect our cash requirements to increase substantially in the foreseeable future as we:

- continue to undertake clinical development of our current product candidates;
- seek regulatory approvals for Marqibo and our other product candidates at the appropriate time in the future;
- implement additional internal systems and infrastructure;
- seek to acquire additional technologies to develop; and
- hire additional personnel.

We expect to incur losses for the foreseeable future as we fund our operations and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. Even if we succeed in developing and commercializing/partnering one or more of our product candidates, which success is not assured, we may not be able to generate significant revenues. Even if we do generate significant revenues, we may never achieve or maintain profitability. Our failure to achieve or maintain profitability could negatively impact the trading price of our common stock.

***If we are unable to successfully manage our growth, our business may be harmed.***

In the future, if we are able to advance Marqibo or our other product candidates to the point of, and thereafter through, clinical trials, we may need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities. Any future growth will place a significant strain on our management and on our administrative, operational and financial resources. Our future financial performance and our ability to commercialize Marqibo and our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We must manage our development efforts and clinical trials effectively, and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing.

***If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.***

We will need to hire additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals, particularly in the San Francisco Bay Area where we are headquartered, is intense, and we cannot be certain that our search for such personnel will be successful. Our ability to attract and retain qualified personnel is critical to our success.

***We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.***

The testing and marketing of pharmaceutical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- withdrawal of prior governmental approvals;
- costs of related litigation;
- substantial monetary awards to patients;
- product recalls;
- loss of revenue; and
- the inability to commercialize our product candidates.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators. We currently do not carry product liability insurance but instead maintain a \$10 million clinical trial insurance policy for our ongoing clinical trials of our product candidates. Even if our agreements with any future collaborators entitle us to indemnification against damages from product liability claims, such indemnification may not be available or adequate should any claim arise.

***If we fail to acquire and develop other product candidates we may be unable to grow our business.***

Although we have no current plans to do so, we may in the future acquire rights to develop and commercialize additional product candidates. Because we currently neither have nor intend to establish internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies and academic and other researchers to sell or license us their product candidates. The success of our strategy depends upon our ability to identify, select and acquire pharmaceutical product candidates.

Proposing, negotiating and implementing an economically viable product acquisition or license agreement is a lengthy and complex process. We compete for partnering arrangements and license agreements with pharmaceutical, biopharmaceutical and biotechnology companies, many of which have significantly more experience than us and have significantly more financial resources than we do. Our competitors may have stronger relationships with certain third parties with whom we are interested in partnering, such as academic research institutions, and may, therefore, have a competitive advantage in entering into partnering arrangements with those third parties. We may not be able to acquire rights to additional product candidates on terms that we find acceptable, or at all.

We expect that any product candidate to which we acquire rights will require significant additional development and other efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. We do not currently have the capital and human resources available to develop additional product candidates and would need to obtain significant amounts of additional capital and personnel to do so. Further, all product candidates are subject to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe or effective for approval by regulatory authorities. Even if our product candidates are approved, they may not be manufactured or produced economically or commercialized successfully.

### **Risks Related to the Clinical Testing, Regulatory Approval and Manufacturing of Our Product Candidates**

*If we are unable to obtain regulatory approval to sell our lead product candidate, Marqibo, or any of our other product candidates, our business will suffer.*

We do not have the approval from the FDA or any foreign regulatory authority needed to market any of our product candidates. With respect to Marqibo and any of our other product candidates, significant FDA regulatory risks exist which may prevent FDA approval of these drug candidates and thereby prevent their commercial use, as described below. Additionally, if Marqibo or any of our product candidates are approved by the FDA, such approval may be withdrawn by the FDA for a variety of reasons, including:

- that clinical or other experience, tests, or other scientific data show that the drug is unsafe for use;
- that new evidence of clinical experience or evidence from new tests, evaluated together with the evidence available to the FDA when the NDA was approved, shows that the drug is not shown to be safe for use under the approved conditions of use;
- that on the basis of new information presented to the FDA, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the approved conditions of use;
- that an NDA contains any untrue statement of a material fact; or
- for a drug approved under the FDA's accelerated approval regulations or as a fast track drug, if any required post-approval study is not conducted with due diligence or if such study fails to verify the clinical benefit of the drug.

Other regulatory risks may arise as a result of a change in applicable law or regulation or the interpretation thereof, and may result in material modification or withdrawal of prior FDA approvals.

*The failure by Congress to timely approve a budget for the federal government and its agencies, including the FDA, could delay our ability to obtain accelerated approval of Marqibo.*

On an annual basis, Congress must approve budgets that govern spending by the federal agencies, including the FDA. A budget for the entire current federal fiscal year, which ends on September 30, 2011, has still not been approved. If the Congress cannot agree on a budget, or if the President vetoes a budget approved by the Congress, then the federal government may be shutdown and non-essential federal employees, including many FDA employees, may be furloughed. We may be required to provide additional information to the FDA prior to the time we plan to file our NDA for Marqibo, which information may need to be reviewed by the FDA. In addition, after we submit our NDA, the FDA staff will need to conduct a review of our NDA submission before it will file. Accordingly, a federal government shutdown may cause significant delays in the FDA's ability to timely review and process our planned NDA submission, which could have a material adverse effect on our business.

*Many of our product candidates are in early stages of clinical trials, which are very expensive and time-consuming. Any failure or delay in completing clinical trials for our product candidates could harm our business.*

Other than Marqibo, the other product candidates that we are developing, Menadione Topical Lotion, Alocrest or Brakiva, are in early stages of development and will require extensive clinical and other testing and analysis before we will be in a position to consider seeking FDA approval to sell such product candidates. In addition to the risks set forth above for Marqibo, which also apply to Menadione Topical Lotion, Alocrest and Brakiva, these product candidates also have additional risks as each is in an earlier stage of development and review.

Conducting clinical trials is a lengthy, time consuming and very expensive process and the results are inherently uncertain. The duration of clinical trials can vary substantially according to the type, complexity, novelty and intended use of the product candidate. We estimate that clinical trials of our product candidates will take at least several years to complete. The completion of clinical trials for our product candidates may be delayed or prevented by many factors, including:

- delays in patient enrollment, and variability in the number and types of patients available for clinical trials;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- poor effectiveness of product candidates during clinical trials;
- safety issues, side effects, or other adverse events;
- an inability to provide sufficient drug supply to the clinical trial sites;
- results that do not demonstrate the safety or effectiveness of the product candidates; and
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines.

In conducting clinical trials, we may fail to establish the effectiveness of a compound for the targeted indication or discover that it is unsafe due to unforeseen side effects or other reasons. Even if our clinical trials are commenced and completed as planned, their results may not support our anticipated product candidate claims. Further, failure of product candidate development can occur at any stage of the clinical trials, or even thereafter, and we could encounter problems that cause us to abandon or repeat clinical trials. These problems could interrupt, delay or halt clinical trials for our product candidates and could result in FDA, or other regulatory authorities, delaying approval of our product candidates for any or all indications. The results from preclinical testing and prior clinical trials may not be predictive of results obtained in later or other larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing promising results in earlier clinical trials. Our failure to adequately demonstrate the safety and effectiveness of any of our product candidates will prevent us from receiving regulatory approval to market these product candidates and will negatively impact our business.

In addition, we or the FDA may suspend or curtail our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in the conduct of these clinical trials or in the composition, manufacture or administration of the product candidates. Accordingly, we cannot predict with any certainty when or if we will ever be in a position to submit an NDA for any of our product candidates, or whether any such NDA would ever be approved.

***If we do not obtain the necessary U.S. or foreign regulatory approvals to commercialize our product candidates, we will not be able to market and sell our product candidates.***

None of our product candidates have been approved for commercial sale in any country. FDA approval is required to commercialize all of our product candidates in the United States and approvals from the FDA equivalent regulatory authorities are required in foreign jurisdictions in order to commercialize our product candidates in those jurisdictions. We possess world-wide rights to develop and commercialize Marqibo and our other product candidates.

In order to obtain FDA approval of any of our product candidates, we must submit to the FDA an NDA, demonstrating that the product candidate is safe for humans and effective for its intended use and otherwise meets the requirements of existing laws and regulations governing new drugs. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, and human tests, which are referred to as clinical trials, as well as additional information and studies. Satisfaction of the FDA's regulatory requirements typically takes many years, depending on the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing as well as for other purposes. To date, none of our product candidates have been approved for sale in the United States or in any foreign market. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. Historically, only a small percentage of all drug candidates that start clinical trials are eventually approved by the FDA for sale. After clinical trials are completed, the FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay or prevent commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us;
- reduce the potential prices we may be able to charge for our product candidates, assuming they are approved for sale; and

- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory approval for any of our product candidates. Additionally, a change in applicable law or regulation, or the interpretation thereof, may result in material modification or withdrawal of prior FDA approvals.

Failure to obtain FDA approval of any of our product candidates will severely undermine our business by reducing our number of saleable products and, therefore, corresponding product revenues. If we do not complete clinical trials and obtain regulatory approval for a product candidate, we will not be able to recover any of the substantial costs invested by us in the development of the product candidate.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates for sale outside the United States.

***Our competitive position may be harmed if a competitor obtains orphan drug designation and approval for the treatment of ALL for a clinically superior drug.***

Orphan drug designation is an important element of our competitive strategy because the latest of our licensors' patents for Marqibo expires in November 2021. In 2007, the FDA granted orphan drug designation for the use of Marqibo in treating adult ALL and adult metastatic uveal melanoma. The company that obtains the first FDA approval for a designated orphan drug for a rare disease generally receives marketing exclusivity for use of that drug for the designated condition for a period of seven years. However, even though we obtained orphan drug status for Marqibo in the treatments noted, the FDA may permit other companies to market a drug for the same designated and approved condition during our period of orphan drug exclusivity if it can be demonstrated that the drug is clinically superior to our drug. This could create a more competitive market for us.

***Even if we obtain regulatory approvals for our products, the terms of approvals and ongoing monitoring and regulation of our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.***

Even if regulatory approval is granted in the United States or in a foreign country, the approved product and its manufacturer, as well as others involved in the manufacturing and packaging process, remain subject to continual regulatory review and monitoring. Any regulatory approval that we receive for a product candidate may be subject to limitations on the indicated uses for which the product may be marketed, or include requirements for potentially costly post-approval clinical trials. In addition, if the FDA and/or foreign regulatory agencies approve any of our product candidates, the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-marketing information on the product will be subject to extensive regulatory requirements that may change over time. We and the manufacturers of our products, our suppliers and our manufacturers' suppliers, and many aspects of the packaging are also required to comply with current good manufacturing practice regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our products or their ingredients or certain packaging materials, and these facilities are subject to ongoing regulatory inspection. Discovery of problems with a product or manufacturer may result in restrictions or sanctions with respect to the product, manufacturer and relevant manufacturing facility, including withdrawal of the product from the market. If we fail to comply with the regulatory requirements of the FDA and other applicable foreign regulatory authorities, or if problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing process;
- warning letters or untitled letters;
- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production and/or sale; and

- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

In order to market any products outside of the United States, we must establish and comply with the numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others.

***Because we are dependent on clinical research institutions and other contractors for clinical testing and for research and development activities, the timing and results of our clinical trials and such research activities are, to a certain extent, beyond our control.***

We depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our preclinical and clinical trials under agreements with us. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed.

***Our reliance on third parties to formulate and manufacture our product candidates exposes us to a number of risks that may delay the development, regulatory approval and commercialization of our products or result in higher product costs.***

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. We contract with one or more manufacturers to manufacture, supply, store and distribute drug supplies for our clinical trials. If any of our product candidates receive FDA approval, we will rely on one or more third-party contractors to manufacture our drugs. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- In connection with the manufacture of our Marqibo product candidate, we are dependent on a single source for many of the materials involved in its manufacture. To the extent there are any technical, regulatory, labor, capacity or other issues affecting such suppliers, our ability to manufacture adequate supplies of Marqibo may be severely and adversely affected.
- Some of our other product candidates, including Marqibo, require complex materials to make saleable goods. As a result, our suppliers may have difficulty consistently meeting the applicable specifications for our product candidates, which could cause disruptions in our ability to produce an adequate supply of our drug products.
- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and/or commercial needs, if any.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards, but we will be ultimately responsible for any of their failures.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation. This may prohibit us from seeking alternative or additional manufacturers for our products.
- Regulatory authorities outside the United States may request an independent body conduct compliance audits of our manufacturers. There can be no assurance of successful outcomes of these audits.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues.

### **Risks Related to Our Ability to Commercialize Our Product Candidates**

*Our success depends substantially on our most advanced product candidate, Marqibo, which is still under development and requires further regulatory approvals. If we are unable to obtain regulatory approval of and commercialize Marqibo alone or with a strategic partner, or experience significant delays in doing so, our ability to generate product revenue and our likelihood of success will be significantly diminished.*

In 2009, we completed enrollment of the rALLY study. We intend to use the results of the rALLY study to file a new drug application, or NDA, with the FDA under an “accelerated approval” pathway. We also plan to conduct a confirmatory Phase 3 clinical trial to commence as early as 2011. The design of this confirmatory study is still under review. A significant portion of our time and financial resources for at least the next twelve months will be used in the development of our Marqibo program. We anticipate that our ability to generate revenues in the near term will depend solely on the successful development, regulatory approval and commercialization of Marqibo or our ability to enter into a partnership or licensing agreement wherein we receive cash payments. If the time period required to obtain FDA approval of Marqibo extends beyond 2011, then we will need to obtain significant additional capital before we obtain FDA approval for an NDA in Marqibo. See “— Risks Related to Our Business — We need to raise additional capital to fund our planned operations beyond 2011....,” above.

All of our other product candidates are in early stages of development. Any of our product candidates could be unsuccessful if they:

- do not demonstrate acceptable safety and efficacy in preclinical studies or clinical trials or otherwise do not meet applicable regulatory standards for approval;
- do not offer therapeutic or other improvements over existing or future therapies used to treat the same conditions;
- are not capable of being produced in commercial quantities at acceptable costs or pursuant to applicable rules and regulations; or
- are not accepted in the medical community and by third-party payors.

If we are unable to commercialize our product candidates, we will not generate product revenues. The results of our clinical trials to date do not guarantee that acceptable efficacy or safety will be shown.

*If we are unable either to create sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will be unable to commercialize our product candidates successfully.*

We currently have no sales, marketing or distribution capabilities nor do we currently have funds sufficient to develop these capabilities. To commercialize our product candidates, we must either develop internal sales, marketing and distribution capabilities, which will be expensive and time consuming, or make arrangements with third parties to perform these services. If we decide to market any of our products directly, we must commit financial and managerial resources to develop marketing capabilities and a sales force with technical expertise and with supporting distribution capabilities. Other factors that may inhibit our efforts to commercialize our product candidates, if approved, directly and without strategic partners include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are not able to partner with a third party and are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our product candidates, which would harm our business. If we rely on pharmaceutical or biotechnology companies with established distribution systems to market our products, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties which may not be successful and which will be only partially in our control. Our product revenues would likely be lower than if we marketed and sold our products directly.

***The terms of our license agreements relating to intellectual property ownership rights may make it more difficult for us to establish collaborations for the development and commercialization of our product candidates.***

The terms of our license agreements obligate us to include intellectual property assignment provisions in any sublicenses or collaboration agreements that may be unacceptable to our potential sublicensees and partners. These terms may impede our ability to enter into partnerships for some of our existing product candidates. Under our license agreement with Tekmira, Tekmira will be the owner of patents and patent applications claiming priority to certain patents licensed to us, and we not only have an obligation to assign to Tekmira our rights to inventions covered by such patents or patent applications, but also, when negotiating any joint venture, collaborative research, development, commercialization or other agreement with a third party, to require such third party to do the same. Our license agreement with Elan relating to Marqibo, provides that Elan will own all improvements to the licensed patents or licensed know-how made by us or any of our sublicensees. Potential collaboration and commercialization partners for these product candidates may not agree to such intellectual property ownership requirements and therefore not elect to partner with us for these product candidates.

***If physicians and patients do not accept and use our product candidates, our ability to generate revenue from sales of our products will be materially impaired.***

Even if the FDA approves Marqibo or any of our product candidates, if physicians and patients do not accept and use them, our business will be adversely affected. Acceptance and use of our products will depend upon a number of factors including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drugs;
- pharmacological benefit and cost-effectiveness of our products relative to competing products;
- availability of reimbursement for our products from government or other healthcare payors;
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any; and
- the price at which we sell our products.

***We are subject to uncertainty relating to reimbursement policies which, if not favorable for Marqibo or our other product candidates, could hinder or prevent their commercial success.***

Our ability to commercialize Marqibo or our earlier-stage product candidates successfully will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not obtain adequate third-party coverage or reimbursement for Marqibo or our other product candidates or we may be required to sell them at a discount.

If approved by the FDA, we expect that private insurers will consider the efficacy, cost effectiveness and safety of Marqibo in determining whether to approve reimbursement for Marqibo and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we do not receive approval for reimbursement of Marqibo from private insurers on a timely or satisfactory basis. Our business could also be adversely affected if private insurers, including managed care organizations, the Medicare program or other reimbursing bodies or payors limit the indications for which Marqibo will be reimbursed to a smaller set than we believe it is effective in treating.

In some foreign countries, particularly Canada and the countries of Europe, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products, including Marqibo, to other available therapies. If reimbursement for our products is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We expect to experience pricing pressures in connection with the sale of Marqibo and our future products due to the potential healthcare reforms discussed below, as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations and additional legislative proposals.

***If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.***

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. If approved, Marqibo will compete with unencapsulated vincristine, which is generic, other cytotoxic agents such as antimetabolites, alkylating agents, cytotoxic antibiotics, vinca alkaloids, platinum compounds and taxanes, and other cytotoxic agents that use different encapsulation technologies. These or other future competing products and product candidates may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

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

Alternative technologies are being developed to treat cancer and immunological disease, several of which are in advanced clinical trials. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel, parties for acquisitions, joint ventures or other collaborations.

***Healthcare reform measures could hinder or prevent the commercial success of Marqibo or our other product candidates.***

The U.S. government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the enactment in 2010 of the Patient Protection and Affordable Healthcare Act. Such government-adopted reform measures may adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. As a result of the recently-passed healthcare legislation in the U.S., as well as fiscal challenges faced by government health administration authorities, the pricing and reimbursement environment presumably will change in the future and become more challenging. In addition, in some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. The recent U.S. legislation and these proposed reforms could result in reduced reimbursement rates for Marqibo and our other potential products, which would adversely affect our business strategy, operations and financial results.

In addition, the Medicare Prescription Drug Improvement and Modernization Act of 2003 reforms the way Medicare will cover and reimburse for pharmaceutical products. This legislation could decrease the coverage and price that we may receive for our products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the recent healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

### **Risks Related to Our Intellectual Property**

*If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish.*

Our success, competitive position and future revenues will depend in large part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We have licensed and sublicensed from third parties rights to numerous issued patents and patent applications. To date, through our license agreements for Marqibo, Alocrest, Brakiva and Menadione Topical Lotion, we hold certain exclusive and co-owned patent rights, including rights under U.S. patents and U.S. patent applications. We also have patent rights to applications pending in several foreign jurisdictions. We have filed and anticipate filing additional patent applications both in the United States and internationally, as appropriate.

The rights to product candidates that we acquire from licensors or collaborators are protected by patents and proprietary rights owned by them, and we rely on the patent protection and rights established or acquired by them. We generally do not unilaterally control, or do not control at all, the prosecution of patent applications licensed from third parties. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we may exercise over internally developed intellectual property.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Even if we are able to obtain patents, any patent may be challenged, invalidated, held unenforceable or circumvented. The existence of a patent will not necessarily protect us from competition. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents or produce drugs in countries where we have not applied for patent protection or that do not respect our patents. Under our license agreements, we generally do not unilaterally control, or do not control at all, the enforcement of the licensed patents or the defense of third party suits of infringement or invalidity.

Furthermore, if we become involved in any patent litigation, interference or other administrative proceedings, we will incur substantial expense and the efforts of our technical and management personnel will be significantly diverted. As a result of such litigation or proceedings we could lose our proprietary position and be restricted or prevented from developing, manufacturing and selling the affected products, incur significant damage awards, including punitive damages, or be required to seek third-party licenses that may not be available on commercially acceptable terms, if at all.

The degree of future protection for our proprietary rights is uncertain in part because legal means afford only limited protection and may not adequately protect our rights, and we will not be able to ensure that:

- we or our licensors or collaborators were the first to make the inventions described in patent applications;
- we or our licensors or collaborators were the first to file patent applications for inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

- any of our pending patent applications will result in issued patents;
- any patents licensed or issued to us will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties;
- we will ultimately be able to enforce our owned or licensed patent rights pertaining to our products;
- any patents licensed or issued to us will not be challenged, invalidated, held unenforceable or circumvented;
- we will develop or license proprietary technologies that are patentable; or
- the patents of others will not have an adverse effect on our ability to do business.

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, we require all of our employees to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

***Our license agreements relating to our product candidates may be terminated in the event we commit a material breach, the result of which would harm our business and future prospects.***

In the event any of our license agreements relating to our product candidates are terminated, we could lose all of our rights to develop and commercialize the applicable product candidate covered by such license, which would harm our business and future prospects. Our rights to Menadione Topical Lotion are governed by a license agreement with Albert Einstein College of Medicine, or AECOM, which provides that AECOM may terminate the agreement, after providing us with notice and an opportunity to cure, for our material breach or default, or upon our bankruptcy. Our rights to Marqibo, Alocrest and Brakiva are governed by a series of agreements which may be individually or collectively terminated, not only by Tekmira, but also by M.D. Anderson Cancer Center, British Columbia Cancer Agency or University of British Columbia under the underlying agreements governing the license or assignment of technology to Tekmira. Tekmira may terminate these agreements for our uncured material breach, for our involvement in a bankruptcy, for our assertion or intention to assert any invalidity challenge on any of the patents licensed to us for these products or for our failure to meet our development or commercialization obligations, including the obligations of continuing to sell each product in all major market countries after its launch. In the event that these agreements are terminated, not only will we lose all rights to these products, we will also have the obligation to transfer all of our data, materials, regulatory filings and all other documentation to our licensor, and our licensor may on its own exploit these products without any compensation to us, regardless of the progress or amount of investment we have made in the products.

***Third party claims of intellectual property infringement would require us to spend significant time and money and could prevent us from developing or commercializing our products.***

In order to protect or enforce patent rights, we may initiate patent litigation against third parties. Similarly, we may be sued by others. We also may become subject to proceedings conducted in the U.S. Patent and Trademark Office, including interference proceedings to determine the priority of inventions, or reexamination proceedings. In addition, any foreign patents that are granted may become subject to opposition, nullity, or revocation proceedings in foreign jurisdictions having such proceedings opposed by third parties in foreign jurisdictions having opposition proceedings. The defense and prosecution, if necessary, of intellectual property actions are costly and divert technical and management personnel from their normal responsibilities.

No patent can protect its holder from a claim of infringement of another patent. Therefore, our patent position cannot and does not provide any assurance that the commercialization of our products would not infringe the patent rights of another. While we know of no actual or threatened claim of infringement that would be material to us, there can be no assurance that such a claim will not be asserted.

If such a claim is asserted, there can be no assurance that the resolution of the claim would permit us to continue marketing the relevant product on commercially reasonable terms, if at all. We may not have sufficient resources to bring these actions to a successful conclusion. If we do not successfully defend any infringement actions to which we become a party or are unable to have infringed patents declared invalid or unenforceable, we may have to pay substantial monetary damages, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay commercialization and development of the affected products.

Any legal action against us or our collaborators claiming damages and seeking to enjoin developmental or marketing activities relating to affected products could, in addition to subjecting us to potential liability for damages, require us or our collaborators to obtain licenses to continue to develop, manufacture or market the affected products. Such a license may not be available to us on commercially reasonable terms, if at all.

An adverse determination in a proceeding involving our owned or licensed intellectual property may allow entry of generic substitutes for our products.

## **Risks Related to Our Securities**

*Our stock price has, and we expect it to continue to, fluctuate significantly, and the value of your investment may decline.*

From January 1, 2009 to December 31, 2010, the market price of our common stock has ranged from a high of \$4.00 per share to a low of \$0.30 per share (as adjusted to give effect to our 1-for-4 reverse stock split in September 2010). The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. You might not be able to sell your shares of common stock at or above the offering price due to fluctuations in the market price of the common stock arising from changes in our operating performance or prospects. In addition, the stock markets in general, and the markets for biotechnology and biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. A variety of factors may affect our operating performance and cause the market price of our common stock to fluctuate. These include, but are not limited to:

- announcements by us or our competitors of regulatory developments, clinical trial results, clinical trial enrollment, regulatory filings, product development updates, new products and product launches, significant acquisitions, strategic partnerships or joint ventures;
- any intellectual property infringement, product liability or any other litigation involving us;
- developments or disputes concerning patents or other proprietary rights;
- regulatory developments in the United States and foreign countries;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- economic or other crises and other external factors;
- actual or anticipated period-to-period fluctuations in our results of operations;
- departure of any of our key management personnel; or
- sales of our common stock.

These and other factors may cause the market price and demand of our common stock to fluctuate substantially, which may limit investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity or value of our common stock.

*If our results do not meet analysts' forecasts and expectations, our stock price could decline.*

Currently, we do not believe there are any securities analysts who cover us or our common stock. The lack of analyst coverage of our business and operations may decrease the public demand for our common stock, making it more difficult for you to resell your shares when you deem appropriate. To the extent we obtain an analyst following in the future, such analysts may provide valuations regarding our stock price and make recommendations whether to buy, hold or sell our stock. Our stock price may be dependent upon such valuations and recommendations. Analysts' valuations and recommendations are based primarily on our reported results and their forecasts and expectations concerning our future results regarding, for example, expenses, revenues, clinical trials, regulatory marketing approvals and competition. Our future results are subject to substantial uncertainty, and we may fail to meet or exceed analysts' forecasts and expectations as a result of a number of factors, including those discussed elsewhere in this "Risk Factors" section. If our results do not meet analysts' forecasts and expectations, our stock price could decline as a result of analysts lowering their valuations and recommendations or otherwise.

***We are at risk of securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced greater than average stock price volatility in recent years. If we faced such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

***Our common stock is considered a "penny stock."***

The SEC has adopted regulations which generally define "penny stock" to be an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. Because the market price of our common stock is currently less than \$5.00 per share, and none of the specific exemptions are applicable, our common stock is considered a "penny stock" according to SEC rules. This designation requires any broker or dealer selling our common stock to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase our common stock. These rules may restrict the ability of brokers or dealers to sell shares of our common stock.

***Because we do not expect to pay dividends, you will not realize any income from an investment in our common stock unless and until you sell your shares at profit.***

We have never paid dividends on our common stock and do not anticipate paying any dividends for the foreseeable future. You should not rely on an investment in our stock if you require dividend income. Further, you will only realize income on an investment in our shares in the event you sell or otherwise dispose of your shares at a price higher than the price you paid for your shares. Such a gain would result only from an increase in the market price of our common stock, which is uncertain and unpredictable.

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

Our certificate of incorporation authorizes the issuance of up to 10,000,000 shares of preferred stock, of which we have designated 1,100,000 shares as Series A-1 Preferred Stock and 400,000 shares as Series A-2 Preferred Stock. We currently have 412,562 shares of Series A-1 Preferred Stock outstanding and no shares of Series A-2 Preferred Stock outstanding. Beyond our Series A-1 and Series A-2 Preferred Stock, our board of directors will have the authority to fix and determine the relative rights and preferences of our preferred shares, as well as the authority to issue such shares, without approval of our common stockholders. As a result, our board of directors could authorize the issuance of a series of preferred stock that is senior to our common stock and that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends, additional registration rights, anti-dilution protection, the right to the redemption to such shares, together with other rights, none of which will be afforded holders of our common stock.

***Because our common stock is primarily traded on the OTC Bulletin Board, the volume of shares traded and the prices at which such shares trade may result in lower prices than might otherwise exist if our common stock was traded on a national securities exchange.***

We were delisted from the Nasdaq Capital Market in September 2009 and trading in our common stock has since been conducted on the OTC Bulletin Board. Stocks traded on the OTC Bulletin Board are often less liquid than stocks traded on national securities exchanges, not only in terms of the number of shares that can be bought and sold at a given price, but also in terms of delays in the timing of transactions and reduced coverage of us by security analysts and the media. This may result in lower prices for our common stock than might otherwise be obtained if our common stock were traded on a national securities exchange, and could also result in a larger spread between the bid and asked prices for our common stock.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our executive offices are located at 2207 Bridgepointe Parkway Suite 250, San Mateo, California 94404. We occupy this space, which consists of 14,411 square feet of office space, pursuant to a written sublease agreement under which we pay approximately \$15,000 per month of rent through the term of the lease, from March 1, 2011 through July 25, 2012.

Additionally, the Company is in the last month of a sublease for our previous headquarters at 7000 Shoreline Ct. Suite 370, South San Francisco, California 94080. This sublease expires on March 31, 2011. We do not use this building for any business purposes.

We believe that our existing facilities are adequate to meet our current requirements. We do not own any real property.

**ITEM 3. LEGAL PROCEEDINGS**

We are not a party to any material legal proceedings.

**ITEM 4. [REMOVED AND RESERVED]**

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### Market for Common Stock

From April 17, 2006 to June 2, 2008, our common stock traded on the NASDAQ Global Market under the symbol "HNAB." From June 3, 2008 to September 9, 2009, our common stock traded on the NASDAQ Capital Market under the same symbol. From September 11, 2009 through December 1, 2010, our common stock has traded on the OTC Bulletin Board under the symbol "HNAB.OB." Since December 2, 2010, our common stock has traded on the OTC Bulletin Board under the symbol "TLON.OB."

The following table lists the high and low sale price for our common stock as quoted, in U.S. dollars, by the NASDAQ Global Market, the NASDAQ Capital Market, and the OTC Bulletin Board, as applicable, during each quarter within the last two fiscal years. All prices reflected below have been adjusted to give effect to a 1-for-4 combination of our common stock that was effected on September 10, 2010.

Quarter Ended	Price Range	
	High	Low
March 31, 2009	\$ 1.32	\$ 0.32
June 30, 2009	4.00	0.52
September 30, 2009	3.76	1.68
December 31, 2009	2.60	0.52
March 31, 2010	1.12	0.60
June 30, 2010	1.40	0.56
September 30, 2010	0.76	0.30
December 31, 2010	0.75	0.39

#### Record Holders

As of March 21, 2011, we had approximately 122 holders of record of our common stock, one of which was Cede & Co., a nominee for Depository Trust Company, or DTC. Shares of common stock that are held by financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are considered to be held of record by Cede & Co. as one stockholder.

#### Dividends

We have not paid or declared any dividends on our common stock and we do not anticipate paying dividends on our common stock in the foreseeable future.

#### Issuer Purchases of Equity Securities

None

#### Recent Sales of Unregistered Securities

On May 20, 2010, a holder of warrants issued by us in our October 2009 private placement exercised its right to purchase 1.3 million shares of our common stock at an exercise price of \$0.04 per share. The sale of these shares was made pursuant to a private transaction that did not involve a public offering, and accordingly, we believe this transaction was exempt from the registration requirements of the Securities Act of 1933 pursuant to Section 4(2) thereof and the rules and regulations promulgated thereto, that the holder acquired the shares for investment and not distribution, it could bear the risks of the investment, and it could hold the securities for an indefinite period of time. The holder received written disclosures that the securities had not been registered under the Securities Act and any resale must be made pursuant to a registration or an available exemption from such registration.

**ITEM 6. SELECTED FINANCIAL DATA**

Not applicable.

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this Annual Report. This discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Item 1A of this Annual Report, our actual results may differ materially from those anticipated in these forward-looking statements.*

### Overview

We are a biopharmaceutical company dedicated to developing and commercializing new, differentiated cancer therapies designed to improve and enable current standards of care. We currently have four product candidates in various stages of development:

- Marqibo® (vincristine sulfate liposomes injection), a novel, targeted Optisome™ encapsulated formulation product candidate of the FDA-approved anticancer drug vincristine, being developed for the treatment of adult acute lymphoblastic leukemia, or ALL. We plan to submit a new drug application to the FDA in 2011 seeking accelerated approval of Marqibo for the treatment of adult ALL.
- Menadione Topical Lotion, a novel supportive care product candidate, being developed for the prevention and/or treatment of the skin toxicities associated with the use of epidermal growth factor receptor inhibitors, a type of anti-cancer agent used in the treatment of certain cancers.
- Brakiva™ (topotecan liposome injection), a novel targeted Optisome™ encapsulated formulation product candidate of the FDA-approved anticancer drug topotecan.
- Alocrest™ (vinorelbine liposome injection), a novel, targeted Optisome™ encapsulated formulation product candidate of the FDA-approved anticancer drug vinorelbine, being developed for the treatment of solid tumors such as non-small-cell lung cancer.

### Revenues

We do not expect to generate any significant revenue from product sales or royalties in the foreseeable future. We may have revenues in the future only if we are able to develop and commercialize our products, license our technology and/or enter into strategic partnerships. If we are unsuccessful, our ability to generate future revenues will be significantly diminished.

### Research and Development Expenses

Research and development expenses, which account for the bulk of our expenses, consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for laboratory development, manufacturing, and other expenses relating to the acquiring, design, development, testing, and enhancement of our product candidates, including milestone payments for licensed technology. We expense research and development costs as they are incurred.

While expenditures on current and future clinical development programs are expected to be substantial, particularly in light of our available resources, they are subject to many uncertainties, including the results of clinical trials and whether we develop any of our drug candidates with a partner or independently. As a result of such uncertainties, we cannot predict with any significant degree of certainty the duration and completion costs of our research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;

- the costs of manufacturing our drug candidates; and
- the costs, requirements, timing of, and the ability to secure regulatory approvals.

#### *General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and related expenses for executive, finance, business development and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including accounting and general legal activities.

#### *Share-Based Compensation*

Share-based compensation expenses consist primarily of expensing the fair-market value of a share-based award over the vesting term. This expense is included in our operating expenses for each reporting period. As of December 31, 2010, we estimate that there is \$2.5 million in total, unrecognized compensation costs related to non-vested share-based awards, which is expected to be recognized over a weighted average period of 3.5 years.

### **CRITICAL ACCOUNTING POLICIES**

The accompanying discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. We believe there are certain accounting policies that are critical to understanding our financial statements, as these policies affect the reported amounts of expenses and involve management's judgment regarding significant estimates. We have reviewed our critical accounting policies and their application in the preparation of our financial statements and related disclosures with the Audit Committee of our Board of Directors. Our critical accounting policies and estimates are described below.

#### *Share-Based Compensation*

We account for share-based compensation in accordance with FASB ASC TOPIC 718 “*Compensation – Stock Compensation*.” We have adopted a Black-Scholes-Merton model to estimate the fair value of stock options issued and the resultant expense is recognized in the statement of operations each reporting period. See Note 5 of our financial statements included elsewhere in this Form 10-K for further information regarding the required disclosures related to share-based compensation.

#### *Financial Instruments with Characteristics of Both Equity and Liabilities*

The Company has issued certain financial instruments, including warrants to purchase common stock and rights to purchase shares of Series A-1 and A-2 Preferred Stock, which have the characteristics of both equity and liabilities. These instruments were evaluated to be classified as liabilities at the time of issuance and are revalued at fair value from period to period with the resulting change in value included in other income/ (expense). See Notes 4, 5, 6 and 8 of our financial statements included elsewhere in this Form 10-K.

#### *Licensed In-Process Research and Development*

Licensed in-process research and development relates primarily to technology, intellectual property and know-how acquired from another entity. We evaluate the stage of development as well as additional time, resources and risks related to development and eventual commercialization of the acquired technology. As we historically have acquired non-FDA approved technologies, the nature of the remaining efforts for completion and commercialization generally include completion of clinical trials, completion of manufacturing validation, interpretation of clinical and preclinical data and obtaining marketing approval from the FDA and other regulatory bodies. The cost in resources, probability of success and length of time to commercialization are extremely difficult to determine. Numerous risks and uncertainties exist with respect to the timely completion of development projects, including clinical trial results, manufacturing process development results and ongoing feedback from regulatory authorities, including obtaining marketing approval. Additionally, there is no guarantee that the acquired technology will ever be successfully commercialized due to the uncertainties associated with the pricing of new pharmaceuticals, the cost of sales to produce these products in a commercial setting, changes in the reimbursement environment or the introduction of new competitive products. Due to the risks and uncertainties noted above, we will expense such licensed in-process research and development projects when incurred. However, the cost of acquisition of technology is capitalized if there are alternative future uses in other research and development projects or otherwise based on internal review. All milestone payments will be expensed in the period the milestone is reached.

### ***Clinical Study Activities and Other Expenses from Third-Party Contract Research Organizations***

Much of our research and development activities related to clinical study activity are conducted by various third parties, including contract research organizations, which may also provide contractually defined administration and management services. Expense incurred for these contracted activities are based upon a variety of factors, including actual and estimated patient enrollment rates, clinical site initiation activities, labor hours and other activity-based factors. On a regular basis, our estimates of these costs are reconciled to actual invoices from the service providers, and adjustments are made accordingly.

### ***Qualifying Therapeutic Discovery Project administered under Section 48D of the Internal Revenue Code***

In November 2010, we were notified that we would receive a \$0.7 million grant authorized by The Patient Protection and Affordable Care Act of 2010 for certain of our product candidates. The Internal Revenue Service awarded the grant under the Qualifying Therapeutic Discovery Project (“QTDP”) administered under Section 48D of the Internal Revenue Code. Through December 31, 2010, we have received \$0.6 million in funding related to the grant with an additional \$0.1 million recorded as a receivable. The additional receivable amount was received as funds in January 2011.

## RESULTS OF OPERATIONS

### Year Ended December 31, 2010 Compared to Year Ended December 31, 2009

**General and administrative expenses** . For the year ended December 31, 2010, general and administrative, or G&A, expense was \$5.6 million, as compared to \$4.9 million for the year ended December 31, 2009. The increase of \$0.7 million is due to increased personnel related expenses of \$0.3 million and increased costs for insurance related to our June 2010 Financing.

**Research and development expenses** . The following table summarizes our R&D expenses incurred for preclinical support, contract manufacturing for clinical supplies and clinical trial services provided by third parties, as well as milestone payments for in-licensed technology for each of our current major product development programs for the years ended December 31, 2010 and 2009, plus the cumulative costs for our various product candidates for the last five years or since we began development of a product candidate if it has not been in development for five years. The table also summarizes unallocated costs, which consist of personnel, facilities and other costs not directly allocable to development programs.

Product candidates (\$ in thousands)	2010	2009	Annual % Change	Product candidate
				costs (5 years) Jan. 1, 2006 to Dec. 31, 2010
Marqibo	\$ 11,873	\$ 5,437	118%	\$ 25,729
Menadione	154	602	-74%	6,436
Brakiva	4	444	-99%	3,767
Alocrest	21	2	950%	3,437
Discontinued/out-licensed product candidates	-	8	N/A	\$ 9,224
QTDP grants	(704)	-	N/A	
Total third party costs	2,745	2,399	14%	
Allocable costs and overhead	1,054	637	65%	
Personnel related expense	4,813	4,672	3%	
Share-based compensation expense	235	491	-52%	
Total research and development expense	<u>\$ 20,195</u>	<u>\$ 14,692</u>	37%	

**Marqibo** . Based upon a pre-NDA follow-up meeting with the FDA completed on November 8, 2010, we and the FDA agreed that we would simultaneously submit all modules of our proposed NDA as a complete, original, new drug application, as opposed to initiating a partial, rolling submission by the end of 2010. We do not anticipate that this change will affect the timing of submission completion, review nor potential approval. We anticipate submitting the complete NDA during the first half of 2011. If we receive accelerated approval, we will need to conduct a confirmatory Phase 3 trial to receive full FDA approval. We anticipate initiating a confirmatory Phase 3 trial of Marqibo in ALL as early as 2011.

In 2010, Marqibo costs increased by \$6.4 million in 2010 compared to 2009. The main cause of the increased costs was a \$5.75 million payment made to Tekmira as part of the September 2010 amendment to the license agreement. We had lower costs related to clinical trials as our main study, rALLY, was completed in December 2009. However, these costs were offset by increased costs related to the planned 2011 NDA submission. We also continued enrollment in our pilot Phase 2 trial in metastatic uveal melanoma. We expect to spend approximately \$15 million on Marqibo in 2011, for personnel, consultants and Clinical Research Organizations, the majority of which will be spent on the NDA submission, continuation of the Phase 2 trial in metastatic uveal melanoma and preparation for the confirmatory Phase 3 trial. We estimate that we will need to spend an additional \$45 million to \$50 million on external costs to run the trial needed to obtain full FDA approval. External costs include drug production, clinical trial costs, data management and supporting activities not provided by our full-time employees. These costs are impacted by the size and duration of the clinical trials. We expect that it will take several years until we will have completed development and obtained full FDA approval of Marqibo, if ever.

**Menadione Topical Lotion (MTL)** . We have analyzed data from the recently completed MTL Phase 1 program. The Phase 1 program has successfully demonstrated that MTL is generally safe and well-tolerated. The dose limiting toxicity, skin irritation and redness, was primarily observed at the 0.2% lotion strength. The apparent maximum tolerated lotion strength is 0.1%. MTL applied twice daily at all strengths, including the highest lotion strength tested (0.2%) resulted in no appreciable systemic exposure.

MTL costs decreased by \$0.4 million in 2010 compared to 2009, due to the completion of the Phase 1 program at the end of 2009. As this drug is early in its clinical development, both the registration strategy and total expenditures to obtain FDA approval are still being evaluated. While we are still evaluating the development plan for MTL following completion of our Phase 1 study, we estimate that it will cost an aggregate of approximately \$55 million of external costs in order to obtain full FDA approval for MTL, if ever. External costs include drug manufacture and clinical trial costs. Our strategy is to seek a partner to enhance and accelerate the future development of MTL.

*Brakiva.* Brakiva costs decreased by \$0.4 million in 2010 compared to 2009 due to decreased enrollment in the Phase 1 clinical trial program. We are exploring options for further development of Brakiva beyond the phase 1 trial. As this drug is early in its clinical development, both the registration strategy and total expenditures to obtain FDA approval are still being evaluated.

*Alocrest.* We completed enrollment in a Phase 1 clinical trial in early 2008. This Phase 1 trial was designed to assess safety, tolerability and preliminary efficacy in patients with advanced solid tumors. We are currently exploring options for the continued development of Alocrest and do not expect to incur significant project costs in 2011.

*QTDP Grants.* In November 2010, we were notified that we would receive a \$0.7 million QTDP grant under The Patient Protection and Affordable Care Act of 2010 for certain of our product candidates. The Internal Revenue Service issued the funding under the under section 48D of the Internal Revenue Code. Through December 31, 2010, we have received \$0.6 million in funding related to the grant with an additional \$0.1 million recorded as a receivable. The additional receivable amount was received in January 2011. The entire grant amount was recorded as a reduction in current research and development expenses in statement of operations.

*Discontinued/Out-licensed projects.* We did not pursue development on our Zensana product candidates in 2009 which was out-licensed in 2007. We did not incur any expenses in 2010 related to the continued disposition of this product and we do not expect to incur any significant expenses in 2011.

*Other R&D expenses.* Third-party costs related to indirect support of our clinical trials and product candidates increased by \$0.3 million in 2010 compared to 2009. The increase is largely due to costs related to increased consultants to support our product candidate development. We expect these costs to remain slightly elevated through the NDA submission and then to decrease thereafter.

Allocable costs increased by \$0.4 million as a result of increased resources needed for the NDA submission preparation. We expect these costs to increase slightly through the NDA submission and then decrease thereafter.

Personnel related costs increased by \$0.1 million in 2010 compared to 2009. The increase was due largely to increased recruiting costs as we added key positions in 2010 related to our NDA submission. Stock compensation decreased by \$0.3 million due to a lower valuation for options issued in 2010 due to the Company's lower stock price.

*Interest expense.* For the year ended December 31, 2010, interest expense was \$3.8 million as compared to interest expense of \$3.4 million for the year ended December 31, 2009. The increase resulted from a larger average balance outstanding on our loan facility with Deerfield. We originally entered into this loan agreement in October 2007.

*Gain or loss on change in fair market value of liabilities re-measured at fair value.*

We have certain financial instruments that are recorded as liabilities. We re-measure the fair value of these liabilities at each reporting period with the gain or loss recognized in the statement of operations. For the twelve months ended December 31, 2010, we recorded a net gain related to these liabilities of \$3.5 million, compared to a loss of \$1.1 million for the same period in 2009. The value of these liabilities is largely dependent on the price of our common stock, and as the stock price increases or decreases, the value of these instruments will increase or decrease in relation. For additional details, see Notes 4, 5, 6 and 8 of our financial statements included elsewhere in this Form 10-K.

*Income tax expense.* There was no current or deferred income tax expense (other than state minimum tax) for the years ended December 31, 2010 and 2009 because of our operating losses. A 100% valuation allowance has been recorded against our \$45.0 million of deferred tax assets as of December 31, 2010. Historical performance leads management to believe that realization of these assets is uncertain. As a result of the valuation allowance, our effective tax rate differs from the statutory rate.

## **Liquidity and Capital Resources**

As of December 31, 2010, we had a stockholder's deficit of approximately \$41.9 million, and for the fiscal year ended December 31, 2010, we experienced a net loss of \$26.0 million. We have financed operations primarily through equity and debt financing and expect such losses to continue over the next several years. We currently have a limited supply of cash available for operations. As of December 31, 2010, we had aggregate cash and cash equivalents and available-for-sale securities of \$22.6 million, which we believe is sufficient to continue operations through late 2011. We have drawn down \$27.5 million of long-term debt under the loan facility agreement with Deerfield Management, with the entire balance due in June 2015. In November 2010, we were notified that we would receive a \$0.7 million grant authorized by The Patient Protection and Affordable Care Act of 2010 for certain of our product candidates. The Internal Revenue Service awarded the grant under the Qualifying Therapeutic Discovery Project ("QTDP") administered under Section 48D of the Internal Revenue Code. Through December 31, 2010, we have received \$0.6 million in funding related to the grant with an additional \$0.1 million recorded as a receivable. The additional receivable amount was received as funds in January 2011. We have elected to record the grants received and receivable as a credit against current research and development expenses in statement of operations. On June 7, 2010, we entered into an Investment Agreement with certain investors pursuant to which we sold 0.4 million shares of convertible preferred stock at the stated value of \$100 per share, for gross proceeds of \$40 million.

The Investment Agreement provides that the investors have the right, but not the obligation, to make additional investments, as follows:

- at any time prior to the date we receive marketing approval from the U.S. Food and Drug Administration for any of our product candidates (“Marketing Approval Date”), the Purchasers may purchase up to an additional 0.2 million shares of Series A-1 Preferred Stock at a purchase price of \$100 per share for an aggregate purchase price of \$20 million (“Additional Investment”); and
- at any time beginning 15 days and within 120 days following the Marketing Approval Date, the investors may purchase up to an aggregate of 0.4 million shares of Series A-2 Convertible Preferred Stock at the stated value of \$100 per share for an aggregate purchase price of \$40 million.

We currently do not have enough capital resources to fund our entire development plan beyond 2011 and our financial statements reflect substantial doubt about our ability to continue as a going concern, which is also stated in the report from our auditors on the audit of our financial statements as of and for the year ended December 31, 2010. Our plan of operation for the year ending December 31, 2011 is to continue implementing our business strategy, including the continued development of our main product candidate Marqibo, which includes submitting a complete NDA to the FDA in the first half of 2011. We do not generate any recurring revenue and will require substantial additional capital before we will generate cash flow from our operating activities, if ever. We will be unable to continue development of our product candidates unless we are able to obtain additional funding through equity or debt financings or from payments in connection with potential strategic transactions. We can give no assurances that additional capital that we are able to obtain, if any, will be sufficient to meet our needs. Moreover, there can be no assurance that such capital will be available to us on favorable terms or at all, especially given the current economic environment which has severely restricted access to the capital markets. If anticipated costs are higher than planned or if we are unable to raise additional capital, we will have to significantly curtail planned development to maintain operations before the end of 2011.

As part of our planned research and development, we intend to use clinical research organizations and third parties to help perform our clinical studies and manufacturing. As indicated above, at our current and desired pace of clinical development of our product candidates, over the next 12 months we expect to spend approximately between \$14 million and \$15 million on clinical development (including milestone payments that may be triggered under the license agreements relating to our product candidates). We expect to spend approximately \$5.5 million on general corporate and administrative expenses and \$2.7 million in interest payments for our long-term debt.

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

- costs associated with conducting preclinical and clinical testing;
- costs of establishing arrangements for manufacturing our product candidates;
- payments required under our current and any future license agreements and collaborations;
- costs, timing and outcome of regulatory reviews;
- costs of obtaining, maintaining and defending patents on our product candidates; and
- costs of increased general and administrative expenses.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate.

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

We do not have any “off-balance sheet agreements,” as that term is defined by SEC regulation.

## RECENT ACCOUNTING PRONOUNCEMENTS

There are no accounting pronouncements that we recently adopted or are pending our adoption that are expected to have a material impact on our financial position or results of operations.

### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The response to this Item is submitted as a separate section of this report commencing on Page F-1.

### ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

### ITEM 9A. CONTROLS AND PROCEDURES

#### *Evaluation of Disclosure Controls and Procedures*

We conducted an evaluation as of December 31, 2010, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

#### *Management's Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15 (f) of the Exchange Act. Internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's assessment included evaluation of such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2010.

#### *Limitations on the Effectiveness of Controls*

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit 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 Talon have been detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

*Changes in Internal Controls over Financial Reporting*

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fourth quarter of the year ended December 31, 2010 that has materially affected, or is 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

##### Directors and Executive Officers

The following table lists our executive officers and directors and their respective ages and positions as of the date of this report:

<u>Name</u>	<u>Age</u>	<u>Position(s) Held</u>
Steven R. Deitcher, M.D.	46	President, Chief Executive Officer and Director
Craig W. Carlson	63	Senior Vice President, Chief Financial Officer
Anne E. Hagey, M.D.	42	Vice President, Chief Medical Officer
Nishan de Silva, M.D.	38	Director
Andrew Ferrer	31	Director
Howard P. Furst, M.D.	43	Director
Jonathan S. Leff	42	Director
Paul V. Maier	63	Director
Leon E. Rosenberg, M.D.	77	Chairman of the Board
Robert J. Spiegel	61	Director

**Steven R. Deitcher, M.D.**, has been President, Chief Executive Officer and a director of Talon since August 2007, and served as our Executive Vice President of Development and Chief Medical Officer from May 2007 to August 2007. Prior to joining Talon, Dr. Deitcher served as Vice President and Chief Medical Scientist at Nuvelo, Inc. since 2004. Prior to joining Nuvelo, from 1998 to 2004, Dr. Deitcher held a variety of positions in both the Department of Vascular Medicine and the Department of Hematology/Oncology while at The Cleveland Clinic Foundation, including Head of the Section of Hematology and Coagulation Medicine in the Department of Hematology/Oncology. Prior to that, he spent four years at The University of Tennessee in positions including Associate Chairman, Department of Medicine; Director, Combined Pediatric and Adult Thrombosis Clinic; and Director, Special Coagulation Laboratory. Dr. Deitcher earned his B.S. and M.D. in the Honors Program in Medical Education at Northwestern University Medical School.

**Craig W. Carlson**, joined Talon as Vice President on March 1, 2010, was appointed Chief Financial Officer effective April 1, 2010, and was promoted to Senior Vice President on December 16, 2010. Mr. Carlson has held senior leadership and executive financial management positions for the past 25 years, including positions at two public healthcare companies. Most recently, from February 2009 to February 2010, Mr. Carlson served as Chief Financial Officer and Chief Operating Officer for 20 Cent Ventures, a new business incubator focused primarily on applying life science technologies to high value niche opportunities worldwide, where he was responsible for managing several businesses, including four international subsidiaries. From July 2006 to March 2008, he was Chief Financial Officer of Neurobiological Technologies, Inc. and from 1993 to 2005 Mr. Carlson worked at Cygnus, Inc where he served as Chief Financial Officer and Chief Operating Officer. Mr. Carlson received his M.B.A. from the Stanford Graduate School of Business, his M.S. Ed. in Counseling from Hofstra University, and his B.A. in Political Science from Union College.

**Anne E. Hagey, M.D.**, has served as our Vice President, Chief Medical Officer since April 2008. Pursuant to the terms of a separation agreement dated January 11, 2011, we and Dr. Hagey agreed that she would resign her employment with Talon effective March 31, 2011. Prior to joining Talon, from August 2000 to November 2007, Dr. Hagey was employed at Abbott Laboratories, most recently serving as a Global Project Head overseeing clinical oncology drug development. Before becoming a Global Project Head in 2005, Dr. Hagey was an associate medical director and a graduate of the Physician Development Program at Abbot Laboratories. Dr. Hagey has been a clinical associate and attending physician at the University of Chicago in pediatric hematology/oncology since 2001. She conducted her fellowship at the University of California, Los Angeles in the Department of Microbiology and Molecular Genetics and the Department of Pediatric Hematology-Oncology and Bone Marrow Transplant. She was also a Resident and Intern in pediatrics at Baylor College of Medicine, Texas Children's Hospital. Dr. Hagey has been a Research Assistant at Loyola University Medical School, a Research Intern at Case Western Reserve University Medical School, and a Research Intern at Abbot Laboratories in the Department of Corporate Molecular Biology. Dr. Hagey earned a Doctor of Medicine from Loyola University Chicago Stritch School of Medicine and a Bachelor of Sciences degree in Biochemistry from University of Illinois, Urbana-Champaign.

**Nishan de Silva, M.D.**, a director of Talon since June 2010, serves as a Principal of Warburg Pincus LLC. Dr. de Silva joined Warburg Pincus in 2003 and focuses on healthcare investments. Prior to joining Warburg Pincus, he worked in healthcare venture capital at Sprout Group and as a management consultant at McKinsey & Company. Dr. de Silva is also currently a director of Allos Therapeutics and Prottox Therapeutics, both publicly-traded life science companies. Dr. de Silva holds an M.D. from The University of Pennsylvania, an M.B.A. in Healthcare Management from The Wharton School, and an A.B. in Biology from Harvard College.

**Andrew Ferrer**, a director of Talon since June 2010, is an Associate of Warburg Pincus LLC, a global private equity firm, where he focuses on managing the firm's healthcare investments. Prior to joining Warburg Pincus, Mr. Ferrer worked at Berkshire Partners from 2005 to 2007 and Goldman Sachs from 2003 to 2005. Mr. Ferrer holds an A.B. from the Woodrow Wilson School of Public and International Affairs at Princeton University and an M.B.A. from Harvard Business School.

**Howard P. Furst, M.D.**, has served as a director of Talon since December 2009. Dr. Furst has over 20 years of experience in the healthcare industry and is currently a partner at Deerfield Management, a healthcare investment fund based in New York City, where he is primarily responsible for overseeing the firm's private investments. Prior to joining Deerfield Management in 2007, Dr. Furst was a portfolio manager for the healthcare group at Magnetar Capital, an investment fund, from 2006 to 2007. Prior to joining Magnetar Capital, Dr. Furst was a principal at Maverick Capital, an investment firm, where he was primarily responsible for managing the firm's investments in the pharmaceutical and biotechnology sectors. Dr. Furst received his M.D. from the New York University School of Medicine, an M.B.A. with a dual concentration in finance and healthcare administration from the Wharton School of Business at the University of Pennsylvania, and a B.A. from the University of Pennsylvania. Dr. Furst also serves as a director of NitroMed, Inc., a privately-held specialty pharmaceutical company.

**Jonathan S. Leff**, a director of Talon since June 2010, is a General Partner of Warburg Pincus & Co., a global private-equity firm, and as a Managing Director and Member of Warburg Pincus LLC where he is responsible for the firm's investment efforts in biotechnology and pharmaceuticals. Prior to joining Warburg Pincus in 1996, he was a consultant at Oliver, Wyman & Co. Mr. Leff is currently a director of Allos Therapeutics, Inc., Inspire Pharmaceuticals, Inc., InterMune, Inc. and Protox Therapeutics, all publicly-traded life science companies. Mr. Leff is also currently a director of several private companies and not-for-profit organizations. Mr. Leff received his A.B. in Government from Harvard College and his M.B.A. from Stanford University Graduate School of Business.

**Paul V. Maier** was appointed a director of Talon in March 2008. Since November 2009, Mr. Maier has served as Chief Financial Officer of Sequenom, Inc., a publicly-held biotechnology company. From January 2007 until November 2009, he served as an independent financial consultant. From October 1992 to January 2007, Mr. Maier served as Senior Vice President, Chief Financial Officer of Ligand Pharmaceuticals, Inc., a publicly-held biopharmaceutical company based in San Diego, CA. Prior to joining Ligand, Mr. Maier served as Vice President, Finance at DFS West, a division of DFS Group, L.P., a private multinational retailer from October 1990 to October 1992. From February 1990 to October 1990, Mr. Maier served as Vice President and Treasurer of ICN Pharmaceuticals, Inc., a pharmaceutical and biotechnology research products company. Mr. Maier held various positions in finance and administration at SPI Pharmaceuticals, Inc., a publicly held subsidiary of ICN Pharmaceuticals Group, from 1984 to 1988, including Vice President, Finance from February 1984 to February 1987. Mr. Maier also serves on the boards of directors of Pure Bioscience, Inc. and International Stem Cell Corp., both publicly-held companies. Mr. Maier received an M.B.A. from Harvard Business School and a B.S. from Pennsylvania State University.

**Leon E. Rosenberg, M.D.**, has served on our Board of Directors since February 2004 and has been our non-executive Chairman of the Board since March 2007. Dr. Rosenberg has been a Professor in the Princeton University Department of Molecular Biology and the Woodrow Wilson School of Public and International Public Affairs since September 1997. Since July 1999, he has also been Professor Adjunct of Genetics at Yale University School of Medicine. From January 1997 to March 1998, Dr. Rosenberg served as Senior Vice President, Scientific Affairs of Bristol-Myers Squibb, and from September 1991 to January 1997, Dr. Rosenberg served as President of the Bristol-Myers Squibb Pharmaceutical Research Institute. From July 1984 to September 1991, Dr. Rosenberg was Dean of the Yale University School of Medicine. Dr. Rosenberg also serves on the Boards of Directors of Lovelace Respiratory Research Institute, Karo Bio AB, and Medicines for Malaria Venture. Dr. Rosenberg received B.A. and M.D. degrees, both summa cum laude, from the University of Wisconsin. He completed his internship and residency training in internal medicine at Columbia Presbyterian Medical Center in New York City.

**Robert J. Spiegel, M.D.**, was appointed a director of our company in July 2010 after being designated by Warburg Pincus pursuant to its rights under our June 2010 Investment Agreement. From 1983 until his retirement in November 2009, Dr. Spiegel was employed by Schering Plough, serving in a number of positions of increasing responsibility, including Chief Medical Officer from 1998 until 2009. Prior to joining Schering Plough, Dr. Spiegel was an Assistant Professor, Department of Medicine, NYU Medical Center. Dr. Spiegel obtained his M.D. from the University of Pennsylvania and a B.A., cum laude from Yale University. Dr. Spiegel also serves as a director of Geron Corporation and Capstone Therapeutics, Inc., both publicly-held biopharmaceutical companies.

## **Experience, Qualifications, Attributes and Skills of Directors**

We look to our directors to lead us through our continued growth as an early-stage public biopharmaceutical company. Our directors bring their leadership experience from a variety of life science companies and professional backgrounds which we require to continue to grow and bring value to our stockholders. Dr. Deitcher's academic and clinical expertise in oncology and hematology offers a unique perspective into the development and practical application of our product candidates. Dr. Deitcher's current position as our President and CEO also allows him to provide a unique insight into our business, including our development and growth. Dr. de Silva's and Dr. Furst's scientific and financial expertise, including their substantial experience evaluating and investing in public and private healthcare companies, provides our board of directors with valuable insight into the financial and operational aspects of our decision-making processes. Likewise, Mr. Leff's and Mr. Ferrer's financial and business acumen, as well their experience evaluating and investing in public and private healthcare companies, make them each well suited to serve as a director. In addition, Mr. Leff has substantial experience serving on the boards of public and private pharmaceutical companies. Mr. Maier has significant experience with early stage biopharmaceutical companies and brings depth of knowledge in building stockholder value, growing a company from inception and navigating significant corporate transactions and the public company process. As a result of his experience in the role of chief financial officer and treasurer of public companies, Mr. Maier also brings extensive finance, accounting and risk management knowledge to us. Dr. Rosenberg's medical background and experience in the pharmaceutical industry allows him to contribute significant scientific and operational expertise. Dr. Spiegel, a medical oncologist and former pharmaceutical executive, possesses skills and experience that allow him to provide unique insight and perspective into our business and operations and constructive feedback to our executive management.

Pursuant to the terms of our June 2010 Investment Agreement, Warburg Pincus has the right to designate up to five persons as directors of our company. Currently, Messrs. Ferrer and Leff and Drs. de Silva and Spiegel were each appointed directors upon designation by Warburg Pincus.

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

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our officers, directors and persons who are the beneficial owners of more than 10% of our common stock to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. Officers, directors and beneficial owners of more than 10% of our common stock are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. Based solely on a review of the copies of the Forms 3, 4 and 5 that we received with respect to transactions during 2010, we believe that all such forms were filed on a timely basis, except for the reporting of the November 1, 2010 determination that certain performance criteria had been met with respect to stock options granted to each of Steven R. Deitcher and Tyler M. Nielsen on February 16, 2010. With respect to Dr. Deitcher, the satisfaction of the performance condition was reported on a Form 4 filed on February 4, 2011. With respect to Mr. Nielsen, the satisfaction of the performance condition was not reported on a Form 4 but was later reported on a timely filed Form 5.

### **Code of Ethics**

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees of our company. A copy of our Code of Business Conduct and Ethics is available on our Investor Relations page of our company's website at [www.talontx.com](http://www.talontx.com). If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the code to an executive officer or director, we will promptly disclose the nature of the amendment or waiver by filing with the SEC a current report on Form 8-K.

### **Audit Committee**

The current members of our Audit Committee are Mr. Maier (Chair), Dr. Rosenberg and Dr. Spiegel. Our Board of Directors has determined that Mr. Maier qualifies as an "audit committee financial expert," as defined by applicable rules of the SEC. The Board has further determined that Mr. Maier is "independent" within the meaning of the applicable listing standard of the NASDAQ Stock Market.

## **ITEM 11. EXECUTIVE COMPENSATION**

### **Executive Compensation**

The following summary compensation table reflects cash and non-cash compensation for the 2009 and 2010 fiscal years awarded to or earned by (i) each individual serving as our principal executive officer during the fiscal year ended December 31, 2010; (ii) each individual that served as an executive officer at the end of the fiscal year ended December 31, 2010 and who received in excess of \$100,000 in total compensation during such fiscal year; and (iii) up to two additional individuals who received in excess of \$100,000 in total compensation during such fiscal year but was not serving as an executive officer at the end of the fiscal year. We refer to these individuals as our "named executive officers."

### Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Option Awards (1)	Non-Equity Incentive Plan Compensation(2)	All Other Compensation (3)	Total
Steven R. Deitcher <i>President &amp; CEO</i>	2010	\$ 441,000	\$ –	\$ 900,125	\$ 308,700(4)	\$ 17,624(5)	\$ 1,667,449
	2009	420,000	–	32,299	210,000	17,905(5)	680,204
Craig W. Carlson (6) <i>Sr. VP, CFO</i>	2010	\$ 245,833	\$ 11,500(7)	\$ 377,791	\$ 88,500	\$ 14,520(8)	\$ 738,144
	2009	–	–	–	–	–	–
Anne E. Hagey <i>VP, Chief Medical Officer</i>	2010	\$ 345,000	\$ –	\$ 78,626	\$ –	\$ 17,007(9)	\$ 440,633
	2009	335,000	–	16,154	130,000	17,514(9)	498,668
Tyler M. Nielsen (10) <i>Controller, Former Interim Chief Financial Officer</i>	2010	\$ 145,600	\$ –	\$ 35,798	\$ 30,000	\$ 7,881(11)	\$ 219,279
	2009	140,000	–	2,692	35,000	7,935(11)	185,627

- (1) Amounts reflect the aggregate grant date fair value of option awards granted in the respective fiscal years as computed in accordance with Financial Accounting Standards Board's Accounting Standards Codification 718 "Compensation – Stock Compensation," excluding the effect of estimated forfeitures. For awards that are subject to performance conditions, amounts reflect the assumption that the highest level of performance conditions will be achieved.
- (2) Amount reflects cash incentives both paid and accrued for services related to 2009 and 2010. All accrued bonuses relating to performance in 2009 and 2010 included in totals were paid early in the first quarters of 2009 and 2010, respectively. Cash incentives relate to services performed during the fiscal year pursuant to performance incentives earned.
- (3) Except as otherwise noted for a named executive officer, these amounts consist solely of matching contributions made to the named executives' respective 401(k) plan contributions.
- (4) Dr. Deitcher was awarded a cash performance bonus of \$308,700 for 2010. However, in lieu of cash, \$88,200 of such performance bonus was paid by the issuance of 179,192 shares of restricted stock pursuant to our 2010 Equity Incentive Plan. The restricted shares vest in their entirety on June 15, 2011.
- (5) Consists of \$16,500 in matching contributions made to Dr. Deitcher's 401(k) plan in each of 2010 and 2009, as well as \$1,124 and \$1,405 in premiums paid for life insurance in 2010 and 2009, respectively.
- (6) Mr. Carlson's employment with us commenced on March 1, 2010 and his appointment as our Chief Financial Officer was effective as of April 1, 2010.
- (7) Represents amount paid to Mr. Carlson as a performance bonus for 2010 in excess of his maximum targeted bonus of \$88,500, which amount is reflected under "Non-Equity Incentive Plan Compensation," above.
- (8) Consists of \$14,013 in 401(k) plan matching contributions and \$507 in premiums paid for life insurance benefits.
- (9) Consists of \$16,500 in 401(k) plan matching contributions in each of 2010 and 2009, as well as \$507 and \$1,114 in premiums paid for life insurance benefits in 2010 and 2009, respectively.
- (10) Mr. Nielsen, our Controller, was appointed interim Chief Financial Officer effective as of November 16, 2009, and served in this interim position until Mr. Carlson's appointment as Chief Financial Officer, which was effective April 1, 2010. Mr. Nielsen continues to serve as our Controller.
- (11) Consists of \$7,280 and \$7,000 in 401(k) plan matching contributions in each of 2010 and 2009, as well as \$601 and \$935 in premiums paid for life insurance for each of 2010 and 2009, respectively.

#### Employment Agreements and Other Compensation Matters

##### *Steven R. Deitcher, M.D.*

*Salary and Bonus.* Dr. Deitcher's employment with us is governed by an employment agreement dated June 6, 2008, which was amended January 6, 2011. The employment agreement, which replaced and superseded a prior agreement dated May 6, 2007, provides for Dr. Deitcher's employment as Chief Executive Officer for a term ending December 31, 2011, unless terminated earlier. The agreement may be renewed for one or more additional one-year periods upon agreement by the parties. Pursuant to the agreement, Dr. Deitcher was entitled to an initial annual base salary of \$420,000, which amount will be reviewed by the board of directors at least annually and never decreased. During 2010, Dr. Deitcher's annualized base salary was \$441,000 and was increased to \$454,230 for 2011.

At the discretion of our board of directors, Dr. Deitcher is also eligible to receive an annual bonus in an amount targeted at 50% of his base salary based upon the achievement of specified Company goals approved by the board of directors, except that the bonus shall be equal to 70% of his base salary in the event all specified goals are satisfied in their entirety. For 2010, the performance goals consisted of, among other items, several clinical and regulatory development milestones for our product candidates, budget performance, and business development and management objectives. Our board determined that all of such 2010 objectives were substantially achieved and, therefore, awarded Dr. Deitcher a bonus of \$308,700. Of this amount, Dr. Deitcher agreed to accept \$88,200 in the form of a restricted stock grant of 179,192 shares of our

common stock pursuant to our 2010 Equity Incentive Plan. The shares subject to such grant vest in their entirety on June 15, 2011, subject to Dr. Deitcher's continued employment.

*Stock Options.* The dollar amounts indicated for Dr. Deitcher in 2010 in the Summary Compensation Table, above, under the Options Award column reflect the aggregate grant date fair value of the following stock options granted in 2010, as computed in accordance with Financial Accounting Standards Board's Accounting Standards Codification 718 "*Compensation – Stock Compensation*," excluding the effect of estimated forfeitures:

- A 10-year stock option granted on February 16, 2010, relating to the purchase of 250,000 shares of common stock at an exercise price of \$0.76 per share, one-third of which vests on the first anniversary of the grant date and the remaining vest in 24 equal monthly installments thereafter;
- A 10-year stock option granted on February 16, 2010, relating to the purchase of 125,000 shares of common stock at an exercise price of \$0.76 per share, one-third of which vests on the first anniversary of the grant date and the remaining vest in 24 equal monthly installments thereafter. The right to purchase such shares were further conditioned upon the achievement in 2010 of two regulatory milestones relating to our Marqibo product candidate, one of which (submission to the FDA of the first portion of our NDA for Marqibo) was not satisfied. As a result, the right to purchase 62,500 shares subject to the option lapsed;
- A 10-year stock option granted on June 7, 2010, relating to the purchase of 87,500 shares of common stock at an exercise price of 0.92 per share, one-third of which vests on the first anniversary of the grant date and the remaining vest in 24 equal monthly installments thereafter; and
- A 10-year stock option granted on December 21, 2010, relating to the purchase of 1,635,000 shares of common stock at an exercise price of 0.495 per share, which vests in 48 monthly installments commencing on the first month anniversary of the grant date.

*Post-Termination Benefits.* In the event Dr. Deitcher is terminated upon a “change of control,” he will receive (i) his then-current annualized base salary and health insurance for a period of 12 months following the date of the termination, (ii) the maximum discretionary bonus (at the 70% targeted rate) for which he would have been eligible in the year of the termination, and (iii) an acceleration in the vesting of all options to purchase shares of our common stock then held by him. If Dr. Deitcher is terminated by us other than for “cause” or upon a change of control, or if Dr. Deitcher terminates his employment for “good reason,” or if we elect not to renew the employment agreement at the end of its term, then Dr. Deitcher will receive (x) his then-current annualized base salary and health insurance for a period of 12 months following the date of the termination, (y) the maximum discretionary bonus (at the 50% targeted rate) for which he would have been eligible in the year of the termination, prorated for the number of months Dr. Deitcher was employed by us in the year of termination, and (z) an acceleration in the vesting of all of his stock options to provide for 12 additional months of vesting.

The term “cause” under the employment agreement means the following conduct or actions taken by Dr. Deitcher: (i) his willful and repeated failure or refusal to perform his duties under the agreement that is not cured by within 30 days after written notice thereof is given by us; (ii) any willful, intentional or grossly negligent act having the effect of injuring, in a material way (whether financial or otherwise), our business or reputation; (iii) willful and material misconduct in respect of his duties or obligations; (iv) the conviction of any felony or a misdemeanor involving a crime of moral turpitude; (v) the determination by us that Dr. Deitcher engaged in material harassment or discrimination prohibited by law; (vi) any misappropriation or embezzlement of our property; (vii) a breach of the non-solicitation, invention assignment and confidentiality provisions of the employment agreement; or (viii) a material breach of any other material provision of the employment agreement that is not cured within 30 days after we provide written notice thereof.

The term “change of control” means any of the following: (A) the direct or indirect acquisition by a person in one or a series of related transactions of our securities representing more than 50% of our combined voting power; or (B) the disposition by us of all or substantially all of our business and/or assets in one or a series of related transactions, other than a merger effected to change our state of domicile.

The term “good reason” means (1) a material breach by us of the employment agreement, which we do not cure within 30 days after written notice thereof is given to us; (2) a change in the lines of reporting such that Dr. Deitcher no longer directly reports to our Board; (3) a reduction in Dr. Deitcher’s compensation or other benefits except such a reduction in connection with a general reduction in compensation or other benefits of all senior executives; (4) a material reduction in Dr. Deitcher’s authority, duties, responsibilities, or title; or (5) a relocation of Dr. Deitcher’s principal place of performance by more than 30 miles from our current South San Francisco office location.

#### ***Craig W. Carlson***

*Salary and Bonus.* Mr. Carlson’s employment with us is governed by the terms of a letter agreement dated February 5, 2010, as amended on February 17, 2010. Pursuant to the letter agreement, as amended, Mr. Carlson’s employment with us commenced March 1, 2010, but his appointment as Chief Financial Officer was not effective until April 1, 2010. The letter agreement provides that he is entitled to an annualized base salary of \$295,000, which was increased to \$323,850 for 2011, and he is eligible to receive an annual performance cash bonus in an amount up to 30% of his annualized base salary.

*Stock Option Awards* . The dollar amounts indicated for Mr. Carlson in 2010 in the Summary Compensation Table, above, under the Options Award column reflect the aggregate grant date fair value of the following stock options granted in 2010, as computed in accordance with Financial Accounting Standards Board's Accounting Standards Codification 718 "*Compensation – Stock Compensation*," excluding the effect of estimated forfeitures:

- A 10-year stock option granted March 1, 2010, upon the commencement of Mr. Carlson's employment with us relating to the purchase of 87,500 shares of common stock at an exercise price of \$0.76 per share, one-third of which vests on the first anniversary of the grant date and the remaining vest in 24 equal monthly installments thereafter;
- A 10-year stock option granted on June 7, 2010, relating to the purchase of 62,500 shares of common stock at an exercise price of 0.92 per share, one-third of which vests on the first anniversary of the grant date and the remaining vest in 24 equal monthly installments thereafter; and
- A 10-year stock option granted on December 21, 2010, relating to the purchase of 705,000 shares of common stock at an exercise price of 0.495 per share, which vests in 48 monthly installments commencing on the first month anniversary of the grant date.

The letter agreement further provides that if we terminate Mr. Carlson's employment without "cause," or if he terminates his employment for "good reason," then he is entitled to continue receiving his then current annualized base salary and medical benefits for a period of six months following such termination. For purposes of the letter agreement, the term "cause" means the following actions committed by Mr. Carlson: (i) his willful and repeated failure, disregard or refusal by to perform his employment duties, or his willful misconduct in respect of his duties or obligations; (ii) any willful, intentional or grossly negligent act having the effect of materially injuring (whether financial or otherwise) our business or reputation or any of our affiliates; (iii) conviction of any felony or a misdemeanor involving a crime of moral turpitude; (iv) engagement in illegal harassment; (v) misappropriation or embezzlement by Mr. Carlson of our property; or (vi) a material breach by Mr. Carlson of any of his obligations under any other agreement or policy.

The term "good reason" means (1) a reduction in Mr. Carlson's annual base salary or annual target bonus rate or a material reduction in the benefits provided to him, taken as a whole, in each case without his consent, but not if all senior executives also incur such reduction in compensation or other benefits, or (2) a significant reduction in Mr. Carlson's duties and responsibilities, but in each case after we have failed to correct such event after 30 days' written notice from Mr. Carlson.

#### ***Anne E. Hagey***

*Salary and Bonus*. Dr. Hagey's employment with us is governed by the terms of a letter agreement dated March 16, 2008. The letter agreement provides that Dr. Hagey is entitled to an initial annual base salary of \$335,000, which was increased to \$345,000 for 2010, and is eligible for an annual performance bonus targeted at 40% of her base salary.

*Stock Option Awards* . The dollar amounts indicated for Dr. Hagey in 2010 in the Summary Compensation Table, above, under the Options Award column reflect the aggregate grant date fair value of the following stock options granted in 2010, as computed in accordance with Financial Accounting Standards Board's Accounting Standards Codification 718 "*Compensation – Stock Compensation*," excluding the effect of estimated forfeitures:

- A 10-year stock option granted on February 16, 2010, relating to the purchase of 87,500 shares of common stock at an exercise price of \$0.76 per share, one-third of which vests on the first anniversary of the grant date and the remaining vest in 24 equal monthly installments thereafter; and
- A 10-year stock option granted on February 16, 2010, relating to the purchase of 87,500 shares of common stock at an exercise price of \$0.76 per share, one-third of which vests on the first anniversary of the grant date and the remaining vest in 24 equal monthly installments thereafter. The right to purchase such shares were further conditioned upon the achievement in 2010 of two regulatory milestones relating to our Marqibo product candidate, one of which (submission to the FDA of the first portion of our NDA for Marqibo) was not satisfied. As a result, the right to purchase 43,750 shares subject to the option lapsed.

*Separation Agreement* . Pursuant to a Separation and Mutual Release Agreement dated January 11, 2011, between Dr. Hagey and us, Dr. Hagey resigned her employment with us effective as of March 31, 2011. In exchange for a mutual release of claims, we agreed to continue to pay Dr. Hagey her current annualized base salary for a period of one additional month following her termination of employment.

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

The following table sets forth information concerning stock options held by the named executive officers at December 31, 2010:

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price (\$)	Option Expiration Date	
Steven R. Deitcher	100,000	–	6.60	05/21/2017	(1)
	25,000	–	6.96	08/24/2017	(2)
	162,500	–	4.48	12/14/2017	(3)
	25,000	50,000	0.56	02/24/2019	(4)
	–	250,000	0.76	02/16/2020	(5)
	–	62,500	0.76	02/16/2020	(6)
	–	87,500	0.92	06/07/2020	(7)
	–	1,635,000	0.495	12/21/2020	(8)
Craig W. Carlson	–	87,500	0.76	03/01/2020	(9)
	–	62,500	0.92	06/07/2020	(7)
	–	705,000	0.495	12/21/2020	(8)
Anne E. Hagey	33,334	16,666	4.16	04/23/2018	(10)
	12,500	25,000	0.56	02/24/2019	(4)
	–	87,500	0.76	02/16/2020	(5)
	–	43,750	0.76	02/16/2020	(6)
Tyler M. Nielsen	7,500	–	28.44	02/22/2016	(11)
	16,250	–	27.28	12/12/2016	(12)
	6,250	–	6.64	06/25/2017	(13)
	12,500	–	4.48	12/14/2017	(3)
	2,083	4,167	0.56	02/24/2019	(4)
	–	10,000	0.76	02/16/2020	(5)
–	67,500	0.495	12/21/2020	(8)	

- (1) Option granted May 21, 2007, and which vested in three equal annual installments commencing on the first anniversary of the grant.
- (2) Option granted August 24, 2007, and which vested in three equal annual installments commencing on the first anniversary of the grant.
- (3) Option granted December 14, 2007, and which vests in three equal annual installments commencing on the first anniversary of the grant.
- (4) Option granted February 24, 2009, and which vests in three equal annual installments commencing on the first anniversary of the grant.
- (5) Option granted February 16, 2010, one-third of which is exercisable on the first anniversary of the grant and the remaining two-thirds becomes exercisable in 24 equal monthly installments beginning March 2011.
- (6) Option granted February 16, 2010, the exercisability of which was subject to both continued employment and the achievement of a regulatory milestone relating to Marqibo, which was satisfied in 2010. Exercisability of the option is also subject to continued employment, one-third of which vests on the first anniversary of the grant date and the remaining two-thirds vest in 24 equal monthly installments beginning in March 2011.
- (7) Option granted June 7, 2010, one-third of which vests on the first anniversary of the grant and the remaining two-third vest in 24 equal monthly installments beginning July 2011.
- (8) Option granted December 21, 2010 and which vests in 48 equal monthly installments commencing January 21, 2011.
- (9) Option granted March 1, 2010 upon the commencement of Mr. Carlson's employment, one-third of which vests on the first anniversary of the grant and the remaining two-third vest in 24 equal monthly installments beginning April 2011.
- (10) Option granted April 23, 2008 and becomes exercisable in equal annual installments commencing on the first anniversary of the grant.
- (11) Option granted February 22, 2006, and which vested in three equal installments commencing on the first anniversary of the grant.
- (12) Option granted December 12, 2006, and which vested in three equal installments commencing on the first anniversary of the grant.
- (13) Option granted June 25, 2007, and which vested in three equal installments commencing on the first anniversary of the grant.

### Compensation of Directors

Our non-employee directors are entitled to receive the following in consideration for their service on the Board: (1) a cash fee of \$2,500 for attendance at each regular quarterly meeting of the Board; (2) an annual retainer fee of \$20,000, as compensation for special Board and other meetings; and (3) an annual stock option grant relating to 40,000 shares of common stock, which option vests upon the first anniversary of the grant and accelerates upon a "change of control" of the Company. In lieu of the foregoing compensation, Dr. Rosenberg, as our non-executive chairman of the Board, is entitled to an annual retainer of \$50,000, a meeting fee of \$4,000 and an annual stock option grant of 75,000 shares. Mr. Maier, as Chair of our Audit Committee, is entitled to receive, in addition to the compensation set forth above for non-employee directors, an annual stock option grant relating to 10,000 shares of common stock. The following table sets forth the compensation paid to our directors for their service in 2010.

<b>Name (1)</b>	<b>Fees Earned or Paid in Cash</b>	<b>Option Awards (2)</b>	<b>Total</b>
Nishan de Silva (3)	\$ 7,500	\$ 5,263	\$ 12,763
Andrew Ferrer (3)	7,500	5,263	12,763
Howard P. Furst	30,000	5,882	35,882
Jonathan S. Leff (3)	7,500	5,263	12,763
Paul V. Maier	30,000	7,353	37,353
Leon E. Rosenberg	62,000	11,029	73,029
Robert J. Spiegel (4)	7,500	5,263	12,763
Michael Weiser (5)	22,500	5,882	28,382
Linda E. Wiesinger (5)	22,500	5,882	28,382

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- (1) Steven R. Deitcher, our President and Chief Executive Officer, has been omitted from this table since he receives no additional compensation for serving on our Board; his compensation is described above under “Management and Board of Directors – Executive Compensation.”
- (2) Amounts reflect the grant date fair value of stock option awards granted in February 2010, computed pursuant to Financial Accounting Standards Board’s Accounting Standards Codification 718 “*Compensation – Stock Compensation*,” excluding the effect of estimated forfeitures.
- (3) Dr. de Silva and Messrs. Ferrer and Leff were appointed directors on June 7, 2010.
- (4) Dr. Spiegel was appointed to our Board on July 30, 2010.
- (5) Dr. Weiser and Ms. Wiesinger each resigned from our Board on June 7, 2010.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

**Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth certain information regarding the ownership of our common stock and Series A-1 Preferred Stock as of March 25, 2011, by: (i) each of our current directors; (ii) each of our “named executive officers,” as set forth above; (iii) all of our current directors and executive officers as a group; and (iv) all those known by us to be beneficial owners of at least 5% of our common stock. Beneficial ownership is determined under rules promulgated by the SEC. Under those rules, beneficial ownership includes any shares as to which the individual has sole or shared voting power or investment power and also any shares which the individual has the right to acquire within 60 days through the exercise or conversion of any stock option, convertible security, warrant or other right. Inclusion of shares in the table does not, however, constitute an admission that the named stockholder is a direct or indirect beneficial owner of those shares. Unless otherwise indicated, each person or entity named in the table has sole voting power and investment power (or shares that power with that person’s spouse) with respect to all shares of capital stock listed as owned by that person or entity. Unless otherwise indicated, the address of each of the following persons is c/o Talon Therapeutics, Inc., 2207 Bridgepointe Parkway Suite 250 San Mateo, California.

Name	Shares of Common Stock Beneficially Owned	Percent of Class	Shares of Series A-1 Preferred Beneficially Owned	Percent of Class
Steven R. Deitcher <sup>(1)</sup>	822,212	3.8	–	–
Craig W. Carlson <sup>(2)</sup>	107,465	*	–	–
Anne E. Hagey <sup>(2)</sup>	94,792	*	–	–
Tyler M. Nielsen <sup>(3)</sup>	60,370	*	–	–
Jonathan S. Leff <sup>(4)</sup>	52,935,076	71.4	371,307	90.0
Nishan M. de Silva <sup>(4)</sup>	52,935,076	71.4	371,307	90.0
Andrew Ferrer <sup>(4)</sup>	52,935,076	71.4	371,307	90.0
Howard P. Furst <sup>(2)</sup>	10,000	*	–	–
Paul V. Maier <sup>(5)</sup>	39,250	*	–	–
Leon E. Rosenberg <sup>(6)</sup>	102,300	*	–	–
Robert J. Spiegel	–	–	–	–
All directors and officers as a group (11 persons)	54,171,465	72.0	371,307	90.0
Warburg Pincus & Co. <sup>(7)(8)</sup> 450 Lexington Avenue New York, NY 10017	52,935,076	71.4	371,307	90.0
James E. Flynn <sup>(9)</sup> 780 Third Avenue, 37 <sup>th</sup> Floor New York, NY 10017	10,622,721	38.7	41,255	10.0
OrbiMed Advisors LLC <sup>(10)</sup> 767 Third Avenue, 30th Floor New York, NY 10017	1,476,544	6.7	–	–

\* represents less than one percent.

- (1) Includes 638,020 shares issuable upon the exercise of stock options.
- (2) Represents shares issuable upon the exercise of stock options.
- (3) Includes 59,946 shares issuable upon the exercise of stock options.
- (4) Mr. Leff is a Member and Managing Director of Warburg Pincus LLC (“WP LLC”), a New York limited liability company that manages each of the Warburg Pincus Purchasers. Dr. de Silva and Mr. Ferrer are employees of WP LLC. Messrs. Leff and Ferrer and Dr. de Silva disclaim beneficial ownership of all capital stock held by the Warburg Pincus Purchasers, except to the extent of any indirect pecuniary interest therein. See also Note (8), below.
- (5) Includes 37,500 shares issuable upon the exercise of stock options.
- (6) Includes 102,050 shares issuable upon the exercise of stock options.

- (7) Pursuant to the Investment Agreement, the Warburg Pincus Purchasers purchased an aggregate of 371,370 shares of Series A-1 Preferred in two closings held on June 7, 2010 and September 10, 2010. Of this amount, Warburg Pincus Private Equity X, L.P. (“WPX”) purchased 359,797 shares, which are convertible into 51,294,163 shares of common stock as of March 25, 2011, and Warburg Pincus X Partners, L.P. (“WPPX”) purchased 11,510 shares, which are convertible into 1,640,913 shares as of March 25, 2011. Warburg Pincus X, L.P. (“WP X LP”) is a Delaware limited partnership and the sole general partner of each of the Warburg Pincus Purchasers. Warburg Pincus X LLC (“WP X LLC”) is a Delaware limited liability company and the sole general partner of WP X LP. Warburg Pincus Partners, LLC (“WPP LLC”) is a New York limited liability company and the sole member of WP X LLC. Warburg Pincus LLC (“WP LLC”) is a New York limited liability company that manages each of the Warburg Pincus Purchasers. Warburg Pincus & Co. (“WP”) is a New York general partnership and the managing member of WPP LLC. Each of WPX, WPPX, WP X LP, WP X LLC, WPP LLC, WP LLC and WP may be deemed to share the power to (a) dispose or to direct the disposition of the 52,935,076 shares of common stock the Warburg Pincus Purchasers may be deemed to beneficially own (and convert into) as of March 25, 2011 and (b) vote or direct the vote of the 52,935,076 shares of common stock the Warburg Pincus Purchasers may be deemed to beneficially own for voting purposes as of March 25, 2011. Charles R. Kaye and Joseph P. Landy are Managing General Partners of WP and Co-Presidents and Managing Members of WP LLC and may be deemed to control the Warburg Pincus Purchasers. Messrs. Kaye and Landy disclaim beneficial ownership of all shares held by the Warburg Pincus Purchasers. Beneficial ownership information is based on information known to the Company and a Schedule 13D/A filed with the SEC on September 14, 2010 by WPX, WPPX, WP X LP, WP X LLC, WPP LLC, WP LLC, WP, Mr. Kaye and Mr. Landy.
- (8) Beneficial ownership of Warburg Pincus & Co. does not reflect the contractual right of the Warburg Pincus Purchasers to purchase additional capital stock pursuant to the Investment Agreement.
- (9) Pursuant to the Investment Agreement, the Deerfield Purchasers purchased an aggregate of 41,255 shares of Series A-1 Preferred in two closings held on June 7, 2010 and September 10, 2010. Of this amount, Deerfield Private Design Fund, L.P. purchased 13,168 shares, Deerfield Private Design International, L.P. purchased 21,213 shares, Deerfield Special Situations Fund International Limited purchased 4,448 shares, and Deerfield Special Situations Fund, L.P. purchased 2,426 shares.
- Beneficial ownership includes (i) 1,161,724 shares of our common stock currently outstanding, 1,877,285 shares of our common stock issuable as of March 25, 2011 upon conversion of Series A-1 Preferred and warrants to purchase 116,172 shares of our common stock held by Deerfield Private Design Fund, L.P.; (ii) 1,871,499 shares of our common stock currently outstanding, 3,024,213 shares of our common stock issuable as of March 25, 2011 upon conversion of Series A-1 Preferred and warrants to purchase 187,150 shares of our common stock held by Deerfield Private Design International, L.P.; (iii) 862,949 shares of our common stock currently outstanding, 634,125 shares of our common stock issuable as of March 25, 2011 upon conversion of Series A-1 Preferred and warrants to purchase 39,250 shares of our common stock held by Deerfield Special Situations Fund International Limited; and (iv) 481,079 shares of our common stock currently outstanding, 345,860 shares of our common stock issuable as of March 25, 2011 upon conversion of Series A-1 Preferred and warrants to purchase 21,415 shares of our common stock held by Deerfield Special Situations Fund, L.P. Deerfield Capital, L.P. is the general partner of Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., and Deerfield Special Situations Fund, L.P.
- (10) OrbiMed Advisors LLC and OrbiMed Capital LLC (collectively, “OrbiMed”) beneficially hold shares and share equivalents issuable from warrants on behalf of Caduceus Capital Master Fund Limited (208,625 common shares and 315,000 warrants), Caduceus Capital II, L.P. (161,200 common shares and 212,500 warrants), UBS Eucalyptus Fund, LLC (151,700 common shares and 212,500 warrants), PW Eucalyptus Fund, Ltd. (9,500 common shares, and 21,000 warrants), and Summer Street Life Sciences Hedge Fund Investors LLC (75,875 common shares and 108,644 warrants). Beneficial ownership information is based on a Schedule 13G/A filed with the SEC on February 11, 2011 by OrbiMed.

## Equity Compensation Plan Information

The following table provides information on our equity-based compensation plans as of December 31, 2010:

<b>Plan category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights</b>	<b>Weighted average exercise price of outstanding options, warrants and rights</b>	<b>Number of securities remaining available for future issuance (excluding securities reflected in column (a))</b>
	<b>(a)</b>	<b>(b)</b>	<b>(c)</b>
<b>Equity compensation plans not approved by stockholders:</b>			
Awards issued outside of any plan <sup>1</sup>	59,927	\$ 2.58	–
2010 Equity Incentive Plan	5,726,500	0.55	2,773,500
<b>Equity compensation plans approved by stockholders:</b>			
2003 Stock Option Plan	64,916	6.83	0
2004 Stock Incentive Plan	898,082	5.73	0

2006 Employee Stock Purchase Plan	<u>8,510</u>	0.41	<u>39,182</u>
<b>Total</b>	6,757,935		2,812,682

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<sup>1</sup> Represents shares of common stock reserved for issuance upon exercise of several individual outstanding stock option awards issued outside of any plan.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

### Certain Relationships and Related Transactions

We have adopted a written policy with respect to related party transactions whereby any proposed transaction between us and any (i) of our executive officers or directors, (ii) shareholder beneficially owning in excess of 5% of our common stock (or its controlled affiliates') stock, (iii) immediate family member of an executive officer or director, or (iv) entity that is owned or controlled by someone listed in items (i) through (iii) above, or an entity in which someone listed in items (i) through (iii) above has a substantial ownership interest or control, must be approved by a majority of the disinterested members of our Audit Committee, unless the transaction is available to all of our employees generally, or involves less than the lesser of \$120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years. If the proposed transaction involves executive or director compensation, it must be approved by the compensation committee.

In the event a proposed transaction has been identified as a related party transaction, such transaction must be presented to our Audit Committee for consideration and approval or ratification. The presentation to the Audit Committee must include a description of all material facts, including the interests, director and indirect, of the related party, the benefits to us of the transaction and whether alternative transactions are available. A majority of disinterested members of the Audit Committee must approve a transaction for us to enter into it.

As described below in Note 4 of our financial statements included elsewhere in this Form 10-K, in June 2010 we entered into an Investment Agreement with certain investors, including the Deerfield Purchasers. Pursuant to the Investment Agreement, the Deerfield Purchasers purchased 40,000 shares of our Series A-1 Preferred Stock at a total purchase price of \$4 million. At the time we entered into the Investment Agreement, the Deerfield Purchasers beneficially owned approximately 23 percent of our outstanding common stock, and pursuant to a Facility Agreement dated October 30, 2007, between us and the Deerfield Purchasers, we borrowed from the Deerfield Purchasers an aggregate of \$27.5 million, all of which remains outstanding. Howard P. Furst, a director of Talon since December 2009, is a partner of Deerfield Management, an affiliate of the Deerfield Purchasers. The terms of the Investment Agreement were reviewed by an independent and disinterested committee of our board of directors and approved by our full board of directors. Dr. Furst was not a member of such board committee and did not participate in any meetings of our board at which the terms of the Investment Agreement were considered. We did not enter into any related party transactions in 2009.

### Director Independence

Our Board of Directors, after reviewing all relevant transactions or relationships between each director, or any of his family members, and Talon, its senior management and its independent registered public accounting firm, has determined that Mr. Maier, Dr. Rosenberg and Dr. Spiegel are "independent" directors within the meaning of all relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in the applicable Nasdaq listing standards.

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

### Fees Billed to the Company by Its Independent Registered Public Accounting Firm

The following is a summary of the fees billed to us by BDO USA, LLP, our independent registered public accounting firm for professional services rendered for fiscal years ended December 31, 2010 and 2009:

<u>Fee Category</u>	<u>2010 Fees</u>	<u>2009 Fees</u>
Audit Fees	\$ 284,222	\$ 256,578
Audit-Related Fees (1)	5,805	-
Tax Fees (2)	59,184	23,425
All Other Fees (3)	-	-
Total Fees	<u>\$ 349,211</u>	<u>\$ 280,003</u>

- (1) Audit-Related Fees consist principally of assurance and related services that are reasonably related to the performance of the audit or review of the Company's financial statements but not reported under the caption "Audit Fees."
- (2) Tax Fees consist of fees for tax compliance, tax advice and tax planning.
- (3) All Other Fees consist of aggregate fees billed for products and services provided by the independent registered public accounting firm, other than those disclosed above.

## **Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors**

At present, the Audit Committee approves each engagement for audit or non-audit services before the Company engages its independent public accountants to provide those services. The Audit Committee has not established any pre-approval policies or procedures that would allow the Company's management to engage its independent auditor to provide any specified services with only an obligation to notify the audit committee of the engagement for those services. None of the services provided by the Company's independent auditors for fiscal year 2010 was obtained in reliance on the waiver of the pre-approval requirement afforded in SEC regulations.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

<b>Exhibit No.</b>	<b>Description</b>
2.1	Agreement and Plan of Merger dated June 17, 2004 by and among the Registrant, Hudson Health Sciences, Inc. and EMLR Acquisition Corp. (incorporated by reference to Exhibit 2.0 of the Registrant's Form 8-K filed June 24, 2004).
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended (incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2010).
3.2	Certificate of Designation of Series A-1 Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed June 11, 2010).
3.3	Certificate of Designation of Series A-2 Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed June 11, 2010).
3.4	Amended and Restated Bylaws of the Registrant, as amended (incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-Q for the quarter ended June 30, 2010).
3.5	Certificate of Ownership merging Talon Therapeutics, Inc. with and into Hana Biosciences, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed December 2, 2010).
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form SB-2/A (SEC File No. 333-118426) filed October 12, 2004).
4.2	Form of option to purchase an aggregate of 138,951 shares of common stock originally issued to Yale University and certain employees thereof (incorporated by reference to Exhibit 4.3 of the Registrant's Annual Report on Form 10-KSB (SEC File No. 000-50782) for the year ended December 31, 2004).
4.3	Schedule of options in form of Exhibit 4.2 (incorporated by reference to Exhibit 4.4 of the Registrant's Annual Report on Form 10-KSB (SEC. File No. 000-50782) for the year ended December 31, 2004).
4.4	Form of Promissory Note issued to lenders in connection with October 30, 2007 Facility Agreement. (incorporated by reference to Exhibit 4.9 to the Registrant's Form 10-K for the year ended December 31, 2007).
4.5	Form of Series A warrant to purchase common stock issued in connection with October 2009 private placement (incorporated by reference to Exhibit 4.8 of the Registrant's Registration Statement on Form S-1 filed November 3, 2009, SEC File No. 333-162836).
4.6	Schedule of warrants issued on form of warrant attached as Exhibit 4.5 hereof (incorporated by reference to Exhibit 4.9 of the Registrant's Registration Statement on Form S-1 filed November 3, 2009, SEC File No. 333-162836).
4.7	Form of Series B warrant to purchase common stock issued in connection with October 2009 private placement (incorporated by reference to Exhibit 4.10 of the Registrant's Registration Statement on Form S-1 filed November 3, 2009, SEC File No. 333-162836).
4.8	Schedule of warrants issued on form of warrant attached as Exhibit 4.7 hereof (incorporated by reference to Exhibit 4.11 of the Registrant's Registration Statement on Form S-1 filed November 3, 2009, SEC File No. 333-162836).
10.1	Talon Therapeutics, Inc. 2004 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed June 27, 2007). *
10.2	Form of stock option agreement for use in connection with 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-K for the year ended December 31, 2006). *

- 10.3 2003 Stock Option Plan of Talon Therapeutics, Inc. (incorporated by reference to Appendix B of the Registrant's Definitive Proxy Statement on Schedule 14A filed April 7, 2006). \*
- 10.4 Summary terms of non-employee director compensation (incorporated by reference to Exhibit 10.1 of Registrant's Form 10-Q for the quarter ended March 31, 2007). \*
- 10.5 2006 Employee Stock Purchase Plan of Talon Therapeutics, Inc. (incorporated by reference to Appendix D of the Registrant's Definitive Proxy Statement on Schedule 14A filed April 7, 2006). \*
- 10.6 Amended and Restated License Agreement dated April 30, 2007 between the Registrant and Tekmira Pharmaceuticals Corp., as successor in interest to Inex Pharmaceuticals Corp. (incorporated by reference to Exhibit 10.4 of the Registrant's Form 10-Q for the quarter ended June 30, 2007).+
- 10.7 Sublicense Agreement dated May 6, 2006 among the Registrant, Inex Pharmaceuticals Corporation and the University of British Columbia (incorporated by reference to Exhibit 10.5 of the Registrant's Form 10-Q for the quarter ended June 30, 2006).+
- 10.8 Registration Rights Agreement dated May 6, 2006 between the Registrant and Inex Pharmaceuticals Corporation (incorporated by reference to Exhibit 10.6 of the Registrant's Form 10-Q for the quarter ended June 30, 2006).
- 10.9 Amended and Restated License Agreement among Elan Pharmaceuticals, Inc., Inex Pharmaceuticals Corporation (for itself and as successor in interest to IE Oncology Company Limited), as assigned to the Registrant by Inex Pharmaceuticals Corporation on May 6, 2006 (incorporated by reference to Exhibit 10.8 of the Registrant's Form 10-Q for the quarter ended June 30, 2006).
- 10.10 Form of common stock purchase agreement dated May 17, 2006 between the Registrant and certain investors (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed May 17, 2006).
- 10.11 Sublease Agreement dated May 31, 2006 between the Registrant and MJ Research Company, Inc., including amendment thereto dated May 31, 2006 (incorporated by reference to Exhibit 10.15 of the Registrant's Form 10-Q for the quarter ended June 30, 2006).
- 10.12 Research and License Agreement dated October 9, 2006 between the Registrant and Albert Einstein College of Medicine of Yeshiva University, a division of Yeshiva University (incorporated by reference to Exhibit 10.38 to the Registrant's Form 10-K for the year ended December 31, 2006).+
- 10.13 Patent and Technology License Agreement dated February 14, 2000 (including amendment dated August 15, 2000) between the Board of Regents of the University of Texas System on behalf of the University of Texas M.D. Anderson Cancer Center and the Registrant, as successor in interest to Inex Pharmaceuticals Corp. (incorporated by reference to Exhibit 10.3 of the Registrant's Form 10-Q for the quarter ended June 30, 2007).+
- 10.14 Facility Agreement dated October 30, 2007 among the Registrant, Deerfield Private Design Fund, L.P., Deerfield Special Situations Fund L.P., Deerfield Special Situations Fund International Limited, and Deerfield Private Design International, L.P. (incorporated by reference to Exhibit 10.24 to the Registrant's Form 10-K for the year ended December 31, 2007).
- 10.15 Security Agreement dated October 30, 2007 between the Registrant in favor of Deerfield Private Design Fund, L.P., Deerfield Special Situations Fund L.P., Deerfield Special Situations Fund International Limited, and Deerfield Private Design International, L.P. (incorporated by reference to Exhibit 10.25 to the Registrant's Form 10-K for the year ended December 31, 2007).
- 10.16 Letter agreement dated March 16, 2008 between the Registrant and Anne E. Hagey, M.D. (incorporated by reference to Exhibit 10.2 of the Registrant's Form 10-Q for the quarter ended March 31, 2008). \*
- 10.17 Employment Agreement by and between the Registrant and Steven R. Deitcher, dated June 6, 2008 (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed June 11, 2008). \*
- 10.18 Second Amendment to Sublease Agreement dated May 19, 2008 by and between MJ Research Company and the Registrant (incorporated by reference to Exhibit 10.2 of the Registrant's Form 10-Q for the quarter ended June 30, 2008).

- 10.19 Amendment No. 1 dated June 2, 2009 to Amended and Restated License Agreement dated April 30, 2007 between the Registrant and Tekmira Pharmaceuticals Corp. (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended June 30, 2009).+
- 10.20 Agreement dated September 3, 2009 by and among the Registrant, Deerfield Private Design Fund, L.P., Deerfield Special Situations Fund L.P., Deerfield Special Situations Fund International Limited, and Deerfield Private Design International, L.P. (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed September 10, 2009).
- 10.21 Form of Securities Purchase Agreement entered into among the Registrant and certain accredited investors on October 7, 2009 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed October 8, 2009).
- 10.22 Talon Therapeutics, Inc. 2010 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed February 22, 2010). \*
- 10.23 Form of Stock Option Agreement under 2010 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed February 22, 2010). \*
- 10.24 Amendment No. 2 dated September 20, 2010 to Amended and Restated License Agreement dated April 30, 2007 between the Registrant and Tekmira Pharmaceuticals Corp. (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2010).+
- 10.25 Letter agreement dated February 5, 2010 between the Registrant and Craig W. Carlson, as amended on February 17, 2010 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended March 31, 2010).
- 10.26 Investment Agreement dated June 7, 2010 among the Registrant and the Purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 11, 2010).
- 10.27 Form of Indemnification Agreement dated June 7, 2010 between the Registrant and each of Jonathan Leff, Nishan de Silva and Andrew Ferrer (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed June 11, 2010).
- 10.28 Registration Rights Agreement dated June 7, 2010 among the Registrant and the Holders identified therein (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed June 11, 2010).
- 10.29 First Amendment dated June 7, 2010 to Facility Agreement dated October 30, 2007 among the Registrant and the Lenders identified therein (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed June 11, 2010).
- 23.1 Consent of BDO USA, LLP, Independent Registered Public Accounting Firm (filed herewith).
- 24.1 Power of Attorney (included on signature page hereof).
- 31.1 Certification of Chief Executive Officer (filed herewith).
- 31.2 Certification of Chief Financial Officer (filed herewith).
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).

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+ Confidential treatment has been granted as to certain omitted portions of this exhibit pursuant to Rule 406 of the Securities Act or Rule 24b-2 of the Exchange Act.

\* Indicates a management contract or compensatory plan or arrangement required to be filed as an exhibit to this Form 10-K.



**Index to Financial Statements of  
Talon Therapeutics, Inc.**

**Audited Financial Statements:**

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## Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders  
Talon Therapeutics, Inc.  
San Mateo, California

We have audited the accompanying balance sheets of Talon Therapeutics, Inc. as of December 31, 2010 and 2009 and the related statements of operations and comprehensive loss, changes in redeemable, convertible preferred stock and stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2010. 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 audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the 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 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, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Talon Therapeutics, Inc. at December 31, 2010 and 2009, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP

San Francisco, California  
March 28, 2011

**TALON THERAPEUTICS, INC.**

**BALANCE SHEETS**

	<u>December 31, 2010</u>	<u>December 31, 2009</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 4,573,254	\$ 9,570,453
Available-for-sale, equity securities	74,000	68,000
Available-for-sale, debt securities	17,993,745	—
Prepaid expenses and other current assets	253,901	114,067
Total current assets	<u>22,894,900</u>	<u>9,752,520</u>
Property and equipment, net	97,231	252,455
Restricted cash	125,000	125,000
Debt issuance costs, net	904,909	1,193,594
Total assets	<u>\$ 24,022,040</u>	<u>\$ 11,323,569</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 6,051,982	\$ 4,027,075
Other short-term liabilities	1,787	43,586
Total current liabilities	<u>6,053,769</u>	<u>4,070,661</u>
Notes payable, net of discount	23,340,144	22,597,050
Other long-term liabilities	4,753	6,540
Investors' right to purchase future shares of Series A-1 and A-2 preferred stock (Note 4)	5,131,000	-
Warrant liabilities, non-current (Note 6)	712,965	2,145,511
Total long term liabilities	<u>29,188,862</u>	<u>24,749,101</u>
Total liabilities	<u>35,242,631</u>	<u>28,819,762</u>
Commitments and contingencies (Notes 4, 6, 8, 10, 12 and 14):		
Redeemable convertible preferred stock; \$100 par value:		
10 million shares authorized, 0.4 million and 0 shares issued and outstanding at December 31, 2010 and December 31, 2009, respectively; aggregate liquidation value of \$42.4 million and \$0 at December 31, 2010 and December 31, 2009, respectively	30,643,219	-
Stockholders' deficit:		
Common stock; \$0.001 par value:		
350 million and 200 million shares authorized, 21.2 million and 19.9 million shares issued and outstanding at December 31, 2010 and December 31, 2009, respectively	21,234	19,912
Additional paid-in capital	119,241,956	117,632,111
Accumulated other comprehensive loss	(15,841)	(24,000)
Accumulated deficit	<u>(161,111,159)</u>	<u>(135,124,216)</u>
Total stockholders' deficit	<u>(41,863,810)</u>	<u>(17,496,193)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$ 24,022,040</u>	<u>\$ 11,323,569</u>

See accompanying notes to financial statements.

**TALON THERAPEUTICS, INC.**  
**STATEMENTS OF OPERATIONS**  
**AND COMPREHENSIVE LOSS**

	<b>Years Ended</b>	
	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Operating expenses:		
General and administrative	\$ 5,570,820	\$ 4,907,690
Research and development	20,194,878	14,692,417
Total operating expenses	<u>25,765,698</u>	<u>19,600,097</u>
Loss from operations	<u>(25,765,698)</u>	<u>(19,600,097)</u>
Other income (expense):		
Interest income	49,247	12,935
Interest expense	(3,750,471)	(3,442,893)
Other expense, net	(3,512)	(4,908)
Change in fair value of warrant liabilities	(55,509)	(1,103,666)
Change in fair value of investors' right to purchase future shares of Series A-1 and A-2 preferred stock	<u>3,539,000</u>	<u>—</u>
Total other expense	<u>(221,245)</u>	<u>(4,538,532)</u>
Net loss	\$ (25,986,943)	\$ (24,138,629)
Deemed dividends attributable to preferred stock	<u>(32,308,787)</u>	<u>—</u>
Net loss applicable to common stockholders	<u>(58,295,730)</u>	<u>(24,138,629)</u>
Net loss per share, basic and diluted	\$ (2.81)	\$ (2.27)
Weighted average shares used in computing net loss per share, basic and diluted	20,737,470	10,637,854
Comprehensive loss:		
Net loss	\$ (25,986,943)	\$ (24,138,629)
Unrealized holdings gains (losses) arising during the period	8,159	(60,000)
Comprehensive loss	<u>\$ (25,978,784)</u>	<u>\$ (24,198,629)</u>

See accompanying notes to financial statements.

**TALON THERAPEUTICS, INC.**

**STATEMENT OF CHANGES IN REDEEMABLE, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**

	Redeemable Convertible Preferred Stock		Common Stock		Additional paid-in capital	Accumulated Other Comprehensive income (loss)	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount				
Balance at January 1, 2009	—	\$ —	8,096,532	\$ 8,097	\$ 104,455,758	\$ 36,000	\$(110,985,587)	\$ (6,485,732)
Stock-based compensation of employees amortized over vesting period of stock options	—	—	—	—	1,046,926	—	—	1,046,926
Issuance of shares under employee stock purchase plan	—	—	49,221	49	40,113	—	—	40,162
Issuance of shares upon exercise of warrants	—	—	876,206	876	665,280	—	—	666,156
Proceeds from October 2009 from private placement	—	—	7,663,999	7,664	7,827,671	—	—	7,835,335
Issuance of shares to satisfy warrant redemption obligation	—	—	3,226,536	3,226	3,596,363	—	—	3,599,589
Unrealized loss on available-for-sale securities	—	—	—	—	—	(60,000)	—	(60,000)
Net loss	—	—	—	—	—	—	(24,138,629)	(24,138,629)
Balance at December 31, 2009	—	—	19,912,493	\$ 19,912	\$ 117,632,111	\$ (24,000)	\$(135,124,216)	\$ (17,496,193)
Stock-based compensation of employees amortized over vesting period of stock options	—	—	—	—	744,376	—	—	744,376
Issuance of shares under employee stock purchase plan	—	—	57,677	58	35,238	—	—	35,296
Issuance of shares upon exercise of warrants	—	—	1,264,137	1,264	1,537,357	—	—	1,538,621
Issuance of Series A-1 redeemable, convertible preferred stock, net of issuance costs of \$1,431,781, and fair value of investors' right to acquire future shares of Series A-1 and A-2 preferred stock	400,000	29,898,219	—	—	—	—	—	—
Additional Series A-1 redeemable, convertible shares issued upon completion of second closing	12,562	745,000	—	—	(745,000)	—	—	(745,000)
Beneficial conversion feature on Series A-1 redeemable, convertible preferred stock	—	(29,898,219)	—	—	29,898,219	—	—	29,898,219
Deemed dividend attributable to beneficial conversion feature on Series A-1 redeemable, convertible preferred stock	—	29,898,219	—	—	(29,898,219)	—	—	(29,898,219)
Issuance of warrants related to Series A-1 redeemable, convertible preferred stock	—	—	—	—	37,874	—	—	37,874
Unrealized gain on available-for-sale securities	—	—	—	—	—	8,159	—	8,159
Net loss	—	—	—	—	—	—	(25,986,943)	(25,986,943)
Balance at December 31, 2010	412,562	\$ 30,643,219	21,234,307	\$ 21,234	\$ 119,241,956	\$ (15,841)	\$(161,111,159)	\$ (41,863,810)

See accompanying notes to financial statements.

**TALON THERAPEUTICS, INC.**  
**STATEMENTS OF CASH FLOWS**

	<b>Twelve Months Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (25,986,943)	\$ (24,138,629)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	158,721	174,562
Share-based compensation to employees for services	744,376	1,046,926
Amortization of discount and debt issuance costs	1,031,779	913,271
Loss on disposal of equipment	3,002	—
Change in fair value of warrant liability	55,509	1,103,666
Change in fair value of investors' right to purchase future shares of Series A-1 and A-2 preferred stock	(3,539,000)	—
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses and other assets	(148,480)	17,596
Increase (decrease) in accounts payable and accrued liabilities	2,024,907	(198,788)
Net cash used in operating activities	<u>(25,656,129)</u>	<u>(21,081,396)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(6,499)	(16,954)
Proceeds from maturities and sales of available-for-sale securities	5,245,500	—
Purchase of available-for-sale securities	(23,228,440)	—
Net cash used in investing activities	<u>(17,989,439)</u>	<u>(16,954)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of warrants and options and issuance of shares under employee stock purchase plan	85,862	75,210
Payments on capital leases	(43,586)	(62,885)
Proceeds from issuances of notes payable	—	5,000,000
Proceeds from private placement of Series A-1 preferred stock for \$40 million less cash issuance costs of \$1.4 million	38,606,093	11,657,398
Net cash provided by financing activities	<u>38,648,369</u>	<u>16,669,723</u>
Net decrease in cash and cash equivalents	(4,997,199)	(4,428,627)
Cash and cash equivalents, beginning of period	9,570,453	13,999,080
Cash and cash equivalents, end of period	<u>\$ 4,573,254</u>	<u>\$ 9,570,453</u>
Supplemental disclosures of cash flow data:		
Cash paid for interest	\$ 2,708,750	\$ 2,325,200
Supplemental disclosures of noncash financing activities:		
Equipment financed with capital leases	—	9,895
Unrealized gain (loss) on available-for-sale securities	\$ 8,159	\$ (60,000)
Fair value of warrants issued to nonemployee as partial payment of services rendered	\$ 37,874	\$ —
Extinguishment of warrant liabilities, net of cash proceeds from warrant exercise	\$ 1,488,055	\$ 3,871,844

See accompanying notes to financial statements.

## TALON THERAPEUTICS, INC.

### NOTES TO FINANCIAL STATEMENTS Years Ended December 31, 2010 and 2009

#### NOTE 1. BUSINESS DESCRIPTION, BASIS OF PRESENTATION AND LIQUIDITY

##### BUSINESS

Talon Therapeutics, Inc. (“Talon”, “we”, “our”, “us” or the “Company”) is a biopharmaceutical company based in San Mateo, California, which seeks to acquire, develop, and commercialize innovative products to strengthen the foundation of cancer care. The Company is committed to creating value by accelerating the development of its product candidates, including entering into strategic partnership agreements and expanding its product candidate pipeline by being an alliance partner of choice to universities, research centers and other companies. Our product candidates consist of the following:

- Marqibo® (vincristine sulfate liposomes injection), our lead product candidate, is a novel, targeted Optisome™ encapsulated formulation product candidate of the FDA-approved anticancer drug vincristine. The Company is currently developing Marqibo primarily for the treatment of adult acute lymphoblastic leukemia, or ALL. The Company plans to submit a new drug application to the Food and Drug Administration, or FDA, in 2011 seeking accelerated approval of Marqibo for the treatment of adult ALL in second or greater relapse or that has progressed following two or more prior lines of anti-leukemia therapy.
- Menadione Topical Lotion, a novel supportive care product candidate being developed for the prevention and/or treatment of the skin toxicities associated with the use of epidermal growth factor receptor inhibitors, or EGFRIs, a type of anti-cancer agent used in the treatment of lung, colon, head and neck, pancreatic and breast cancer.
- Brakiva™ (topotecan liposome injection), a novel targeted Optisome™ encapsulated formulation product candidate of the FDA-approved anticancer drug topotecan.
- Alocrest™ (vinorelbine liposome injection), a novel, targeted Optisome™ encapsulated formulation product candidate of the FDA-approved anticancer drug vinorelbine.

##### BASIS OF PRESENTATION AND LIQUIDITY

The accompanying audited financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) and the instructions to Form 10-K.

As of December 31, 2010, the Company has a stockholder's deficit of approximately \$41.9 million, and for the fiscal year ended December 31, 2010, the Company experienced a net loss of \$26.0 million. The Company has financed operations primarily through equity and debt financing and expects such losses to continue over the next several years. The Company currently has a limited supply of cash available for operations. As of December 31, 2010, the Company had aggregate cash and cash equivalents and available-for-sale securities of \$22.6 million, which it believes is sufficient to continue operations through late 2011. The Company has drawn down \$27.5 million of long-term debt under the loan facility agreement with Deerfield Management, with the entire balance due in June 2015. In November 2010, we were notified that we would receive a \$0.7 million grant authorized by The Patient Protection and Affordable Care Act of 2010 for certain of our product candidates. The Internal Revenue Service awarded the grant under the Qualifying Therapeutic Discovery Project (“QTDP”) administered under Section 48D of the Internal Revenue Code. Through December 31, 2010, we have received \$0.6 million in funding related to the grant with an additional \$0.1 million recorded as a receivable. The additional receivable amount was received as funds in January 2011. The company elected to record the grants received and receivable as a credit against research and development expenses in the statement of operations. On June 7, 2010, the Company entered into an Investment Agreement with certain investors pursuant to which it sold 0.4 million shares of redeemable convertible preferred stock at the stated value of \$100 per share, for gross proceeds of \$40 million.

The Investment Agreement provides that the investors have the right, but not the obligation, to make additional investments, as follows:

- at any time prior to the date the Company receives marketing approval from the U.S. Food and Drug Administration for any of its product candidates (“Marketing Approval Date”), the Purchasers may purchase up to an additional 0.2 million shares of Series A-1 Preferred Stock at a purchase price of \$100 per share for an aggregate purchase price of \$20 million (“Additional Investment”); and

- at any time beginning 15 days and within 120 days following the Marketing Approval Date, the investors may purchase up to an aggregate of 0.4 million shares of Series A-2 Convertible Preferred Stock at the stated value of \$100 per share for an aggregate purchase price of \$40 million.

The Company does not generate any recurring revenue and will require substantial additional capital before it will generate cash flow from its operating activities, if ever. The Company does not currently have sufficient capital to fund its entire development plan beyond 2011. The Company's continued operations are entirely reliant upon obtaining additional capital. The Company will be unable to continue development of its product candidates unless it is able to obtain additional funding through equity or debt financings or from payments in connection with potential strategic transactions. The Company can give no assurances that any additional capital that it is able to obtain, if any, will be sufficient to meet its needs. Moreover, there can be no assurance that such capital will be available to the Company on favorable terms or at all, especially given the current economic environment which has severely restricted access to the capital markets. If anticipated costs are higher than planned or if the Company is unable to raise additional capital, it will have to significantly curtail planned development to maintain operations through 2011. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern.

## **NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### **USE OF ESTIMATES**

The preparation of financial statements in conformity with GAAP requires management to make estimates based upon current assumptions that affect the reported amounts of assets and liabilities, disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Examples include provisions for deferred taxes, the valuation of the warrant liabilities and investors' rights to purchase shares of Series A-1 and A-2 preferred stock, the computation of beneficial conversion feature and the cost of contracted clinical study activities and assumptions related to share-based compensation expense. Actual results may differ materially from those estimates.

### **SEGMENT REPORTING**

The Company has determined that it currently operates in only one segment, which is the research and development of oncology therapeutics and supportive care for use in humans. All assets are located in the United States.

### **CASH AND CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS**

The Company considers all highly-liquid investments with a maturity of three months or less when acquired to be cash equivalents. Short-term investments consist of investments acquired with maturities exceeding three months and are classified as available-for-sale. All short-term investments are reported at fair value, based on quoted market price, with unrealized gains or losses included in other comprehensive loss.

### **INVESTMENTS IN DEBT AND MARKETABLE EQUITY SECURITIES**

The Company determines the appropriate classification of all debt and marketable equity securities as held-to-maturity, available-for-sale or trading at the time of purchase, and re-evaluates such classification as of each balance sheet date in accordance with FASB ASC 320. Investments in equity securities that have readily determinable fair values are classified and accounted for as available for sale. We assess whether temporary or other-than-temporary unrealized losses on our marketable securities have occurred due to declines in fair value or other market conditions based on the extent and duration of the decline, as well as other factors. Because we have determined that all of our debt and marketable equity securities are available-for-sale, unrealized gains and losses are reported as a component of accumulated other comprehensive gain (loss) in stockholders' equity. Any other-than-temporary unrealized losses would be recorded in the consolidated statement of operations.

### **CONCENTRATIONS OF CREDIT RISK**

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company's credit risk lies with the exposure to loss in the event of nonperformance by these financial institutions as balances on deposit exceed federally insured limits.

## **FAIR VALUE OF FINANCIAL INSTRUMENTS**

Financial instruments include cash and cash equivalents, available-for-sale securities, and accounts payable. Available-for-sale securities are carried at fair value. Cash and cash equivalents and accounts payable are carried at cost, which approximates fair value due to the relative short maturities of these instruments. The fair value of the Company's warrant liabilities and available-for-sale securities are discussed in Notes 6 and 9, respectively. The Company has issued certain financial instruments, including warrants to purchase common stock and rights to purchase shares of Series A-1 and A-2 Preferred Stock, which have the characteristics of both equity and liabilities. These instruments were evaluated to be classified as liabilities at the time of issuance and are revalued at fair value from period to period with the resulting change in value included in other income/(expense).

## **PROPERTY AND EQUIPMENT**

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets using the straight-line method. Tenant improvement costs are depreciated over the shorter of the life of the lease or their economic life, and equipment, computer software and furniture and fixtures are depreciated over three to five years.

## **DEBT ISSUANCE COSTS**

As discussed in Note 3, the debt issuance costs relate to fees paid in the form of cash and warrants to secure a firm commitment to borrow funds. These fees are deferred, and if the commitment is exercised, amortized over the life of the related loan using the interest method. If the commitment expires unexercised, the deferred fee is expensed immediately.

## **FINANCIAL INSTRUMENTS WITH CHARACTERISTICS OF BOTH EQUITY AND LIABILITIES**

The Company has issued certain financial instruments, including warrants to purchase common stock and rights to purchase shares of Series A-1 and A-2 Preferred Stock, which have the characteristics of both equity and liabilities. These instruments were evaluated to be classified as liabilities at the time of issuance and are revalued at fair value from period to period with the resulting change in value included in other income/(expense).

## **LICENSED IN-PROCESS RESEARCH AND DEVELOPMENT**

Licensed in-process research and development relates primarily to technology, intellectual property and know-how acquired from another entity. The Company evaluates the stage of development as well as additional time, resources and risks related to development and eventual commercialization of the acquired technology. As the Company has historically acquired non-FDA approved technologies, the nature of the remaining efforts for completion and commercialization generally include completion of clinical trials, completion of manufacturing validation, interpretation of clinical and preclinical data and obtaining marketing approval from the FDA and other regulatory bodies. The cost in resources, probability of success and length of time to commercialization are extremely difficult to determine. Numerous risks and uncertainties exist with respect to the timely completion of development projects, including clinical trial results, manufacturing process development results and ongoing feedback from regulatory authorities, including obtaining marketing approval. Additionally, there is no guarantee that the acquired technology will ever be successfully commercialized due to the uncertainties associated with the pricing of new pharmaceuticals, the cost of sales to produce these products in a commercial setting, changes in the reimbursement environment or the introduction of new competitive products. Due to the risks and uncertainties noted above, the Company will expense such licensed in-process research and development projects when incurred. However, the cost of acquisition of technology is capitalized if there are alternative future uses in other research and development projects or otherwise based on internal review. All milestone payments are expensed in the period the milestone is reached.

## **CLINICAL STUDY ACTIVITIES AND OTHER EXPENSES FROM THIRD-PARTY CONTRACT RESEARCH ORGANIZATIONS**

A significant amount of the Company's research and development activities related to clinical study activity are conducted by various third parties, including contract research organizations, which may also provide contractually defined administration and management services. Expense incurred for these contracted activities are based upon a variety of factors, including actual and estimated patient enrollment rates, clinical site initiation activities, labor hours and other activity-based factors. On a regular basis, the Company's estimates of these costs are reconciled to actual invoices from the service providers, and adjustments are made accordingly.

## **SHARE-BASED COMPENSATION**

The Company accounts for share-based compensation in accordance with FASB ASC TOPIC 718 "*Compensation – Stock Compensation* ." The Company has adopted a Black-Scholes-Merton model to estimate the fair value of stock options issued and the resultant expense is recognized in the operating expense for each reporting period. See Note 5 for further information regarding the required disclosures related to share-based compensation.

## **INCOME TAXES**

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between financial statement carrying amounts of existing assets and liabilities, and their respective tax bases and operating loss and tax credit carryforwards. 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 income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

## **COMPUTATION OF NET LOSS PER COMMON SHARE**

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from stock options, stock warrants and restricted stock would have an anti-dilutive effect because the Company incurred a net loss during each period presented. See Note 7.

## **RECLASSIFICATION**

Approximately \$0.9 million in research and development expenses have been reclassified as general administrative expenses for the twelve months ended December 31, 2009 in the Company's statement of operations, to conform to the current year presentation.

## **RECENT ACCOUNTING PRONOUNCEMENTS**

There are no accounting pronouncements that the Company recently adopted or are pending the Company's adoption that are expected to have a material impact on the Company's financial position or results of operations .

## **NOTE 3. FACILITY AGREEMENT**

On October 30, 2007, the Company entered into a Facility Agreement (the "Facility Agreement") with certain affiliates of Deerfield Management (collectively, "Deerfield"), pursuant to which Deerfield agreed to loan to the Company up to \$30 million. The covenants of the loan agreement require that the Company comply with all regulatory agency requirements and the requirements of the Company's license agreements. The Company is also prohibited from disposing of certain assets related to certain product candidates the Company is currently developing. In accordance with and upon execution of the Facility Agreement, the Company paid a loan commitment fee of \$1.1 million to Deerfield Management. The Company has drawn down an aggregate of \$27.5 million since October 30, 2007, of which the entire amount was outstanding at December 31, 2010. There are no additional draws available under the Facility Agreement. Pursuant to the Facility Agreement, the Company is required to make quarterly interest payments on outstanding principal, at a stated annual rate of 9.85%. Under the original terms of the Facility Agreement, all outstanding indebtedness was required to be repaid in full on October 30, 2013. However, on June 7, 2010, the Company and Deerfield entered into an amendment to the Facility Agreement that, among other terms, extended the maturity date of the outstanding principal to June 30, 2015. The Company deemed this modification unsubstantial as the change in the present value of cash flows related to the payment of interest and principal was less than 10%. The Company's obligations under the Facility Agreement are secured by all assets owned (or that will be owned in the future) by the Company, both tangible and intangible. The effective interest rate on the \$27.5 million notes payable, including discount on debt, is approximately 14.5%. As of December 31, 2010, the Company had accrued \$0.7 million in interest payable that was paid in January 2011. The fair value of the loan payable as of December 31, 2010 was \$14.1 million.

*Discount on Debt* . The Company issued certain warrants to Deerfield as part of the Facility Agreement. The fair value of these warrants when issued was \$6.0 million. The total value of the warrants was recorded as a discount on the note payable with this discount amortized over the life of the loan agreement, through June 2015. As of December 31, 2010, the remaining debt discount is approximately \$4.2 million.

*Summary of Notes Payable* . From November 1, 2007 through May 20, 2009, the Company drew down \$27.5 million of the \$30.0 million in total loan proceeds available under the Facility Agreement. The Company is not required to pay back any portion of the principal amount until June 30, 2015. The table below is a summary of the change in carrying value of the notes payable, including the discount on debt for the twelve months ended December 31, 2010 and 2009:

(\$ in thousands)	<b>Carrying Value at January 1,</b>	<b>Gross Borrowings Incurred</b>	<b>Debt Discount Incurred</b>	<b>Amortized Discount</b>	<b>Carrying Value at December 31,</b>
<b>2010</b>					
Notes payable	\$ 27,500	\$ —	\$ —	\$ —	\$ 27,500
Discount on debt	(4,903)	—	—	743	(4,160)
Carrying value	<u>\$ 22,597</u>				<u>\$ 23,340</u>
<b>2009</b>					
Notes payable	\$ 22,500	\$ 5,000	\$ —	\$ —	\$ 27,500
Discount on debt	(5,648)	—	—	745	(4,903)
Carrying value	<u>\$ 16,852</u>				<u>\$ 22,597</u>

A summary of the debt issuance costs and changes during the periods ending December 31, 2010 and 2009 is as follows:

(\$ in thousands)	<b>Deferred Transaction Costs on January 1,</b>	<b>Period Amortized Deferred Transaction Costs</b>	<b>Deferred Transaction Costs on December 31,</b>
<b>2010</b>	<u>\$ 1,194</u>	<u>\$ (289)<sup>2</sup></u>	<u>\$ 905</u>
<b>2009</b>	\$ 1,361	\$ (167)	\$ 1,194

<sup>2</sup> Includes approximately \$0.1 million expense related to unallocated long-term deferred transaction costs that were expensed in the twelve months ended December 31, 2010 related to termination of the commitment period of funding of the Facility Agreement. The commitment period expired in October 2009.

## NOTE 4. REDEEMABLE CONVERTIBLE PREFERRED STOCK

### Private Placement of Preferred Stock

On June 7, 2010, the Company, Warburg Pincus Private Equity X, L.P. and Warburg Pincus X Partners, L.P. (collectively, “Warburg Pincus”) and Deerfield (together with Warburg Pincus, the “Purchasers”) entered into an Investment Agreement pursuant to which the Company issued and sold to the Purchasers an aggregate of 400,000 shares of its newly-designated Series A-1 Convertible Preferred Stock at the stated value of \$100 per share for an aggregate purchase price of \$40 million.

The Investment Agreement provides that the Purchasers also have the right, but not the obligation, to make additional investments in the Company as follows:

- at any time prior to the date the Company receives marketing approval from the U.S. Food and Drug Administration for the first of its product candidates (“Marketing Approval Date”), the Purchasers may purchase up to an additional 0.2 million shares of Series A-1 Preferred Stock at a purchase price of \$100 per share for an aggregate purchase price of \$20 million (“Additional Investment”); and
- at any time beginning 15 days and within 120 days following the Marketing Approval Date, the Purchasers may purchase up to an aggregate of 400,000 shares of Series A-2 Convertible Preferred Stock at the stated value of \$100 per share for an aggregate purchase price of \$40 million (“Subsequent Investment”).

The Investment Agreement required that the Company seek approval of its stockholders to amend the Company’s certificate of incorporation to: (i) increase the authorized number of shares of Common Stock, (ii) effect a reverse split of its Common Stock at a ratio to be agreed upon with the Purchasers, and (iii) provide that the number of authorized shares of Common Stock may be increased or decreased by the affirmative vote of the holders of a majority of the issued and outstanding Common Stock and preferred stock, voting together as one class, notwithstanding the provisions of Section 242(b)(2) of the Delaware General Corporation Law (collectively, the “Stockholder Approval”). These amendments were approved by stockholders at a special meeting on September 2, 2010.

### Terms of the Preferred Shares

During the period from the initial issuance of the Series A-1 Preferred Stock on June 7, 2010 and prior to the Second Closing under the Investment Agreement on September 10, 2010, as discussed below, the Series A-1 Preferred Stock were initially subject to the following terms:

- the stated value of the Series A-1 Preferred Stock, initially \$100 per share, accreted at a rate of 12% per annum;
- each share of Series A-1 Preferred Stock was convertible into shares of the Company’s Common Stock at a conversion price of \$0.5152 per share, subject to a limitation on the number of shares of Common Stock then available for issuance;
- if Stockholder Approval, among other things, was not obtained, the Series A-1 Preferred Stock was redeemable at the holders’ election any time after December 7, 2010, at a redemption price equal to the greater of (i) 250% of the then-accreted value of the Series A-1 Preferred Stock, plus any unpaid dividends accrued thereon and (ii) market value of common stock shares the holder would receive if the Series A-1 Preferred Stock are converted into common stock immediately prior to the redemption.

On September 10, 2010, the Company and the Purchasers conducted a second closing pursuant to the terms of the Investment Agreement, which is referred to herein as the Second Closing. In addition to the Stockholder Approval, the Purchasers’ obligations to complete the Second Closing were subject to a number of customary closing conditions, including the continued accuracy of the representations and warranties made by the Company in the Investment Agreement and the Company’s compliance with its contractual obligations thereunder. At the Second Closing, the shares of Series A-1 Preferred Stock that were originally sold and issued on June 7, 2010 automatically became subject to the Series A-1 Revised Terms. In addition, the Company issued to the Purchasers an additional 12,562 shares of Series A-1 Preferred Stock in satisfaction of an aggregate of \$1.2 million in accretion on the initial 400,000 shares of Series A-1 Preferred Stock since their issuance date on June 7, 2010.

As a result of the Company obtaining Stockholder Approval on September 2, 2010 and the completion of the second closing under the Investment Agreement on September 10, 2010, the terms of the Series A-1 Preferred Stock were adjusted to have the following material terms (hereafter the “Series A-1 Revised Terms”):

- the stated value of the Series A-1 Preferred Stock, initially \$100 per share, accretes at a rate of 9% per annum for a five-year term, compounded quarterly, and following such five-year term, the holders are thereafter entitled to cash dividends at 9% of the accreted stated value per annum, payable quarterly;
- each share of Series A-1 Preferred Stock is convertible into shares of the Company’s Common Stock at a conversion price of \$0.736 per share;
- upon a liquidation of the Company, as defined, including a change in control of the Company, holders of the Series A-1

Preferred Stock would be entitled to receive a liquidation preference per share equal to the greater of (i) 100% of the then-accreted value of the Series A-1 Preferred Stock and (ii) the amount which the holder would have received if the Series A-1 Preferred Stock had been converted into common stock immediately prior to the liquidation; and

- the Series A-1 Preferred Stock is not redeemable except as noted above.

The terms of the Series A-2 Preferred Stock are identical to the Series A-1 Revised Terms, except the conversion price is \$1.104 per share.

Upon closing of the initial investment on June 7, 2010, the Warburg Purchasers received the right to designate five out of nine members of the Company's Board of Directors. The Purchasers also received certain other rights including registration rights for all securities contemplated in the Investment Agreement and the right to participate in any future financing transactions.

The Purchasers are not permitted to transfer or sell preferred stock until the earlier of (a) June 7, 2011 for the initial 400,000 shares of Series A-1 Preferred Stock issued on June 7, 2010, and the applicable first anniversary date of the applicable closing date for the future tranches of shares of Series A-1 or Series A-2 Preferred Stock, (b) June 7, 2012, or (c) the date following the first period of 20 consecutive trading days during which the closing price of the Company's common stock exceeds 200% of the conversion price. Transfer and sale restrictions could also lapse upon occurrence of certain other events.

Additionally, as a condition to the initial closing under the Investment Agreement, the Company and Deerfield amended the Facility Agreement. The maturity date of the principal outstanding pursuant to the loan under the Facility Agreement was extended from October 30, 2013 to June 30, 2015.

### **Accounting Treatment**

The Company has allocated the proceeds from the financing between Series A-1 Preferred Shares and the Purchasers' rights to purchase additional shares of Series A-1 and A-2 Preferred Stock in connection with the Additional Investments and Subsequent Investments.

- *Outstanding Series A-1 Preferred Stock* – Due to certain contingent redemption features of this instrument, the Company classified the 400,000 shares of Series A-1 Preferred Stock sold on June 7, 2010 in the mezzanine section (between equity and liabilities) on the accompanying balance sheet. The Company recorded the residual value of these shares as \$29.9 million on June 7, 2010, net of transaction costs of \$1.4 million and \$8.7 million allocated to the rights to purchase additional Preferred Stock in the future. When the 400,000 shares of Preferred Stock were issued on June 7, 2010, approximately 121,000 shares were convertible due to the limited remaining authorized shares of common stock available for conversion. At the Second Closing, the remaining 279,000 shares of Preferred Stock became convertible when the reverse stock split and the additional shares of common stock were authorized.
- *Additional Series A-1 Preferred Stock Issued During Second Closing* – At the Second Closing on September 10, 2010, the Company issued an additional 12,562 shares to the Purchasers to capture the accretion to the stated value of the Preferred Stock from June 7, 2010, when the shares were issued through the second closing. The carrying value of the Preferred Stock was increased by the estimated fair value of these shares on September 10, 2010, which was \$0.7 million. The Company reduced shareholder's equity by the same amount. All of these additional shares were convertible upon issuance.
- *Rights to Purchase Preferred Stock in the Additional and Subsequent Investments* – The Company determined that the Purchasers' rights to purchase future shares of Preferred Stock in connection with the Additional and Subsequent Investments are freestanding instruments that are required to be classified as liabilities and carried at fair value. The treatment of these instruments as a liability is due to certain redemption features of the underlying Preferred Stock.

The following table summarizes the fair value of right to purchase future shares of Preferred Stock outstanding as of December 31, 2010 and the changes in the valuation in the twelve month periods then ended:

(\$ in thousands)	<b>Fair value Value on acquisition date,</b>	<b>Net change in fair value of liabilities</b>	<b>Fair Value at December 31, 2010</b>
Investors' rights to purchase future shares of series A-1 and A-2 preferred stock	\$ 8,670	\$ (3,539)	\$ 5,131

The following table summarizes the assumptions used in applying the Black-Scholes-Merton option pricing model to determine the fair value of the liability related to the rights to purchase outstanding during the twelve months ended December 31, 2010, respectively:

	<b>Twelve Months Ended December 31, 2010</b>
<b><u>Rights to purchase future shares of preferred stock</u></b>	
Risk-free interest rate	0.29 – 0.50%
Expected life (in years)	0.9 – 1.5
Volatility	1.03 – 1.09
Dividend Yield	8.4 – 11.4%

- **Beneficial Conversion Feature** – Because the conversion price of the shares of Preferred Stock was less than the fair market price of the Company's common stock at the date Preferred Stock was sold and issued, the in-the-money conversion feature (Beneficial Conversion Feature, or BCF) requires separate recognition and is measured at the intrinsic value (i.e., the amount of the increase in value that preferred stockholders would realize upon conversion based on the value of the conversion shares on the commitment date). The BCF is limited to the proceeds allocated to preferred shares and is initially recorded as a discount to preferred shares and included as additional paid-in capital. Because there is not a stated redemption date of the shares of the convertible Series A-1 Preferred Stock, the BCF is immediately accreted to the Preferred Shares as a deemed preferred stock dividend. Through the twelve months ended December 31, 2010, the Company has recognized aggregate BCF of \$29.9 million.
- **Accretion on Preferred Stock** - For the period from June 7, 2010 to September 10, 2010 (the date of the Second Closing), the 400,000 shares of Series A-1 Preferred Stock accreted value to the stated rate of \$100 at an annual rate of 12%, compounded quarterly. Upon the Second Closing, the 412,652 shares of Series A-1 Preferred Stock accreted value to the stated rate of \$100 at an annual rate of 9%, compounded quarterly. The total accretable value from June 7, 2010 to December 31, 2010 was \$2.4 million. The Company will not recognize the value of the accretion to the preferred stock until such time that it becomes probable that the shares of preferred stock will become redeemable. The accretable value is included, for loss per share purposes only, as a dividend to preferred stockholders and the loss attributable to common shareholders is increased by the value of the accretion for the period.

## NOTE 5. STOCKHOLDERS' DEFICIT

In connection with the one-for-four reverse stock split the Company implemented at the close of business on September 10, 2010, the number of outstanding shares of common stock and equity awards was proportionately adjusted to reflect the reverse stock split. As a result, the number of outstanding shares of common stock and equity awards was determined by dividing the number of outstanding shares and equity awards by four. The per share exercise price of stock options and warrants was determined by multiplying the exercise price by four. All historical share and per share amounts have been adjusted to reflect the reverse stock split. All stock options and warrants were appropriately adjusted to give effect to the Reverse Stock Split.

**Issuances of Common Stock** . On October 7, 2009, the Company entered into a securities purchase agreement pursuant to which it agreed to sell in a private placement an aggregate of 13.6 million units of its securities, each unit consisting of (i) either (a) one share of common stock, or (b) a seven-year warrant to purchase one share of common stock at an exercise price of \$0.04 per share (a "Series A Warrant"), and (ii) a seven-year warrant to purchase one-tenth of one share of common stock at an exercise price of \$2.40 (a "Series B Warrant"), which represented the closing bid price of the Company's common stock on October 7, 2009.

Pursuant to the securities purchase agreement, the Company sold 7.7 million units for \$8.5 million, or \$1.20 per unit. These units consisted of shares of common stock and Series B Warrants, with a fair value of \$7.8 million and \$0.6 million, respectively. The Company also sold 2.8 million units consisting of Series A Warrants and Series B Warrants at a purchase price of \$3.2 million, or \$1.16 per unit. The total cash proceeds of the offering were, net of offering costs of \$0.7 million, approximately \$11.7 million. The Company also issued 3.2 million units to Deerfield, consisting of shares of common stock and Series B Warrants, with fair values of \$3.6 million and \$0.3 million, respectively. These units were issued to satisfy a \$3.87 million warrant redemption obligation of the Company to Deerfield, as discussed in Note 3 above. As described in Note 6, all warrants issued in the offering are classified as liabilities.



On December 30, 2009 and May 19, 2010, the Company issued 0.9 million and 1.3 million shares of common stock upon the exercise of Series A Warrants for total proceeds of \$0.1 million.

**Stock Incentive Plans** . As of December 31, 2010, the Company had three stockholder approved stock incentive plans under which it grants or has granted options to purchase shares of our common stock and restricted stock awards to employees: the 2010 Equity Incentive Plan (the “2010 Plan”), the 2004 Stock Incentive Plan (the “2004 Plan”) and the 2003 Stock Option Plan (the “2003 Plan”). The Board of Directors, or the Chief Executive Officer when designated by the Board, is responsible for administration of the employee stock incentive plans and determines the term, exercise price and vesting terms of each option. In general, stock options issued under all the current plans have a vesting period of three years and expire ten years from the date of grant. Additionally, the Company has an Employee Stock Purchase Plan, the 2006 Employee Stock Purchase Plan (the “2006 Plan”).

On February 16, 2010, the Company’s Board of Directors adopted the 2010 Equity Incentive Plan. Under the 2010 Plan, the Board or a committee appointed by the Board may award nonqualified stock options, incentive stock options, restricted stock, restricted stock units, performance awards, and stock appreciation rights to participants. Officers, directors, employees or non-employee consultants or advisors (including our subsidiaries and affiliates) are eligible to receive awards under the 2010 Plan. The total number of shares of our common stock available for grants of awards to participants under the 2010 Plan is 8.5 million shares. The Company intends for all future stock option awards to be issued under the 2010 Plan, with no additional awards being issued under the 2003 Plan or 2004 Plan.

**Stock Options** . The following table summarizes information about stock options outstanding at December 31, 2010 and December 31, 2009 and changes in outstanding options in the twelve months then ended, all of which are at fixed prices:

	Number Of Shares Subject To Options Outstanding (in 000’s)	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value (\$ in 000’s)
<b>Outstanding January 1, 2009</b>	1,118	\$ 9.44		
Options granted	326	0.64		
Options exercised	—	—		
Options cancelled	(235)	8.24		
<b>Outstanding December 31, 2009</b>	1,209	\$ 7.2	8.1	\$ 12
Options granted	5,982	0.56		
Options exercised	—	—		
Options cancelled	(442)	7.39		
<b>Outstanding December 31, 2010</b>	<u>6,749</u>	<u>\$ 1.32</u>	<u>9.3</u>	<u>\$ 7</u>
<b>Exercisable at December 31, 2010</b>	<u>840</u>	<u>\$ 6.53</u>	<u>5.9</u>	<u>\$ 3</u>

Exercise Price	Options Outstanding			Options Exercisable	
	Number of Shares Subject to Options Outstanding (in 000’s)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life of Options Outstanding	Number of Options Exercisable (in 000’s)	Weighted Average Exercise Price
\$ 0.28 - \$ 0.76	5,840	\$ 0.54	9.7 yrs	145	\$ 0.55
\$ 0.77 - \$ 4.48	597	3.11	7.3 yrs	383	3.99
\$ 4.49 - \$ 10.00	217	6.68	5.6 yrs	217	6.68
\$ 10.01 - \$ 43.92	95	25.38	4.9 yrs	95	25.38
<b>\$ 0.28 - \$ 43.92</b>	<u>6,749</u>	<u>\$ 1.32</u>	<u>9.3 yrs</u>	<u>840</u>	<u>\$ 6.53</u>

The weighted-average grant date fair value of options granted during the twelve months ended December 31, 2010 and 2009 was \$0.44 and \$0.64, respectively. During the years ended December 31, 2010 and 2009, the Company recorded share-based compensation cost from all equity awards to employees of \$0.7 million and \$1.0 million, respectively.

**Employee Stock Purchase Plan.** The 2006 Employee Stock Purchase Plan (the “2006 Plan”) allows employees to contribute a percentage of their gross salary toward the semi-annual purchase of shares of our common stock. The price of each share will not be less than the lower of 85% of the fair market value of our common stock on the last trading day prior to the commencement of the offering period or 85% of the fair market value of our common stock on the last trading day of the purchase period. A total of 0.2 million shares of common stock were initially reserved for issuance under the 2006 Plan. The Company issued 0.1 million shares in 2010 pursuant to the 2006 Plan.

**Assumptions .** The following table summarizes the assumptions used in applying the Black-Scholes-Merton option pricing model to determine the fair value of new awards granted during the twelve months ended December 31, 2010 and 2009, respectively:

	December 31,	
	2010	2009
<b>Stock options</b>		
Risk-free interest rate	2.35 – 3.05%	1.90%
Expected life (in years)	5.5 - 6.02	5.5 - 6.0
Volatility	0.99 – 1.02	0.85 – 0.95
Dividend Yield	0%	0%
<b>Employee stock purchase plan</b>		
Risk-free interest rate	0.19% - 0.61%	0.27% - 1.11%
Expected life (in years)	0.5 - 2.0	0.5 - 2.0
Volatility	1.18 – 1.89	1.30 – 2.45
Dividend Yield	0%	0%

The Company estimates the fair value of each option award on the date of grant using the Black-Scholes-Merton option-pricing model and uses the assumptions as allowed by ASC 718, “*Compensation – Stock Compensation .*” Through October 2010, as allowed by ASC 718-10-55, companies with a short period of publicly traded stock history, the Company’s estimate of expected volatility was based on the average expected volatilities of a sampling of other peer companies with similar attributes to it, including industry, stage of life cycle, size and financial leverage as well as the Company’s own historical data. For options issued after October 2010, the Company used its own historical data to estimate expected volatility. As the Company has so far only awarded “plain vanilla” options as described by the SEC’s Staff Accounting Bulletin Topic No. 14, “*Share-Based Payment*”, it used the “simplified method” for determining the expected life of the options granted. The Company will continue to use the “simplified method” under certain circumstances, which it will continue to use as it does not have sufficient historical data to estimate the expected term of share-based awards. The risk-free rate for periods within the contractual life of the option is based on the U.S. treasury yield curve in effect at the time of grant valuation. ASC 718 does not allow companies to account for option forfeitures as they occur. Instead, estimated option forfeitures must be calculated upfront to reduce the option expense to be recognized over the life of the award and updated upon the receipt of further information as to the amount of options expected to be forfeited. Based on our historical information, the Company currently estimates that 22% annually of its stock options awarded with annual vesting mechanisms will be forfeited.

The Company has elected to track the portion of its federal and state net operating loss carryforwards attributable to stock option benefits in a separate memo account. Therefore, these amounts are no longer included in our gross or net deferred tax assets. The benefit of these net operating loss carryforwards will only be recorded in equity when they reduce cash taxes payable.

**Common Stock Warrants.** As of December 31, 2010, the Company had outstanding warrants to purchase an aggregate of approximately 2.0 million shares of its common stock, all of which were available for exercise. Warrants to purchase 0.2 million shares of common stock at \$6.28 per share expired on April 22, 2010. Warrants to purchase 0.2 million shares of common stock at \$23.20 per share expired on October 24, 2010. On June 7, 2010, the Company issued a five-year warrant to purchase 0.1 million shares of common stock at an exercise price of \$0.92 as partial payment for financial advisory services provided in connection with the transactions contemplated by the June 2010 Investment Agreement.

On December 30, 2009 and May 16, 2010, certain investors exercised their Series A Warrants issued in conjunction with the Company’s October 2009 private placement, purchasing 0.9 million and 1.3 million shares of common stock, respectively. The exercise price of the Series A Warrants was \$0.04 per share of common stock.

At December 30, 2010, there are outstanding Series A Warrants to purchase an aggregate of 0.6 million shares of common stock and Series B Warrants to purchase an aggregate of 1.4 million shares of common stock in connection with the Company’s October 2009 private placement. As a result of an anti-dilution provision contained in the Series B Warrants issued in the Company’s October 2009 private placement, the exercise price of the Series B Warrants was reduced to \$1.20 per share after giving effect to the issuance of Series A-1 Preferred Stock on June 7, 2010.

The following table summarizes the warrants outstanding as of December 31, 2010 and 2009 and the changes in outstanding warrants in the twelve month periods then ended:

	Number Of Shares Subject To Warrants Outstanding (in 000's)	Weighted-Average Exercise Price
<b>Warrants outstanding January 1, 2009</b>	2,033	\$ 7.60
Warrants granted	4,131	0.84
Warrants cancelled	(65)	7.40
Warrants redeemed	(1,536)	5.24
Warrants exercised	(877)	0.04
<b>Warrants outstanding December 31, 2009</b>	3,686	2.64
Warrants granted	54	0.92
Warrants cancelled	(439)	14.61
Warrants exercised	(1,264)	0.04
<b>Warrants outstanding December 31, 2010</b>	2,037	\$ 2.99

#### NOTE 6. WARRANT LIABILITIES

The Company had outstanding warrants to purchase 2.0 million and 3.2 million shares of common stock that were classified as liabilities on the balance sheet as of December 31, 2010 and 2009, respectively. The fair value of the warrants classified as liabilities was \$0.7 million and \$2.1 million on December 31, 2010 and 2009, respectively. During the twelve months ended December 31, 2010 and 2009, the Company recognized a loss of \$0.1 million and \$1.1 million, respectively related to the revaluation of the warrant liabilities. Additionally, the Company has reduced the warrant liability due to exercise of Series A Warrants (see Note 4) by \$1.5 million and \$0.9 million during the twelve month periods ended December 31, 2010 and 2009, respectively.

The following table summarizes the fair value of warrants classified as liabilities and outstanding as of December 31, 2010 and 2009 and the changes in the valuation in the twelve month periods then ended:

(\$ in thousands)	Fair value Value at January 1,	Reduction of liability due to redemption or exercise	Additional liability incurred	Net change in fair value of liabilities	Fair Value at December 31,
<b>2010</b>					
Warrants classified as liabilities	\$ 2,146	\$ (1,488)	\$ —	\$ 55	\$ 713
<b>2009</b>					
Warrants classified as liabilities	\$ 1,450	(4,503) <sup>3</sup>	4,094	1,103	\$ 2,146

All warrants that were classified as liabilities as of December 30, 2010 and December 31, 2009 were issued to various investors pursuant to the October 2009 private placement. The warrants issued were Series A and Series B Warrants as discussed in Note 5. The Company classified these warrants as liabilities based on certain cash settlement provisions available to the warrant holders upon certain reorganization events in the equity structure, including mergers. Specifically, in the event the Company is acquired in an all cash transaction, a transaction whereby it ceases to be a publicly held entity under Rule 13e-3 of the Securities Exchange Act of 1934, or a reorganization involving an entity not traded on a national securities exchange, the warrant holders may elect to receive an amount of cash equal to the value of the warrants as determined in accordance with the Black-Scholes-Merton option pricing model with certain defined assumptions. At any time when the resale of the warrant shares is not covered by an effective registration statement under the Securities Act of 1933, the warrant holders can elect a cashless exercise of all or any portion of shares outstanding under a warrant, in which case they would receive a number of shares with a value equal to the intrinsic value on the date of exercise of the portion of the warrant being exercised. Additionally, warrant holders have certain registration rights and the Company would be obligated to make penalty payments to them under certain circumstances if we were unable to maintain effective registration of the shares underlying the warrants with the SEC.

<sup>3</sup> \$ 3.9 million relates to satisfaction of liability owed to Deerfield, which was satisfied by the issuance of 3.2 million equity units as part of the October 2009 financing transaction. \$0.9 million relates to exercise of Series A Warrant on December 30, 2009.

**Assumptions** . The following table summarizes the assumptions used in applying the Black-Scholes-Merton option pricing model to determine the fair value of the liability related to warrants outstanding during the twelve months ended December 31, 2010 and 2009, respectively:

	<b>Twelve Months Ended December 30,</b>	
	<b>2010</b>	<b>2009</b>
<b><i>Warrant liabilities</i></b>		
Risk-free interest rate	1.91 - 3.28%	1.20 – 3.39%
Expected life (in years)	5.77 - 6.52	4.14 – 7.00
Volatility	0.92 - 0.99	0.99 – 2.31
Dividend Yield	0%	0%

For additional details on the change in value of these liabilities, see Note 8. Changes in the Company’s stock price or volatility would result in a change in the value of the warrants and impact the statement of operations. A 10% increase in the Company’s stock price would cause the fair value of the warrants and the warrant liability to increase by approximately 10%.

**NOTE 7. BASIC NET LOSS PER COMMON SHARE**

Basic net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted net income or loss per share is based upon the weighted average number of common shares outstanding during the period, plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is anti-dilutive.

Basic and diluted net loss per share was determined as follows:

(in thousands, except per share amounts)	<b>Twelve Months Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
Net loss	\$ (25,987)	\$ (24,139)
Deemed dividend to preferred shareholders, additional accretion	(2,411)	—
Deemed dividend to preferred shareholders, BCF	(29,898)	—
Net loss applicable to Common Stock	(58,296)	(24,139)
Weighted average shares used in computing net loss per share, basic and diluted	20,737	10,638
Net loss per share, basic and diluted	\$ (2.81)	\$ (2.27)

The securities in the table below were excluded from the computation of diluted net loss per common share for the twelve months ended December 31, 2010 and 2009 because such securities were anti-dilutive during the periods presented:

(in thousands)	<b>2010</b>	<b>2009</b>
Warrants	2,037	3,686
Stock options and Employee Stock Purchase Plans	6,797	1,296
Convertible redeemable preferred stock	57,623	—
Total	66,457	4,982

## NOTE 8. FAIR VALUE MEASUREMENTS

ASC 820 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under ASC 820 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under ASC 820 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1 - Quoted prices in active markets for identical assets or liabilities;
- Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Our Level 2 assets exclusively include U.S. government obligations with quoted prices that are traded less frequently than exchange-traded instruments. All of our Level 2 asset values are determined using a pricing model with inputs that are observable in the market or can be derived principally from or corroborated by observable market data. The pricing model information is provided by third party entities (e.g. banks or brokers). In some instances, these third party entities engage external pricing services to estimate the fair value of these securities; and
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table represents the fair value hierarchy for our financial assets and liabilities held by the Company measured at fair value on a recurring basis for the year ended December 31, 2010 and December 31, 2009:

### 2010

(in \$ thousands)

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3<sup>4</sup></u>	<u>Total</u>
<b>Assets</b>				
Available-for-sale equity securities	\$ 74	\$ —	\$ —	\$ 74
Available-for-sale debt securities	—	17,994	—	17,994
Total	<u>\$ 74</u>	<u>\$ 17,994</u>	<u>\$ —</u>	<u>\$ 18,068</u>
<b>Liabilities</b>				
Warrant liabilities	—	—	\$ 713	\$ 713
Right to purchase future Series A-1 and A-2 preferred stock	—	—	5,131	5,131
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,844</u>	<u>\$ 5,844</u>

### 2009

(in \$ thousands)

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>Assets</b>				
Available-for-sale equity securities	\$ 68	\$ —	\$ —	\$ 68
<b>Liabilities</b>				
Warrant liabilities	\$ —	\$ —	\$ 2,146	\$ 2,146

<sup>4</sup> See notes 4 and 6 of these Notes to the Financial Statements for a roll forward of the Company's Level 3 Assets for the twelve months ended December 31, 2010 and 2009.

## NOTE 9. AVAILABLE-FOR-SALE SECURITIES

On December 31, 2010, the Company had \$18.1 million in total available-for-sale securities which consisted of equity and debt investments. All the Company's U.S. treasury obligation investments are in securities with original maturities less than twelve months. The following table summarizes the investments classified as available-for-sale securities during the twelve months ended December 31, 2010 and 2009:

<b>December 31, 2010</b> (in \$ thousands)	<b>Input Level</b>	<b>Amortized or Historical Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
Money market funds	Level 2	\$ 2,016	\$ —	\$ —	\$ 2,016
U.S. treasury obligations	Level 2	17,992	2	—	17,994
Equity securities	Level 1	92	—	(18)	74
<b>Total available-for-sale securities</b>		<b>20,100</b>	<b>2</b>	<b>(18)</b>	<b>20,084</b>
Less: amounts classified as cash equivalents		2,016	—	—	2,016
Amounts classified as available-for-sale securities		<u>\$ 18,084</u>	<u>\$ 2</u>	<u>\$ (18)</u>	<u>\$ 18,068</u>
<b>December 31, 2009</b> (in \$ thousands)	<b>Input Level</b>	<b>Amortized or Historical Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
Equity securities	Level 1	\$ 92	\$ —	\$ (24)	\$ 68
Less: amounts classified as cash equivalents		—	—	—	—
Amounts classified as available-for-sale securities		<u>\$ 92</u>	<u>\$ —</u>	<u>\$ (24)</u>	<u>\$ 68</u>

## NOTE 10. LICENSE AGREEMENTS

*Tekmira License Agreement*. Pursuant to an Amended and Restated License Agreement dated April 30, 2007, as amended effective May 27, 2009 (the "License Agreement"), between the Company and Tekmira Pharmaceuticals Corporation ("Tekmira"), the Company holds exclusive, worldwide rights to develop and commercialize three oncology drug candidates, Marqibo, Brakiva, and Alocrest. On September 20, 2010, the Company and Tekmira entered into Amendment No. 2 to the License Agreement (the "Amendment"), which amends the License Agreement as follows:

- The Company's maximum aggregate obligation for milestone payments to Tekmira for all three product candidates was decreased from \$37.0 million to \$19.0 million. All of the affected milestone payment obligations relate to amounts triggered by the achievement of regulatory milestones for the Company's Marqibo drug candidate.
- The Amendment modified the royalty rates payable by the Company for net sales of Marqibo by eliminating a tiered royalty rate structure based upon the amount of net sales and instead provides for a single royalty rate without regard to the amount of net sales.
- In consideration of the foregoing, the Company agreed to make a one-time payment to Tekmira of \$5.75 million.

The \$5.75 million payment to Tekmira was recognized as expense in the Condensed statement of operations during the twelve months ended December 31, 2010.

*Menadione Topical Lotion License Agreement*. In October 2006, the Company entered into a license agreement with the Albert Einstein's College of Medicine (AECOM). In consideration for the license, we agreed to issue the college \$0.2 million of our common stock. We also made a cash payment within 30 days of signing the agreement and we agreed to pay annual maintenance fees. Further, we agreed to make milestone payments in the aggregate amount of \$2.8 million upon the achievement of various clinical and regulatory milestones, as described in the agreement, of which we have achieved one milestone and have paid AECOM total consideration of \$0.3 million. We may also make annual maintenance fees as part of the agreement. We also agreed to make royalty payments to the College on net sales of any products covered by a claim in any licensed patent.

## NOTE 11. PROPERTY AND EQUIPMENT

Property and equipment consists of the following at December 31:

	<u>2010</u>	<u>2009</u>
Property and equipment: (in \$ thousands)		
Furniture & fixtures	\$ 53	\$ 53
Computer hardware	252	250
Computer software	212	232
Manufacturing equipment	164	164
Tenant improvements	144	144
	<u>825</u>	<u>843</u>
Less accumulated depreciation	(728)	(591)
Property and equipment, net	<u>\$ 97</u>	<u>\$ 252</u>

For the years ended December 31, 2010 and 2009, depreciation expense was approximately \$0.2 million in each period.

## NOTE 12. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities consist of the following at December 31:

(in \$ thousands)	<u>2010</u>	<u>2009</u>
Trade accounts payable	\$ 1,725	\$ 1,009
Clinical research and other development related costs	2,340	1,232
Accrued personnel related expenses	1,202	980
Interest payable	683	683
Accrued other expenses	102	123
<b>Total</b>	<u>\$ 6,052</u>	<u>\$ 4,027</u>

## NOTE 13. INCOME TAXES

There was no current or deferred income tax expense (other than state minimum tax) for the years ended December 31, 2010 and 2009 because of the Company's operating losses.

The components of deferred tax assets (there were no deferred tax liabilities) as of December 31, 2010 and 2009 are as follows:

Deferred tax assets consist of the following:

(in \$ thousands)	<u>December 31,</u>	
	<u>2010</u>	<u>2009</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 6,709	\$ 24,082
Research and development credit	2,504	4,795
Capitalized research costs	23,996	20,659
Stock-based compensation	7,558	7,262
Accruals and reserves	474	54
Total deferred tax asset	<u>41,242</u>	<u>56,852</u>
Less valuation allowance	(41,242)	(56,852)
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

A reconciliation between our effective tax rate and the U.S. statutory tax rate follows:

	<b>For the Years Ended,</b>	
	<b>December 31, 2010</b>	<b>December 31, 2009</b>
<b>Footnote Disclosure:</b>		
Tax Benefit at Federal Statutory Rate	34.0%	34.0%
State Taxes, Net of Federal Benefit	5.8%	5.8%
Permanent Book/Tax Differences	-2.6%	-2.1%
Tax Credit	-8.7%	7.8%
Gain/loss on Call Options	5.4%	0%
Change in Valuation Allowance	-33.9%	-45.5%
Provision (Benefit) for Taxes	<u>0.0%</u>	<u>0.0%</u>

On June 7, 2010, the Company experienced an ownership change as defined by section 382 of the Internal Revenue Code. Sections 382 and 383 establish an annual limit on the deductibility of pre-ownership change net operating loss and credit carryforwards. As a result of this ownership change, on June 7, 2010 the Company's carrying amount of its federal and state net operating loss carryforwards were reduced by \$70.4 million and \$68.4 million, respectively. The Company has also reduced the amount of deferred tax asset related to its federal R&D credit carryforward by \$1.1 million. State R&D credits have an indefinite carryover period, and thus are not limited. Additionally, the Company reduced the amount of deferred tax asset related to its federal orphan drug credit carryforward by \$4.4 million.

As of December 31, 2010, the Company had potentially utilizable federal and state net operating loss tax carryforwards of approximately \$16.3 million each. The net operating loss carryforwards expire in various amounts for federal tax purposes from 2022 through 2030 and for state tax purposes from 2018 through 2030. As of December 31, 2010, the Company also had research and development credit carryforwards of approximately \$0.1 and \$1.8 million for federal and state tax reporting purposes and orphan drug credit carryforwards of approximately \$1.2 million for federal purposes. The research and development credit carryforwards will expire in 2030 for federal purposes and carryforward indefinitely for state purposes. The orphan drug credit carry forward expires in 2030 for federal purposes.

Management maintains a valuation allowance for its deductible temporary differences (i.e. deferred tax assets) when it concludes that it is more likely than not that the benefit of such deferred tax assets will not be recognized. The ultimate realization of deferred tax assets is dependent upon the Company's ability to generate taxable income during the periods in which the temporary differences become deductible. Management considers the historical level of taxable income, projections for future taxable income, and tax planning strategies in making this assessment. Management's assessment in the near term is subject to change if estimates of future taxable income during the carryforward period are reduced. The Company's valuation allowance decreased by \$15.6 million and increased by \$10.6 million in the years ended December 31, 2010 and 2009, respectively.

The Company has adopted the provisions of FIN 48 as of January 1, 2007, which is now codified as part of ASC 740. The total amount of unrecognized tax benefits as of December 31, 2010 was \$0.8 million. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

Unrecognized Tax Benefits (in \$ thousands)	<b>2010</b>		<b>2009</b>	
	\$	954	\$	438
<b>Balance as of January 1, 2010</b>		954		438
Additions for current year tax positions		624		494
Reductions for current year tax positions		-		-
Additions for prior year tax positions		14		22
Reductions for prior year tax positions		(810)		-
Settlements		-		-
<b>Balance as of December 31, 2010</b>	<u>\$</u>	<u>782</u>	<u>\$</u>	<u>954</u>

None of the unrecognized tax benefits as of December 31, 2010 would affect the Company's effective tax rate if recognized. As the Company would currently need to increase their valuation allowance for any additional amounts benefited, the effective rate would not be impacted until the valuation allowance was removed.

Penalties and interest expense related to income taxes are included as a component of other expense and interest expense, respectively, if they are incurred. For the years ended December 31, 2010 and 2009, no penalties or interest expense related to income tax positions were recognized. As of December 31, 2010 and 2009, no penalties or interest related to income tax positions were accrued. The Company does not anticipate that any of the unrecognized tax benefits will increase or decrease significantly in the next twelve months.

The Company is subject to federal and California state income tax. As of December 31, 2010, the Company's federal returns for the years ended 2002 through the current period and state returns for the years ended 2004 through the current period are still open to examination. Net operating losses and research and development carryforwards that may be used in future years are still subject to inquiry given that the statute of limitation for these items would be from the year of the utilization. There are no tax years under examination by any jurisdiction at this time.

**NOTE 14. COMMITMENTS AND CONTINGENCIES**

*Lease Agreements.* The Company entered into a three year sublease, which commenced on May 31, 2006, for property at 7000 Shoreline Court in South San Francisco, California, where the Company's executive offices were located until March 15, 2011. The total cash payments due for the duration of the sublease equaled approximately \$0.1 million at December 31, 2010.

On February 10, 2011, the Company entered into a seventeen month sublease for property at 2207 Bridgepointe Parkway in San Mateo, California, which commenced on March 1, 2011. The total cash payments due over the seventeen month sublease period are under \$0.3 million. No expense was recognized related to this sublease in the twelve months ended December 31, 2010.

Approximate expenses associated with operating leases were as follows:

(in \$ thousands)	<b>Years Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
Rent expense	\$ 487	\$ 580

**NOTE 15. 401(K) SAVINGS PLAN**

During 2004, the Company adopted a 401(k) Plan (the "401(k) Plan") for the benefit of its employees. The Company elects to match contributions to the 401(k) Plan equal to 100% of the first 5% of wages deferred by each participating employee. During both 2010 and 2009, the Company incurred total charges of approximately \$0.2 million for employer matching contributions.

**NOTE 16. RESTRICTED CASH**

On May 31, 2006, the Company entered into a sublease agreement for its former headquarters at 7000 Shoreline Court in South San Francisco, California. The sublease required the Company to issue a security deposit in the amount of \$125,000. To satisfy this obligation the Company opened a \$125,000 letter of credit, with the sublessor as the beneficiary in case of default or failure to comply with the sublease requirements. In order to fund the letter of credit, the Company was required to deposit a compensating balance of \$125,000 into a restricted money market account with its financial institution. This compensating balance for the line of credit will be restricted until our sublease expires on March 31, 2011.

## INDEX TO EXHIBITS FILED WITH THIS REPORT

### Index to Exhibits Filed with this Report

<b>Exhibit No.</b>	<b>Description</b>
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer.
31.2	Certification of Chief Financial Officer.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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**Consent of Independent Registered Public Accounting Firm**

Talon Therapeutics, Inc.  
San Mateo, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-172229, 333-145663, 333-135252, 333-126878 and 333-126877) of Talon Therapeutics, Inc. of our report dated March 28, 2011, relating to the financial statements, which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP  
San Francisco, California

March 28, 2011

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**CERTIFICATION**

I, Steven R. Deitcher, certify that:

1. I have reviewed this annual report on Form 10-K of Talon Therapeutics, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and
  - (d) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 28, 2011

By: /s/ Steven R. Deitcher  
Steven R. Deitcher, M.D.  
President & Chief Executive Officer

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**CERTIFICATION**

I, Craig W. Carlson, certify that:

1. I have reviewed this annual report on Form 10-K of Talon Therapeutics, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and
  - (d) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 28, 2011

By: /s/ Craig W. Carlson

Craig W. Carlson

Senior Vice President, Chief Financial Officer

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**CERTIFICATIONS PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 200 2**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Talon Therapeutics, Inc. do hereby certify that to the best of his knowledge:

(a) the Annual Report on Form 10-K of Talon Therapeutics, Inc. for the year ended December 31, 2010 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(b) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Talon Therapeutics, Inc.

Dated: March 28, 2011

By: /s/ Steven R. Deitcher  
Steven R. Deitcher, M.D.  
President & Chief Executive Officer

Dated: March 28, 2011

By: /s/ Craig W. Carlson  
Craig W. Carlson  
Senior Vice President, Chief Financial Officer

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