

Harbor BioSciences, Inc.  
Form 10-K  
March 31, 2011  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-K**

x **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

Commission File Number 001-34584

**HARBOR BIOSCIENCES, INC.**

(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation or organization)  
9171 Towne Centre Drive, Suite 180  
San Diego, CA  
(Address of principal executive offices)

13-3697002  
(I.R.S. Employer  
Identification No.)

92122  
(Zip Code)

Registrant's telephone number, including area code: (858) 587-9333

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

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

Common Stock, par value \$0.01 per share

Title of Class

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

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 requirement for the past 90 days. YES  NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES  NO

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2. (Check One).

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 aggregate market value of the voting stock held by nonaffiliates of the Registrant as of June 30, 2010, the end of the Company's most recently completed second fiscal quarter, was approximately \$9,475,550 based on the closing stock price of \$0.27 for the Registrant's Common Stock as reported by the NASDAQ Capital Market\*.

As of March 25, 2011, there were outstanding 35,465,838 shares of the Registrant's Common Stock, \$.01 par value per share.

\* Excludes the common stock held by executive officers, directors and stockholders whose ownership exceeded 10% of the Registrant's common stock outstanding at June 30, 2010. This calculation does not reflect a determination that such persons are affiliates for any other purposes.

### DOCUMENTS INCORPORATED BY REFERENCE

None.

**Table of Contents**

**Harbor BioSciences, Inc.**

**Form 10-K**

**For the Fiscal Year Ended December 31, 2010**

**INDEX**

	<b>Page</b>
<b><u>PART I</u></b>	
Item 1. <u>Business</u>	3
Item 1A. <u>Risk Factors</u>	19
Item 1B. <u>Unresolved Staff Comments</u>	28
Item 2. <u>Properties</u>	28
Item 3. <u>Legal Proceedings</u>	28
Item 4. <u>Reserved</u>	28
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	29
Item 6. <u>Selected Financial Data</u>	30
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	31
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	35
Item 8. <u>Financial Statements and Supplementary Data</u>	36
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	75
Item 9A(T). <u>Controls and Procedures</u>	75
Item 9B. <u>Other Information</u>	76
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	77
Item 11. <u>Executive Compensation</u>	82
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters</u>	91
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	92
Item 14. <u>Principal Accountant Fees and Services</u>	93
Item 15. <u>Exhibits and Financial Statement Schedules</u>	94

---

**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

*This Annual Report on Form 10-K, and the information incorporated herein, contains forward-looking statements that involve and are subject to risks and uncertainties. In particular, statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are contained or incorporated by reference in this Annual Report on Form 10-K. We have based these forward-looking statements on our current expectations about future events. While we believe these expectations reflected in this Annual Report on Form 10-K are reasonable, the inclusion of any forward-looking statements should not be regarded as a representation that any of our plans will be achieved and such forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. Such forward-looking statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words, believe, may, might, can, could, will, would, should, estimate, continue, anticipate, intend, seek, plan, project, expect, or similar expressions. The actual future results for Harbor BioSciences, Inc. may differ materially from those discussed here for various reasons, including those discussed in this Annual Report in Part I, Item 1A under the heading Risk Factors, Part II, Item 7 entitled Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere throughout this Annual Report on Form 10-K. Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. The forward-looking statements included in this Annual Report are made only as of the date hereof. We do not undertake any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements as a result of new information, to reflect future events or developments. When used in this Annual Report, unless otherwise indicated, we, our and us refers to Harbor BioSciences, Inc.*

**PART I**

**Item 1. Business**

**GENERAL OVERVIEW**

Harbor BioSciences, Inc. ( Harbor BioSciences or the Company ), a clinical-stage pharmaceutical company, is engaged in the discovery and development of products for the treatment of diseases related to aging. Our current development efforts are primarily focused on a series of steroid hormone analogs that are derived from the human adrenal metabolome.

We are a development-stage company with two product candidates which recently completed Phase I/IIa clinical trials: Apoptone<sup>®</sup> (HE3235) in patients with late-stage prostate cancer, and Triolex<sup>®</sup> (HE3286) in obese type 2 diabetes mellitus patients. Apoptone and Triolex represent two of the lead candidates from Harbor BioSciences' small molecule platform based on metabolites or synthetic analogs of endogenous human steroids.

Drawn from our unique and proprietary platform, our research program has identified additional lead candidates active in preclinical models of cancer, metabolic conditions, autoimmune conditions, lung inflammation, bone degeneration and organ regeneration.

Our principal executive offices are located at 9171 Towne Centre Drive, Suite 180, San Diego, California 92122, and our telephone number is (858) 587-9333. We incorporated in Delaware in 1992.

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

On March 26, 1997, Hollis-Eden, Inc., a Delaware corporation, was merged with and into us, then known as Initial Acquisition Corp. (IAC), a Delaware corporation. Upon consummation of the merger of Hollis-Eden, Inc. with IAC, Hollis-Eden, Inc. ceased to exist and IAC changed its name to Hollis-Eden Pharmaceuticals, Inc.

Effective February 9, 2010, we changed our name from Hollis-Eden Pharmaceuticals, Inc. to Harbor BioSciences, Inc. The name change was effected pursuant to Section 253 of the General Corporation Law of the State of Delaware by the merger of our wholly owned subsidiary into us. We were the surviving corporation and, in connection with the merger, we amended our Amended and Restated Certificate of Incorporation to change our name to Harbor BioSciences, Inc.

## **Table of Contents**

Effective February 18, 2010, our common stock began trading under a new NASDAQ symbol, HRBR and CUSIP number 41150V 103 . The Company's common stock was then delisted from the NASDAQ Stock Market at the opening of business on September 23, 2010. The Company's shares now trade on the OTC Markets ( OTC ).

In November 2010, we received notice from the U.S. Internal Revenue Service (IRS) that the Company had been awarded approximately \$489,000 in grants under the Qualifying Therapeutic Discovery Project Program. This program was created under the Patient Protection and Affordable Care Act of 2010 to provide tax credits or grants representing up to 50 percent of eligible qualified investments in therapeutic discovery projects during tax years 2009 and 2010.

After a determination by U.S. Department of Health and Human Services that Apoptone and Triolex projects met the definition of a qualifying therapeutic discovery project, the IRS certified the qualifying investment and approved the award amount of approximately \$244,479 per project. The qualified investments represent 2009 research and development expenses; there are no future performance obligations related to these grants.

Harbor BioSciences, Triolex Apoptone, and the Harbor BioSciences stylized logo are trademarks of Harbor BioSciences, Inc. This filing also includes trademarks owned by other parties. All other trademarks mentioned are the property of their respective owners. Use or display by us of other parties' trademarks or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or product owners.

Our periodic and current reports that we file with the Securities and Exchange Commission, or SEC, are available free of charge, on our website, as soon as reasonably practicable after we have electronically filed them with, or furnished them to, the SEC. Our Internet address is [www.harborbiosciences.com](http://www.harborbiosciences.com). The reference to our website does not constitute incorporation by reference of the information contained on our website.

## **Harbor BioSciences Approach**

Under conditions of stress, chronic infections or systemic inflammation, changes to adrenal products themselves, their metabolism, and perturbations of signaling pathways in peripheral tissues, may drive the growth of certain tumors and be causative to diseases of advancing age, including metabolic syndrome, autoimmune diseases, immune mediated inflammatory disease and an impaired ability to fight infections. Our development strategy is based on the hypothesis that hormone derived products are critical to the regulation of the body's complex biological systems. We believe that in young, healthy adults, products such as cortisol, progesterone, dehydroepiandrosterone (DHEA) and its metabolome which include estrogen and testosterone, provide important signals that determine whether biological pathways are engaged to properly regulate the biological processes in our body.

Today, most drug developers are taking a *ground up* approach, first striving to intellectualize and identify critical components in the intricate functional biochemical cascades, and then attempting to design drugs that can successfully block or stimulate those specific pathways resulting in validated molecular targets for specific diseases. While this approach has resulted in a number of successful drugs, frequently their use is limited by serious side effects. In contrast, ours is a *top down* forward pharmacology approach, beginning with the discovery of new members of the human steroid metabolome. Then, by applying traditional pharmaceutical development methodology, our goal is to discover and develop compounds that modify critical endocrine pathways based on the intrinsic activity of native endogenous molecule. The methodology we use is based on an approach to drug discovery and development with a successful history as applied to early discoveries in human hormones. We have now applied this approach to new discoveries being made in the vast unexplored human metabolome and it has the potential to produce new

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

pharmaceutical product candidates to treat a myriad of diseases associated with advancing age, including certain cancers, metabolic and autoimmune diseases as well as immune-mediated inflammatory diseases such as that which results in tissue destruction resulting from chronic

## **Table of Contents**

infections. We believe that by applying these drug development principles we have the potential to produce pharmaceuticals that may address a number of large and important markets, including many with unmet medical needs.

## **TECHNOLOGY**

### **Platform**

Our primary technology development efforts are focused on a series of steroid hormones and their synthetic analogs that promise to be useful in treating a wide variety of medical conditions if successfully developed. Many of these compounds are known to either depleted or elevated during advancing age, a process accelerated by infectious diseases and chronic systemic disorders. In certain indications, high plasma concentrations of these hormones are positively correlated with attenuated disease and the maintenance of youthful blood concentrations is often associated with good health with advancing age.

The chemistry and biochemistry of steroids have been extensively studied and utilized in the development of various drugs, especially for hormonal imbalances, for the treatment of infections and cancer as well as inflammatory conditions. Harbor BioSciences' inventory of greater than 700 steroid compounds is a targeted synthesized chemical library intended for medicinal chemistry applications. The compound library considers components of the mammalian metabolome as existing drug leads and generates chemical neighbors (analogues) as potential pharmaceutical candidates. Many of the library compounds are previously undiscovered metabolic products as well as novel structural analogues with potentially improved pharmaceutical properties. We believe this library contains the largest sample of compounds associated with the DHEA metabolome and may contain many unique chemical structures with diverse biological properties.

The unifying theme of our focused library is to make drug-like molecules that have unique target recognition characteristics that can be used to explore a structure-activity relationship in order to optimize pharmaceutical properties for a selected target. Design features may include oral bioavailability so that the compound may be given orally, and selected for features of both metabolic and chemical stability with a chemical composition that is novel to gain intellectual property protection for patent purposes. In addition the synthesis of the selected compound is optimally facile and cost-effective in consideration of commercialization.

## **OUR DRUG CANDIDATES IN DEVELOPMENT**

We are currently focused on the development of proprietary synthetic steroid derivatives derived from the human 19-carbon steroid scaffold of the mammalian steroid metabolome. We have conducted clinical trials with our lead drug development candidates: Apoptone<sup>®</sup> (HE3235), for late-stage prostate cancer; Triolex<sup>®</sup> (HE3286), for the treatment of obese type 2 diabetes, metabolic and autoimmune disorders; Neumune (HE2100), for the treatment of sepsis a condition that rises with excess radiation exposure; and HE2000, for the prevention of opportunistic infections in immune suppressed patients. Each of these compounds is described in more detail below. In addition, our research program focused on the identification and characterization of new steroid hormones in the human metabolome and has potentially identified new human hormones that may become future pharmaceutical candidates or nutraceutical products.

### ***Apoptone (HE3235)***



**Prostate Cancer**

Apoptone is a second-generation compound we have selected for clinical development in the area of hormone driven cancers, such as prostate cancer. Apoptone was discovered by screening our proprietary steroid chemical library against a prostate cancer LNCaP cell line. It was selected based on a combination of its potency against cancer and desirable pharmaceutical properties. It has been tested in a number of preclinical cancer models and has shown indications of activity in controlling the incidence, growth and development of new tumors in these models. We believe that Apoptone is a disease-modifying agent that may directly induce apoptosis, or cell death, in tumor cells, a result that differs from traditional hormone blockade therapies that

---

## **Table of Contents**

interrupt the tumor cell growth signal through direct androgen or estrogen receptor mediated mechanisms. While hormone blockade therapy can effectively control prostate cancer for a period of time, it often fails and the cancer growth resumes spreading to other organs, usually the bone.

In 2008, we initiated a Phase I/IIa clinical trial with Apoptone in late-stage castrate resistant prostate cancer ( CRPC ) patients who have failed hormone therapy and at least one round of chemotherapy. In December 2009, the trial was amended to include a group of CRPC patients with progressive disease that have not been previously treated with chemotherapy. The open-label dose ranging clinical trial is complete and was conducted in various clinical sites including some within the Prostate Cancer Clinical Trial Consortium ( PCCTC ). It evaluated the safety, tolerance, pharmacokinetics and potential activity of Apoptone when administered twice daily in late-stage prostate cancer patients. The potential activity of the compound was measured by the effect on time to disease progression, as determined by prostate-specific antigen ( PSA ) blood tests, computerized tomography ( CT ), magnetic resonance imaging ( MRI ), or bone scintigraphy, and its effect on circulating tumor cells ( CTC ). Activity was found at the lowest dose studied (10 mg) and no frank toxicity was observed at the highest dose tested (700 mg) which is 70 times greater. The dose escalation algorithm was halted due to a drug-drug interaction observation with a patient's concomitant medication that presented safety concerns with the use of yet higher doses. The compound is staged for Phase IIb clinical trials. Approximately 234,000 patients are diagnosed each year with prostate cancer, and global sales for leading prostate cancer drugs range approximately from \$500 million to \$1 billion annually.

### **Breast Cancer**

We are also exploring the potential of Apoptone in breast cancer. In pre-clinical models of MNU-induced breast cancer, Apoptone successfully treated established tumors and prevented the formation of new tumors. It appeared to be synergistic when given in combination with concurrent taxane chemotherapy. A report on the pre-clinical activity in breast cancer has recently appeared in the peer-reviewed scientific literature.

### **Apoptone Development Status**

Apoptone is manufactured using several organic synthesis steps from the starting material androsterone. The active pharmaceutical ingredient is formulated to an oral dosage form using commonly used excipients in approved (oral dosage) products. Non-clinical toxicology studies have been done that enable the use of Apoptone in clinical studies in late-stage prostate cancer and breast cancer patients using 28-day cycles of therapy. Encouraging data were first reported from the Phase I/IIa clinical trial for in castration resistant prostate cancer – also referred to as hormone resistant prostate cancer – at the ASCO Genitourinary Cancers Symposium in San Francisco, March 6, 2010. Preliminary results from the study, conducted in part with which included participating member sites of the PCCTC, were first reported on November 16, 2009. The phase I/IIa trial was an open-label study with the primary objectives of assessing safety, tolerability, pharmacokinetics and activity of Apoptone in men with CRPC and an ECOG performance status score of less than or equal to 2 (ambulatory and capable of at least self-care). Patient cohorts are defined by oral daily doses of 10 mg, 20 mg, 30 mg, 50 mg, 100 mg, 200 mg, 350 mg and 700 mg. Subjects were treated until toxicity or disease progression; CT and bone scans were obtained every two cycles to assess progression. Based on encouraging signs of activity, the PCCTC recommended an extension of the current trial into CRPC patients that had not been treated with chemotherapy. Accordingly, the subject eligibility criteria were amended to include earlier-stage, chemotherapy-naïve patients in 100 mg and 350 mg expansion cohorts. The clinical trial is now complete. There were 68 patients enrolled in the trial on an intent-to-treat basis. There were 42 taxane-resistant prostate cancer patients entered into the clinical trial at 7 dose levels. Of these 28 (67%) reached their first reassessment (two 28-day cycles), 15 (58%) of these had stable disease on scans or imaging and have received up to 9 additional treatment cycles before disease progression. The Kaplan-Meier estimate for the median time to progression is 15.9 weeks (range 8-24) for this trial. Due to early signs of activity, the 20 mg dose group was expanded to include 14 taxane resistant patients. Eleven of these were evaluable with an actual median time to progression of 19.7 weeks (range 8-24). The 100 mg and 350 mg dose groups were each expanded to include 11 additional pre-chemotherapy patients in order to gain information on the healthier pre-chemotherapy patients and the tolerability of Apoptone



## **Table of Contents**

at higher dose levels. The Kaplan-Meier estimate for the median time to progression for the 10 patients that completed 2 or more cycles in each cohort was 24 weeks in the 100 mg cohort; (21, > 24) and 24 weeks (16, 35). in the 350 mg cohort. Changes in PSA levels were consistent with the properties of a tumor-differentiating agent. The drug was well tolerated and no overt dose-limiting toxicities were reported. The mechanism of action has been partially elucidated and the biochemical molecular points of interaction have been found in prostate cancer cells. Apoptone is a molecular entity that represents a new therapeutic approach for the treatment of hormone dependent cancers with perhaps a more favorable side effect profile than found with presently approved treatments. Several patents have been obtained for the pharmaceutical formulation of Apoptone and its use for the treatment of prostate cancer, breast cancer and benign prostate hypertrophy.

## **Competition**

Two forms of taxotere chemotherapy are presently approved therapies to treat castrate resistant prostate cancer. Despite current treatments, there is an ongoing need for novel oral agents that can control the growth of prostate cancer that is progressing on conventional therapies or hormone treatments. Accordingly, there are a number of companies with drug candidates in development targeting late-stage castration resistant prostate cancer, including compounds already in Phase III clinical trials. Abiraterone<sup>®</sup> produced by Cougar Biotechnology, Inc. (acquired by Johnson & Johnson) is an agent that impedes the synthesis of androgens by inhibition of an enzyme that transforms precursor molecules into the hormone testosterone. Many forms of prostate cancer are dependent on the presence of androgens in order to grow. MDV-3100, produced by Medivation, Inc., is also an agent that blocks the action of androgens on prostate cancer cells through interference at the androgen receptor and stopping their growth. PROVENGE<sup>®</sup>, produced by Dendreon, Inc., is an autologous immune cell therapy that primes the patient's cells against prostate cancer and was recently approved. Apoptone is believed to be a disease modification agent with a mechanism of action that distinguishes it from these competitive drug candidates.

## ***Triolex (HE3286)***

## **Inflammatory Processes in Chronic Diseases**

One of our primary focus areas is diseases that result from chronic inflammatory processes. Properly regulated, inflammation is a protective, life saving response to invading pathogens. However, chronic and unproductive inflammation can cause devastating tissue damage and loss of organ function. Chronic inflammation can arise from over-stimulation of the immune system, often resulting in the release of destructive products such as reactive oxygen species, destructive proteolytic enzymes as well as additional pro-inflammatory mediators. The over-production of these dangerous biochemical products is often due to the presence of persistent low-grade infections, conditions in which the body's surveillance system is unable to differentiate between itself and invasion of foreign substances and biochemical dysregulation that occurs with advancing age. Chronic inflammation has been implicated in the pathogenesis of many diseases ranging from autoimmune conditions, such as arthritis and psoriasis, to infectious diseases, including human immunodeficiency virus (HIV), malaria and tuberculosis, lung inflammation such as asthma, cystic fibrosis and chronic obstructive pulmonary disease, neuroinflammatory conditions such as Parkinson's and Alzheimer's disease, to metabolic diseases, including diabetes and cardiovascular diseases as well as a number of different cancer types.

## **Current Treatments for Chronic Inflammation**

Some of the most widely used drugs for reducing inflammation belong to the corticosteroid class of compounds, which are also derived from the mammalian steroid metabolome. Market research indicates that U.S. physicians issue tens of millions of new prescriptions for corticosteroids each year for a wide range of conditions. While these drugs are highly effective, chronic use leads to immune suppression, bone loss, tissue necrosis and other serious side effects including mental depression.

Over the last decade, a number of new drugs have been introduced that are focused on inhibiting specific components of the pro-inflammatory cascade, including agents that bind and neutralize specific inflammatory

## **Table of Contents**

cytokines, such as TNF-alpha and IL-1 beta, as well as drugs that inhibit specific enzymes, such as COX-2, that produce pro-inflammatory mediators. While these drugs have demonstrated significant activity in a number of clinical trials involving chronic inflammatory diseases, such as arthritis, inflammatory bowel disease and psoriasis, most have also demonstrated significant untoward limitations. Many cause dangerous immune suppression and other serious side effects that limit their utility. Most focus on a specific inflammatory mediator, which means they may not remain perpetually effective due to redundancies and compensatory effects in biological pathways. Our goal has been to develop compounds that mediate homeostasis to regain control of the inflammatory process and restore homeostasis.

### **Obesity, Chronic Inflammation, Insulin Resistance and Diabetes**

Diabetes is a disease of insulin signaling that is comprised of a constellation of syndromes. Insulin is a hormone needed to transport glucose from the blood into cells, where it can either be stored or converted to the energy needed by the cell to perform its biochemical processes. When insulin is insufficient or when insulin signaling functions improperly, the result is high blood glucose levels, which over time can lead to a host of severe medical conditions including nerve disease, blindness, limb amputation, heart attack, stroke and death. There are two forms of diabetes: type 1, a chronic condition in which little or no insulin is produced, and type 2, a condition in which the body becomes resistant to the effects of insulin or the body produces some, but not enough, insulin to maintain a normal blood sugar level.

Epidemiological studies have clearly defined risk factors for the development or progression of type 2 diabetes, including genetics, and prenatal and postnatal environmental factors, including low birth weight, obesity, nutrient excess, inactivity, gestational diabetes, metabolic dysregulation with advancing age and obesity. Obesity in some individuals, through recently elucidated mechanisms, can lead to insulin resistance, hyper-glycemia, beta-cell dysfunction and ultimately overt diabetes. In turn, diabetes-related hyperglycemia and associated metabolic abnormalities can further alter signal transduction and gene-expression thus contributing to a forward feeding cycle that results in disease progression.

The need for new classes of agents to treat type 2 diabetes is significant. There are over 25 million Americans with type 2 diabetes, 92 million in China and 220 million worldwide. Obese diabetes is a syndrome that is increasing rapidly as a result of advancing age and the rising incidence of obesity. Clinical data indicates only 36% of type 2 diabetics are currently able to maintain the American Diabetes Association maximum recommended HbA1c, (a form of hemoglobin that is primarily used to identify the average plasma glucose concentration over a prolonged period of time), glucose level of less than 7.0 %. Large clinical studies have shown that failure to achieve these glucose targets, especially in obese patients, can progressively lead to severe health consequences including neuropathy, blindness, amputation, heart attack, stroke and death. Patients in large clinical trials consistently have a median BMI of 32 indicating that over half the population of T2DM is obese.

Academic researchers have increasingly linked obesity-induced chronic inflammation with type 2 diabetes and elucidated its potential role in potentiating insulin resistance. In the setting of type 2 diabetes, evidence suggests that the pathology may arise through perturbations in NFkB signaling, particularly *via* the TLR4 and TNFa receptors. TLR4 is a receptor expressed on the surface of macrophages and other cells and is stimulated by dietary fatty acids as well as certain pathogens such as bacteria from the gut flora. Stimulation of the TLR4 receptor induces a cascade of pro-inflammatory signals including the production of TNFa, which in turn results in activation events that stimulates a complex network of signaling pathways that culminates in the activation of NFkB and the expression of a number of genes under its control involved in inflammation and the cellular stress response. Persistent stimulation can lead to the chronic inflammatory state and produce the associated pathologies that typifies the metabolic syndrome condition.

The development of widely effective agents to treat obese-type 2 diabetes has elusive and safety concerns have arisen from the chronic administration of many of the currently available medications. Advances in genomic, proteomic and metabolomic sciences over the last decade, however, have led to the development of targeted diagnostics and therapeutics. These leverage knowledge of the basis for an individual's pathology to create a more personalized approach to healthcare. Diagnostic testing is envisioned to enable identification of an



## **Table of Contents**

individual's susceptibility to disease, predict how a given patient will respond to a particular drug, and match patients to the right medication. These new sciences of personalized medicine has the potential to improve the design of clinical trials, eliminate unnecessary treatments, reduce the incidence of adverse reactions to drugs, increase the efficacy of treatments and through identifying the right drug for the right patient, ultimately improve health outcomes.

### **Current Treatments for Type 2 Diabetes**

There are several pharmaceutical approaches to treating type obese-2 diabetes. These include drugs designed to increase insulin production by the pancreas, reduce glucose production by the liver, and drugs, referred to as insulin sensitizers, designed to increase the body's sensitivity to insulin, thereby improving glucose disposal from the bloodstream. Metformin is usually the first intervention prescribed by physicians when an individual is diagnosed with type 2 diabetes. Frequently clinicians will combine drugs that assert different metabolic actions to control the disease in an effort to achieve target levels of glucose control.

### **Triolex to Treat Chronic Inflammation in Type 2 Diabetes**

Triolex is a next-generation compound that we are developing for the treatment of individuals diagnosed with certain chronic inflammatory processes.

In the setting of obese-type 2 diabetes, evidence suggests that the mechanism of action for Triolex may be through regulation of the MAPK and NFkB pathways, particularly when it's stimulated through the TLR4 and TNFa receptors. Triolex may be the first in a new class of insulin sensitizers to target obesity-mediated dysregulated metabolism. This is a major component of the type 2 diabetes syndrome that is characterized by the presence of a chronic inflammatory state. Through regulation of the MAPK and NFkB pathways, our scientists believe potential mechanisms of action for Triolex involve control of genes whose products are involved in the inflammatory signaling pathway that includes TNFa and IL-6. These cytokines are also thought to be critically involved in the pathogenesis of certain autoimmune diseases such as ulcerative colitis and rheumatoid arthritis, and are also implicated in the pathogenesis of metabolic diseases such as non-alcoholic steatohepatitis, cardiovascular disorders, neuroinflammatory disease, cancer and in general, diseases associated with advancing age.

Based on biochemical experiments, Triolex has been shown to act on the NFkB pathway and is independent from the PPARg pathway that is targeted by other insulin sensitizers. Instead, the action of Triolex is associated with down-regulation of the pro-inflammatory JNK, IKK and p38 kinase pathways that cross-over into the NFkB pathway. Chronic activation of these kinase pathways lead to impairment of the insulin receptor substrate-1 protein (IRS-1) function, an important cellular mediator of insulin signaling and glucose transport.

A single-dose Phase I clinical trial conducted during 2007 demonstrated that Triolex is orally bioavailable in humans, with significant drug concentrations detected in the blood at the lowest dose tested. The findings also showed that all doses of Triolex tested appear to be safe and well tolerated in healthy volunteers with no reported drug related serious adverse side effects to date.

A Phase I/II double-blind, placebo-controlled, multi-dose ranging clinical trial with Triolex in obese insulin-resistant subjects was initiated in 2007 and evaluated the safety, tolerance and pharmacokinetics of Triolex when administered for 28 days to obese adult subjects. The potential activity of Triolex to decrease insulin resistance was assessed. In addition, an open-label cohort of six patients with type 2 diabetes mellitus was studied.



Triolex was found to be safe and increased insulin sensitivity in insulin resistant subjects. There was no trend in adverse events to differentiate between placebo- and treated-subjects, nor was there an increase in adverse events with dose escalation. Baseline and day 29 hyperinsulinemic-euglycemic clamp studies were performed on 36 subjects dosed twice daily. To test the hypothesis that HE3286 would improve insulin sensitivity in insulin-resistant subjects, these subjects were stratified by the median baseline value of 5; 21 subjects had M values < 5 (operationally defined as insulin-resistant), and 13 had M values of > 5 (operationally

## Table of Contents

defined as insulin-sensitive). Pretreatment, insulin resistant subjects had significantly higher fasting insulin, HOMA2 %B, HOMA2 IR, and LPS-stimulated PBMC MCP-1, TNF $\alpha$ , and IL-6, and a trend for increased IL-1 $\beta$  confirming greater insulin resistance, inflammatory responses and beta cell function than insulin sensitive subjects.

After 29 days of treatment, there were significant differences in changes from baseline for M values between all Triolex-treated and placebo subjects, and for C-reactive protein. In order to test the hypothesis that Triolex would benefit insulin resistant, but not insulin sensitive subjects, the day 29 changes in M-values were compared in Triolex-treated subjects. M values increased in insulin resistant, and decreased in insulin sensitive subjects, and this difference was highly significant. When compared to placebo, insulin resistant Triolex treated subjects also showed significant improvement in M and a trend for decreased C-reactive protein, whereas insulin sensitive subjects did not. When an additional subset of 6 insulin resistant subjects with baseline insulin >10  $\mu$ U/mL were tested for serum cytokine changes using a 20 mg Triolex dose, significant decreases in serum TNF $\alpha$  and increases in adiponectin at day 29.

During 2008, a Phase IIa clinical trial was initiated with Triolex seeking early signs of activity in type 2 diabetes patients. The clinical trial proceeded in two stages. Stage 1 was a double-blinded placebo controlled 12-week dosing trial that was exploratory in nature and enrolled 96 patients who were on a stable dose of metformin with hemoglobin A1c (HbA1c) level in excess of 7.5 percent. The primary objectives of the study were to evaluate the change in HbA1c from baseline to week 12 and to evaluate the safety and tolerance of Triolex given 10 mg per day (5 mg BID) as compared to placebo. A final analysis for activity (HbA1c) in the clinical study of unaudited data was performed on all subjects that completed day 84 of the study (72 patients). There was no statistical difference between treatment and placebo for HbA1c in the overall patient population. However, a retrospective analysis of unaudited data was performed on the subpopulation of patients that represented the inflamed, obese, insulin-resistant, diabetic subgroup according to FDA guidance. This group is reflective of the impaired glucose tolerance subjects that responded to treatment in the company's Phase I study. The analysis included patients divided into two strata with baseline values either less than or greater than (or equal to) the following criteria: BMI at least 27.3; fasting plasma insulin levels at least 3  $\mu$ U/mL; and serum monocyte chemotactic protein-1 (MCP-1) levels at least 400 pg/mL. This phenotype represented 42% of all subjects (90 patients) with values for these parameters at baseline. Twenty-seven individuals in the high BMI strata completed 84 days of dosing. Those patients treated with Triolex (13) were showed improvements in their clinical parameters compared to the corresponding placebo patients (14). These included significantly decreased HbA1c (-0.53 %,  $p = 0.01$ ), fasting plasma glucose (-26.80 mg/dL,  $p < 0.02$ ), body weight (-2.0 kg,  $p = 0.0005$ ) and significantly increased anhydroglucitol (+0.7  $\mu$ g/mL,  $p = 0.03$ ), which signifies decreased post prandial glucose excursions. More HE3286 subjects decreased weight (12/13 vs. 8/14, Fisher's Exact Test  $p < 0.08$ ) and increased 1,5 anhydroglucitol (8/9 vs. 4/10, Fisher's Exact Test  $p < 0.04$ ). The low BMI strata had a significant increase in HbA1c (+0.7%,  $p < 0.005$ ) but with no detectable changes in any other parameter. There were significant differences between the high BMI and low BMI patients in their response to Triolex. The strata differed significantly in HbA1c (1.15 %,  $p < 0.002$ ), glucose (26.8 mg/dL,  $p < 0.02$ ), body weight (2.2 kg,  $p < 0.0001$ ) and cholesterol (23.5 mg/dL,  $p < 0.006$ ) and significant trends were detected for differences in LDL cholesterol (14.8 mg/dL,  $p = 0.08$ ), triglycerides (21.8 mg/dL,  $p < 0.09$ ) and HOMA2 %B (25 %,  $p < 0.06$ ).

Stage 2 of the Phase IIa clinical trial was in treatment naïve patients (no metformin) with inclusion criteria that restricted the lower limit of BMI to 28, insulin  $\geq 4$   $\mu$ U/mL, C-peptide  $\geq 2$  ng/mL and MCP-1  $\geq 400$  pg/mL. There was no significant overall treatment effect on day 84 HbA1c in Cohort 2 treatment-naïve subjects, despite restrictive inclusion criteria. Subjects were again stratified by BMI. Higher BMI subjects were defined as BMI  $\geq 31.3$  kg/m<sup>2</sup>. At baseline, higher BMI subjects (32 of 69 subjects, 46%) had significantly higher resistin and statistical trends for higher CRP, C-peptide, HOMA2 %B, leptin, and lower fructosamine when compared to the low BMI subjects. HB HE3286-treated subjects showed a statistically significant decrease in HbA1c at day 112 when compared to the corresponding placebo group (-1.1 %,  $p < 0.05$ ). In this group there was a higher proportion of subjects with decreased HbA1c (8/9 vs. 6/13, Fisher's Exact Test  $p < 0.08$ ), and a higher portion with > 1% decrease (5/9 vs. 2/13, Fisher's Exact Test  $p < 0.08$ ). The HE3286 treated subjects had a significantly greater frequency in decreased CRP (8/9 vs. 5/14; Fisher's Exact Test  $p < 0.03$ ), and a statistical trend for a day

## **Table of Contents**

84 decrease (-1.1 mg/L,  $p = 0.08$ ). Post prandial glucose excursions were decreased as evidenced by the greater frequency of subjects with increased day 84 1,5-anhydroglucitol (median, + 1.4  $\mu\text{g}/\text{mL}$ ; 7/8 vs. 6/14 placebos, Fisher's Exact Test  $p < 0.03$ ). In contrast, low BMI patients ( $28 \text{ kg}/\text{m}^2$  -  $31.3 \text{ kg}/\text{m}^2$ ) treated with HE3286 had significantly higher day 84 HbA1c change ( $p < 0.005$ ) from baseline (+0.18 %) when compared to the placebo group (-0.93 %) due to a large placebo effect in these patients. There was also a statistical trend for decreased day 84 fructosamine (-11.75  $\mu\text{mol}$ ,  $p < 0.08$ ) in the placebo but with an absence of a significant difference in day 84 fasting plasma glucose.

Overall Triolex has demonstrated a good safety profile with no consistent pattern of adverse events associated with its use. The side effects associated with the use of currently approved thiazolidenedione insulin sensitizers, have not been observed with Triolex.

## **Competition in Diabetes**

Given the large market opportunities for products that treat the indications for which we are currently developing our compounds, most major pharmaceutical companies and many biotechnology companies have programs directed toward finding drugs to treat the indications that we are exploring and the competition in these markets is intense. In metabolism and type 2 diabetes, there are a number of drugs, such as Actos<sup>®</sup> from Takeda Pharmaceuticals and Avandia<sup>®</sup> from GlaxoSmithKline (already approved for improving insulin sensitivity), glucagon-like peptide-1 (such as Victoza by Novo Nordisk), dipeptidyl peptidase-4 inhibitors (such as Januvia<sup>®</sup> by Merck & Co., Inc. and Onglyza<sup>®</sup> by Bristol Myers Squibb) and numerous other drugs in various stages of development. While Actos<sup>®</sup> and Avandia<sup>®</sup> currently account for a significant share of the market for insulin sensitizers to treat type 2 diabetes, they are known to cause the unwanted side effects of weight gain and edema and were recently either restricted (Avandia) or given black box warning (Actos) by the FDA because of increased treatment-related heart failure risk with the use of the medication.

## **Autoimmune Disease and Chronic Inflammation**

### **Current Treatments for Autoimmune Diseases**

Immune modulators that correct immune dysregulation and chronic inflammatory conditions by inhibition or enhancement of single cytokine targets such as TNF $\alpha$  and IL-1 $\beta$  or their receptors have been developed by a number of companies. For example, Amgen's Enbrel<sup>®</sup> targets TNF $\alpha$  as does Johnson & Johnson's Remicade<sup>®</sup>. Other immune-modulating drugs such as Celebrex<sup>®</sup> from Pfizer target COX-2. While these targeted approaches have shown clinical benefit and have generated significant sales volumes, redundancy in the immune system can limit their effectiveness. In addition, side effects, health care costs and reimbursement issues are limiting their long-term global utility. We have shown our compounds affect cytokine cascades through direct interactions in the endocrine system. This may make them more attractive drug candidates than those currently available as they directly interact through the endocrine system. This pharmaceutical candidate may represent the first in a new class of agent to treat these diseases assuming they are successfully developed and commercialized.

### **Rheumatoid Arthritis**

Rheumatoid arthritis is a type of chronic arthritis that occurs in joints on the extremities of the body (such as hands, wrists or knees). In rheumatoid arthritis, the immune system attacks the joints and sometimes other organs. According to the Centers for Disease Control and Prevention, or (CDCP), an estimated 50 million people were treated for some form of arthritis and other rheumatic conditions in 2009, 22% of the US adult population.

Based upon the published studies in rodent models of collagen-induced and collagen antibody-induced arthritis, where Triolex demonstrated activity, a Phase I clinical trial was initiated in rheumatoid arthritis patients in 2008. A 28-day oral dose ranging study assessed the safety, pharmacokinetics and potential for drug-drug interactions in stable rheumatoid arthritis patients also receiving methotrexate. Triolex was found to be safe and well tolerated. No drug-drug interaction was found. Triolex is now positioned to enter clinical studies in patients with active rheumatoid arthritis.

## **Table of Contents**

### **Ulcerative Colitis**

Inflammatory bowel disease is comprised of ulcerative colitis, a chronic inflammation of the large intestine, or colon, and Crohns disease, a condition of inflammation of the small intestines. Ulcerative colitis and Crohns disease together affect approximately 500,000 to 2 million people in the United States.

Based upon published observations with Triolex in preclinical models widely used by both the pharmaceutical industry and academia to test agents as potential treatments for ulcerative colitis, we commenced a Phase I/II clinical trial in ulcerative colitis patients in 2008. This Phase I/II dose ranging study evaluated the safety, tolerance, pharmacokinetics and activity of Triolex when administered orally for 28 days to patients with active, mild-to-moderate ulcerative colitis. Triolex at the doses studied was found to be safe and well tolerated but offered no indication of a treatment advantage in this acute inflammatory setting when compared to placebo. Triolex is staged for long-term clinical trials directed towards the control of the chronic inflammatory processes associated with this disease, a clinical setting believed to be consistent with the pharmacological properties of the compound.

### **Neuroinflammation**

The Company is investigating the use of Triolex<sup>®</sup> as a treatment for Parkinson's disease (PD) with funding from The Michael J. Fox Foundation. The terms of the collaboration call for MJFF to fund up to approximately \$150,000 toward pre-clinical development of Triolex in rodents. If these studies are successful, additional funding may be awarded by MJFF to continue the clinical development of Triolex for the treatment of PD.

### **Pulmonary Diseases and other Autoimmune Diseases**

The Company is also interested in exploring the potential for Triolex and other new compounds from our technology platform in a variety of pulmonary diseases including, cystic fibrosis, chronic pulmonary disease and asthma. In addition Triolex has shown utility in pre-clinical models of multiple sclerosis and lupus erythematosus.

### **Triolex Development Status**

Triolex is manufactured economically using a multi-step organic synthesis from the widely abundant and inexpensive starting material, DHEA. It is formulated for oral administration with commonly used excipients in approved (oral dosage) products. Diseases associated with chronic inflammation are thought to require drug exposures of extended duration to observe definitive treatment effects. Long term toxicology studies have been completed that qualify Triolex for use in clinical studies of 6 months duration or longer. There were no untoward side effects detected. Patent claims have been allowed for the composition, pharmaceutical formulations and methods of use to treat a variety of inflammatory diseases including type 2 diabetes and autoimmune conditions such as rheumatoid arthritis and ulcerative colitis in the United States, Europe and elsewhere. Applications with pending claims are filed to extend patent coverage in regions of economic interest including China, Japan and Korea.

**NEUMUNE (HE2100)**

**Neumune as treatment for acute radiation exposure; an ER $\beta$  selective agonist.**

In December 2010, The Company reported on the safety, tolerability and signs of hematologic activity in four double-blinded, randomized, placebo-controlled studies of NEUMUNE in healthy human subjects, published in *The Journal of Radiological Protection*. Those studies demonstrated that Neumune has the potential to directly enhance innate immunity in humans and defined the compound as a highly selective ER $\beta$  ligand. ER $\beta$  ligand treatment has been suggested as a potentially safe anti-inflammatory and neuroprotective strategy in multiple sclerosis and other neurodegenerative diseases. In May of 2010, the Company reported that Neumune could ameliorate neuroinflammation in mice and has the potential to limit relapses in patients with multiple sclerosis. The Company is actively soliciting partnerships to develop an orally bioavailable, metabolically.

## **Table of Contents**

### ***HE2000***

#### **HE2000 in Infectious Disease**

The Company conducted clinical trials in HIV, AIDS and malaria from the late 1990 s and early 2002. While the primary market opportunities for pharmaceuticals have traditionally been in the U.S., Europe and Japan, our adrenal steroid hormones have a number of attributes that make them potentially useful globally. Included are the potential broad-spectrum activity in multiple infectious diseases, the attractive safety profile to date, the low likelihood of resistance and the relative ease of manufacture. Increasing focus on the infectious disease crises around the world such as those represented by HIV, malaria and tuberculosis has led to a number of recent third party initiatives designed to provide funding for effective approaches to these diseases.

HE2000 has been tested in a series of Phase I/II and Phase II clinical trials in HIV/AIDS patients in the U.S. and South Africa. In all of these studies, HE2000 treatment appeared to be generally well tolerated with mild to moderate pain at the injection site as the most common adverse event. In addition to assessing the safety profile of HE2000 in clinical trials, we have also assessed the effect of HE2000 on a wide variety of immune and inflammatory markers that are associated with HIV disease progression.

Results from a study employing intermittent subcutaneous dosing of HE2000 in South African HIV patients that received no other therapy demonstrated long-lasting, statistically significant declines in a number of key inflammatory mediators, including TNF $\alpha$ , IL-1 and IL-6 when compared to placebo-treated patients. In this study, we also observed significant durable increases in a wide variety of immune cell subsets associated with innate and cell-mediated immunity following treatment with HE2000. In addition, patients that received HE2000 in this trial experienced a decline in virus levels in the blood over the course of the study, which correlated with an increase in HIV specific T cell mediated immunity. HE2000 was then tested as a monotherapy in late-stage AIDS patients. During this study, patients experienced a statistically significant reduction in the number of opportunistic infections compared to those treated with placebo and the life-threatening tuberculosis infections were completely quelled after 4-months of treatment.

The ability of HE2000 to reduce pro-inflammatory mediators while stimulating innate and cell-mediated immunity has potential implications for the treatment of a number of other infectious diseases, including parasitic infections such as malaria. Based on multiple pre-clinical studies performed by collaborators at the Walter Reid Naval Hospital and the University of Vermont, we performed two Phase II clinical studies in malaria patients at Mahidol University in Bangkok, Thailand. Results indicated that HE2000 was effective in reducing parasite count and cleared malarial parasites in most patients within seven days.

In a series of animal model studies, we have also shown of tuberculosis that HE2000 is effective when given as a monotherapy in either the acute or chronic phase of this bacterial infection and it HE2000 appears to have a synergistic effect when combined with the current three-drug regimen considered the standard of care for antibiotic treatment of the TB infection.

#### **Government Regulation**

#### **General**

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

The manufacturing and marketing of our proposed drug candidates and our research and development activities are, and will continue to be, subject to regulation by federal, state and local governmental authorities in the U.S. and other countries. In the U.S., pharmaceuticals are subject to rigorous regulation by the Food and Drug Administration, ( FDA ), which reviews and approves the marketing of drugs. The Federal Food, Drug and Cosmetic Act, the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacturing, labeling, storage, record keeping, advertising and promotion of our potential products.



## **Table of Contents**

### **Approval Process**

The process of obtaining FDA approval for a new drug may take many years and generally involves the expenditure of substantial resources. The steps required before a new drug can be produced and marketed for human use include clinical trials and the approval of a New Drug Application.

*Preclinical Testing.* In the preclinical phase of development, the promising compound is subjected to extensive laboratory and animal testing to determine if the compound is biologically active and safe.

*Investigational New Drug, or IND.* Before human tests can start, the drug sponsor must file an IND application with the FDA, showing how the drug is made and the results of animal testing. An IND becomes effective 30 days following receipt by the FDA.

*Human Clinical Testing.* The human clinical testing program usually involves three phases which generally are conducted sequentially, but which, particularly in the case of anti-cancer and other life-saving drugs, may overlap or be combined. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA as part of the IND filing. Each clinical study is conducted under the auspices of an independent Institutional Review Board, or IRB, for each institution at which the study will be conducted. The IRB will consider, among other things, the design of the clinical trial, ethical factors, the risk to human subjects and the potential benefits of therapy relative to the risk.

In Phase I clinical trials, studies usually are conducted on healthy volunteers or, in the case of certain terminal illnesses such as AIDS or cancer patients with disease that have failed to respond to other treatment, to determine the maximum tolerated dose, side effects and pharmacokinetics of a product. Phase II studies are conducted on a small number of patients having a specific disease to determine initial efficacy in humans for that specific disease, the most effective doses and schedules of administration, and possible adverse effects and safety risks. Phase II/III differs from Phase II in that the trials involved may include more patients and, at the sole discretion of the FDA, be considered the pivotal trials, or trials that will form the basis for FDA approval. Phase III normally involves the pivotal drug trials consisting of broad scope of studies on diseased patients, in order to evaluate the overall benefits and risks of the drug for the treated disease compared with other available therapies. The FDA continually reviews the clinical trial plans and results and may suggest design changes or may discontinue the trials at any time if significant safety or other issues arise.

*New Drug Application, or NDA.* Upon successful completion of Phase III clinical trials, the drug sponsor files an NDA with the FDA for approval containing details of the chemistry, manufacture and quality control information that has been developed, nonclinical data, results of human tests, and proposed labeling.

The testing and approval process is likely to require substantial time, from several months to years, and there can be no assurance that any FDA approval will be granted on a timely basis, if at all. The approval process is affected by a number of factors, primarily the side effects of the drug (safety) and its therapeutic benefits (efficacy). Additional preclinical or clinical trials may be required during the FDA review period and may delay marketing approval. The FDA may also deny an NDA if applicable regulatory criteria are not met.

Outside the U.S., we will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for our products. The requirements governing human clinical trials ex-US usually follow International Conference on Harmonization of Technical Requirements

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

for Registration of Pharmaceuticals for Human Use ( ICH ) Good Clinical Practices ( GCP ) or country-specific GCPs which are based on the ICH GCPs. Regulatory approval outside the U.S. typically includes the risks and costs associated with obtaining FDA approval but may also include additional risks and costs.

*Post Approval.* If the FDA approves an NDA, the drug sponsor is required to submit reports periodically to the FDA containing adverse reactions, production, quality control and distribution records. The FDA may also require post-marketing testing to support the conclusion of efficacy and safety of the product, which can involve significant expense. After FDA approval is obtained for initial indications, further clinical trials may be necessary to gain approval for the use of the product for additional indications.

## **Table of Contents**

### **Manufacturing**

We do not have, and do not intend to establish, manufacturing facilities to produce our drug candidates or any future products. We plan to control our capital expenditures by using contract manufacturers to make our products. We believe that there are a sufficient number of high-quality FDA-approved contract manufacturers available, and we have had discussions, and in some cases established relationships, to fulfill our near-term production needs for both clinical and commercial applications.

The manufacture of our drug candidates or any future products, whether done by outside contractors as planned or internally, will be subject to rigorous regulations, including the need to comply with the FDA's current Good Manufacturing Practice regulations. As part of obtaining FDA approval for each product, each of the manufacturing facilities must be inspected, approved by and registered with the FDA. In addition to obtaining FDA approval of the prospective manufacturer's manufacturing and quality control procedures, domestic and foreign manufacturing facilities are subject to periodic inspection by the FDA and/or foreign regulatory authorities.

### **Patents**

We currently own or have obtained licenses to a number of U.S. and foreign patents and patent applications. We consider the protection of our technology, whether owned or licensed, to the exclusion of use by others, to be vital to our business. While we intend to focus primarily on patented or patentable technology, we may also rely on trade secrets, unpatented property, know-how, regulatory exclusivity, patent extensions and continuing technological innovation to develop our competitive position. In the U.S. and certain foreign countries, the exclusivity period provided by patents covering pharmaceutical products may be extended by a portion of the time required to obtain regulatory approval for a product.

In certain countries, some pharmaceutical-related technology such as disease treatment methods are not patentable or only recently have become patentable, and enforcement of intellectual property rights in many countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many countries can be expected to be problematic or unpredictable. We cannot guarantee that any patents issued or licensed to us will provide us with competitive advantages or will not be challenged by others. Furthermore, we cannot be certain that others will not independently develop similar products or will not design around patents issued or licensed to us.

In most cases, patent applications in the U.S. are maintained in secrecy until 18 months after the earliest filing or priority date. Publication of discoveries in the scientific or patent literature, if made, tends to lag behind actual discoveries by at least several months. U.S. patent applicants can elect to prevent publication until the application issues by agreeing not to file the application outside the U.S. This option is rarely used for pharmaceutical patent applications. Consequently, we cannot be certain that a patent owner or licensor of its intellectual property was the first to invent the technology or compounds covered by pending patent applications or issued patents or that it was the first to file patent applications for such inventions. In addition, the patent positions of biotechnology and pharmaceutical companies, including our own, are generally uncertain, partly because they involve complex legal and factual questions.

In addition to the considerations discussed above, companies that obtain patents claiming products, uses or processes that are necessary for, or useful to, the development of our drug candidates or future products could bring legal actions against us claiming infringement. Patent litigation is typically costly and time consuming, and if such an action were brought against us, it could result in significant cost and diversion of our attention. We may be required to obtain licenses to other patents or proprietary rights, and we cannot guarantee that licenses would be made available on terms acceptable to us. If we do not obtain such licenses, we could encounter delays in product market introductions while we attempt to develop or license technology designed around such patents, or we could find that the development, manufacture or sale of products

requiring such licenses is foreclosed.

Further, we cannot guarantee that patents that are issued will not be challenged, invalidated or infringed upon or designed around by others, or that the claims contained in such patents will not interfere with the patent

## **Table of Contents**

claims of others, or provide us with significant protection against competitive products, or otherwise be commercially valuable. To the extent that we are unable to obtain patent protection for our products or technology, our business may be materially adversely affected by competitors who develop substantially equivalent technology.

For a discussion of the risks associated with patent and proprietary rights, see below under Item 1A Risk Factors .

## **Technology Agreements**

### **PHARMADIGM**

In August 2002, we entered into a Sublicense Agreement with Pharmadigm, Inc. (currently known as Inflabloc Pharmaceuticals, Inc.). Under the agreement, we obtained exclusive worldwide rights to certain intellectual property of Pharmadigm and the University of Utah and we agreed to make aggregate payments of \$0.9 million in cash or in shares of our common stock, at our option, over the following year. We elected to make such payments in equity and have issued a total of 168,921 shares of our common stock in complete satisfaction of this requirement. We will also make additional milestone and royalty payments to Pharmadigm if we meet specified development and commercialization milestones for products covered by its patents. No such milestones have been met to date. The principal patents licensed under the agreement, originally licensed to Pharmadigm from the University of Utah, relate to inventions by Dr. Raymond Daynes and Dr. Barbara A. Areneo. Dr. Daynes served as a scientific consultant for the Company from 1999 to mid-2003.

### **AESON THERAPEUTICS**

In October 2000, we acquired a 21% equity stake in Aeson Therapeutics Inc. ( Aeson ) and an exclusive worldwide sublicense to three issued patents in the area of adrenal steroids in exchange for \$2.0 million in cash and 208,672 shares of our common stock valued at \$2 million. As part of the transaction, Aeson and its stockholders granted us an exclusive option to acquire the remainder of Aeson at a predetermined price. In March 2002, we amended certain aspects of our agreements with Aeson. Under the amendments, we paid Aeson \$1.2 million, which extended the initial date by which we could exercise our option to acquire the remainder of Aeson to September 30, 2002. We also received additional equity securities of Aeson as a result of this payment. We elected not to exercise the option to acquire the remainder of Aeson by September 30, 2002. On June 7, 2006, we acquired substantially all of the assets of Aeson. As consideration for Aeson's assets, we agreed (i) to issue a total of 35,000 shares of our common stock to Aeson at the closing of the acquisition and (ii) to issue to Aeson's stockholders up to a total of 165,000 additional shares of our common stock if certain development milestones are achieved. We have not achieved any of the development milestones to date.

### **CHINA**

In January of 2011, the Company announced that it had licensed the research and development and commercialization rights for three of its products, exclusively in the People's Republic of China and Hong Kong, to China State Institute of Pharmaceutical Industry ( CIPI ), a subsidiary of China National Pharmaceutical Group Corporation. Harbor BioSciences retains the rights to these products in the U.S. and the rest of the world, and CIPI will make available to the Company all pre-clinical and clinical data it generates. Under the terms of the agreement, CIPI will advance HE2000, Apoptone and Triolex forward through development simultaneously without any financial support from Harbor BioSciences. The agreements provide the opportunity for Harbor BioSciences to capture value for our research and development efforts completed to date,

while retaining U.S. and other world-markets rights.

China National Pharmaceutical Group Corporation

China National Pharmaceutical Group Corporation ( Sinopharm Group ) is the largest pharmaceutical and healthcare group under State-Owned Assets Supervision and Administration Commission of the State Council ( SASAC ) in China. The group has 22 wholly-owned subsidiaries and holding companies, one H-share

---

## **Table of Contents**

company trading on the Hong Kong stock exchange, Sinopharm Group Co., Ltd., and three A-share companies trading on the Shanghai stock exchange, Beijing Tiantan Biological Products Corporation Limited, China National Medicines Co., Ltd. and Shenzhen Accord Pharmaceutical Co., Ltd.

Sinopharm Group researches and develops, manufactures, distributes, and markets medicine and other healthcare products. Sinopharm Group manages factories, research laboratories, traditional Chinese medicine plantations, and marketing and distribution networks that extend throughout the country. Sinopharm Group also runs about a dozen retail pharmacy chains. Sinopharm Group has operations in Africa, France, Germany, Hong Kong, the US, and Vietnam.

In 2009, the group's sale revenue had reached 65 billion Yuan (approximately \$10 billion). Among the 129 enterprises under SASAC, Sinopharm Group is ranked 50th and 38th in terms of sales revenue and total profit respectively. In 2010, Sinopharm Group's revenue is estimated to be 80 billion Yuan (approximately \$12.3 billion). During the period from 2003 to 2009, it is reported that their sales revenue, gross profit and total assets grew at an annual average rate of 30%, 51% and 33% respectively.

The Sinopharm Group has agreed to supply the licensed products to Harbor BioSciences for use in clinical studies and sales outside of China and Hong Kong. Harbor BioSciences can also elect to distribute these compounds in countries that accept the State Food and Drug Administration's (SFDA) drug approval process. Therefore, we believe that CIPI is uniquely positioned to advance these compounds, placing Harbor Biosciences on the forefront of the increasingly globalized pharmaceutical industry.

### The International Conference on Harmonization

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Since its inception in 1990, ICH has evolved, through its ICH Global Cooperation Group, to respond to the increasingly global face of drug development, so that the benefits of international harmonization for better global health can be realized. Harmonization ensures that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner worldwide. Specifically, China has been steadily improving its regulatory regime governing food and pharmaceutical industries in recent years, aligning the country with international standards of practice. Regional Harmonization Initiatives (RHI) include Asia-Pacific Economic Cooperation (APEC), Association of Southeast Asian Nations (ASEAN), Gulf Cooperation Council (GCC), Pan American Network on Drug Regulatory Harmonization (PANDRH) and the Southern African Development Community (SADC). Development in each of these regions may or may not require bridge studies, depending on the genetic diversity within each population, but in any event, costs for such studies would be borne by each regional partner.

### **Business Strategy**

We believe that our agreement with CIPI places Harbor Biosciences on the forefront of a rapidly evolving global pharmaceutical industry. China offers relatively rapid product development, especially in the context of Phase II and III studies, diluted risk (defrayed costs), low cost supply and validation of technology, as well as huge, expanding and increasingly affluent markets for our specific indications. As the R&D arm of the Sinopharm Group, CIPI is uniquely qualified and positioned to develop our small molecules. By the terms of our agreement, CIPI will bear all development costs for each candidate compound and Harbor BioSciences will retain the rights to all its products in the U.S. and the rest of the world. This will afford us several exciting opportunities to capitalize on regional licensing and partnership agreements as well as agreements with Health Ministries of individual governments, including socialized medicine countries. Our partnership with CIPI includes a low cost supply agreement by which China will supply API or finished products into the rest of the world, in accordance with specific agreements and regulatory requirements. Such agreements may include payments of up front fees to Harbor Biosciences with additional payments for milestones achieved

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

in China. Concurrently, Harbor Biosciences is actively attempting to develop partnerships and/or licensing agreements in order to monetize its other assets, including Neumune and several novel, naturally occurring steroid hormones that may be suitable for either pharmaceutical or nutraceutical development. All together, Harbor Biosciences



**Table of Contents**

seeks to capitalize on at least six compounds in various stages of development, including Apoptone, Triolex, HE2000, Neumune, HE3413 and HE3177. In addition, our pipeline contains potential pre-clinical candidates with improved pharmaceutical properties aimed at pharmaceutically accepted targets including ER $\beta$ . It is the Company's intention to reduce its burn rate to match revenue recognition from milestones achieved in China and the execution of potential licenses and partnerships with the rest of the world.

**Employees**

As of March 25, 2011, we had 14 full-time equivalent, non-union employees. We believe that our relations with our employees are good.

**Executive Officers and Senior Management**

Our executive officers and senior management and their ages as of March 25, 2011 are as follows:

Name	Age	Position
James M. Frincke, Ph.D.	60	Chief Executive Officer
Christopher L. Reading, Ph.D.	63	Chief Scientific Officer
Dwight R. Stickney, M.D.	68	Chief Medical Officer
Robert W. Weber	60	Chief Financial Officer and Secretary

**James M. Frincke, Ph.D.** joined Harbor BioSciences as Vice President, Research and Development in November 1997, was promoted to Executive Vice President in March 1999, to Chief Scientific Officer in December 2001, to Chief Operating Officer in February 2008 and to Chief Executive Officer in 2009. Dr. Frincke joined Harbor BioSciences, Inc. from Prolinx, Inc., where he served as Vice President, Therapeutics Research and Development from 1995 to 1997. During his 30 years in the biotechnology industry, Dr. Frincke has managed major development programs including drugs, biologicals, and cellular and gene therapy products aimed at the treatment of cancer, infectious diseases, organ transplantation, autoimmune disease and type 2 diabetes. Since joining the biotechnology industry, Dr. Frincke has held vice president, research and development positions in top tier biotechnology companies including Hybritech/Eli Lilly and SyStemix Inc. (acquired by Novartis). In various capacities, he has been responsible for all aspects of pharmaceutical development including early stage research programs, product evaluation, pharmacology, manufacturing, and the management of regulatory and clinical matters for lead product opportunities. Dr. Frincke has authored or co-authored more than 100 scientific articles, abstracts and regulatory filings. Dr. Frincke received his B.S. in Chemistry and his Ph.D. in Chemistry from the University of California, Davis. Dr. Frincke performed his postdoctoral work at the University of California, San Diego.

**Christopher L. Reading, Ph.D.** joined Harbor BioSciences as Vice President of Scientific Development in January 1999, was promoted to Executive Vice President, Scientific Development in March 2002 and to Chief Scientific Officer in February 2008. Before Harbor BioSciences, Inc., Dr. Reading was Vice President of Product and Process Development at Novartis Inc.-owned SyStemix Inc. During this time, he successfully filed three investigational new drug applications (INDs) in the areas of stem cell therapy technology and stem cell gene therapy for HIV/AIDS. Prior to joining SyStemix, Dr. Reading served on the faculty of the M.D. Anderson Cancer Center in Houston for nearly 13 years. His positions there included Associate and Assistant Professor of Medicine in the Departments of Hematology and Tumor Biology. During his career, Dr. Reading has given more than 25 national and international scientific presentations, published more than 100 peer-reviewed journal articles and 15 invited journal articles as well as written nearly 20 book chapters, and received numerous grants and contracts which supported his research activities. Dr. Reading has served on the National Science Foundation Advisory Committee for Small Business Innovative Research Grants (SBIR) as well as on the editorial boards of *Journal of Biological Response Modifiers* and *Molecular Biotherapy*. He holds a number of patents for his work with monoclonal antibodies and devices. Dr. Reading received his Ph.D. in Biochemistry at the University of California at

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

Berkeley and completed postdoctoral study in tumor biology at The University of California at Irvine. He earned his B.A. in cell biology at the University of California at San Diego.

---

## **Table of Contents**

**Dwight R. Stickney, M.D.** joined Harbor BioSciences as Medical Director, Oncology in May 2000, was appointed Vice President, Medical Affairs in March 2003 and was promoted to Chief Medical Officer in February 2008. Dr. Stickney joined Harbor BioSciences, Inc. from the Radiation Oncology Division of Radiological Associates of Sacramento Medical Group, Inc., in Sacramento, California, where he served as a Radiation Oncologist since 1993. While at Radiological Associates, he served as Chairman of the Radiation Oncology Division from 1997 to 1999 and was a member of the Radiation Study section of the National Institute of Health's Division of Research Grants from 1993 to 1997. He also served as the Director of Radiation Research for Scripps Clinic and Research Foundation in La Jolla, California. Dr. Stickney has taught in medical academia as Associate Professor of Radiation Medicine at Loma Linda University School of Medicine and has served as Director of the International Order of Forrester's Cancer Research Laboratory and on the Board of Directors of the California Division of the American Cancer Society. Earlier in his career, Dr. Stickney held positions with Burroughs Wellcome and the Centers for Disease Control, and academic teaching appointments at The University of California at Los Angeles and The University of California at Riverside. He has also served as a consultant for a number of biotechnology companies on the design and conduct of clinical trials. Dr. Stickney has authored or co-authored over 80 scientific articles, abstracts and book chapters. He is named inventor on numerous issued patents and patent applications. Dr. Stickney holds a Bachelor of Science in Microbiology, a Masters of Science in Immunology, and a M.D. from Ohio State University. In addition, he is certified as a Diplomat of the American Board of Internal Medicine and Hematology and a Diplomat of the American Board of Radiology, Therapeutic Radiology.

**Robert W. Weber** joined Harbor BioSciences in March 1996 and currently serves as the Chief Financial Officer and Secretary. Mr. Weber has over thirty years of experience in financial management. He has been employed at executive levels by multiple start-up companies and contributed to the success of several turnaround situations. He previously served as Vice President of Finance at Prometheus Products, a subsidiary of Sierra Semiconductor (now PMC Sierra), from 1994 to 1996, and Chief Financial Officer for Amercom, a personal computer telecommunications software publishing company, from 1993 to 1994. From February 1988 to August 1993, Mr. Weber served as Chief Financial Officer of Instromedix, a company that develops and markets medical devices and software. Mr. Weber brings a broad and expert knowledge of many aspects of financial management. In various capacities, he has been responsible for all aspects of finance and accounting including cost accounting, cash management, SEC filings, treasury, investor relations, private and venture financing, corporate legal matters, acquisitions/divestitures as well as information technology, human resources and facilities. Mr. Weber received a B.S. from GMI Institute of Technology (now Kettering University) and a MBA from the Stanford Graduate School of Business.

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

*In evaluating our business, you should consider the following discussion of risks, in addition to other information contained in this Annual Report on Form 10-K, as well as our other public filings with the Securities and Exchange Commission. Any of the following risks could materially adversely affect our business, financial condition, results of operations and prospects and, as a result, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.*

***We are still a development stage company.***

We have never had any revenues from sales of products. None of our drug candidates has been approved for commercial sale and we do not expect that any of our present or future drug candidates will be commercially available for a number of years, if at all. We have incurred losses since our inception and we expect to continue to incur significant additional operating losses for the foreseeable future as we fund clinical trials and other expenses in support of regulatory approval of our drug candidates.

## **Table of Contents**

*We need to raise additional money before we achieve profitability; if we fail to raise additional money, it could be difficult or impossible to continue our business.*

As of December 31, 2010, our cash and cash equivalents totaled approximately \$5.9 million. Based on our current plans, we believe these financial resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements into the late 2011. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We will require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

we may not obtain additional financial resources when necessary or on terms favorable to us, if at all; and any available additional financing may not be adequate.

If we cannot raise additional funds when needed, or on acceptable terms, we will not be able to continue to develop our drug candidates.

*We may need to liquidate the Company in a voluntary dissolution under Delaware law or seek protection under the provisions of the U.S. Bankruptcy Code, and in either event, it is unlikely that stockholders would receive any value for their shares.*

We have not generated any revenues from product sales, and have incurred losses in each year since our inception in 1994. We expect that it will be very difficult to raise capital to continue our operations and our independent registered public accounting firm has issued an opinion with an explanatory paragraph to the effect that there is substantial doubt about our ability to continue as a going concern. We do not believe that we could succeed in raising additional capital needed to sustain our operations without some strategic transaction, such as a partnership or merger. If we are unable to consummate such a transaction, we expect that we would need to cease all operations and wind down. Although we are currently evaluating our strategic alternatives with respect to all aspects of our business, we cannot assure you that any actions that we take would raise or generate sufficient capital to fully address the uncertainties of our financial position. As a result, we may be unable to realize value from our assets and discharge our liabilities in the normal course of business. If we are unable to settle our obligations to our creditors or if we are unable to consummate a strategic transaction, we would likely need to liquidate the Company in a voluntary dissolution under Delaware law or seek protection under the provisions of the U.S. Bankruptcy Code. In that event, we, or a trustee appointed by the court, may be required to liquidate our assets. In either of these events, we might realize significantly less from our assets than the values at which they are carried on our financial statements. The funds resulting from the liquidation of our assets would be used first to satisfy obligations to creditors before any funds would be available to pay our stockholders, and any shortfall in the proceeds would directly reduce the amounts available for distribution, if any, to our creditors and to our stockholders. In the event we are required to liquidate under Delaware law or the federal bankruptcy laws, it is highly unlikely that stockholders would receive any value for their shares. See *Liquidity and Capital Resources* in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* and Note 1 to our financial statements.

*We may be unable to obtain a quorum for meetings of our stockholders or obtain necessary stockholder approvals and therefore be unable to take certain actions*

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

Our bylaws require that a quorum, consisting of a majority of the outstanding shares of voting stock, be represented in person or by proxy in order to transact business at a meeting of our stockholders. In addition, amendments to our amended and restated certificate of incorporation, such as an amendment to increase our authorized capital stock, require the approval of a majority of our outstanding shares. Under Rule 452 of the New

---

## **Table of Contents**

York Stock Exchange, the U.S. broker-dealer may vote shares absent direction from the beneficial owner on certain matters, such as an amendment to our amended and restated articles of incorporation to increase authorized shares that are to be used for general corporate purposes and the ratification of our auditors. As a result, unless more stockholders elect to be presented in person or by proxy in future annual or special meetings of stockholders, we may be unable to obtain a quorum at such meetings or obtain stockholder approval of proposals when needed.

If we are unable to obtain a quorum at our stockholders meeting and thus fail to get stockholder approval of corporate actions, such failure could have a materially adverse effect on us. In addition, brokers may only vote on those matters for which broker discretionary voting is allowed under Rule 452 of the New York Stock Exchange, and we may not be able to obtain the required number of votes to approve certain proposals that require a majority of all outstanding share to approve the proposal due to our reliance on broker discretionary voting. Therefore, it is possible that even if we are able to obtain a quorum for our meetings of the stockholders we still may not receive enough votes to approve proxy proposals presented at such meeting and, depending on the proposal in question, such failure could have a material adverse effect on us.

***If we do not obtain government regulatory approval for our products, we cannot sell our products and we will not generate revenues.***

Our principal efforts are currently centered on a proprietary class of small compounds that we believe shows promise for the treatment of several diseases and disorders. However, all drug candidates require approval by the U.S. Food and Drug Administration ( FDA ) before they can be commercialized in the United States as well as approval by various foreign government agencies before they can be commercialized in other countries. These regulations change from time to time and new regulations may be adopted. While limited clinical trials of our drug candidates have been conducted to date, significant additional trials are required, and we may not be able to demonstrate that our drug candidates are safe or effective. In addition, success in early development does not mean that later development will be successful because, for example, drug candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical testing. Our clinical experience with our drug candidates is limited, and to date our drug candidates have been tested in less than the number of patients that will likely need to be studied to gain regulatory approval. The data collected from clinical trials with larger patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of these drug candidates. In addition, we do not know whether early results from any of our ongoing clinical trials will be predictive of final results of any such trial. If we are unable to demonstrate the safety and effectiveness of a particular drug candidate to the satisfaction of regulatory authorities, the drug candidate will not obtain required government approval and we will experience potentially significant delays in, or be required to abandon, development of the drug candidate. If we do not receive FDA or foreign approvals for our drug candidates, we will not be able to sell products and will not generate revenues. If we receive regulatory approval of one of our drug candidates, such approval may impose limitations on the indicated uses for which we may market the resulting product, which may limit our ability to generate significant revenues. Further, U.S. or foreign regulatory agencies could change existing, or promulgate new, regulations at any time, which may affect our ability to obtain approval of our drug candidates or require significant additional costs to obtain such approvals. In addition, if regulatory authorities determine that we or a partner conducting research and development activities on our behalf have not complied with regulations in the research and development of one of our drug candidates, then they may not approve the drug candidate and we will not be able to market and sell it. If we were unable to market and sell our drug candidates, our business and results of operations would be materially and adversely affected.

***Recent publicity concerning the safety of certain drug products has resulted in heightened scrutiny by the FDA in the process of approving new drugs, which could delay or limit any regulatory approvals we may obtain for our drug candidates.***

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products,

---

**Table of Contents**

revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products after approval. In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials by drug development companies. As a result, the FDA may require us to conduct additional preclinical studies or clinical trials during the clinical development of one or more of our drug candidates as a condition precedent to approval which could potentially delay our development plans, limit the indications for which our drug candidates are ultimately approved, and otherwise adversely impact us.

*If we do not successfully commercialize our products, we may never achieve profitability.*

We have experienced significant operating losses to date because of the substantial expenses we have incurred to acquire and fund development of our drug candidates. We have never had significant operating revenues and have never commercially introduced a product. Our accumulated deficit was approximately \$258.4 million as of December 31, 2010. Our net losses for fiscal years 2010, 2009 and 2008 were approximately \$6.6 million, \$15.6 million and \$21.6 million, respectively. Many of our research and development programs are at an early stage. Potential drug candidates are subject to inherent risks of failure. These risks include the possibilities that no drug candidate will be found safe or effective, meet applicable regulatory standards or receive the necessary regulatory clearances. Even if we were ultimately to receive regulatory approval for one or more of our drug candidates, we may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost effectiveness, the cost of manufacturing the product on a commercial scale, the effect of competition with other drugs, or because we may have inadequate financial or other resources to pursue one or more of our drug candidates through commercialization. If we are unable to develop safe, commercially viable drugs, we may never achieve profitability. If we become profitable, we may not remain profitable.

*As a result of our intensely competitive industry, we may not gain enough market share to be profitable.*

The biotechnology and pharmaceutical industries are intensely competitive. We have numerous competitors in the U.S. and elsewhere. Because we are pursuing potentially large markets, our competitors include major multinational pharmaceutical companies, specialized biotechnology firms as well as academic institutions, government agencies and private and public research institutions. Several of these entities have already successfully marketed and commercialized products that will compete with our drug candidates, assuming that our drug candidates gain regulatory approval. A large number of companies including Merck & Co., Inc., GlaxoSmithKline, Takeda Pharmaceuticals, Amylin Pharmaceuticals, Inc., AstraZeneca, Novartis, Novo Nordisk, Pfizer Inc., Sanofi-Aventis and Eli Lilly and Co. are developing and marketing new drugs for the treatment of type 2 diabetes. Similarly, a large number of companies, including Merck & Co., Inc., Pfizer Inc., Johnson & Johnson Inc. and Amgen Inc., are developing and marketing new drugs for the treatment of chronic inflammatory conditions. In addition, there are also a number of other companies with drug candidates in development targeting late-stage prostate cancer, including compounds already in Phase 3 clinical trials. One or more such compounds may be approved before any of our drug candidates could potentially be approved. Many, if not all, of these competing drug development programs are being conducted by pharmaceutical and biotechnology companies with considerably greater financial resources, human resources and experience than ours.

## **Table of Contents**

All of these competitors have greater financial and other resources, larger research and development staffs and more effective marketing and manufacturing organizations than we do. In addition, academic and government institutions have become increasingly aware of the commercial value of their research findings. These institutions are now more likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to develop and market commercial products.

Our competitors may succeed in developing or licensing technologies and drugs that are more effective or less costly than any we are developing. Our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates before we do. If competing drug candidates prove to be more effective or less costly or better-marketed than our drug candidates, our drug candidates, even if approved for sale, may not be able to compete successfully with our competitors' existing products or new products under development. Similarly, we cannot predict whether any of our drug candidates, if approved, will have sufficient advantages to cause healthcare professionals to adopt our products over competing products. If we are unable to compete successfully, we may never be able to sell enough products at a price sufficient to permit us to generate profits.

### ***Our common stock has a very limited trading market***

Our common stock was recently delisted from the NASDAQ Stock Market. Our common stock is now traded on the OTC Markets, an inter-dealer quotation system that provides significantly less liquidity than the NASDAQ Stock Market or any other national securities exchange. In addition, trading in our common stock has historically been extremely limited. Because of the thinness of the market for our stock, the price of our common stock may be subject to manipulation. This limited trading may adversely affect the liquidity of our common stock, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts' and the media's coverage of us. As a result, there could be a larger spread between the bid and the ask prices of our common stock and you may not be able to sell shares of our common stock when or at prices you desire.

### ***Substantial sales of our stock may impact the market price of our common stock.***

As evidenced by the completion of our registered direct offering completed in June 2010, future sales of substantial amounts of our common stock, including shares that we may issue upon exercise of options and warrants or conversion of convertible securities, could adversely affect the market price of our common stock. Further, if we raise additional funds through the issuance of common stock or securities convertible into or exercisable for common stock, the percentage ownership of our stockholders will be reduced and the price of our common stock may fall.

### ***Issuing preferred stock with rights senior to those of our common stock could adversely affect holders of common stock.***

Our charter documents give our board of directors the authority to issue shares of preferred stock without a vote or action by our stockholders. The board also has the authority to determine the terms of preferred stock, including price, preferences and voting rights. The rights granted to holders of preferred stock may adversely affect the rights of holders of our common stock. For example, a series of preferred stock may be granted the right to receive a liquidation preference—a pre-set distribution in the event of liquidation—that would reduce the amount available for distribution to holders of common stock. In addition, the issuance of preferred stock could make it more difficult for a third party to acquire a majority of our outstanding voting stock. As a result, common stockholders could be prevented from participating in transactions that would offer an optimal price for their shares.



*If we were to lose the services of members of our management team, or fail to attract or retain qualified personnel in the future, our business objectives would be more difficult to implement, adversely affecting our operations.*

Our ability to successfully implement our business strategy depends upon the continued services of our management team. If we lose the services of one or more of these individuals, replacement could be difficult and may take an extended period of time and could impede significantly the achievement of our business objectives.

## **Table of Contents**

***Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.***

Our results of operations could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, precipitated an economic recession from which the global economy is in stages of recovery. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary and our stock price may further decline.

***Failure to protect our proprietary technology could impair our competitive position.***

We own or have obtained a license to a number of U.S. and foreign patents and patent applications. Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to our ability to commercialize our drug candidates, if approved and our ability to operate our business without infringing the proprietary rights of third parties. We place considerable importance on obtaining patent protection for significant new technologies, products and processes. Legal standards relating to the validity of patents covering pharmaceutical and biotechnology inventions and the scope of claims made under such patents are still developing. In some of the countries in which we intend to market our drug candidates, if approved, pharmaceuticals are either not patentable or have only recently become patentable. Past enforcement of intellectual property rights in many of these countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries may be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions. Our domestic patent position is also highly uncertain and involves complex legal and factual questions. The applicant or inventors of subject matter covered by patent applications or patents owned by or licensed to us may not have been the first to invent or the first to file patent applications for such inventions. Due to uncertainties regarding patent law and the circumstances surrounding our patent applications, the pending or future patent applications we own or have licensed may not result in the issuance of any patents. Existing or future patents owned by or licensed to us may be challenged, infringed upon, invalidated, found to be unenforceable or circumvented by others. Further, any rights we may have under any issued patents may not provide us with sufficient protection against similar competitive products or technologies that do not infringe our patents or otherwise cover commercially valuable products or processes.

***Litigation or other disputes regarding patents and other proprietary rights may be expensive, cause delays in bringing products to market and harm our ability to operate.***

The manufacture, use or sale of our drug candidates may infringe on the patent rights of others. If we are unable to avoid infringement of the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming and can preclude, delay or suspend commercialization of our drug candidates. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, or fail to successfully defend an infringement action or have the patents we are alleged to infringe declared invalid, we may:

- incur substantial money damages;
- encounter significant delays in bringing our drug candidates to market;
- be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment without first obtaining licenses to do so; and/or

not be able to obtain any required license on favorable terms, if at all.

## **Table of Contents**

In addition, if another party claims the same subject matter or subject matter overlapping with the subject matter that we have claimed in a U.S. patent application or patent, we may decide or be required to participate in interference proceedings in the U.S. Patent and Trademark Office in order to determine the priority of invention. Loss of such an interference proceeding would deprive us of patent protection sought or previously obtained and could prevent us from commercializing our products. Participation in such proceedings could result in substantial costs, whether or not the eventual outcome is favorable. These additional costs could adversely affect our financial results.

### ***Litigation may be expensive and time consuming and may adversely affect our operations.***

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. Participation in such proceedings is time consuming and could result in substantial costs, whether or not the eventual outcome is favorable. These additional costs could adversely affect our financial results.

### ***Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information.***

In order to protect our proprietary technology and processes, we also rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

### ***Existing and/or future pricing regulations and reimbursement limitations may limit our potential profits from the sale of our products.***

The requirements governing product licensing, pricing and reimbursement vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after product-licensing approval is granted. As a result, we may obtain regulatory approval for a drug candidate in a particular country, but then be subject to price regulations that reduce our profits from the sale of the product. In some foreign markets pricing of prescription pharmaceuticals is subject to continuing government control even after initial marketing approval. In addition, certain governments may grant third parties a license to manufacture our product without our permission. Such compulsory licenses may be on terms that are less favorable to us and would likely have the effect of reducing our revenues.

Varying price regulation between countries can lead to inconsistent prices and some re-selling by third parties of products from markets where products are sold at lower prices to markets where those products are sold at higher prices. Any practice of exploiting price differences between countries could undermine our sales in markets with higher prices and reduce the sales of our future products, if any.

While we do not have any applications for regulatory approval of our drug candidates currently pending, any decline in the size of the markets in which we may in the future sell commercial products, assuming our receipt of the requisite regulatory approvals, could cause the perceived market value of our business and the price of our common stock to decline.

Our ability to commercialize our drug candidates successfully also will depend in part on the extent to which reimbursement for the cost of our drug candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations. Third-party payers are increasingly challenging the prices charged for medical products and services. If we succeed in bringing any of our drug candidates to the market, such drug candidates may not be considered cost effective and reimbursement may not be available or sufficient to allow us to sell such drug candidates on a profitable or competitive basis.

## **Table of Contents**

In March 2010, President Obama signed into law The Patient Protection and Affordable Care Act and The Health Care and Education Reconciliation Act of 2010. It is unknown what the overall effect of such legislation has on us.

*Delays in the conduct or completion of preclinical or clinical studies or the analysis of the data from preclinical or clinical studies may result in delays in our planned filings for regulatory approvals, or adversely affect our ability to enter into collaborative arrangements.*

The current status of our two lead drug candidates is set forth below. We have completed:

- Phase I and I/II clinical trials with Triolex in the United States under an IND, for the treatment of metabolic disorders;
- Phase IIa clinical trial with Triolex in the United States in type 2 diabetes patients under an IND for the treatment of metabolic disorders;
- Phase I/II clinical trial with Triolex in the United States under an IND for the treatment of gastrointestinal inflammatory conditions;
- Phase I clinical trial with Triolex in the United States in rheumatoid arthritis patients under an IND for the treatment of inflammatory conditions; and
- Phase I/IIa clinical trial with Apoptone in the United States in late-stage prostate cancer patients who have failed hormone therapy and at least one round of chemotherapy treatment or have not received chemotherapy under an IND for the treatment of hormone-sensitive cancers including prostate cancer.

Any of the following reasons, among others, could delay or suspend the completion of our future studies:

- delays in enrolling volunteers;
- interruptions in the manufacturing of our drug candidates or other delays in the delivery of materials required for the conduct of our studies;
- we may not be able to enter collaborative arrangements besides the CIPI agreements;
- we can not control the uncertainties and lack direct control over the developments of our licensed compounds in China;
- lower than anticipated retention rate of volunteers in a clinical trial;
- unfavorable efficacy results;
- serious side effects experienced by study participants relating to the drug candidate;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- failure to conduct a clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of a clinical trial operations or clinical trial site by regulatory authorities resulting in the imposition of a clinical hold;
- new communications from regulatory agencies about how to conduct these studies; or
- failure to raise additional funds resulting in lack of adequate funding to continue a clinical trial or study.

*If the manufacturers of our drug candidates do not comply with current Good Manufacturing Practices regulations, or cannot produce sufficient quantities of our drug candidates to enable us to continue our development, we will fall behind on our business objectives.*

Manufacturers producing our drug candidates must follow current Good Manufacturing Practices regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to current Good Manufacturing Practices regulations and cannot be brought up to such a standard, we will be required to find alternative manufacturers that do conform. This may be a long and difficult process, and may delay our ability to receive FDA or foreign regulatory approval of our drug candidates.

We also rely on our manufacturers to supply us with a sufficient quantity of our drug candidates to conduct clinical trials. If we have difficulty in the future with obtaining our required quantity and quality of supply, we could experience significant delays in our development programs and regulatory process.

## **Table of Contents**

*Our ability to achieve any significant revenue may depend on our ability to establish effective sales and marketing capabilities.*

Our efforts to date have focused on the development and evaluation of our drug candidates. As we continue preclinical and clinical studies and seek to commercialize our drug candidates, we may need to build a sales and marketing infrastructure. As a company, we have no experience in the sales and marketing of pharmaceutical products. If we fail to establish a sufficient marketing and sales force or to make alternative arrangements to have our drug candidates marketed and sold by others on attractive terms, it will impair our ability to commercialize our drug candidates and to enter new or existing markets. Our inability to effectively enter these markets would materially and adversely affect our ability to generate significant revenues.

*We may face product liability claims related to the use or misuse of our drug candidates, which may cause us to incur significant losses.*

We are currently exposed to the risk of product liability claims due to administration of our drug candidates in clinical trials, since the use or misuse of our drug candidates during a clinical trial could potentially result in injury or death. If we are able to commercialize our products, we will also be subject to the risk of losses in the future due to product liability claims in the event that the use or misuse of our commercial products results in injury or death. We currently maintain liability insurance on a claims-made basis. Because we cannot predict the magnitude or the number of claims that may be brought against us in the future, we do not know whether the insurance policies' coverage limits are adequate. The insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. Any claims against us, regardless of their merit, could substantially increase our costs and cause us to incur significant losses.

*Our securities could be subject to extreme price fluctuations that could adversely affect your investment.*

The market prices for securities of life sciences companies are highly volatile particularly those that are not profitable. Publicized events and announcements, most of which we cannot control, may have a significant impact on the market price of our common stock, which has been, and is likely to continue to be, volatile. For example:

- biological or medical discoveries by competitors;
- public concern about the safety of our drug candidates;
- delays in the conduct or analysis of our preclinical or clinical studies;
- unfavorable results from preclinical or clinical studies;
- delays in obtaining or failure to obtain purchase orders of our drug candidates;
- announcements in the scientific and research community;
- changes in the potential commercial markets for our drug candidates;
- unfavorable developments concerning patents or other proprietary rights;
- unfavorable domestic or foreign regulatory or governmental developments or actions;
- broader economic, industry and market trends unrelated to our performance;
- issuances of new equity securities by us, pursuant to our effective shelf registration statement or otherwise;
- discussion of us or our stock price by the financial and scientific press and in online investor communities; or
- additions or departures of key personnel



## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

may have the effect of temporarily or permanently driving down the price of our common stock. In addition, the stock market from time to time experiences extreme price and volume fluctuations which particularly affect the market prices for emerging and life sciences companies, such as ours, and which are often unrelated to the operating performance of the affected companies. For example, our stock price has ranged from \$0.12 to \$0.98 between January 1, 2009 and March 11, 2011.

These broad market fluctuations may adversely affect the ability of a stockholder to dispose of his shares at a price equal to or above the price at which the shares were purchased. In addition, in the past, following periods

**Table of Contents**

of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Any litigation against the Company, including this type of litigation, could result in substantial costs and a diversion of management's attention and resources, which could materially adversely affect our business, financial condition and results of operations.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our corporate headquarters are currently located at 9171 Towne Centre Drive, Suite 180, San Diego, CA 92122, where we have leased approximately 6,377 square feet of office space through July 2011. We believe that our facilities are adequate for our current operations.

**Item 3. Legal Proceedings**

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. While it is impossible to predict accurately or to determine the eventual outcome of these matters, as of the date of this report, we do not believe that we are engaged in any legal proceedings that are expected, individually or in the aggregate, to have a material adverse effect on our business, financial condition or operating results.

**Item 4. Removed and Reserved.**

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

Our common stock was traded on the NASDAQ Capital Market under the symbol HRBR until we were delisted in September 2010. Our common stock is now traded on the OTC Bulletin Board under the symbol HRBR.OB.

The following table sets forth the quarterly high and low sales prices for our common stock from January 1, 2009 through March 11, 2011.

2009		
First Quarter	\$ 0.85	\$ 0.37
Second Quarter	0.76	0.29
Third Quarter	0.70	0.43
Fourth Quarter	0.67	0.43
2010		
First Quarter	\$ 0.75	\$ 0.45
Second Quarter	0.60	0.27
Third Quarter	0.33	0.18
Fourth Quarter	0.20	0.13
2011		
January 1 - March 11	\$ 0.24	\$ 0.14

On March 11, 2011, the closing price of our common stock as reported by the OTC Markets was \$0.22 share. There were approximately 8,500 stockholders of record and beneficial stockholders of our common stock as of such date. We have not paid cash dividends on our common stock and do not intend to do so in the foreseeable future.

There were no unregistered sales of equity securities in 2010.

We made no repurchases of our securities during the year ended December 31, 2010.

**Table of Contents****Item 6. Selected Financial Data**

The following data summarizes certain selected financial data for each of the five years ended December 31, 2010 through 2006 and the period from inception (August 15, 1994) to December 31, 2010. The information presented should be read in conjunction with the financial statements and related notes included elsewhere in this report (in thousands, except per share amounts).

	2010	2009	2008	2007	2006	Period from Inception (Aug. 15, 1994) to December 31, 2010
<b>Statement of Operations Data:</b>						
Contract revenues	\$	\$	\$	\$ 645	\$ 444	\$ 1,208
Research and development	3,759	10,555	16,070	18,319	23,764(1)	175,013
General and administrative	2,771	5,140	6,537	8,150	9,644(1)	90,688
Settlement of Dispute						3,000
Total operating expenses	6,530	15,695	22,607	26,469	33,408	268,701
Interest income (expense)	16	138	1,048	2,781	2,741	17,379
Other income (expense)	(83)	(69)	(6)	(78)	(8)	8,315
Net loss	\$ (6,597)	\$ (15,626)	\$ (21,565)	\$ (23,121)	\$ (30,231)	\$ (258,429)
Net loss per share, basic and diluted	\$ (0.20)	\$ (0.53)	\$ (0.74)	\$ (0.80)	\$ (1.20)	
Weighted average number of common Shares outstanding, basic and diluted	32,803	29,319	29,060	28,955	25,131	
<b>Balance Sheet Data:</b>						
Cash and equivalents	\$ 5,923	\$ 9,738	\$ 24,152	\$ 43,215	\$ 67,135	
Total assets	6,096	10,286	25,157	45,123	68,512	
Total current liabilities.	1,235	1,286	1,952	3,018	6,734	
Stockholders' equity	\$ 4,861	\$ 9,000	\$ 23,205	\$ 42,105	\$ 61,778	

Share-Based Payment (ASC 718), expense was not included in financial results for any of the previous years prior to 2006. (See ASC 718, Share-Based Payments in the Notes to Financial Statements).

## **Table of Contents**

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

*The following discussion contains forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements" elsewhere in this Annual Report on Form 10-K. This discussion and analysis should be read in conjunction with the financial statements and notes included elsewhere in this Annual Report.*

#### **General**

We are a development-stage pharmaceutical company engaged in the discovery and development of drug candidates for the treatment of diseases and disorders in which the body is unable to mount an appropriate immune or metabolic response due to disease or the process of aging. Our initial technology development efforts are primarily focused on a series of adrenal steroid hormones and hormone analogs that are derived from our Hormonal Signaling Technology Platform.

We have been unprofitable since our inception. As of December 31, 2010, we had an accumulated deficit of approximately \$258.4 million. We expect to incur substantial additional operating losses for the foreseeable future as we allocate resources to activities in support of the development of our drug candidates. In addition, in the future, we may have to meet the substantial new challenge of developing the capability to market products if we are successful in obtaining regulatory approval for any of our current or future drug candidates. Accordingly, our activities to date are not as broad in depth or scope as the activities we may undertake in the future, and our historical operations and financial information are not indicative of the future operating results or financial condition or ability to operate profitably as a commercial enterprise when and if we succeed in bringing any drug candidates to market.

On March 26, 1997, Hollis-Eden, Inc., a Delaware corporation, was merged with and into us, then known as Initial Acquisition Corp. (IAC), a Delaware corporation. Upon consummation of the merger of Hollis-Eden, Inc. with IAC, Hollis-Eden, Inc. ceased to exist, and IAC changed its name to Hollis-Eden Pharmaceuticals, Inc.

Effective February 9, 2010, we changed our name from Hollis-Eden Pharmaceuticals, Inc. to Harbor BioSciences, Inc. The name change was effected pursuant to Section 253 of the General Corporation Law of the State of Delaware by the merger of our wholly owned subsidiary into us. We were the surviving corporation and, in connection with the merger, we amended our Amended and Restated Certificate of Incorporation to change our name to Harbor BioSciences, Inc.

Effective February 18, 2010, our common stock began trading under a new NASDAQ symbol, "HRBR" and CUSIP number "41150V 103". Our common stock was delisted from NASDAQ in September, 2010 and is now traded on the OTC Markets with the symbol HRBR.OB.

#### **Results of Operations**

We have devoted substantially all of our resources to the payment of research and development expenses and general and administrative expenses. From inception through December 31, 2010, we have incurred approximately \$175.0 million in research and development expenses, \$90.7 million in general and administrative expenses, and \$3.0 million in a settlement of dispute. From inception, (August 15, 1994), through December 31, 2010 we have generated approximately \$1.2 million in revenues (which resulted from providing research and development

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

services under our Study Funding Agreement with Cystic Fibrosis Foundation Therapeutics, Inc., (CFFT). We have earned \$9.1 million in other income. The other income and expense is comprised of \$7.6 million in deemed discount expense, \$0.4 million in interest expense and a \$0.3 million loss on disposal of assets. These expenses have been offset by \$17.4 million in interest income. The combination of these resulted in a net loss of \$258.4 million for the period from inception, (August 15, 1994), until December 31, 2010.

Research and development and general and administrative expenses include the expense for ASC 718 share-based payments for all fiscal years starting with 2006, (See ASC 718 Share-Based Payments in the Notes to Financial Statements).

Research and development expenses were \$3.8 million, \$10.6 million and \$16.1 million in 2010, 2009 and 2008, respectively. The research and development expenses relate primarily to the ongoing development,

## **Table of Contents**

preclinical testing and clinical trials for our drug candidates. Research and development expenses decreased \$6.8 million in 2010 compared to 2009; \$5.5 million in 2009 compared to 2008, due primarily to a decrease in general clinical and preclinical research and development projects resulting from reduced personnel and a decline in stock option compensation expense.

General and administrative expenses were \$2.8 million, \$5.1 million and \$6.5 million in 2010, 2009 and 2008, respectively. General and administrative expenses relate to salaries and benefits, facilities, patent fees, legal, accounting/auditing, investor relations, consultants, insurance and travel. General and administrative expenses decreased \$2.3 million in 2010 compared to 2009, \$1.4 million in 2009 compared to 2008 due mainly to a decrease in salaries expense resulting from reduced personnel, legal fees, Directors and Officers insurance and stock option compensation expense.

Other income and expenses were (\$0.07) million, \$0.07 million and \$1.0 million in 2010, 2009 and 2008, respectively. The increase in expense of \$0.12 million for 2010 compared to 2009 was due mainly to the disposal of assets combined with lower interest rates and lower cash balances. The \$0.9 million decrease in other income and expense for 2009 compared to 2008 was due mainly to lower interest rates and lower cash balances. Included in the 2010 loss was \$0.08 related to the sale of our laboratory equipment and \$0.07 million for 2009.

## **Liquidity and Capital Resources**

Our operations to date have consumed substantial capital without generating any revenues other than the amount received under our collaboration with CFFT. We have financed our operations since inception primarily through the sale of our equity securities raising a total of \$205 million, net of expenses. In addition, we have received a total of \$18 million from the exercise of warrants and stock options from inception. As of December 31, 2010, our cash and cash equivalents totaled approximately \$5.9 million. Based upon our current plans, we believe that our existing capital resources will be sufficient to meet our operating expenses into late 2011. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time.

Our future capital requirements will depend upon many factors, including progress with preclinical testing and clinical trials, the number and breadth of our programs, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, the time and costs involved in obtaining regulatory approvals, competing technological and market developments, and our ability to establish collaborative arrangements, effective commercialization, marketing activities and other arrangements. We may incur negative cash flows and net losses for the foreseeable future.

We expect that it will be very difficult to raise capital to continue our operations and our independent registered public accounting firm has issued an opinion with an explanatory paragraph to the effect that there is substantial doubt about our ability to continue as a going concern. We do not believe that we could succeed in raising additional capital needed to sustain our operations without some strategic transaction, such as a partnership in addition to the China license agreements or a merger. If we are unable to consummate such a transaction, we expect that we would need to cease all operations and wind down. Although we are currently evaluating our strategic alternatives with respect to all aspects of our business, we cannot assure you that any actions that we take would raise or generate sufficient capital to fully address the uncertainties of our financial position. As a result, we may be unable to realize value from our assets and discharge our liabilities in the normal course of business. If we are unable to settle our obligations to our creditors or if we are unable to consummate a strategic transaction, we would likely need to liquidate the Company in a voluntary dissolution under Delaware law or seek protection under the provisions of the U.S. Bankruptcy Code. In that event, we, or a trustee appointed by the court, may be required to liquidate our assets. In either of these events, we might realize significantly less from our assets than the values at which they are carried on our financial statements. The funds resulting from the liquidation of our assets would be used first to satisfy obligations to creditors before any funds would be available to pay our stockholders, and any shortfall in the proceeds would directly reduce the amounts available for distribution, if any, to our creditors and to our stockholders. In the event we are required to liquidate under Delaware law or the federal bankruptcy laws, it is highly unlikely that stockholders would receive any value for their

shares.



**Table of Contents****Off-Balance Sheet Arrangements**

Harbor BioSciences, Inc. currently does not have any off-balance sheet arrangements.

**Contractual Obligations:**

As of December 31, 2010, we had the following contractual obligations

Contractual Obligations	Total	Payments Due by Period			
		Less than one year	One to three years	Three to five years	More than Five years
Operating Leases	\$ 94	\$ 94	\$	\$	\$

We may also be required to make substantial milestone or royalty payments in cash based on the terms of some of our agreements (See Note 6 to the Financial Statements).

Our operations to date have consumed substantial capital without generating any revenues other than the amount received under our collaboration with CFFT. We will continue to require substantial and increasing amounts of funds to conduct necessary research and development and preclinical and clinical testing of our drug candidates, and to market any drug candidates that receive regulatory approval. We do not expect to generate revenue from operations for the foreseeable future, and our ability to meet our cash obligations as they become due and payable may depend for at least the next several years on our ability to sell securities, borrow funds or some combination thereof. Based upon our current plans, we believe that our existing capital resources will be sufficient to meet our operating expenses and capital requirements into late 2011. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We may not be successful in raising necessary funds. As of December 31, 2010, our cash and cash equivalents totaled approximately \$5.9 million.

Our future capital requirements will depend upon many factors, including progress with preclinical testing and clinical trials, the number and breadth of our programs, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, the time and costs involved in obtaining regulatory approvals, competing technological and market developments, and our ability to establish collaborative arrangements, effective commercialization, marketing activities and other arrangements. We may incur increasing negative cash flows and net losses for the foreseeable future. We are seeking additional funding through public or private financing or through collaborative arrangements with strategic partners. Our auditor has stated in the opinion that there is substantial doubt about the Company's ability to continue as a going concern.

**Critical Accounting Policies**

Certain of our accounting policies require the application of judgment and estimates by management, which may be affected by different assumptions and conditions. These estimates are typically based on historical experience, terms of existing contracts, trends in the industry and

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

information available from other outside sources, as appropriate. We believe the estimates and judgments associated with our reported amounts are appropriate in the circumstances. Actual results could materially vary from those estimates under different assumptions or conditions.

All research and development costs are expensed as incurred. The value of acquired in-process research and development is charged to expense on the date of acquisition. Research and development expenses include, but are not limited to, acquired in-process technology deemed to have no alternative future use, license fees related to license agreements, preclinical and clinical trial studies, payroll and personnel expense, and lab supplies, consulting and research-related overhead. Research and development expenses paid in the form of cash and our stock to related parties aggregated \$11.5 million for the period from inception (August 15, 1994) to December 31, 2003 (see Note 6, Colthurst, Edenland and Mr. Prendergest and Aeson Therapeutics ). No such related party expenses were incurred in 2010, 2009 or 2008.

As of January 1, 2006, we account for share-based payments in accordance with ASC 718. Under the fair value recognition provisions of this statement, share-based payments cost is measured at the grant date based on the value of the award and is recognized as expense over the vesting period. Determining the fair value of share-based awards at the grant date requires judgment, including estimating our stock price volatility and employee

## **Table of Contents**

stock option exercise behavior. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations could be materially impacted.

Our expected volatility is based upon the historical volatility of our stock. Our expected life for our options is based on historical stock option activity. Because share-based payments expense is recognized in our statement of operations based on awards ultimately expected to vest, the amount of expense has been reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. If factors change and we employ different assumptions in the application of ASC 718, the compensation expense that we record in future periods may differ significantly from what we have recorded in the current period.

On July 13, 2006, ASC 740-10, Accounting for Uncertainty in Income Taxes, which is effective for fiscal years beginning after December 15, 2006, which establishes recognition and measurement thresholds that must be met before a tax benefit can be recognized in the financial statements. The Company has adopted ASC 740-10 on January 1, 2007, and it has had no material impact on its financial statements.

## **Impact of Recently Issued Accounting Pronouncements**

Effective April 1, 2009, the Company adopted three accounting standard updates that were intended to provide additional application guidance and enhanced disclosures regarding fair value measurements and impairments of securities. They also provide additional guidelines for estimating fair value in accordance with fair value accounting. The first update, as codified in ASC 820-10-65, provides additional guidelines for estimating fair value in accordance with fair value accounting. The second accounting update, as codified in ASC 820-10-65, changes accounting requirements for other-than-temporary-impairment (OTTI) for debt securities by replacing the current requirement that a holder have the positive intent and ability to hold an impaired security to recovery in order to conclude an impairment was temporary with a requirement that an entity conclude it does not intend to sell an impaired security and it will not be required to sell the security before the recovery of its amortized cost basis. The third accounting update, as codified in ASC 825-10-65, increases the frequency of fair value disclosures. These updates were effective for fiscal years and interim periods ended after June 15, 2009. The adoption of these accounting updates did not have any impact on our financial statements.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820-10 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). These tiers include:

Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets;

Level 2, defined as inputs other than quoted prices in active markets that are directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are no active; and

Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant value drivers are observable.

Our level 1 assets primarily include our cash and cash equivalents (mainly money market accounts). Valuations are obtained from readily available pricing sources. We do not currently have Level 2 or 3 assets.

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

We do not have any debt instruments as of December 31, 2010 or 2009.

In January 2010, the FASB issued ASU No. 2010-06, Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements. ASU 2010-06 amends Codification Subtopic 820-10 to add two new disclosures: (1) transfers in and out of Level 1 and 2 measurements and the reasons for the transfers, and (2) a gross presentation of activity within the Level 3 roll forward. The proposal also includes clarifications to existing disclosure requirements on the level of disaggregation and disclosures regarding inputs

**Table of Contents**

and valuation techniques. The proposed guidance would apply to all entities required to make disclosures about recurring and nonrecurring fair value measurements. The effective date of the ASU is the first interim or annual reporting period beginning after December 15, 2009, except for the gross presentation of the Level 3 roll forward information, which is required for annual reporting periods beginning after December 15, 2010 and for interim reporting periods within those years. Early application is permitted. The Company is currently assessing the impact that the adoption will have on its financial statements.

Effective April 1, 2009, the Company adopted a new accounting standard for subsequent events, as codified in ASC Subtopic 855-10, Subsequent Events. The update modifies the names of the two types of subsequent events either as recognized subsequent events (previously referred to in practice as Type I subsequent events) or non-recognized subsequent events (previously referred to in practice as Type II subsequent events). In addition, the standard modifies the definition of subsequent events to refer to events or transactions that occur after the balance sheet date, but before the financial statements are issued (for public entities) or available to be issued (for nonpublic entities). The update did not result in significant changes in the practice of subsequent event disclosures, and therefore the adoption did not have any impact on our financial statements.

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

At December 31, 2010, our investment portfolio included only cash and money market accounts and did not contain fixed-income securities. There would be no material impact to our investment portfolio, in the short term, associated with any change in interest rates, and any decline in interest rates over time will reduce our interest income, while increases in interest rates over time will increase our interest income.

**Table of Contents**

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

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

	<b>Page</b>
<u>Balance Sheets as of December 31, 2010 and 2009</u>	37
<u>Statements of Operations for the Fiscal Years Ended December 31, 2010, December 31, 2009, December 31, 2008 and the Period From Inception (August 15, 1994) to December 31, 2010</u>	38
<u>Statements of Stockholders' Equity for the Fiscal Years Ended December 31, 1994, through December 31, 2010</u>	39
<u>Statements of Cash Flow for the Fiscal Years Ended December 31, 2010, December 31, 2009, December 31, 2008 and the Period from Inception (August 15, 1994) to December 31, 2010</u>	44
<u>Notes to Financial Statements</u>	45
<u>Report of Independent Registered Accounting Firm</u>	74

**Table of Contents****Harbor BioSciences, Inc.****(A Development Stage Company)****Balance Sheets**

	December 31,	
	2010	2009
	(In thousands, except par value)	
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 5,923	\$ 9,738
Prepaid expenses	100	209
Deposits	28	48
Other receivables	1	81
<b>Total current assets</b>	<b>6,052</b>	<b>10,076</b>
Property and equipment, net of accumulated depreciation of \$273 and \$906	44	176
Restricted cash		34
<b>Total assets</b>	<b>\$ 6,096</b>	<b>\$ 10,286</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY:</b>		
Current liabilities:		
Accounts payable	\$ 201	\$ 136
Accrued expenses	1,005	1,150
Other current Liabilities	29	
<b>Total current liabilities</b>	<b>1,235</b>	<b>1,286</b>
Commitments and contingencies (Notes 6, 11, 12)		
Stockholders' equity: (Notes 3, 7, 8, 9, 10)		
Preferred stock, \$.01, 10,000 shares authorized; no shares issued or outstanding		
Common stock, \$.01 par value, 100,000 shares authorized; 35,525 and 29,493 shares issued and 35,466 and 29,434 outstanding respectively	355	294
Paid-in capital	263,281	260,884
Cost of treasury stock (59 shares)	(346)	(346)
Deficit accumulated during development stage	(258,429)	(251,832)
<b>Total stockholders' equity</b>	<b>4,861</b>	<b>9,000</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 6,096</b>	<b>\$ 10,286</b>

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

**Table of Contents****Harbor BioSciences, Inc.****(A Development Stage Company)****Statements of Operations**

	For the year ended December 31,			Inception (Aug.15, 1994) to December 31, 2010
	2010	2009	2008	2010
	(In thousands, except per share amounts)			
<b>Revenue:</b>				
Contract R&D revenue	\$	\$	\$	\$ 1,208
<b>Total revenue</b>				<b>1,208</b>
<b>Operating expenses:</b>				
<b>Research and development</b>				
R & D operating expenses	3,420	9,923	15,092	164,565
R & D costs related to common stock and stock option grants for collaborations and technology purchases	339	632	978	10,448
<b>Total research and development</b>	<b>3,759</b>	<b>10,555</b>	<b>16,070</b>	<b>175,013</b>
<b>General and administrative</b>				
G & A operating expenses	2,484	4,450	5,025	71,558
G & A costs related to options / warrants granted	287	690	1,512	19,130
<b>Total general and administrative</b>	<b>2,771</b>	<b>5,140</b>	<b>6,537</b>	<b>90,688</b>
<b>Settlement of dispute</b>				<b>3,000</b>
<b>Total operating expenses</b>	<b>6,530</b>	<b>15,695</b>	<b>22,607</b>	<b>268,701</b>
<b>Other income (expense):</b>				
Loss on disposition of assets	(83)	(69)	(6)	(300)
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures				(7,627)
Interest income	16	138	1,048	17,379
Interest expense				(388)
<b>Total other income, net</b>	<b>(67)</b>	<b>69</b>	<b>1,042</b>	<b>9,064</b>
<b>Net loss</b>	<b>\$ (6,597)</b>	<b>\$ (15,626)</b>	<b>\$ (21,565)</b>	<b>\$ (258,429)</b>
<b>Net loss per share, basic and diluted</b>	<b>\$ (0.20)</b>	<b>\$ (0.53)</b>	<b>\$ (0.74)</b>	
<b>Weighted average number of common shares outstanding, basic and diluted</b>	<b>32,803</b>	<b>29,319</b>	<b>29,060</b>	

The accompanying notes are an integral part of these financial statements





**Table of Contents****Harbor BioSciences, Inc.****(A Development Stage Company)****Statements of Stockholders Equity**

	Preferred stock at par value		Common stock at par value		Capital in excess of par value (In thousands)	Cost of Repurchased Common Stock		Deficit accumulated during development stage	Total
	Shares	Amount	Shares	Amount		Shares	Amount		
Contribution by stockholder		\$		\$	103			\$	\$ 103
Common stock issued for cash			2,853		25				25
Common stock issued as consideration for the license agreements (Note 6)			543		5				5
Net loss								(1,277)	(1,277)
Balance at December 31, 1994			3,396		133			(1,277)	(1,144)
Common stock issued for cash			679		250				250
Common stock issued as consideration for amendments to the license agreements (Note 6)			76		28				28
Net loss								(672)	(672)
Balance at December 31, 1995			4,151		411			(1,949)	(1,538)
Common stock issued in conversion of debt (Note 7)			165		371				371
Common stock issued for cash, net of expenses (Note 7)			580		1,234				1,234
Common stock issued as consideration for termination of a finance agreement			15		34				34
Warrants issued to consultants for services rendered					24				24
Net loss								(692)	(692)
Balance at December 31, 1996			4,911		2,074			(2,641)	(567)
Recapitalization of Company upon the merger with Initial Acquisition Corp. (Note 3)			883	58	6,213				6,271
Warrants issued to a certain director upon the successful closure of the merger (Note 3)					570				570
Exercise of warrants, net of expenses			978	10	5,619				5,629
Amortization of deferred compensation					282				282
Exercise of stock options					1				1
Net loss								(5,253)	(5,253)
Balance at December 31, 1997			6,772	68	14,759			(7,894)	6,933
Exercise of warrants			399	4	1,196				1,200
Exercise of stock options			53	1	155				156
Private Placement, net of expenses (Note 7)	4		1,329	13	19,877				19,890
Warrants issued for services in lieu of cash (Note 10)					408				408
Stock issued for license fee (Note 6)			33		500				500
Stock issued for services in lieu of cash			6		95				95
Options issued for services in lieu of cash (Note 9)					240				240

Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

Amortization of deferred compensation	308		308
Net loss		(5,427)	(5,427)

**Table of Contents****Harbor BioSciences, Inc.****(A Development Stage Company)****Statements of Stockholders Equity (Continued)**

	Preferred stock at par value	Common stock at par value	Capital in excess of par value	Cost of Repurchased Common Stock	Deficit accumulated during development stage	Total
	Shares	Amount	Amount	Shares	Amount	
	(In thousands)					
Balance at December 31, 1998	4	8,592	86			24,303
Exercise of warrants		755	8			5,144
Exercise of stock options		10				75
Private Placement, net of expenses (Note 7)		1,368	14			24,773
Preferred Stock Conversion (Note 7,8)	(4)	346	3			
Deferred compensation-Options forfeited (Note 9)						51
Amortization of non-employee options						559
Warrants issued for services in lieu of cash (Note 10)						2,140
Options accelerated vesting (Note 9)						4,900
Net loss					(15,320)	(15,320)
Balance at December 31, 1999		11,071	111			46,625
Exercise of warrants		133	2			760
Exercise of stock options		1				5
Common Stock issued for 401(k)/401(m) plan		6				63
Common Stock issued for In-Process R&D (Note 6)		209	2			2,000
Options granted for license fee		38				598
Amortization of non-employee options						79
Common Stock issued for purchase of technology		132	1			1,847
Net loss					(19,515)	(19,515)
Balance at December 31, 2000		11,590	116			32,463
Exercise of stock options		10				22
Common Stock issued for 401(k)/401(m) plan		16				96
Private Placement, net of expenses (Note 7)		1,280	13			10,657
Warrants issued for services in lieu of cash (Note 10)						80
Amortization of non-employee options						96
Warrants issued for services						208
Net loss					(15,762)	(15,762)
Balance at December 31, 2001		12,896	129			27,860
Exercise of stock options						2
Common Stock issued for 401(k)/401(m) plan		26				137
Common Stock issued for sublicense agreement (Note 6)		50	1			205
Common Stock issued to consultants						17
Amortization of non-employee options						66
Warrants issued for services						247
Net loss					(17,502)	(17,502)
Balance at December 31, 2002		12,972	130			11,032



**Table of Contents****Harbor BioSciences, Inc.**

(A Development Stage Company)

**Statements of Stockholders Equity (Continued)**

	Preferred stock at par value		Common stock at par value		Capital in excess of par value (In thousands)	Cost of Repurchased Common Stock		Deficit accumulated during development stage	Total
	Shares	Amount	Shares	Amount		Shares	Amount		
Common Stock issued for 401(k)/401(m) plan		32			223				223
Exercise of warrants		467		5	3,323				3,328
Exercise of stock options		85		1	955				956
Stock options issued					561				561
Private Placement, net of expenses			1,283	13	14,290				14,303
Common Stock issued for sublicense agreement (Note 6)		119		1	644				645
Common Stock issued for milestone payment		50		1	281				282
Debt Conversion			1,755	17	9,983				10,000
Common Stock issued in lieu of cash / interest		9			142				142
Public Offering, net of expenses			2,500	25	58,576				58,601
Deemed discount on convertible debentures					6,470				6,470
Warrants issued for services					1,398				1,398
Amortization of non-employee options					128				128
Purchase of treasury stock						(59)	(346)		(346)
Net loss								(25,671)	(25,671)
Balance at December 31, 2003		19,272	193	193	189,296	(59)	(346)	(107,091)	82,052
Common Stock issued for 401(k) plan		17			147				147
Exercise of warrants		6			11				11
Exercise of stock options		4			16				16
Common Stock issued for In-Process R&D (Note 6)		48			629				629
Amortization of non-employee options					136				136
Net loss								(24,757)	(24,757)
Balance at December 31, 2004		19,347	193	193	190,235	(59)	(346)	(131,848)	58,234
Common Stock issued for 401(k) plan		25			151				151
Exercise of warrants		42		1	260				261
Exercise of stock options		35		1	123				124
Public Offering, net of expenses (Note 7)		1,333		13	9,502				9,515
Amortization of non-employee options					30				30
Net loss								(29,441)	(29,441)
Balance at December 31, 2005		20,782	208	208	200,301	(59)	(346)	(161,289)	38,874

**Table of Contents****Harbor BioSciences, Inc.****(A Development Stage Company)****Statements of Stockholders Equity (Continued)**

	Preferred stock at par value		Common stock at par value		Capital in excess of par value (In thousands)	Cost of Repurchased Common Stock		Deficit accumulated during development stage	Total
	Shares	Amount	Shares	Amount		Shares	Amount		
Common Stock issued for 401(k) plan			45	1	224				225
Exercise of warrants			10		1				1
Warrants issued to consultants					226				226
Exercise of stock options			34		86				86
Private Placements, net of expenses			8,000	80	48,697				48,777
Stock-Based Compensation Expense					3,534				3,534
Amortization of non-employee warrants					13				13
Restricted stock grant, net of forfeitures			65	1	401				402
Common Stock issued for In-Process R&D			35		180				180
Deferred Compensation					(309)				(309)
Net loss								(30,231)	(30,231)
Balance at December 31, 2006			28,971	290	253,354	(59)	(346)	(191,520)	61,778
Common Stock issued for 401(k) plan			96	1	192				193
Exercise of stock options			9		20				20
Stock-Based Compensation Expense					3,128				3,128
Restricted Stock Forfeitures			(12)		(33)				(33)
Amortization of non-employee warrants					17				17
Deferred Compensation					123				123
Net loss								(23,121)	(23,121)
Balance at December 31, 2007			29,064	291	256,801	(59)	(346)	(214,641)	42,105
Common Stock issued for 401(k) plan			164	1	174				175
Stock-Based Compensation Expense					2,404				2,404
Deferred Compensation					86				86
Net loss								(21,565)	(21,565)
Balance at December 31, 2008			29,228	292	259,465	(59)	(346)	(236,206)	23,205
Common Stock issued for 401(k) plan			271	2	96				98
Restricted Stock Forfeitures			(6)		(3)				(3)
Stock-Based Compensation Expense					1,240				1,240
Deferred Compensation					86				86
Net loss								(15,626)	(15,626)
Balance at December 31, 2009			29,493	\$ 294	\$ 260,884	(59)	\$ (346)	\$ (251,832)	\$ 9,000

**Table of Contents****Harbor BioSciences, Inc.****(A Development Stage Company)****Statements of Stockholders Equity (Continued)**

	Preferred stock at par value		Common stock at par value		Capital in excess of par value (In thousands)	Cost of Repurchased Common Stock		Deficit accumulated during development stage	Total
	Shares	Amount	Shares	Amount		Shares	Amount		
Common Stock issued for 401(k) plan			137	2	41				43
Net Proceeds from Financing			5,895	59	1,730				1,789
Stock-Based Compensation Expense					612				612
Deferred Compensation					14				14
Net loss								(6,597)	(6,597)
Balance at December 31, 2010			35,525	\$ 355	\$ 263,281	(59)	\$ (346)	\$ (258,429)	\$ 4,861

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



**Table of Contents****Harbor BioSciences, Inc.****(A Development Stage Company)****Statements of Cash Flows**

	2010	2009	2008	Period from Inception (Aug. 15, 1994) to December 31, 2010
	( In thousands )			
Cash flows from operating activities:				
Net loss	\$ (6,597)	\$ (15,626)	\$ (21,565)	\$ (258,429)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	21	208	315	2,243
Disposal of assets	85	69	6	316
Compensation expense related to equity awards	626	1,323	2,490	11,284
Amortization of deemed discount on convertible debentures				6,470
Amortization of deferred issuance cost				1,157
Common stock issued for 401k/401m plan	43	98	174	1,550
Common stock issued as consideration for amendments to the license / finance agreements				67
Common stock and options issued as consideration for license fees, milestone payment, interest, note repayment and services				2,859
Expense related to warrants issued as consideration to consultants				4,369
Expense related to warrants issued to a director for successful closure of merger				570
Expense related to stock options issued				5,718
Expense related to common stock issued for the purchase of technology				1,848
Common stock issued as consideration for In-Process R&D				2,809
Deferred compensation expense related to options issued				1,210
Changes in assets and liabilities:				
Prepaid expenses	109	53	7	(100)
Deposits	20	20		(28)
Other receivable	80	(81)	645	(1)
Other Receivable from related party				
Accounts payable	65	(187)	(132)	892
Accrued expenses	(145)	(479)	(933)	959
Other Liabilities	29			29
Net cash used in operating activities	(5,664)	(14,602)	(18,993)	(214,208)
Cash flows provided by investing activities:				
Proceeds from sale of property and equipment	26	197		223
Purchase of property and equipment		(9)	(70)	(2,825)
Net cash provided by (used in) investing activities	26	188	(70)	(2,602)
Cash flows from financing activities:				
Restricted Cash	34			
Contributions from stockholder				104
Net proceeds from sale of preferred stock				4,000
Net proceeds from sale of common stock	1,789			185,323
Net proceeds from issuance of convertible debentures and warrants				9,214
Purchase of treasury stock				(346)
Proceeds from issuance of debt				371
Net proceeds from recapitalization				6,271
Net proceeds from warrants/options exercised				17,796
Net cash provided by financing activities	1,823			222,733

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

Net increase (decrease) in cash and equivalents	(3,815)	(14,414)	(19,063)	5,923
Cash and equivalents at beginning of period	9,738	24,152	43,215	
Cash and equivalents at end of period	\$ 5,923	\$ 9,738	\$ 24,152	\$ 5,923
<b>Supplemental disclosure of cash flow information:</b>				
Interest paid	\$	\$	\$	\$ 388
Conversion of debt to equity				10,371
Warrants issued to consultants in lieu of cash, no vesting				559
Warrants issued in lieu of cash, commissions on private placement				733
Warrants issued in connection with convertible debentures				371

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

---

**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements**

**1. The Company**

Harbor BioSciences, Inc., ( Harbor BioSciences or the Company ), a development stage pharmaceutical company, is engaged in the discovery, development and commercialization of products for the treatment of diseases related to aging. From inception (August 15, 1994) through March 1997, the Company's efforts were directed toward organizing, licensing technology and preparing for offerings of shares of its common stock. Since 1997, the Company has been expanding its intellectual property, developing its lead drug candidates, performing preclinical tests and has entered into and completed multiple clinical studies. Our primary technology development efforts are focused on a series of adrenal steroid hormones and synthetic analogs that may be useful in treating a wide variety of medical conditions, if successfully developed. These adrenal hormones are depleted during advancing age, a process accelerated by infectious diseases and chronic immune system disorders. High plasma concentrations of these hormones are positively correlated with attenuated disease, in certain indications, and their maintenance is often associated with healthy aging.

During the past three years, the Company has devoted substantially all of its research, development and clinical efforts and financial resources toward the development of Apoptone and Triolex. The Company has incurred a net loss of \$6.6 million in 2010, has had cumulative net losses of \$258.4 million from inception to date and has limited financial resources at December 31, 2010.

These events raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. In an effort to preserve cash, the Company initiated steps during 2009 to significantly reduce its operating costs including a substantial reduction in personnel, closure of its laboratory, sale of equipment and reduction of leased space. Expense reduction and cash preservation activities continued during 2010 and will continue into 2011.

The Company is seeking to maximize the value of its remaining assets. The Company is currently evaluating its strategic alternatives, which include the following:

- Pursue potential strategic transactions, which could include mergers, license agreements or other collaborations, with third parties;
- Sell or out-license the Company's remaining assets, including the Company's library of compounds; or
- Implement an orderly wind down of the Company if other alternatives are not deemed viable and in the best interests of the Company.

If we do not raise additional cash, the Company will be out of cash to fund further operations into late 2011.

**2. Summary of Accounting Policies**

***Cash Equivalents***

The Company considers any liquid investments with maturity of three months or less when purchased to be cash equivalents. At December 31, 2010 the Company's cash equivalents are approximately \$5.9 million and are deposited primarily in a money market account with a financial institution.

***Property and Equipment***

Property and equipment are stated at cost. The Company provides for depreciation using the straight-line method over the estimated useful lives of the assets. The cost of major additions and improvements is capitalized.

**Table of Contents****HARBOR BIOSCIENCES, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

while maintenance and repair costs that do not improve or extend the lives of the respective assets are charged to operations as incurred.

Property and equipment balances and corresponding lives were as follows:

	December 31		Lives
	2010	2009	
	(in thousands)		
Machinery, equipment and information systems	110	864	5-7 years
Equipment held for sale	21		
Furniture and fixtures	186	218	5-7 years
Total	317	1,082	
Less: Accumulated depreciation	(273)	(906)	
	\$ 44	\$ 176	

Depreciation expense associated with property and equipment was approximately \$21,000, \$208,000 and \$315,000 in 2010, 2009 and 2008, respectively.

In accordance with ASC Topic 360, Property, Plant and Equipment, the Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which there are identifiable assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. The Company had no impairments in 2010, 2009 and 2008.

***Accrued Expenses***

Accrued expenses include approximately \$0.3 million and \$0.3 million in accrued vacation expense, \$0.7 million and \$0.9 million in other research and development / general and administrative expenses as of December 31, 2010 and 2009, respectively.

***Revenue Recognition***

In December 2003, the Securities and Exchange Commission ( SEC ) issued ASC Topic 605, Revenue Recognition, which updates and summarizes the Commission's views on the application of generally accepted accounting principles to revenue recognition in financial statements. The Company believes that its revenue recognition policies conform to the requirements of ASC Topic 605.

Contract revenue is recognized as the services are performed on a cost reimbursement basis. Revenue associated with development milestones, if any, is recognized based upon the achievement of the milestones, as defined in the respective agreements. Overall, revenue is considered to be realized or realizable and earned when there is persuasive evidence of a revenue arrangement in the form of a contract or purchase order, the services have been performed, the price is fixed or determinable and collectability is reasonably assured.

***Research and Development***

All research and development costs are expensed as incurred. The value of acquired in-process research and development is charged to expense on the date of acquisition. Research and development expenses include, but

---

**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

are not limited to, acquired in-process technology deemed to have no alternative future use, license fees related to license agreements, preclinical and clinical trial studies, payroll and personnel expense, lab supplies, consulting and research-related overhead. Research and development expenses paid in the form of cash and Company stock to related parties aggregated \$11.5 million for the period from inception (August 15, 1994) to December 31, 2003 (see Note 6, Colthurst, Edenland and Mr. Prendergest and Aeson Therapeutics). No such related party expenses were incurred in 2010, 2009 or 2008.

***Accounting for Share-Based Payments***

The Company has an equity-based incentive compensation plan known as The 2005 Equity Incentive Plan (the Plan). The Plan allows us to grant stock options and other stock or stock-based awards, including stock appreciation rights, stock purchase awards, restricted stock awards and restricted stock units awards. The Plan also allows us to provide equity compensation to non-employee directors and consultants. The exercise price for an option granted under the Plan is typically not less than the fair market value of the common stock subject to such option. The term of any options granted under the Plan may not exceed 10 years from the date of the grant. Options issued to employees generally vest over a four-year period, with 25% vesting on the first anniversary date and the balance vesting monthly during years two, three and four.

Prior to (ASC Topic 718), Compensation-Stock Compensation, all stock options for employees (with the exception of three grants) have been granted at or above the market price where the exercise price of the option equaled or exceeded the market price of the stock on the date of the grant. As a result, under previous rules, there was no stock-based compensation expense for those grants. Compensation expense was taken for the three options granted at below market value (see 2005 Annual Report on Form 10-K, Notes to Financial Statements *No. 9 Stock Options* for more detail). As of December 31, 2010 the Plan has 8,235,608 shares of common stock reserved for issuance.

Effective January 1, 2006, we adopted ASC Topic 718, requiring us to recognize expense related to the fair value of our stock-based compensation awards. We elected the modified prospective transition method as permitted by ASC Topic 718; accordingly, results from prior periods have not been restated. Under this transition method, stock-based compensation expense for the fiscal year ended December 31, 2010, 2009 and 2008 includes:

- a) compensation expense for all stock-based compensation awards granted prior to January 1, 2006 but not yet vested, based on the grant date fair value estimated in accordance with the original provisions of ASC Topic 718, and
- b) compensation expense for all stock-based compensation awards granted subsequent to December 31, 2005 based on the grant-date fair value estimated in accordance with the provisions of ASC Topic 718.

The fair value of each stock option granted is estimated on the date of grant using the Black-Scholes option-pricing model. The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect the Company's experience. Compensation

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

expense is recognized using the straight-line method for all stock-based awards issued after January 1, 2006. Compensation expense is recognized only for those options expected to vest, with forfeitures estimated at the date of grant based on the Company's historical experience and future expectations. Prior to the adoption of ASC Topic 718, the effect of forfeitures on the pro forma expense amounts was not recognized. ASC Topic 718, requires forfeitures to be estimated at the time of the grant and revised as necessary in subsequent periods if actual forfeitures differ from those estimates.



**Table of Contents****HARBOR BIOSCIENCES, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

## Black-Scholes Option Valuation Assumptions (1)

	December 31, 2010	Fiscal Years Ended December 31, 2009	December 31, 2008
Risk-free interest rate	4.35%	4.5%	3.75%
Expected dividend yield	0%	0%	0%
Expected life(2)	6.32 years	7.04 years	6.60 years
Expected volatility(3)	88%	85%	75%

- (1) Forfeitures are estimated as 7.78% for 2010, 7.88% for 2009 and 6.20% for 2008 because of the Company's restructuring in 2009, there were greater than normal forfeitures of stock options.
- (2) The 2010, 2009 and 2008 expected life is based on historical experience
- (3) The expected stock price volatility is estimated based on historical experience.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of the Company's options.

***401(k) Matching Contributions***

Our Company sponsors a 401(k) savings plan, to which eligible domestic employees may voluntarily contribute a portion of their income, subject to statutory limitations. In addition to the participant's own contributions to these 401(k) savings plans, we match such contributions up to a designated level. Total matching contributions related to employee savings plans were approximately \$76,000, \$120,000 and \$175,000 in 2010, 2009 and 2008, respectively.

***Income Taxes***

The Company provides for income taxes under the principles of ASC Topic 740, Income Taxes, which requires that provision be made for taxes currently due and for the expected future tax effects of temporary differences between book and tax bases of assets and liabilities.

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

On July 13, 2006 ASC Topic 740 was issued, Accounting for Uncertainty in Income Taxes, which establishes recognition and measurement thresholds that must be met before a tax benefit can be recognized in the financial statements. The Company adopted ASC Topic 740 on January 1, 2007, and it has had no material impact on its financial statements.

### *Financial Instruments*

The Company's financial instruments consist primarily of cash and accounts payable. These financial instruments are stated at their respective carrying values, which approximate their fair values, due to their short-term nature.

### *Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported

**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could materially differ from those estimates.

***Concentrations of Risk***

Financial instruments, which potentially expose the Company to concentrations of credit risk, consist primarily of cash and cash equivalents. The Company places its cash with high quality financial institutions.

Cash and cash equivalents are maintained at financial institutions and, at times, balances may exceed federally insured limits. We have never experienced any losses related to these balances. All of our non-interest bearing cash balances were fully insured at December 31, 2010 due to a temporary federal program in effect from December 31, 2010 through December 31, 2012. Under the program, there is no limit to the amount of insurance for eligible accounts. Beginning 2013, insurance coverage will revert to \$250,000 per depositor at each financial institution, and our non-interest bearing cash balances may again exceed federally insured limits. At December 31, 2010 the Company had no interest-bearing amounts on deposit in excess of federally insured limits.

***Net Loss per Share***

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed in a manner consistent with basic net loss per share after giving effect to potentially dilutive securities. Potential common shares of 7,379,164, 5,010,334 and 9,466,150 related to the Company's outstanding stock option and warrants were excluded from the computation of diluted net loss per share for the years ended December 31, 2010, 2009 and 2008 because their effect on net loss per share is anti-dilutive.

***Recent Accounting Pronouncements***

Effective April 1, 2009, the Company adopted three accounting standard updates which were intended to provide additional application guidance and enhanced disclosures regarding fair value measurements and impairments of securities. They also provide additional guidelines for estimating fair value in accordance with fair value accounting. The first update, as codified in ASC Subtopic 820-10-65, Financial Instruments, provides additional guidelines for estimating fair value in accordance with fair value accounting. The second accounting update, as codified in ASC Subtopic 820-10-65, changes accounting requirements for other-than-temporary-impairment (OTTI) for debt securities by replacing the current requirement that a holder have the positive intent and ability to hold an impaired security to recovery in order to conclude an impairment

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

was temporary with a requirement that an entity conclude it does not intend to sell an impaired security and it will not be required to sell the security before the recovery of its amortized cost basis. The third accounting update, as codified in ASC Subtopic 825-10-65, increases the frequency of fair value disclosures. These updates were effective for fiscal years and interim periods ended after June 15, 2009. The adoption of these accounting updates did not have any impact on our financial statements.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC Subtopic 820-10 establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurement) and the lowest priority to unobservable inputs (level 3 measurement). Our level 1 assets primarily include our cash and cash equivalents (mainly money market accounts). Valuations are obtained from readily available pricing sources. We do not currently have Level 2 or 3 assets.

In January 2010, the FASB issued ASU No. 2010-06, Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements. ASU 2010-06 amends Codification Subtopic

**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

820-10 to add two new disclosures: (1) transfers in and out of Level 1 and 2 measurements and the reasons for the transfers, and (2) a gross presentation of activity within the Level 3 roll forward. The proposal also includes clarifications to existing disclosure requirements on the level of disaggregation and disclosures regarding inputs and valuation techniques. The proposed guidance would apply to all entities required to make disclosures about recurring and nonrecurring fair value measurements. The effective date of the ASU is the first interim or annual reporting period beginning after December 15, 2009, except for the gross presentation of the Level 3 roll forward information, which is required for annual reporting periods beginning after December 15, 2010 and for interim reporting periods within those years. Early application is permitted. The Company is currently assessing the impact that the adoption will have on its financial statements.

Effective April 1, 2009, the Company adopted a new accounting standard for subsequent events, as codified in ASC Subtopic 855-10, Subsequent Events. The update modifies the names of the two types of subsequent events either as recognized subsequent events (previously referred to in practice as Type I subsequent events) or non-recognized subsequent events (previously referred to in practice as Type II subsequent events). In addition, the standard modifies the definition of subsequent events to refer to events or transactions that occur after the balance sheet date, but before the financial statements are issued (for public entities) or available to be issued (for nonpublic entities). The update did not result in significant changes in the practice of subsequent event disclosures, and therefore the adoption did not have any impact on our financial statements.

**3. Recapitalization**

During March 1997, Hollis-Eden Inc. was merged (the Merger) with and into the Company (then known as Initial Acquisition Corp. (IAC)). Upon consummation of the Merger, Hollis-Eden Inc. ceased to exist, and IAC changed its name to Hollis-Eden Pharmaceuticals, Inc. IAC (now called Hollis-Eden Pharmaceuticals, Inc.) was the continuing legal entity and registrant for SEC reporting purposes. The IAC Merger was accounted for as a recapitalization of Hollis-Eden Inc. by an exchange of Common Stock of Hollis-Eden Inc., for the net assets of IAC, consisting primarily of \$6.5 million in cash and other receivables.

Under the terms of the merger agreement, each share of Hollis-Eden Inc. Common Stock outstanding converted into one share of Common Stock of Hollis-Eden Pharmaceuticals, Inc. Common Stock ( Company Common Stock ), and all warrants and options to purchase Hollis-Eden Inc. Common Stock outstanding converted into the right to receive the same number of shares of Company Common Stock.

Upon the consummation of the Merger, pursuant to an agreement, the Company issued warrants to purchase an aggregate of 50,000 shares of Company Common Stock at an exercise price of \$0.10 per share to a director and former officer. Additional paid-in capital was increased by \$570,000 with an offsetting \$570,000 charge recorded to operations during the three months ended March 31, 1997.

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

Effective February 9, 2010, we changed our name from Hollis-Eden Pharmaceuticals, Inc. to Harbor BioSciences, Inc. The name change was effected pursuant to Section 253 of the General Corporation Law of the State of Delaware by the merger of our wholly owned subsidiary into us. We were the surviving corporation and, in connection with the merger, we amended our Amended and Restated Certificate of Incorporation to change our name to Harbor BioSciences, Inc.

Effective February 18, 2010, our common stock began trading under a new NASDAQ symbol, "HRBR" and CUSIP number "41150V 103". In September 2010, our stock was de-listed from the NASDAQ Stock Market and is now traded on the OTC Bulletin Board under the symbol HRBR.OB

#### **4. Other Receivable from Related Party**

On April 23, 2001, the Company entered into a promissory note with a stockholder/officer in the amount of \$16,875. Interest was at 4.5% per annum. The promissory note was paid in full prior to the due date of April 23, 2004.

**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

On May 22, 1998, the Company entered into a promissory note with a stockholder/officer in the amount of \$200,000. Interest was at 5.5% per annum. The note was repaid in full in May 2003.

On March 21, 2005, the Company entered into a promissory note with an employee with a maximum loan amount of \$20,000. Interest was at 6% per annum. The first installment of \$10,000 was made on the commencement date. A second installment of \$10,000 was made on April 20, 2005. The loan was repaid with a balance of approximately \$2,000 forgiven on May 10, 2007.

**5. Income Taxes**

The Company has available a federal and state net operating loss carryforward of approximately \$189.6 million and \$163.5 million at December 31, 2010, respectively, which may be carried forward as an offset to taxable income, if any, in future years through its expiration for California in 2020 and for Federal in 2029. The Company has research and development credit carryforward of approximately \$11.2 million and \$7.0 million, respectively, for federal and state at December 31, 2010. The Company has a net federal and state deferred tax asset of approximately \$83.4 million and \$18.5 million at December 31, 2010, respectively, mainly comprised of research and development credits, the net operating loss carryforwards, and capitalized start-up cost. The increase in the valuation allowance in 2010 was approximately \$1.8 million. The net deferred tax assets have been fully reserved due to the uncertainty of the Company being able to generate taxable income under the more likely than not criteria of ASC Topic 740. The federal and state net operating loss carryforwards begin expiring in 2017 and 2010, respectively.

The difference between the Company's expected Federal tax benefit calculated using a 34% tax rate and the Company's zero tax benefit for all years is primarily related to a full valuation allowance established against the Company's net operating loss carryforwards for 2010 and the tax effects of stock compensation under ASC Topic 718.

If certain substantial changes in the Company's ownership should occur, there would potentially be an annual limitation on the amount of the carryforwards, which could be utilized in a tax year. The Company has not performed a Section 382 change in control test to date. Until this test is performed, the Company cannot be certain of the use of the loss carryforwards.

On January 1, 2007, the Company adopted the provision of ASC 740, which clarifies the accounting for uncertain tax positions. The provision requires that the Company recognize the impact of a tax position in our financial statement if the position is more likely than not to be sustained upon examination and on the technical merits of the position. The adoption of this provision had no material impact to the Company's financial statement due to its full valuation allowance position. The total amount of unrecognized tax benefits as of December 31, 2010 was \$14.7 million, if recognized, would affect other tax accounts, primarily deferred taxes in future periods, and would not affect the Company's effective tax rate since the Company maintains a full valuation allowance against its deferred tax assets.

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

A reconciliation of the beginning and ending balance of unrecognized tax benefits is as follows:

Balance at December 31, 2009	\$ 14,717,000
Gross increase	
Gross decrease	
Balance at December 31, 2010	\$ 14,717,000

The Company does not anticipate any material change in the total amount of unrecognized tax benefits will occur within the next twelve months.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income taxes expense. The Company had no accrual for interest or penalties on the Company's balance sheets at December 31, 2010, and had not recognized interest and/or penalties in the statement of operations for the period ended December 31, 2010, since the unrecognized tax benefits do not result in tax liabilities.



**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

The Company is subject to examination for tax years after 2006 for federal purposes and after 2005 for California state tax purposes.

**6. Related Party Licenses and other Agreements and Contingencies**

***Colthurst, Edenland and Mr. Prendergast***

During 1994, the Company entered into two license agreements and one research, development and option agreement as discussed in the following paragraphs.

Pursuant to a license agreement dated May 18, 1994 ( Colthurst License Agreement ) with related parties, Patrick T. Prendergast, a significant stockholder at the time, and with Colthurst Limited, a company controlled by Mr. Prendergast, the Company acquired the exclusive worldwide rights to Mr. Prendergast's patent rights, know-how and background technology relating to the treatment of human/animal immunodeficiency. The agreement was amended on August 11, 1995 to change the license fee payment terms as discussed below in paragraph four of this Note. Per the license agreement, the Company agreed to pay royalties on product revenues.

On August 25, 1994, the Company entered into a license agreement ( Edenland License Agreement ) with a related party, Edenland Inc., a company controlled by Mr. Prendergast, for the exclusive worldwide rights to Mr. Prendergast's patent rights, know-how and background technology related to the substance tradenamed HE317 and to any other pharmaceutical product that became subject to the license agreement under the research, development and option agreement discussed below. The agreement was amended on August 11, 1995 to change the license fee payment terms as discussed in the following paragraph. Per the Edenland License Agreement, the Company agreed to pay royalties on product revenues.

Effective August 11, 1995, Edenland, Inc., Colthurst Limited and the Company entered into amendments concerning the license fee payment terms to the two agreements described above. Under this amendment, the Company agreed to pay a license fee by April 28, 1996 plus additional license fees within 24 months of April 1996. The balances of these fees were paid in full by May 1997. As consideration for entering into certain amendments, the Company issued 75,472 shares of the Company's common stock to Edenland, Inc. and Colthurst Limited.

Per the amended Colthurst License Agreement, a renewal annual license fee was payable commencing May 1998. The Company paid this fee in 1998 by issuing shares of its common stock and, in 1999, paid in cash.

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

In August 1994, the Company entered into a Research, Development and Option Agreement, with Edenland, Inc. and Mr. Prendergast. The agreement provided for the development of HE317 to a certain stage of development and granted the Company the right of first option on new products developed by Edenland, Inc. The agreement committed the Company to pay for certain development costs up to the amount of \$3.0 million with certain contingencies for funding. In October 1996, the Company and Edenland, Inc. entered into an amendment, which accelerated the date that the \$3.0 million payment for HE317 or other product development costs was to be made. The Company paid \$2.7 million during 1997 and the remaining \$300,000 in April 1998.

On January 20, 2000, the Company reached a settlement regarding various disputes with Mr. Prendergast, Colthurst and Edenland. The parties entered into two new technology agreements, the Technology Assignment Agreement and the Sponsored Research and License Agreement.

The Technology Assignment Agreement (Assignment Agreement) replaced the Colthurst License Agreement. Pursuant to the Assignment Agreement, Mr. Prendergast and Colthurst assigned to the Company ownership of all patents, patent applications and current or future improvements of the technology under the Colthurst License Agreement, including HE2000, the Company's lead clinical compound at the time. The annual license fee of \$500,000 and the royalty obligations under the Colthurst License Agreement were eliminated. In consideration for the foregoing, the Company agreed to issue to Colthurst 660,000 shares of Common Stock and

**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

a warrant to purchase an aggregate of 400,000 shares of Common Stock at \$25 per share. Only 132,000 of such shares of Common Stock were issued in 2000, with the remaining 528,000 shares to be issued over the next four years conditioned on continued compliance with the agreement and, in particular, satisfaction of the Conditions (as defined below). In addition, all of the shares under the warrant vest over four years conditioned on continued compliance with the agreement and, in particular, satisfaction of the Conditions (as defined below). The Sponsored Research and License Agreement replaced the Edenland License Agreement and the Research, Development and Option Agreement. Pursuant to the Sponsored Research and License Agreement, Edenland exclusively licensed to the Company a number of compounds, together with all related patents and patent applications, and the Company funded additional preclinical research projects conducted by Edenland. The Company would also have exclusive license rights to all results of such research and would have royalty obligations to Edenland on sales of new products, if any, resulting from such research. None of the compounds licensed under the Sponsored Research and License Agreement have been developed by the Company and, as described below, this agreement is now terminated.

As stated above, the issuance of the additional shares of Common Stock and the vesting of the warrant was dependent upon the satisfaction of certain conditions (the Conditions). In accordance with ASC Subtopic 505-50 these future events could not be determined at the date of the agreements (January 2000). Accordingly, the shares and warrants are accounted for as they vest or are issued. During 2000, the Company recorded a research and development charge for \$1.9 million representing the fair value of the 132,000 shares issued under the Assignment Agreement.

Because all of the Conditions were not satisfied, the Company did not issue any additional shares to Colthurst and believed it had no obligation to issue any additional shares and that the warrant would not vest as to any shares of Common Stock.

After arbitration proceedings during 2004 and 2005, pursuant to which Colthurst sought more than \$25 million in damages for the non-issuance of the 528,000 shares of common stock and the warrant to purchase up to 400,000 shares of common stock, in February 2006 the parties agreed to a settlement and release of all issues in dispute between the parties. Under the settlement agreement, (1) the Company agreed to make a payment of \$3 million in cash and (2) the parties agreed to terminate the Sponsored Research and License Agreement between the Company and Edenland Inc. The \$3.0 million was accrued as an expense as of December 31, 2005. Under the settlement agreement, the Colthurst parties remain prohibited from conducting any further research, development or commercialization activities of any kind relating in any way to the technology (including HE2000) that was assigned to the Company under the Assignment Agreement.

***Aeson Therapeutics***

In October 2000, the Company acquired a 21% equity stake in Aeson Therapeutics Inc. (Aeson) and an exclusive worldwide sublicense to three issued patents in the area of adrenal steroids in exchange for \$2.0 million in cash and 208,672 shares of Common Stock valued at \$2 million. The cash and shares were expensed as in-process R&D during the fourth quarter of 2000. As part of the transaction, Aeson and its stockholders granted the Company an exclusive option to acquire the remainder of Aeson at a predetermined price.

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

In March 2002, the Company amended certain of its agreements with Aeson. Under the amendments, the Company paid Aeson \$1.2 million, which extended the initial date by which the Company could exercise its option to acquire the remainder of Aeson to September 30, 2002. The Company also received additional equity securities as a result of its \$1.2 million payment. The \$1.2 million payment was expensed as in-process R&D. The Company elected not to exercise the option to acquire the remainder of Aeson by September 30, 2002.

On June 7, 2006, the Company acquired substantially all of the assets of Aeson. As consideration for Aeson's assets, the Company agreed (i) to issue a total of 35,000 shares of common stock to Aeson at the closing

**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

of the acquisition and (ii) to issue to Aeson's stockholders up to a total of 165,000 additional shares of common stock if certain development milestones are achieved. The acquisition was expensed as in-process research and development. The Company has not achieved any of the development milestones.

***Pharmadigm***

In August 2002, we entered into a Sublicense Agreement with Pharmadigm, Inc. (currently known as Inflabloc Pharmaceuticals, Inc.). Under the agreement, we obtained exclusive worldwide rights to certain intellectual property of Pharmadigm and the University of Utah and we agreed to make aggregate payments of \$0.9 million in cash or in shares of our common stock, at our option, over the next year. This cost was expensed in the third quarter of 2002. We elected to make such payments in equity and have issued a total of 168,921 shares of our common stock in complete satisfaction of this requirement (of which 118,921 shares were issued the quarter ended March 31, 2003). We may also make substantial additional milestone and royalty payments in cash to Pharmadigm if we meet specified development and commercialization milestones for products covered by the patents. To date, no such milestones have been met. The principal patents licensed under the agreement, originally licensed to Pharmadigm from the University of Utah, relate to inventions by Dr. Raymond Daynes and Dr. Barbara A. Areneo. Dr. Daynes served as a scientific consultant to the Company from 1999 to mid-2003.

***Congressional Pharmaceutical***

In February 2004, the Company acquired Congressional Pharmaceutical Corporation (CPC) and replaced CPC as the exclusive licensee to certain intellectual property rights held by the University of Chicago. These intellectual property rights consist of a series of patents and patent applications that relate to discoveries made by David J. Grdina, Ph.D., Professor of Radiation and Cellular Oncology at the University of Chicago. The patented technology covers a series of compounds that have the potential to protect against DNA mutations that can occur as a result of radiation injury or chemotherapy. In the acquisition the Company issued approximately 50,000 shares of common stock to the former stockholders of CPC valued at approximately \$650,000, in accordance with Emerging Issues Task Force No. 99-12. In addition, if the Company achieves certain development milestones, it will be required to issue additional shares of our common stock to the former stockholders of CPC. In the event all of the milestones are achieved, the total number of additional shares that the Company would be required to issue to the former stockholders of CPC is 275,000, more than half of which would be issued only upon FDA approval of CPC's product. No such milestone has been met to date. Furthermore, upon regulatory approval and commercialization of products covered by the licensed intellectual property, the Company may be required to pay royalties to the former stockholders of CPC and the University of Chicago. Following the acquisition, Dr. Grdina agreed to an exclusive consulting arrangement with the Company in the fields of hematopoiesis and radiation and chemotherapy exposure. In March 2007, the Company terminated its consulting agreement with Dr. Grdina. In May 2007, the University of Chicago terminated the license agreement with the Company.

***AFRRI Collaboration***

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

The Company performed work on two task orders that were issued under a collaboration with the Armed Forces Radiobiology Research Institute ( AFRRRI ). Under these task orders, the Company conducted radiation studies with a subcontractor. The task orders committed AFRRRI to reimburse the Company for \$2.0 million in subcontractor fees. The reimbursement amounts from AFRRRI were recorded in the same timeline as the subcontractor fees, resulting in no impact on the statement of operations. There was no activity during 2007 under the AFRRRI collaboration. The Company terminated its collaborative research and development agreement with AFRRRI effective August 12, 2007.

**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

***Study Funding Agreement***

The Company has a Study Funding Agreement with Cystic Fibrosis Foundation Therapeutics, Inc. ( CFFT ). The agreement commits CFFT to provide a total of \$1.7 million to be paid in seven tranches based on the Company's completion of certain agreed-upon events. The agreement also contains a provision indicating that upon termination of this agreement by either party, CFFT shall pay the Company for all work performed through the date of termination, plus reasonable costs of bringing the study to an orderly close.

In return for this funding, the Company has agreed to pay CFFT a minimum royalty over a specified period following regulatory approval in the United States of America. Additional compensation is due to CFFT if net sales of this compound exceed a specified amount over a period of time.

Revenue is recognized under this agreement on a percentage of completion method for each distinct agreed-upon event. No revenue was recorded in 2009.

This agreement expired December 31, 2009.

***Agreements China State Institute of Pharmaceutical Industry Agreements***

In January 2011, the Company announced that it had licensed the research and development and commercialization rights for three of its products, exclusively in the People's Republic of China and Hong Kong, to China State Institute of Pharmaceutical Industry ( CIPI ). Harbor BioSciences retains the rights to these products in the U.S. and the rest of the world, and CIPI will make available to the company all pre-clinical and clinical data it generates.

CIPI was recently formed by a merger of the Shanghai Institute of Pharmaceutical Industry and other institutes and companies. CIPI's R&D focus has been in the areas of cancer, infectious diseases, cardiovascular, autoimmune disorders, endocrinology and CNS. CIPI is a subsidiary of the China National Pharmaceutical Group Corporation ( Sinopharm Group ), China's largest pharmaceutical and health industrial group under the state-owned Assets Supervision and Administration Commission of the State Council. Sinopharm Group's core businesses include R&D, manufacturing, distribution and retail sales. Its products are manufactured in more than 10 pharmaceutical and biological production facilities. Sinopharm Group has more than 20 joint ventures with global pharmaceutical companies and through trade and cooperative relations, has a presence in more than 100 countries and regions. Sinopharm Group reported in June 2010 six-month revenues of approximately \$4.75 billion U.S. and net profits of approximately \$137 million U.S.

CIPi is a major supplier of both generic drugs and traditional Chinese medicines in China and Hong Kong. The three license agreements cover Harbor BioSciences compounds HE2000, Apoptone and Triolex for any clinical use in the People's Republic of China and Hong Kong. CIPi plans to develop the Harbor BioSciences compounds for major indications including diabetes, cancer, inflammation and infectious diseases

The Company believes these are the first drug development agreements between a western pioneer drug company and a government-owned Chinese drug developer for pharmaceutical development to be conducted in the People's Republic of China. CIPi, a low cost drug manufacturer, has agreed to supply the licensed products to Harbor BioSciences for use in clinical studies and sales outside of China and Hong Kong. The Company can also elect to distribute these compounds in countries that accept the State Food and Drug Administration's (SFDA) drug approval process.

Clinical drug development candidates licensed to CIPi include Triolex, which has completed Phase IIa clinical trials in patients with Type 2 diabetes and is in early stage development for ulcerative colitis and rheumatoid arthritis; Apoptone, which has demonstrated activity in Phase I/IIa trials of prostate cancer; and HE2000, which has shown to limit opportunistic infections, including tuberculosis, in humans infected with the HIV-1 virus, to reduce parasite levels in patients with uncomplicated malaria and to attenuate non-productive lung inflammation in animal models.



**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

The Company will receive milestone payments for Triolex, Apoptone and HE2000, excluding infectious diseases, at the completion of Phase II and III clinical studies and upon approval by the SFDA. The Company will also receive royalties based on net profits for the life of each agreement. The term of each agreement runs until the latter of (1) the expiration of the last licensed patent or any Company, CIPI or joint improvement patent and (2) the first documented third party sale of a competing generic product in the licensed territory. In addition, the Company is CIPI's sole agent with commercial development and sales rights to all of CIPI's improvements that are sold outside the licensed territory. Sales of licensed drugs that are covered by CIPI's improvements outside the territory bear a royalty to Harbor BioSciences.

**7. Common Stock**

***Reverse Stock Splits***

During February 1995, there was a 3-for-5 reverse stock split of the Company's common stock and in March 1996, a 1-for-2.65 reverse stock split of the Company's common stock. Both reverse stock splits have been retroactively reflected for all periods presented.

***Common Stock Financings***

In January 1996, the Company completed a \$367,522 round of debt financing with a group of private investors. These notes, with an 8% interest rate, were due on or before the earlier of (i) January 21, 1997 or (ii) the closing of a private or public offering of securities. During April 1996, the debt financing plus accrued interest was converted into 164,962 shares of common stock at a price of \$2.25 per share. In April 1996, the Company privately issued 580,005 shares of the Company's common stock at an offering price of \$2.25 per share. Total proceeds from this offering aggregated \$1,234,499.

During May 1998, the Company completed a private financing totaling \$20.6 million in gross proceeds. The Company issued 1,329,201 shares of common stock, (of which 192,061 shares were subject to adjustment based on future average stock price (Adjustable Common Stock)), 4,000 shares of 5% Series A Convertible Preferred Stock and warrants to purchase 1,437,475 shares of common stock in the financing. The warrants entitled the holders to purchase up to a total of 1,437,475 shares of common stock at a price of \$17.00 per share.

The Convertible Preferred Stock had an initial conversion price of \$20.30 for the first seven months, after which it could be adjusted, either up or down, based on the future stock prices of the Company's common stock. The Convertible Preferred Stock was converted to common stock in January 1999 (See Note 8).

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

In January 1999, the Company completed two private placements of an aggregate of 1,367,868 shares of common stock at prices ranging from \$18.00 to \$18.50 per share. In connection with the private placements, the Company issued warrants to purchase an aggregate of 90,000 shares of the Company's common stock, with an exercise price of \$18.25 per share, as a finder's fee. The Company raised approximately \$25.0 million in gross proceeds.

During December 2001, the Company raised \$11.5 million in gross proceeds from the sale of 1.28 million shares of newly issued common stock in a private placement at a price of \$9.00 per share. The investors were a group of qualified institutional buyers and institutional accredited investors. The Company also issued warrants to purchase up to 128,000 shares of common stock having an exercise price of \$12.00 per share to investors. As a finders fee, the Company issued to its placement agent two warrants for a total of 112,640 shares of common stock, one warrant with an exercise price of \$9.00 and the other with an exercise price of \$12.00.

On February 25, 2003, we completed a private placement in which we issued \$10.0 million aggregate principal amount of three-year convertible debentures ( debentures ), bearing interest at 7.5% per year, and warrants to purchase up to 701,760 shares of common stock. The debentures were convertible into common stock at a price of \$5.70 per share, which represented a discount from the price of our common stock on the

**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

commencement date. Also issued in connection with this private placement were warrants to purchase up to 350,880 shares of common stock which are exercisable at a price per share of \$6.17, subject to adjustment, and warrants to purchase up to 350,880 shares of common stock which are exercisable at a price per share of \$6.71, subject to adjustment. The warrants were exercisable until February 25, 2007.

In connection with the issuance of the debentures and warrants, we recorded approximately \$3.5 million related to the beneficial conversion feature and approximately \$3.0 million for the detachable warrants on the debentures. The total amount of the deemed discount on the debentures as a result of the warrant issuance and the beneficial conversion feature amounts to \$6.5 million. The beneficial conversion feature and warrant value (deemed discount) were amortized over the term of the debentures and as conversion of the debentures occurred.

On June 20, 2003, convertible debentures with a face value of \$0.5 million were converted into 87,720 shares of our common stock leaving a \$9.5 million aggregate principal amount of convertible debentures outstanding. On August 11, 2003, the remaining aggregate principal amount of convertible debentures with a face value of \$9.5 million were converted into 1,666,680 shares of our common stock with a value of \$5.70 per share.

During June 2003, the Company completed a private placement of common stock and warrants, from which it received gross proceeds of \$14.7 million. In October 2003 the Company completed a public offering of an aggregate of 2,500,000 shares of common stock at a price of \$25.00 per share and received \$62.5 million in gross proceeds from this offering.

On June 1, 2005 the Company raised approximately \$10.0 million in gross proceeds from the sale of 1,333,333 shares of the Company's common stock at an exercise price of \$6.17 per share. Additionally, the Company issued a four-year warrant to purchase up to an additional 266,667 shares of common stock at an exercise price of \$10.00 per share. In connection with this transaction, the Company incurred approximately \$0.5 million in direct costs and recorded net proceeds of approximately \$9.5 million.

On February 6, 2006 the Company raised approximately \$26.0 million in gross proceeds from the sale of 4,000,000 shares of the Company's common stock at a price of \$6.50 per share. The direct costs related to this financing were \$1.7 million, resulting in net proceeds of \$24.3 million. Additionally, the Company issued four-year warrants to purchase up to an additional 800,000 shares of common stock at an exercise price of \$8.75 per share. The warrants were not exercisable until six months following issuance.

On June 7, 2006 the Company issued 35,000 shares of the Company's common stock to Aeson Therapeutics, Inc. (Aeson) in connection with the purchase of substantially all of Aeson's assets, resulting in an expense of \$180,000. Upon certain events, the Company may be obligated to issue an additional 165,000 shares. The acquisition was expensed as in-process research and development. To date, the Company has not achieved any of the development milestones.

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

On November 13, 2006 the Company raised approximately \$26.0 million in gross proceeds from the sale of 4,000,000 shares of the Company's common stock at a price of \$6.50 per share. The direct costs related to this financing were \$1.6 million, resulting in net proceeds of \$24.4 million. Additionally, the Company issued four-year warrants to purchase up to an additional 800,000 shares of common stock at an exercise price of \$8.75 per share. The warrants were not exercisable until six months following issuance.

On June 10, 2010 the Company raised approximately \$2.06 million in gross proceeds from the sale of approximately 5.9 million shares of its common stock and warrants to purchase approximately 3.5 million shares of its common stock. The shares of common stock and warrants to purchase common stock were sold in units, with each unit consisting of one share of common stock and a warrant to purchase 0.6 of a share of common stock. The purchase price per unit is \$0.35.

**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

**8. Preferred Stock**

During May 1998, as part of a private placement, the Company issued 4,000 shares of Convertible Preferred Stock for proceeds of \$4.0 million. The proceeds of the offering are included in the proceeds to the May 1998 financing described in Note 7, above.

During January 1999, the Company issued 346,127 shares of common stock in connection with the conversion of the Series A Convertible Preferred Stock and additional shares relating to the Adjustable Common Stock. The Adjustable Common Stock was issued during the private placement of May 1998 and was subject to adjustment based on the future average stock price of the Company's common stock as described in Note 7. Upon conversion, all outstanding shares of Preferred stock and Adjustable Common stock were eliminated.

In November 1999, the Company adopted a Shareholders Rights Plan in which Preferred Stock purchase rights ( Rights ) were distributed as a dividend at the rate of one Right for each share of common stock held as of the close of business on November 29, 1999. Each right entitled stockholders to buy, upon certain events, one one-hundredth of a share of a new Series B junior participating preferred stock of the Company at an exercise price of \$100.00. The Rights are designed to guard against partial tender offers and other abusive tactics that might be used in an attempt to gain control of the Company or to deprive stockholders of their interest in the long-term value of the Company. The Rights were exercisable only if a person or group acquires 15% or more of the Company's common stock or announces a tender offer of which the consummation would result in ownership by a person or group of 15% or more of the Company's common stock. The Rights were redeemable for one cent per Right at the option of the Board of Directors prior to this event occurring. The Rights expired on November 14, 2009.

Effective October 19, 2009, the Company executed an Amended and Restated Rights Agreement (the Rights Agreement ) between the Company and American Stock Transfer and Trust Company, LLC, as Rights Agent, amending and restating the Rights Agreement dated as of November 15, 1999 (the Original Rights Agreement ). The purposes of this amendment of the Original Agreement include, among other things: to extend the expiration date of the Preferred Stock purchase rights issued from November 14, 2009 to November 14, 2019; to change how many new shares of common stock the Rights holders can purchase at a price of \$100 per Right (the Purchase Right ) after the 15% threshold is crossed from two times the number of the Company's common stock that the Purchase Price is worth to five times the number of Company's common stock that the Purchase Price is worth; to decrease the redemption price for Company-initiated redemption of the Rights from \$0.01 to \$0.0001.

**9. Stock Options and Restricted Stock**

**Stock Options**

*1997 Stock Option Plan*

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

The 1997 Stock Option Plan (the 1997 Option Plan ) was approved by the Company's stockholders in 1997. Under the 1997 Option Plan, shares of common stock have been reserved for issuance to employees, officers, directors, and consultants of the Company and provides for the grant of incentive and nonstatutory stock options. The Board of Directors determines terms of the stock option agreements, including vesting requirements. The exercise price of incentive stock options must equal at least the fair market value on the date of grant. The options expire not later than ten years from the date of the grant and generally are exercisable ratably over a three-year or four-year period beginning one-year from the date of the grant.

### *2005 Equity Incentive Plan*

In June 2005, the Company's stockholders approved an amendment and restatement of the 1997 Option Plan to become the 2005 Equity Incentive Plan (the 2005 Equity Plan ). Options granted under the 1997 Option Plan prior to its amendment and restatement will continue to be subject to the terms and conditions set forth in

**Table of Contents****HARBOR BIOSCIENCES, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

the agreements evidencing such options and the terms of the 1997 Option Plan except that the Board may elect to extend one or more of the features of the 2005 Equity Plan to stock awards granted under the 1997 Option Plan. The approval of the 2005 Equity Plan in June 2005 increased the number of shares reserved for issuance beyond those reserved for issuance under the 1997 Option Plan by 350,000 shares for a total of 5,500,000 reserved shares. The 2005 Equity Plan will allow the Company greater flexibility in designing equity incentives, including stock appreciation rights, stock purchase awards, restricted stock awards and restricted stock unit awards. In December 2005, the Board of Directors amended the 2005 Equity Plan to reserve an additional 100,000 shares to be used only for the grant of stock awards to persons not previously employed by the Company, or following a bona fide period of non-employment, as an inducement material to those persons entering into employment with the Company with the meeting of the Rule 4350(i)(1)(A)(iv) of the NASDAQ Marketplace Rules, and to provide that any such inducement grants must be granted either by a majority of the Company's independent directors or a committee comprised of a majority of independent directors.

On March 18, 2006, the Board of Directors amended and restated the 2005 Equity Plan to reserve an additional 500,000 shares for issuance under the 2005 Equity Plan, which was subsequently approved by the Company's stockholders in June 2006.

On March 30, 2007 the Board of Directors amended and restated the 2005 Equity Plan to reserve an additional 1,500,000 shares for issuance, for a total of 7,500,000 reserved shares and 100,000 inducement shares. The amendment was approved by the Company's stockholders in June 2007. The approval of the amendment allows the Company to continue to grant stock options and other awards at levels determined appropriate by our Board of Directors.

On March 28, 2008, the Board of Directors amended and restated the 2005 Equity Plan to reserve an additional 800,000 shares for issuance under the 2005 Equity Plan, which was subsequently approved by the Company's stockholders in June 2008.

The following table summarizes stock option activity under the Plan and the 2005 Equity Plan for 1997 through 2010 (in thousands, except per share amounts):

	Shares In Thousands	Price Per Share Range	Weighted Average
1997			
Granted	518	\$ 6.75-8.70	\$ 7.13
Outstanding, December 31, 1997	518	\$ 6.75-8.70	\$ 7.13
1998			
Granted	341	13.25-16.75	14.52

Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

Forfeited	100	8.70	8.70
Outstanding, December 31, 1998	759	\$ 6.75-16.75	\$ 10.24
1999			
Granted	776	10.56-16.63	12.70
Forfeited	61	14.06-14.63	14.63
Outstanding, December 31, 1999	1,474	\$ 6.75-16.75	\$ 11.36
2000			
Granted	774	6.50-15.06	8.18
Exercised	1	6.75	6.75
Forfeited	24	6.75-15.13	14.22
Outstanding, December 31, 2000	2,223	\$ 6.50-16.75	\$ 10.22



**Table of Contents****HARBOR BIOSCIENCES, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

	Shares In Thousands	Price Per Share Range	Weighted Average
<b>2001</b>			
Granted	170	3.53-11.84	6.13
Forfeited	65	5.09-16.63	13.31
Outstanding, December 31, 2001	2,328	\$ 3.53-16.75	\$ 9.80
<b>2002</b>			
Granted	696	5.15-10.10	9.48
Forfeited	55	5.13-13.13	8.17
Outstanding, December 31, 2002	2,969	\$ 3.53-16.75	\$ 10.98
<b>2003</b>			
Granted	943	2.25-17.83	6.59
Exercised	85	4.50-13.13	11.25
Forfeited	66	4.00-16.75	12.17
Outstanding, December 31, 2003	3,761	\$ 2.25-17.83	\$ 8.88
<b>2004</b>			
Granted	596	8.54-15.20	13.69
Exercised	4	3.53-5.29	3.75
Forfeited	46	10.56-17.83	13.66
Outstanding, December 31, 2004	4,307	\$ 2.25-17.83	\$ 9.50
<b>2005</b>			
Granted	408	5.22-10.75	9.94
Exercised	13	3.53-6.68	5.67
Forfeited	56	5.29-10.47	8.06
Outstanding, December 31, 2005	4,646	\$ 2.25-17.83	\$ 9.57
<b>2006</b>			
Granted	965	4.43-7.08	5.67
Exercised	6	2.25-5.29	3.86
Forfeited	67	4.60-10.69	6.98
Outstanding, December 31, 2006	5,538	\$ 2.25-17.83	\$ 8.93
<b>2007</b>			
Granted	1,740	1.64-5.00	2.13
Exercised	9	2.25	2.25
Forfeited	1,607	2.25-16.75	8.29

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

Outstanding, December 31, 2007	5,662	\$ 1.64-17.83	\$ 7.02
2008			
Granted	1,067	0.65-16.63	2.07
Forfeited	442	1.26-16.75	10.58
Outstanding, December 31, 2008	6,287	\$ 0.65-17.83	\$ 5.93

**Table of Contents****HARBOR BIOSCIENCES, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

	Shares In Thousands	Price Per Share Range	Weighted Average
<b>2009</b>			
Granted	378	0.75-14.97	4.85
Forfeited	3,636	0.75-16.63	6.16
Outstanding, December 31, 2009	3,030	\$ 0.65-17.83	\$ 5.51
<b>2010</b>			
Granted	874	1.00-1.00	1.00
Forfeited	482	0.65-17.83	7.14
Outstanding, December 31, 2010	3,422	\$ 0.65-14.97	\$ 4.13

	Shares (in thousands)	Weighted- Average Exercise Price per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2010	3,422	\$ 4.13	5.33	\$ 0
Exercisable on December 31, 2010	3,167	\$ 4.37	5.06	\$ 0

As of December 31, 2010, the total remaining shares of common stock available for grant under the 2005 Equity Plan is 4,813,537 (which includes 90,000 shares under the inducement pool).

**2005 Non-Employee Directors' Equity Incentive Plan**

The 2005 Non-Employee Directors' Equity Incentive Plan (the "Non-Employee Directors Plan") was approved by the Company's stockholders in June 2006. Under the Non-Employee Directors Plan, 150,000 shares of common stock have been reserved for issuance to non-employee directors and provides for the grant of nonstatutory stock options, stock appreciation rights, stock purchase awards, restricted stock awards, restricted stock unit awards, and other forms of equity compensation. The Board of Directors determines terms of the stock awards, including vesting requirements. The exercise price of all options granted under the Non-Employee Directors Plan must equal at least the fair market value on the date of grant. The options expire not later than ten years from the date of the grant and generally are exercisable ratably during the option holder's continued service period.

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

On March 18, 2006, the Board of Directors amended and restated the 2005 Non-Employee Director's Equity Incentive Plan to reserve an additional 150,000 shares for issuance under the 2005 Non-Employee Director's Equity Incentive Plan which was subsequently approved by the Company's stockholders in June 2006.

On March 30, 2007 the Board of Directors amended and restated the 2005 Directors' Plan to reserve an additional 150,000 shares for issuance for a total of 450,000 shares reserved. The Company's stockholders approved the amendment in June 2007.

**Table of Contents****HARBOR BIOSCIENCES, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

On March 28, 2008, the Board of Directors amended and restated the 2005 Non-Employee Director's Equity Incentive Plan to reserve an additional 150,000 shares for issuance under the 2005 Non-Employee Director's Equity Incentive Plan, which was subsequently approved by the Company's stockholders in June 2008.

The following table summarizes stock option activity under the Non-Employee Directors Plan for 2005 - 2010 (in thousands, except per share amounts):

	Shares	Price Per Share	
		Range	Weighted Average
<b>2005</b>			
Granted	30	\$ 10.75	\$ 10.75
Outstanding, December 31, 2005	30	\$ 10.75	\$ 10.75
<b>2006</b>			
Granted	253	\$ 5.43-11.75	\$ 7.55
Outstanding, December 31, 2006	283	\$ 5.43-11.75	\$ 7.89
<b>2007</b>			
Granted	75	\$ 2.14	\$ 2.14
Forfeited	30	\$ 5.43-6.19	\$ 5.81
Outstanding, December 31, 2007	328	\$ 2.14-11.75	\$ 6.76
<b>2008</b>			
Granted	190	\$ 1.62-10.75	\$ 2.88
Forfeited	70	\$ 1.62-10.75	\$ 5.05
Outstanding, December 31, 2008	448	\$ 1.62-11.75	\$ 5.39
<b>2009</b>			
Forfeited	190	\$ 1.62-10.75	\$ 4.01
Outstanding, December 31, 2009	258	\$ 1.62-11.75	\$ 6.40
<b>2010</b>			
Granted	100	\$ 1.00-1.00	\$ 1.00
Outstanding, December 31, 2010	358	\$ 1.00-11.75	\$ 4.89

Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

	Shares (in thousands)	Weighted- Average Exercise Price per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2010	358	\$ 4.89	6.40	\$ -0-
Exercisable on December 31, 2010	330	\$ 5.23	6.18	\$ -0-

As of December 31, 2010, the total remaining shares of common stock available for grant under the 2005 Non-Employee Directors Equity Incentive Plan is 242,000 shares.

*Non-Plan Options*

During 1995 and 1996, the Company granted non-statutory stock options to purchase a total of 608,000 shares to directors, officers and consultants.

**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

In February 1997, as part of an employment agreement, the Company granted a non-statutory stock option to an executive to purchase 2,400,000 shares of the Company's common stock at a price of \$5.00 per share, which vested ratably over a six-year period. The intrinsic value of the options was \$1,848,000. As a result, the Company recorded as deferred compensation a non-cash charge of \$1,848,000, which was being amortized ratably over the six-year vesting period. Through February 1999, the Company had amortized a total of \$641,333. In March 1999, the Company announced the resignation of this executive, at which time the Company and the executive agreed that the option would remain outstanding for a total of 1,200,000 shares, including the acceleration of vesting of 400,000 shares. This acceleration is considered to be a new grant of options and, as such, the Company took a one-time non-cash charge of \$4.9 million during the first quarter of 1999. No change was made to the terms of the option for the remaining 800,000 shares. In February 2008, 400,000 of the options were forfeited and in February 2009, the remaining 800,000 were forfeited.

In March 1999, the Company granted a non-statutory stock option to purchase 300,000 shares to an officer at an exercise price of \$16.63. The options were forfeited on December 31, 2008.

On June 17, 2004, the Company granted stock options to purchase a total of 80,000 shares of common stock of the Company, at an exercise price of \$11.75 per share, the fair market value of the date of grant, to two new directors. Options to purchase one-third of the total number of shares vest upon the first anniversary of the grant, and options to purchase the remaining shares vest in equal monthly installments over the following two years. At the direction of NASDAQ, with the agreement of the directors, these options were rescinded and cancelled in February 2006 and new options with the same terms were granted under the 2005 Non-Employee Directors' Equity Incentive Plan. No compensation was recognized upon issuance of new options as the exercise price exceeded the stock price at the date of the new grant. The options were forfeited in May 2007.

On June 24, 2004, the Company granted stock options to purchase 50,000 shares of common stock of the Company, at an exercise price of \$11.70 per share, the fair market value at the date of grant, to a new executive officer. Options to purchase one-fourth of the total number of shares vest upon the first anniversary of the grant, and options to purchase the remaining shares vest in equal monthly installments over the following three years. The options were forfeited in November 2006.

On September 20, 2004, the Company granted stock options to purchase 40,000 shares of common stock of the Company, at an exercise price of \$10.79 per share, the fair market value at the date of grant, to a new executive officer. Options to purchase one-fourth of the total number of shares vest upon the first anniversary of the grant, and options to purchase the remaining shares vest in equal monthly installments over the following three years. The options were forfeited in May 2007.

On August 1, 2007, the Company granted stock options to purchase 150,000 shares of common stock of the Company, at an exercise price of \$1.66 per share, the fair market value at the date of grant, to a new executive officer. The options were forfeited in February 2008.





**Table of Contents****HARBOR BIOSCIENCES, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

The following table summarizes stock option activity not pursuant to the Plan for 1995 through 2010 (in thousands, except per share amounts):

	Shares	Price Per Share Range	Weighted Average
<b>1995</b>			
Granted	38	\$ 2.65-7.95	\$ 4.64
Outstanding, December 31, 1995	38	\$ 2.65-7.95	\$ 4.64
<b>1996</b>			
Granted	570	2.25	2.25
Outstanding, December 31, 1996	608	\$ 2.25-7.95	\$ 2.40
<b>1997</b>			
Granted	2,400	5.00	5.00
Forfeited	50	2.25	2.25
Outstanding, December 31, 1997	2,958	\$ 2.25-7.95	\$ 4.51
<b>1998</b>			
Exercised	53	2.25-5.30	2.93
Forfeited	50	2.25	2.25
Outstanding, December 31, 1998	2,855	\$ 2.25-7.95	\$ 4.58
<b>1999</b>			
Granted	300	16.63	16.63
Exercised	10	7.95	7.95
Forfeited	1,220	2.25-5.00	4.95
Outstanding, December 31, 1999	1,925	\$ 2.25-16.63	\$ 6.16
Outstanding, December 31, 2000	1,925	\$ 2.25-16.63	\$ 6.16
<b>2001</b>			
Exercised	10	2.25	2.25
Outstanding, December 31, 2001	1,915	\$ 2.25-16.63	\$ 6.23
Outstanding, December 31, 2002	1,915	\$ 2.25-16.63	\$ 6.23
<b>2003</b>			
Forfeited	165	2.25	2.25

Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

Outstanding, December 31, 2003	1,750	\$ 2.25-16.63	\$ 6.60
2004			
Granted	90	\$ 10.79-11.70	\$ 11.30
Outstanding, December 31, 2004	1,840	\$ 2.25-16.63	\$ 6.83
2005			
Granted	28	\$ 6.39-7.59	\$ 7.00
Exercised	22	2.25	2.25
Outstanding, December 31, 2005	1,846	\$ 2.25-16.63	\$ 6.89

**Table of Contents****HARBOR BIOSCIENCES, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

	Shares	Price Per Share	
		Range	Weighted Average
<b>2006</b>			
Exercised	28	\$ 2.25	\$ 2.25
Forfeited	220	2.25-11.70	3.10
Outstanding, December 31, 2006	1,598	\$ 5.00-16.63	\$ 7.49
<b>2007</b>			
Granted	150	\$ 1.66	\$ 1.66
Forfeited	84	7.59-11.70	10.58
Outstanding, December 31, 2007	1,664	\$ 1.66-16.63	\$ 6.81
<b>2008</b>			
Forfeited	850	\$ 1.66-16.63	\$ 8.52
Outstanding, December 31, 2008	814	\$ 5.00-6.39	\$ 5.02
<b>2009</b>			
Forfeited	802	\$ 5.00-6.39	\$ 5.02
Outstanding, December 31, 2009	12		
Outstanding, December 31, 2010	12		

	Shares (in thousands)	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2010				
Exercisable on December 31, 2010				

For various price ranges, weighted average characteristics of outstanding stock options at December 31, 2010 were as follows:

Range of Exercise Prices	Shares	Outstanding options Remaining	Weighted average price	Exercisable options	Weighted average price
		life (years)		Shares	

Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

\$0.65-\$ 0.83	6,600	7.96	\$ 0.71	5,506	\$ 0.68
\$1.00-\$ 1.00	969,208	8.10	\$ 1.00	738,459	\$ 1.00
\$1.62-\$ 1.64	395,663	6.31	\$ 1.62	344,380	\$ 1.62
\$1.66-\$ 1.66	847,445	6.03	\$ 1.66	847,445	\$ 1.66
\$1.68-\$14.97	1,573,249	3.20	\$ 8.23	1,572,676	\$ 8.23
Balance as of 12/31/2010	3,792,165	5.42	\$ 4.21	3,508,466	\$ 4.46

Options exercisable at December 31, 2010, 2009 and 2008 were 3,508,466, 2,932,551 and 5,411,313 at weighted average exercise prices of \$4.46, \$5.99 and \$7.10, respectively.

**Table of Contents****HARBOR BIOSCIENCES, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

The weighted average, estimated fair values of employee stock options granted during the fiscal years ended December 31, 2010, 2009 and 2008 were \$0.39, \$0.15 and \$1.02 per share, respectively.

The total stock-based compensation expense included in our statement of operations for the fiscal years ended December 31, 2010, 2009 and 2008 was \$0.6 million, \$1.3 million and \$2.5 million, respectively. Of the \$0.6 million stock-based compensation expense in 2010, \$0.4 million relates to awards granted prior to January 1, 2010.

As of December 31, 2010, the unrecognized stock-based compensation expense related to non-vested options and restricted shares was approximately \$0.4 million which is expected to be recognized over a weighted average period of approximately 1.08 years. During the fiscal year ended December 31, 2010 since no options were exercised, the total intrinsic value of the stock options exercised was \$0. The Company issues new shares of common stock upon the exercise of stock options.

Cash proceeds and the intrinsic value related to stock options exercised during the fiscal years 2010, 2009 and 2008 to date, are provided in the following table (in thousands):

	Fiscal year Ended December 31,		
	2010	2009	2008
Proceeds from stock options exercised	\$ 0	\$ 0	\$ 0
Tax benefit related to stock options exercised (1)	NA	NA	NA
Intrinsic value of stock options exercised (2)	\$ 0	\$ 0	\$ 0

- (1) ASC Topic 718 requires that the excess tax benefits received related to stock option exercises be presented as financing cash inflows. The Company currently does not receive a tax benefit related to the exercise of stock options due to the Company's net operating losses.
- (2) The intrinsic value of stock options exercised is the amount by which the market price of the stock on the date of exercise exceeded the market price of the stock on the date of grant.

**Restricted Stock**

The fair value of restricted stock is based on the trading price of the Company's common stock on the date of grant. We issued restricted stock for the first time during 2006 to certain employees. Restricted stock activity is as follows:

Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

(Shares in thousands)	Shares	Weighted- Average Grant Date Fair Value
Outstanding at beginning of year		
Granted	68	\$ 6.20
Forfeited	4	\$ 6.20
Outstanding December 31, 2006	64	\$ 6.20
Vested	22	\$ 6.20
Forfeited	12	\$ 6.20
Outstanding December 31, 2007	30	\$ 6.20
Vested	12	\$ 6.20

**Table of Contents****HARBOR BIOSCIENCES, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

(Shares in thousands)	Shares	Weighted-Average Grant Date Fair Value
Outstanding December 31, 2008	18	\$ 6.20
Vested	9	\$ 6.20
Forfeited	6	\$ 6.20
Outstanding December 31, 2009	3	\$ 6.20
Vested	3	\$ 6.20
Outstanding December 31, 2010		

The market price of the common stock on the date of the grant was initially recorded as deferred compensation within the stockholders' equity section of the Company's balance sheet and subsequently is being amortized over the 4-year vesting period. During the fiscal years ended December 31, 2010, 2009 and 2008 there was approximately \$13,600, \$82,900 and \$85,700 of compensation expense, respectively, was amortized and is included in general and administrative and research and development expense in the statement of operations.

**10. Common Stock Purchase Warrants***Series A Warrants*

During April 1996, in accordance with anti-dilution privileges triggered by an offering in March 1995, the Company issued 1,018,866 Series A Warrants to all stockholders of record as of March 1995 to purchase the same number of shares of common stock at a price of \$11.02 per share. The warrants expired January 2002, except for one warrant for 393,250 shares, which expired January 7, 2006.

**IAC Management Warrants**

During April 1994, the Company issued warrants, to existing shareholders and management, to purchase 160,000 units (the Units) at \$10.00 per Unit, each unit to be identical to the Units issued as part of its initial public offering. Each Unit consists of (i) one share of common stock, \$.01 par value per share and (ii) one Class A Warrant entitling the holder to purchase one share of common stock at a price of \$9.00 per share. All the warrants have expired.

***Representatives Warrants***

In connection with the Company's initial public offering, the Company issued warrants to the underwriters for 60,000 Units at an exercise price of \$11.00 per Unit and 24,000 Class B Warrants at an exercise price of \$5.775 per warrant and were exercisable until May 2000. Each Class B Warrant entitled the holder to purchase one Unit (i.e. one share of common stock and one Class A Warrant). The unexercised warrants have expired.

***Investor Relations Warrant***

During February 1998, as part of payment for services relating to investor relations, the Company issued a warrant to purchase 150,000 shares with an exercise price of \$14.75 per share and an expiration date of February 1999. The warrant was estimated to have a value of \$408,000, which was expensed in 1998. This warrant was exercised.

***1998 Private Placement Warrants***

In connection with the May 1998 private placement, the Company issued warrants to purchase 1,437,475 shares of common stock at an exercise price of \$17.00 per share. The warrants were exercisable until May 2001.



**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

Of the warrants issued, 157,000 were issued as finders fees, and 1,280,475 were issued to the private placement investors. These warrants have expired.

***1999 Agent Warrants***

In connection with the January 1999, private placement, the Company issued warrants as a finders fee to purchase 90,000 shares of common stock at an exercise price of \$18.25 per share. The warrants expired in January 2002.

***1999 Consulting Warrant***

During March 1999, the Company entered into a three-year agreement with a financial consulting organization affiliated with a director of the Company. The Company agreed to issue as compensation for services, a warrant to purchase 500,000 shares of common stock with an exercise price of \$20.50 per share and an expiration date of March 2002. The warrant was not subject to any vesting provisions. The warrant was estimated to have a value of approximately \$2.1 million, which was expensed as a non-cash charge during the first quarter of 1999. During 2001, the expiration date for this warrant was extended to March 2003.

During March 2003, the Company amended the consulting arrangement with the same financial organization affiliated with a director. The Company amended the warrant so that the warrant is now exercisable into an aggregate of 250,000 shares of common stock with an exercise price of \$10.00 per share and an expiration date of the earlier of March 12, 2006 or thirty days after the consulting agreement is terminated. For accounting purposes, the original warrant was considered cancelled and a new warrant issued as a replacement resulting in a non-cash charge of approximately \$0.8 million, which was expensed. The warrant expired without being exercised.

***2001 Consulting Warrants***

During April 2001, the Company issued warrants to purchase 25,000 shares of common stock at an exercise price of \$3.09 per share. The warrants expired April 30, 2006. During July 2001, the Company issued warrants to purchase 25,000 shares of common stock at an exercise price of \$6.225 per share. These warrants were exercisable until July 31, 2006. These warrants, collectively, were issued for compensation for services and were estimated to have a combined value of approximately \$208,000, which was expensed as a non-cash charge. Approximately 15% of these warrants were exercised and the remaining warrants have expired.

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

During the fourth quarter of 2001, the Company issued three-year warrants to purchase 16,870 shares of common stock with exercise prices ranging from \$4.72 to \$10.10 per share. The warrants have no vesting period and were issued in lieu of cash for services. An estimated value for these warrants of approximately \$80,000 was expensed. The majority of these warrants have not been exercised. The unexercised warrants have expired.

### *2001 Private Placement Warrants*

In connection with the December 2001 private placement, the Company issued warrants to purchase 128,000 shares of common stock to investors with an exercise price of \$12.00. Warrants to purchase 68,329 shares of our common stock were exercised and the remaining warrants expired December 11, 2003.

As a finders fee, the Company issued two warrants to the placement agent for a total of 112,640 shares of common stock. One warrant has an exercise price of \$9.00 per share and the other an exercise price of \$12.00 per share. The value ascribed to these warrants based on the Black-Scholes pricing model was \$1.5 million and was included as a charge to equity. These warrants to purchase 68,329 shares of our common stock were previously exercised and the remaining unexercised warrants expired in December 2006.

**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

***2002 Consulting Warrants***

In March 2002, the Company agreed to issue a three-year warrant to a consultant, Dr. Joseph Hollis, to purchase up to 60,000 shares of common stock at an exercise price of \$11.00 per share for services rendered in 2002. Dr. Hollis is the brother of Richard B. Hollis. This warrant expired with 50,000 shares unexercised.

During the fourth quarter of 2002, the Company issued a three-year warrant to purchase up to 10,000 shares of common stock at an exercise price of \$4.54 per share. The warrants were issued in lieu of cash for consulting services performed for the Company during 2002. The unexercised warrants have expired.

All of the 2002 warrants were valued at a total of \$247,000 using the Black-Scholes pricing model. The value of the warrants was expensed and is included in the 2002 operating expenses.

***2003 Convertible Note and Warrants***

On February 25, 2003, the Company completed a private placement in which the Company issued \$10.0 million aggregate principal amount of three-year convertible debentures ( debentures ), bearing interest at 7.5% per year, and warrants to purchase up to 701,760 shares of common stock. The debentures are convertible into common stock at a price of \$5.70 per share, which represented a discount from the price of common stock on the commencement date. Also issued in connection with this private placement were warrants to purchase up to 350,880 shares of common stock which are exercisable at a price per share of \$6.17, subject to adjustment, and warrants to purchase up to 350,880 shares of common stock which are exercisable at a price per share of \$6.71, subject to adjustment. Approximately half of these warrants have been exercised. The balance of these warrants expired February 2007.

In connection with the issuance of the debentures and warrants, the Company recorded approximately \$3.5 million related to the beneficial conversion feature and approximately \$3.0 million for the detachable warrants on the debentures. The total amount of the deemed discount on the debentures as a result of the warrant issuance and the beneficial conversion feature amounts to \$6.5 million. The beneficial conversion feature and warrant value (deemed discount) were amortized over the term of the debentures and as conversion of the debentures occurred.

The placement agent received a warrant to purchase 73,684 shares of common stock having an exercise price of \$5.99 per share. The value ascribed to this warrant based on the Black-Scholes pricing model was \$0.4 million and was expensed as a non-cash charge. This warrant expired in February 2008.

***2003 Private Placement Warrants***

In connection with the June 2003 private placement, the Company issued warrants to purchase 192,456 shares of common stock to investors with an exercise price of \$15.45 per share. Approximately 13,000 warrants have been exercised and the remaining warrants expired in June 2007.

As a finders fee, the Company issued a warrant to the placement agent, for a total of 44,266 shares of common stock with an exercise price of \$13.22 per share. The value ascribed to this warrant based on the Black-Scholes pricing model was \$0.5 million and was charged to equity. This warrant expired in June 2008.

***2004 Consulting Warrants***

During 2004, the Company issued two two-year warrants to purchase up to a total of 12,000 shares of common stock at exercise prices of \$10.15 and \$11.75 per share. The warrants were issued for consulting services performed for the Company and expired during 2006.

The 2004 warrants were valued at a total of \$108,280 using the Black-Scholes pricing model. The value of the warrants is amortized according to the vesting period which approximates the period over which the services

**Table of Contents**

**HARBOR BIOSCIENCES, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

are performed. In 2004, \$102,860 was expensed and is included in the 2004 operating expenses. The additional \$5,420 was expensed in 2005, over the remaining vesting period.

***2005 Financing Warrants***

In connection with the June 2005 subscription agreement with a single institutional investor, the Company issued a four-year warrant to purchase up to an additional 266,667 shares of common stock at an exercise price of \$10.00 per share. The value ascribed to this warrant based on the Black-Scholes pricing model was \$1.8 million and was charged to equity. This warrant expired in June 2009.

***2006 Financing Warrants***

In connection with the February 2006 financing agreement with institutional investors, the Company issued four-year warrants to purchase up to an additional 800,000 shares of common stock at an exercise price of \$8.75 per share. The warrants became exercisable six months following issuance, and expired in February 2010.

In connection with the November 2006 financing agreement with institutional investors, the Company issued four-year warrants to purchase up to an additional 800,000 shares of common stock at an exercise price of \$8.75 per share. The warrants became exercisable six months following issuance, and none have been exercised.

***2006 Consulting Warrants***

During 2006, the Company issued two two-year warrants to purchase up to a total of 14,000 shares of the Company's common stock at exercise prices of \$6.20 and \$5.52 per share. The warrants were issued for consulting services performed for the Company. These warrants expired in September and December 2008.

The 2006 warrants were valued at a total of \$40,320 using the Black-Scholes pricing model. The value of the warrants was amortized according to the vesting period that approximated the period over which the services were performed.

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

In December 2006, the Company issued a consulting warrant to purchase up to a total of 50,000 shares of the Company's common stock at an exercise price of \$5.52. The warrant was issued for consulting services performed for the Company. The warrant was valued at a total of \$215,000 using the Black-Scholes pricing model. The warrant vested immediately and was expensed in 2006. The expense is included in the 2006 operating expenses. This warrant has a ten-year life and has not been exercised.

### *2010 Financing Warrants*

In connection with the June 2010 financing agreement, the Company issued five and a half year warrants to purchase up to an additional 3,537,000 shares of common stock at an exercise price of \$0.50 per share. During the period the warrants are outstanding, if the Company issues equity or grants options below the warrant exercise price, the exercise price will be adjusted to the issued equity price but no lower than \$0.43 without stockholder approval. The warrants became exercisable six months following issuance, and none have been exercised to date.

**Table of Contents****HARBOR BIOSCIENCES, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

The following table summarizes stock warrant activity for 2006 through 2010 (in thousands, except per share amounts):

	Shares	Price Per Share	
		Range	Weighted Average
Outstanding, December 31, 2005	1,652	\$ 3.09-15.45	\$ 9.96
2006			
Issued	1,664	5.52-8.75	8.63
Exercised	10	3.09-6.23	3.22
Forfeited	787	3.09-12.00	10.25
Outstanding, December 31, 2006	2,519	\$ 5.52-15.45	\$ 9.02
2007			
Issued			
Exercised			
Forfeited	470	6.17-15.45	9.91
Outstanding, December 31, 2007	2,049	\$ 5.52-13.22	\$ 8.81
2008			
Issued			
Exercised			
Forfeited	132	5.52-13.22	8.39
Outstanding, December 31, 2008	1,917	\$ 5.52-10.00	\$ 8.84
2009			
Issued			
Exercised			
Forfeited	267	10.00	10.00
Outstanding, December 31, 2009	1,650	\$ 5.52-8.75	\$ 8.65
2010			
Issued	3,537	0.50	0.50
Exercised			
Forfeited	1,600	8.75	8.75
Outstanding, December 31, 2010	3,587	\$ 0.50-5.52	\$ 0.57

For various price ranges, the following table summarizes the weighted average prices of outstanding warrants as of December 31, 2010 (in thousands, except per share amounts):

Range of Exercise Prices	Outstanding Warrants		Exercisable Warrants	
	Shares	Weighted average price	Shares	Weighted average price
\$0.50-\$0.50	3,537	0.50	3,537	0.50
\$5.52-\$5.52	50	5.52	50	5.52
Balance as of 12/31/2010	3,587	\$ 0.57	3,587	\$ 0.57



**Table of Contents****HARBOR BIOSCIENCES, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)****11. Employment Agreement**

We have entered into an employment agreement with Mr. Weber, our Chief Financial Officer, which provides that if Mr. Weber's employment is terminated without cause, Mr. Weber shall be entitled to the following: (i) base salary through date of termination, (ii) one year of severance pay at Mr. Weber's highest salary, (iii) an amount equal to the prior calendar year's bonus awarded to Mr. Weber, (iv) immediate vesting of all unvested stock options held by Mr. Weber, and the continuation of the exercise period of all stock options held by Mr. Weber until the final expiration of the original term of such stock options, and (v) continued receipt for one year of all employee benefit plans and programs in which Mr. Weber and his family were entitled to participate immediately prior to the date of termination. Under Mr. Weber's employment agreement, voluntary termination due to a change in duties or a change of control of the company will be considered the same as termination for any reason other than cause and shall entitle Mr. Weber to receive the benefits described in (i) through (v) above.

*Severance and change in control benefits*

Mr. Weber, our Chief Financial Officer, has a provision in his employment agreement providing for certain severance benefits in the event of termination without cause, as well as a provision in his employment agreement providing for the acceleration of his then unvested options in the event of termination without cause following a change in control of the Company. These severance and acceleration provisions are described in the Employment, Severance and Change of Control Agreements section above, and certain estimates of these change of control benefits are provided in Potential Payments Upon Termination or Change of Control Item 11 below.

**12. Leases**

Rental expenses for principal leased facilities under non-cancelable operating leases were approximately \$ 177,400, \$1,349,000 and \$1,395,600 for 2010, 2009 and 2008 respectively. Future minimum payments for operating leases as of December 31, 2010 are as follows (in thousands):

	<b>Operating Leases</b>
2011	\$ 94
2012	
2013	
2014	
<b>Total minimum lease payments</b>	<b>\$ 94</b>

**13. Fair Value Measurement**

We adopted ASC Topic 820 as of January 1, 2008, for financial instruments measured at fair value on a recurring basis. ASC Topic 820 defines the fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States and expands disclosures about fair value measurements.

**Table of Contents****HARBOR BIOSCIENCES, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC Topic 820 establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). These tiers include:

Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets;

Level 2, defined as inputs other than quoted prices in active markets that are directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and

Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant value drivers are observable.

We measure certain financial instruments at fair value on a recurring basis. Financial assets measured at fair value on a recurring basis are as follows at December 31, 2010.

	Level 1	Level 2	Level 3	Total
	In Thousands			
Money Market Accounts	\$ 3,502	\$ 0	\$ 0	\$ 3,502
Total	\$ 3,502	\$ 0	\$ 0	\$ 3,502

**14. Supplementary Financial Data (Unaudited)****Interim Financial Information****(Unaudited)**

Quarterly and year-to-date computations of loss per share amounts are made independently. Therefore, the sum of the per share amounts for the quarter may not agree with the per share amounts for the year.

	March	Quarter - Ended June	September	December	Total Year
	(In thousands, except per share)				
<b>Year Ended December 31, 2010</b>					

Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

R&D operating expenses	\$ 1,230	\$ 1,111	\$ 874	\$ 205	\$ 3,420
G&A operating expenses	624	589	624	648	2,485
Non-cash charges	282	178	99	66	625
Net loss	(2,137)	(1,874)	(1,642)	(944)	(6,597)
Net loss per share	(0.07)	(0.06)	(0.05)	(0.02)	(0.20)
Cash and cash equivalents	8,387	8,439	6,924	5,923	5,923

**Year Ended December 31, 2009**

R&D operating expenses	\$ 3,266	\$ 2,583	\$ 2,411	\$ 1,663	\$ 9,923
G&A operating expenses	1,755	1,241	738	716	4,450
Non-cash charges	342	462	270	248	1,322
Net loss	(5,295)	(4,251)	(3,413)	(2,667)	(15,626)
Net loss per share	(0.18)	(0.14)	(0.12)	(0.09)	(0.53)
Cash and cash equivalents	20,091	15,173	12,099	9,738	9,738

**15. Subsequent Events**

The Company has evaluated all subsequent events through March 31, 2011, which represents the filing date of this Form 10-K with the Securities and Exchange Commission, to ensure that this Form 10-K includes appropriate disclosure of events both recognized in the financial statements as of December 31, 2010 and events which occurred subsequent to December 31, 2010 but were not recognized in the financial statements. As of March 31, 2011, there were no subsequent events that required recognition or disclosure noted above.

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Harbor BioSciences, Inc.

San Diego, California

We have audited the accompanying balance sheets of Harbor BioSciences, Inc. (the Company) (a development stage company) as of December 31, 2010 and 2009, and the related statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2010 and for the period from inception (August 15, 1994) to 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 Harbor BioSciences, Inc. as of December 31, 2010 and 2009, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2010 and for the period from inception (August 15, 1994) to 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 resulting in accumulated net losses of approximately \$258 million and has limited financial resources 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 Diego, California

March 28, 2011



## **Table of Contents**

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

None.

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

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

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Harbor BioSciences management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Exchange Act Rule 13a-15(e) 15d-15(e). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in enabling the Company to record, process, summarize and report information required to be included in the Company's periodic SEC filings within the required time period.

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

Management is responsible for establishing and maintaining adequate internal control over financial reporting for Harbor BioSciences, Inc. Harbor BioSciences Inc.'s internal control system was designed to provide reasonable assurance to Company management and board of directors regarding the preparation and fair presentation of published financial statements in accordance with accounting principles generally accepted in the United States (GAAP).

Management recognizes its responsibility for fostering a strong ethical climate so that the Company's affairs are conducted according to the highest standards of personal and corporate conduct.

The Company's internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded properly to allow for the preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and the Board of Directors of the Company;
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements; and
- provide reasonable assurance as to the detection of fraud.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Further, because of changing conditions, effectiveness of internal control over financial reporting may vary over time. The Company's processes contain self-monitoring mechanisms, and actions are taken to correct deficiencies as they are identified.

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

Management has assessed the effectiveness of Harbor BioSciences' internal control over financial reporting as of December 31, 2010, based on the criteria for effective internal control described in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2010.

As a result of the Dodd-Frank Wall Street Reform and Consumer Protection Act, smaller reporting companies are not required to provide an attestation report of their registered public accounting firm regarding internal control over financial reporting. Thus, this annual report on Form 10-K does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting.



**Table of Contents**

***Changes in Internal Control over Financial Reporting***

There were no changes in Harbor BioSciences, Inc.'s internal controls over financial reporting that occurred during the quarter ended December 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

- (1) The Company entered into three agreements with China State Institute of Pharmaceutical Industry (CIPI), a subsidiary of China National Pharmaceutical Group Corporation On December 20, 2010.
- (2) The Company licensed the research and development and commercialization rights for HE2000, Apoptone and Triolex (one product per agreement), exclusively in the People's Republic of China and Hong Kong. Harbor BioSciences retains the rights to these products in the U.S. and the rest of the world, and CIPI will make available to the Company all pre-clinical and clinical data it generates. Under the terms of the agreement, CIPI will advance each compound forward through development simultaneously without any financial support from Harbor BioSciences. The agreements provide the opportunity for Harbor BioSciences to capture value for our research and development efforts completed to date, while retaining U.S. and other world-markets rights. Harbor BioSciences will receive milestone payments for Triolex, Apoptone and HE2000, excluding infectious diseases, at the completion of Phase II and III clinical studies and also upon approval by the SFDA. We will also receive royalties based on net profits for the life of each agreement. In addition, Harbor is CIPI's sole agent with commercial development and sales rights to all of CIPI's improvements that are sold outside the licensed territory. Sales of licensed drugs that are covered by CIPI's improvements outside the territory bear a royalty to Harbor. The term of each agreement runs until the latter of (1) the expiration of the last licensed patent or any Harbor, CIPI or joint improvement patent and (2) the first documented third party sale of a competing generic product in the licensed territory.

**Table of Contents**

**PART III**

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

See the section entitled "Executive Officers and Senior Management" in Part I, Item 1 of this Annual Report on Form 10-K for information regarding executive officers and senior management.

**Board of Directors**

Our board of directors is presently composed of four members with three vacancies that will not be filled by vote of our stockholders at the upcoming annual meeting. There are no directors whose terms of office expire at the upcoming annual meeting.

Directors are elected by a plurality of the votes present in person or represented by proxy and entitled to vote at the meeting. Proxies cannot be voted for a greater number of persons than the number of nominees named. In the event that any nominee should be unavailable for election as a result of an unexpected occurrence, such shares will be voted for the election of a substitute nominee as our board of directors may propose upon recommendation from our nominating and corporate governance committee.

Set forth below is biographical information for our board of directors

*Salvatore J. Zizza*

Mr. Zizza, age 65, has served as a member of our board of directors since March 1997 and the non-executive Chairman of our board of directors since March 2009. Mr. Zizza has also served as Lead Independent Director of our board of directors since March 2006. He served as Chairman of our board, President and Treasurer of Initial Acquisition Corp., from 1992 until March 1997, at which time Initial Acquisition Corp. merged with the Company. Mr. Zizza is presently Chairman of Metropolitan Paper Recycling, Inc. Mr. Zizza is also Chairman of Bethlehem Advanced Materials. Mr. Zizza was President and Chief Financial Officer of NICO Construction Company, Inc., until 1985, when NICO merged with The LVI Group, Inc. Prior to joining The LVI Group, Inc., Mr. Zizza was an independent financial consultant and had been a lending officer for Chemical Bank. Mr. Zizza's current and former directorships include: The Gabelli Equity Trust (NYSE), The Gabelli Asset Fund, The Gabelli Growth Fund, The Gabelli Convertible and Income Securities Fund, The Gabelli Utility Trust Fund (NYSE), The Gabelli Global Multimedia Trust (NYSE), The Gabelli Equity Series Fund, The Gabelli Dividend and Income Trust, The Gabelli Gold Fund, the Gabelli International Growth Fund, The Gabelli Global Gold Natural Resources, Westwood Funds, Gabelli 787 Fund, GEE (Amex), Translux (Amex), St. David's School, Board of Governors St. John University, and formerly Earl Scheib Inc. (NASDAQ). Mr. Zizza received a B.S. in Political Science and an M.B.A. from St. John's University.

As the lead independent director, Mr. Zizza brings corporate governance expertise to the Board garnered through his leadership positions and board service with other entities. His experience and qualifications provide sound governance leadership to the Board.

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

*James M. Frincke, Ph.D.*

Dr. Frincke, age 60, joined Harbor BioSciences as Vice President, Research and Development in 1997. Dr Frincke was promoted to Executive Vice President in 1999, to Chief Scientific Officer in 2001, to Chief Operating Officer in February 2008, and to Chief Executive Officer in March 2009. Dr. Frincke joined Harbor BioSciences from Prolinx, Inc., where he served as Vice President, Therapeutics Research and Development from 1995 to 1997. During his 24 years in the biotechnology industry, Dr. Frincke has managed major development programs including drugs, biologicals, and cellular and gene therapy products aimed at the treatment of cancer, infectious diseases and organ transplantation. Since joining the biotechnology industry, Dr. Frincke has held vice president, research and development positions in top tier biotechnology companies including Hybritech/Eli Lilly and SyStemix, Inc. (acquired by Novartis). In various capacities, he has been responsible for all aspects of pharmaceutical development including early stage research programs, product evaluation, pharmacology, manufacturing, and the management of regulatory and clinical matters for lead

## **Table of Contents**

product opportunities. Dr. Frincke has authored or co-authored more than 100 scientific articles, abstracts and regulatory filings. Dr. Frincke received his B.S. in Chemistry and his Ph.D. in Chemistry from the University of California, Davis. Dr. Frincke completed his postdoctoral work at the University of California, San Diego.

Mr. Frincke's experience in the drug research and development has given him extensive knowledge of the pharmaceutical and biotech industries. Mr. Frincke's experience has brought key insight into these critical components of the Company's business.

### *Jerome M. Hauer*

Mr. Hauer, age 59, has served as a member of our board of directors since June 2004. Mr. Hauer has served as chief executive officer at The Hauer Group, a consulting services firm, since March 2006. Mr. Hauer served as senior vice president and co-chair of the homeland security practice of Fleishman-Hillard Government Relations, a government relations service firm, from January 2005 to March 2006. Prior to joining Fleishman-Hillard, Mr. Hauer served as the director of Response to Disaster and Emergencies Institute and assistant professor at the George Washington University School of Public Health from November 2003 to December 2004. Mr. Hauer served as acting assistant secretary for public health emergency preparedness of the U.S. Department of Health and Human Services, or HHS, from June 2002 to November 2003 and as director of the office of public health preparedness of HHS from May 2002 to June 2002. He also served as managing director of the crisis and consequence management group at Kroll Associates, a risk consulting firm, from October 2000 to February 2002. Mr. Hauer served as the first director of the New York City Mayor's Office of Emergency Management under Mayor Rudolph Giuliani. He also served as the director of Emergency Medical Services and Emergency Management as well as director of the Department of Fire and Buildings for the State of Indiana under Governor Evan Bayh. Mr. Hauer serves on the board of directors of Emergent BioSolutions, Inc., a publicly held pharmaceutical company. Mr. Hauer previously served as a member of the Health Advisory Board of the Johns Hopkins School of Public Health and as a member of the National Academy of Science's Institute of Medicine's Committee to Evaluate the R&D Needs for Improving Clinical Medical Response to Chemical or Biological Terrorism Incidents. Mr. Hauer received an M.H.S. in public health from Johns Hopkins University School of Hygiene and Public Health and a B.A. in Psychology and History from New York University.

Mr. Hauer brings extensive experiences in public health with various federal and state agencies as well as proven management skills from his Managing Director and Director positions with multiple organizations. His knowledge and experience in government affairs and operations contributes to the Board's overall expertise.

### *Marc R. Sarni*

Mr. Sarni, age 52, has served as a member of our board of directors since June 2004. Mr. Sarni is a Managing Director of NEW Holdings, LLC, a Principal at Howard Commercial Corp., and formerly a Principal at Cornerstone Investment, LLC, companies engaged in the investment in, and development, brokerage and property management of commercial real estate and formerly residential real estate. Mr. Sarni worked as an investment banker at A.G. Edwards and Sons, Inc., for 17 years, and from 1997 until 2003, Mr. Sarni was the Managing Director responsible for establishing and managing the Healthcare Industry Group within the corporate finance department's Emerging Growth Sector. The Healthcare Industry Group of A.G. Edwards focused primarily on emerging growth medical technology, biotechnology, specialty pharmaceutical and healthcare services companies. Prior to joining A.G. Edwards, Mr. Sarni spent three years working as a Certified Public Accountant at PriceWaterhouse (now PricewaterhouseCoopers LLP). Mr. Sarni currently serves as a member of the Boards of Directors of NEW Holdings, LLC, and Howard Commercial Corp., and the Board of Managers for Ascension Health Ventures, the strategic health venture-investing subsidiary of Ascension Health, the nation's largest Catholic and not-for-profit healthcare system. Mr. Sarni also previously served as a director of Young Innovations, Inc., a publicly held manufacturer and marketer of medical products used primarily in the dental industry, and Microtek Medical Holdings, Inc., a publicly held developer of infection and fluid control, safety, and other medical products directed at the healthcare industry, and Cornerstone Investments, LLC. Mr. Sarni graduated from the University of Missouri at Columbia with a BSBA degree in

Accounting and from the University of Chicago with an M.B.A. in Finance.

## **Table of Contents**

Mr. Sarni's extensive public accounting and investment banking background provides the Board invaluable financial and accounting expertise. As a certified public accountant with proven management skills, having served as the Managing Director of an investment bank, Mr. Sarni brings to the Board strong accounting and financial oversight required for our financial reporting and enterprise and operational risk management.

### **Information Regarding our Board of Directors and its Committees**

During 2010, our board of directors held six meetings. Each board member attended at least 75% of the aggregate number of meetings of our board and of the committees, on which he served, held during the period for which he was a director or committee member, respectively.

Our board of directors have documented our corporate governance practices by adopting a number of corporate governance policies and procedures, as well as a Nominating and Corporate Governance Committee Charter and a Business Code of Conduct and Ethics, to assure that our board will have the necessary authority and practices in place to make decisions that are independent of our management. These guidelines are also intended to align the interests of our directors and management with those of our stockholders. These guidelines set forth the practices our board will follow with respect to board composition and selection, board meetings and the involvement of our senior management and Chief Executive Officer, performance evaluation, and board committees and compensation. Mr. Zizza serves as Lead Independent Director of our board of directors. The Lead Independent Director's duties include, to the extent appropriate, leading executive sessions of our board's independent directors, assisting our Chief Executive Officer with communications with our stockholders, and facilitating communications between the other members of our board of directors.

At such times as an independent director is serving as Chairman of the Board, the leadership of the Board is the responsibility of the Chairman. Mr. Zizza, who is an independent director, has served as Chairman of the Board since March 2009. In accordance with our Corporate Governance Guidelines, if a non-independent director, such as our Chief Executive Officer, is serving as Chairman of the Board, the leadership of the Board would be shared by the Chairman and a lead independent director who would be appointed by the independent directors from among themselves. We believe that this leadership structure provides the appropriate level of independent oversight necessary to ensure that the Board meets its fiduciary obligations to our stockholders, that the interests of management and our stockholders are properly aligned, and that we establish and follow sound business practices and strategies that are in the best interests of our stockholders.

### **Board's Role in Risk Management**

The Board provides oversight with respect to our management of risk, both as a whole and through its standing committees. The Board typically reviews and discusses with management at each of its regular meetings, information presented by management relating to our operational results and outlook, including information regarding risks related to our business and operations, as well as risks associated with the markets we serve. At least annually, the Board reviews and discusses an overall risk assessment conducted by management and the strategies and actions developed and implemented by management to monitor, control and mitigate such risks.

The Audit Committee of our Board also provides risk oversight, focusing in particular on financial and credit risk. The Audit Committee oversees the management of such risks, generally as part of its responsibilities related to the review of our financial results and our internal control over financial reporting, and specifically in connection with its consideration of particular actions being contemplated by us such as financing activities and repurchases of our common stock or convertible notes. The Compensation Committee has responsibility for overseeing the management of risk related to our compensation policies and practices. The Compensation Committee considers risks associated with our business in developing compensation policies and the components of our executive compensation program, and periodically reviews and

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

discusses assessments conducted by management with respect to risk that may arise from our compensation policies and practices for all employees.

As required under the rules of the NASDAQ listing standards, our independent directors meet in regularly scheduled executive sessions at which only independent directors are present. Mr. Zizza, as the Lead Independent Director, presides over these executive sessions.

---

**Table of Contents**

**Nominating and Corporate Governance Committee**

Our board of directors has adopted a Nominating and Corporate Governance Committee Charter, which can be found on our corporate website at [www.harborbiosciences.com](http://www.harborbiosciences.com). The Nominating and Corporate Governance Committee (Nominating Committee) is composed of two directors who are independent (as independence is currently defined in the rules of the NASDAQ listing standards): Messrs. Zizza and Hauer. The Nominating Committee is responsible for identifying, reviewing and evaluating candidates to serve as our directors (consistent with criteria approved by our board), reviewing and evaluating incumbent directors, recommending to our board candidates for election to our board, assessing the performance of our board, and making recommendations to our board regarding the membership of the committees of our board. During 2010, the Nominating Committee held no meetings.

Our board of directors believes that candidates for director should have certain minimum qualifications, including: personal integrity and ethics; no interests that would materially impair his or her ability to exercise independent judgment and otherwise discharge his or her fiduciary duties; ability to represent all stockholders equally; achievement in one or more fields of business, professional, governmental, scientific or educational endeavor; sound judgment based on management or policy-making experience; general understanding of the major issues facing public companies of a similar size and operational scope as us; and ability to devote adequate time to our board and its committees. However, the Nominating Committee retains the right to modify these qualifications from time to time. Candidates for director nominees are reviewed in the context of the current composition of our board, our operating requirements and the long-term interests of our stockholders. In conducting this assessment, the Nominating Committee considers such factors as it deems appropriate given our current needs and the current needs of our board, to maintain a balance of knowledge, experience and capability. In the case of incumbent directors whose terms of office are set to expire, the Nominating Committee reviews such directors' overall service during their term, including the number of meetings attended, level of participation, quality of performance, and any other relationships and transactions that might impair such directors' independence. In the case of new director candidates, the Nominating Committee will also determine whether the nominee must be independent for applicable Securities and Exchange Commission rules and regulations. The Nominating Committee will then compile a list of potential candidates, using its own network of contacts, as well as recommendations from other board members and management. The Nominating Committee may also engage, if appropriate under the circumstances, a professional search firm to assist in identifying qualified candidates. The Nominating Committee will conduct any appropriate or necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of our board. The Nominating Committee will meet to discuss and consider such candidates' qualifications and then select nominees for recommendation to our board by majority vote. The Nominating Committee has not developed a policy regarding diversity.

The Nominating Committee will consider director candidates recommended by our stockholders, provided such candidates are not disqualified from nomination pursuant to our bylaws. The Nominating Committee will accept for consideration only one recommendation from any stockholder or affiliated group of stockholders. The Nominating Committee will also take into account the size and duration of the recommending stockholder's ownership interest in the Company and the extent to which such stockholder intends to maintain its ownership interest in the Company. Our board of directors does not intend for the Nominating Committee to alter the manner in which it evaluates candidates, including the minimum criteria set forth above, based on whether or not the candidate was recommended by a stockholder. Stockholders who wish to recommend individuals for consideration by the Nominating Committee to become nominees for election to our board may do so by delivering a written recommendation to the Nominating Committee at the following address: 9171 Towne Centre Drive, Suite 180, San Diego, California 92122, not less than six months prior to any meeting at which directors are to be elected. Submissions must include the full name of the proposed nominee, a description of the proposed nominee's business experience for at least the previous five years, other director positions held by the nominee, complete biographical information, a description of the proposed nominee's qualifications as a director, and the written consent of the proposed nominee to be named as a nominee and to serve as a director if elected. Any such submission must be accompanied by a representation that the nominating stockholder is a beneficial or record



## **Table of Contents**

owner of our common stock, including the number of shares and when the shares were acquired, and the extent to which the nominating stockholder intends to maintain its ownership interest in the Company.

Notwithstanding the responsibilities of the Nominating Committee described above, the recommendations for director nominees made by the Nominating Committee will be subject to Delaware law and our bylaws.

## **Compensation Committee**

Our board of directors has adopted a Compensation Committee Charter, a copy of which can be found on our corporate website at [www.harborbiosciences.com](http://www.harborbiosciences.com). The Compensation Committee makes recommendations to our board of directors concerning executive salaries and incentive compensation, administers our 2005 Equity Incentive Plan and 2005 Non-Employee Directors Equity Incentive Plan and otherwise determines compensation levels and policies and performs such other functions regarding compensation as our board may delegate. The Compensation Committee is currently composed of two non-employee directors who are independent (as independence is currently defined in the rules of the NASDAQ listing standards): Messrs. Sarni and Zizza. During 2010, the Compensation Committee held no meetings.

## **AUDIT COMMITTEE**

We have a separately designated standing Audit Committee of the board of directors established in accordance with the requirements of Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The Audit Committee oversees our corporate accounting and financial reporting process. For this purpose, the Audit Committee performs several functions. The Audit Committee evaluates the performance and assesses the qualifications of the independent registered public accounting firm; determines the engagement of the independent registered public accounting firm; determines whether to retain or terminate the existing independent registered public accounting firm or to appoint and engage a new independent registered public accounting firm; reviews and approves the retention of the independent registered public accounting firm to perform any proposed non-permissible audit services; and monitors the rotation of partners of the independent registered public accounting firm on our engagement team as required by law. The Audit Committee is also responsible for the review, approval and monitoring of transactions involving the company and related persons (directors and executive officers or their immediate family members, or stockholders owning five percent or greater of the company's outstanding stock) that meet the minimum threshold for disclosure in the proxy statement under the relevant Securities and Exchange Commission rules and regulations (generally, transactions involving amounts exceeding \$120,000 in which a related person has a direct or indirect material interest). The Audit Committee meets and reviews with management and the independent registered public accounting firm: the quarterly financial statements and disclosures prior to the filing of our Quarterly Reports on Form 10-Q; the financial statements and disclosures to be included in our Annual Report on Form 10-K; our policies with respect to risk assessment and risk management; our internal controls; and the results of the annual audit. The Audit Committee is composed of three directors and operates under a written charter adopted by our board of directors. Our board of directors reviews and assesses the adequacy of the Audit Committee's written charter on an annual basis in light of applicable Securities and Exchange Commission rules and regulations. The current members of the Audit Committee are Messrs. Hauer, Sarni and Zizza. During 2010, the Audit Committee held four meetings.

Our board of directors also annually reviews the qualifications of all current Audit Committee members and any relationship they may have that might affect their independence from us or our management, and has determined the definition of independence under the rules of the NASDAQ listing standards and Securities and Exchange Commission rules and regulations for Audit Committee members and has determined that (i) all current Audit Committee members are independent as that concept is defined under Section 10A of the Exchange Act, (ii) all current Audit Committee members are independent as that concept is defined under the rules of the NASDAQ listing standards, (iii) all current Audit Committee members have the ability to read and understand financial statements, and (iv) Mr. Sarni and Mr. Zizza qualify as an audit committee financial expert. The latter determination is based on a qualitative assessment of Mr. Sarni's and Mr. Zizza's level of knowledge and experience

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

based on a number of factors, including their formal education and experience. Mr. Zizza is the Audit Committee Financial Expert designated by our board.

## **Table of Contents**

### **Stockholder Communications with our Board of Directors**

Our board of directors has adopted a formal process by which our stockholders may communicate with our board. Persons interested in communicating concerns or issues to our board may address correspondence to our board, in care of Harbor BioSciences, Inc., at 9171 Towne Centre Drive, Suite 180, San Diego, California 92122. All such communications will be compiled by our secretary and submitted to our board on a periodic basis. All communications must be accompanied by the following information:

A statement as to (i) the number of shares of our common stock that the person holds and (ii) the approximate date on which the person became a stockholder;

Any special interest, meaning an interest not in the capacity as one of our stockholders, of the person in the subject matter of the communication; and

The address, telephone number and e-mail address, if any, of the person submitting the communication.

The following types of communications are not appropriate for delivery to directors under these procedures:

Communications regarding individual grievances or other interests that are personal to the party submitting the communication and would not reasonably be of concern to stockholders generally;

Communications that advocate Harbor BioSciences engaging in illegal, unethical or otherwise improper activities;

Communications that contain offensive, vulgar or abusive content; and

Communications that have no rational relevance to our business or operations.

### **SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE**

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of common stock and other of our equity securities. Officers, directors and greater than ten percent stockholders are required by Securities and Exchange Commission regulation to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, during the fiscal year ended December 31, 2010, all Section 16(a) filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with.

### **Code of Business Conduct and Ethics**

We have adopted the Harbor BioSciences Code of Business Conduct and Ethics, which applies to all officers, directors and employees. The Code of Business Conduct and Ethics is available on our website at [www.harborbiosciences.com](http://www.harborbiosciences.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 any executive officer or director, we will promptly disclose the nature of the amendment or waiver in a Form 8-K filed with the Securities and Exchange Commission.

**Item 11. Executive Compensation**

We currently qualify as a smaller reporting company as such term is defined in Rule 405 of the Securities Act of 1933, as amended, and Item 10 of Regulation S-K. Accordingly, and in accordance with relevant Securities and Exchange Commission rules and guidance, we have elected, with respect to the disclosures required by Item 402 (Executive Compensation) of Regulation S-K, to comply, in some cases, with the requirements applicable to larger companies and, in other cases, with the disclosure requirements applicable to smaller reporting companies. For example, the following overview of our executive compensation is not comparable to the Compensation Discussion and Analysis section that is required of SEC reporting companies that are not smaller reporting companies.

---

**Table of Contents**

*COMPENSATION PHILOSOPHY FOR NAMED EXECUTIVE OFFICERS AND OVERVIEW*

The Compensation Committee of our board of directors approves, administers and interprets our executive compensation and benefit policies, including our 2005 Equity Incentive Plan. The compensation of our named executive officers is designed to attract highly qualified executives with the ability, skills and potential necessary for Harbor BioSciences to achieve its corporate strategies; to encourage those individuals to continually pursue our strategic objectives while effectively managing the risks and challenges inherent to a development stage pharmaceutical/biotechnology company; to reward those individuals adequately and fairly over time; and to retain those individuals who continue to perform at or above our expectations. Our named executive officers' compensation has three primary components: base salary, a yearly discretionary cash bonus, and long-term incentive compensation in the form of stock options and, in certain circumstances, restricted stock awards. In addition, our named executive officers are provided with benefits that are generally available to all of our salaried employees, including matching contributions in the form of our common stock into our named executive officers' 401(k) accounts.

Our Compensation Committee views all three components of our compensation for our named executive officers as related but distinct. Although our Compensation Committee reviews total compensation, we do not believe that significant compensation derived from one component of compensation should negate or reduce compensation from other components. Our Compensation Committee has not adopted any formal or informal policies or guidelines for allocating compensation between long-term and currently paid-out compensation, between cash and non-cash compensation, or among different forms of compensation. This is due in part to the relatively small size of our executive team and the need to tailor each named executive officer's compensation to attract and retain that named executive officer. Our Compensation Committee determines the appropriate level for each compensation component based in part, but not exclusively, on its view of internal equity and consistency, individual performance, current market conditions, consultation with legal counsel and compensation consultants, a review of corporate accomplishments and setbacks during the prior year, consideration of active projects and future projects, review of expiring equity compensation and the dilutive effect of new equity grants, and other information the Compensation Committee deems relevant, such as the compensation survey data referred to below.

*PRIMARY COMPONENTS OF EXECUTIVE COMPENSATION*

The aggregate compensation paid to our named executive officers is composed of three primary components: base salary, a yearly discretionary cash bonus, and long-term incentive compensation in the form of stock options and, in certain circumstances, restricted stock awards. Each component is described below in more detail.

*Base salary.* Our Compensation Committee fixes the base salary of each of our named executive officers at a level it believes enables us to hire and retain these individuals and to reward our named executive officers for satisfactory individual performance and a satisfactory level of contribution to our overall business goals. In determining the base salaries of our named executive officers, the Compensation Committee also takes into account the base salaries paid to executives in other companies with which we believe we compete for talent, including companies of similar size and stage of development operating in the biotechnology industry, as well as other private and public companies located in our geographical location. For newly-hired named executive officers, the base salary is initially established through negotiation at the time the named executive officer is hired, taking into account such named executive officer's qualifications, experience, prior salary and competitive salary information and any unique personal circumstance that motivated the executive to leave his or her prior position and join Harbor BioSciences.

Year-to-year adjustments to each named executive officer's base salary, if any, are based upon individual performance for that year, changes in the general level of base salaries of persons in comparable positions within our industry and geographical location, and the average merit salary increase for such year for all of our employees, as well as other factors the Compensation Committee judges to be pertinent during that assessment period. Our Compensation Committee subscribes to certain executive compensation surveys and other databases



## **Table of Contents**

such as, most recently, the 2008 Radford Biotechnology Survey and the Radford Biotechnology Edition of the Quarterly Summary of Industry Trends Survey Report for the third quarter and fourth quarter 2008, and reviews them periodically when making executive hiring decisions and when reviewing executive compensation. Our Compensation Committee realizes that benchmarking the Company's compensation against the compensation earned at comparable companies may not always be appropriate, but believes that engaging in a comparative analysis of the Company's compensation practices is useful at this point in the life cycle of the Company.

For each named executive officer position, the Compensation Committee generally sets its target base compensation between the 50th and 75th percentile of base compensation paid to executive officers holding equivalent positions in the companies contained in the Radford Biotechnology Survey, a national survey of approximately 1,300 positions in 550 biotechnology organizations. For both 2007 and 2008, this represented a projected increase of approximately 4.0% in base salary over the prior year for the Company's employees as a whole. This approach applies to our named executive officers and generally to all positions company-wide, except that individual base compensation may range below or above those percentiles depending upon job function, scope of responsibility, individual performance and experience, skills, contribution, and market factors when, in the judgment of our Compensation Committee, the value of the individual's experience, performance and specific skill set justifies variation. The Compensation Committee has also historically taken into account information from other sources, including input from other independent members of our board of directors and publicly available data relating to the compensation practices and policies of other companies within and outside of our industry. Generally, the salaries for our named executive officers are adjusted effective January 1 of each year. For 2009 and 2010, the Compensation Committee froze the base salaries for all of the Company's named executive officers such that the base salaries for the named executive officers remained at 2008 levels during 2009 and 2010.

*Annual discretionary cash bonuses.* The annual cash bonus payments to our named executive officers are entirely discretionary. In January 2009, our board of directors approved and authorized our management to cancel all cash bonuses until further notice, related to performance that might otherwise be granted to the Company's named executive officers. In February 2009, management implemented this action and all cash bonuses related to 2009 and 2010 performance that might have otherwise been granted to the Company's named executive officers were cancelled.

We utilize annual incentive bonuses to compensate our named executive officers for achieving Company financial and operational goals. These objectives relate generally to Company-wide goals and performance objectives, as well as other strategic factors such as establishment and maintenance of key strategic relationships, development of our drug candidates, identification and advancement of additional drug candidates, advancement of scientific research and to financial factors such as raising capital, improving our results of operations and increasing the price per share of our common stock. Our Compensation Committee believes that it is most appropriate and meaningful at this point in the life cycle of the Company to determine discretionary cash bonus amounts, if any, to our named executive officers based upon our management team's performance and achievement of Company-wide goals as a whole rather than solely upon an individual named executive officer's achievement of individual performance objectives and departmental or functional area goals.

*Long-term equity incentive awards.* We use stock options and, in certain circumstances, restricted stock awards to reward long-term performance. These options and restricted stock awards are intended to produce the potential for significant value for each named executive officer if our performance is positive and if the named executive officer has an extended tenure with the Company. To conserve our cash resources, we place special emphasis on equity-based incentives to attract, retain and motivate named executive officers as well as other employees.

The Compensation Committee provides our named executive officers with long-term incentive compensation through grants of stock options and restricted stock awards, generally under the 2005 Equity Incentive Plan. We believe that stock options provide our named executive officers with the opportunity to purchase and maintain an equity interest in Harbor BioSciences and to share in the potential appreciation of the value of our common stock. We believe that stock options align our named executive officers' incentives with





## **Table of Contents**

that of our stockholders because options have value only if our stock price increases over time. The stock options also utilize vesting periods that encourage named executive officers to continue in their employment with us. However, because of the evolution of regulatory, tax and accounting treatment of equity incentive programs and because it is important to us to retain our named executive officers and key employees, we realize that it is important in some circumstances that we utilize other forms of equity awards as and when we may deem necessary. For example, in 2006, we granted restricted stock awards to our named executive officers, as we believed that this was an additional way to reward them for and motivate them toward superior performance.

The Compensation Committee considers the grant of each option or restricted stock award subjectively, considering factors such as the individual performance of the named executive officer and the anticipated contribution of the named executive officer to the attainment of our long-term strategic performance goals. Long-term incentives granted in prior years are also taken into consideration. Grants are made to all employees when hired based on salary level and position. All employees, including named executive officers, are eligible for subsequent, discretionary grants, which are generally based on either individual or corporate performance, as well as the position held within the Company.

## **Employment, Severance and Change of Control Agreements**

We have entered into an employment agreement with Mr. Weber, our Chief Financial Officer, which provides that if Mr. Weber's employment is terminated without cause, Mr. Weber shall be entitled to the following: (i) base salary through date of termination, (ii) one year of severance pay at Mr. Weber's highest salary, (iii) an amount equal to the prior calendar year's bonus awarded to Mr. Weber, (iv) immediate vesting of all unvested stock options held by Mr. Weber, and the continuation of the exercise period of all stock options held by Mr. Weber until the final expiration of the original term of such stock options, and (v) continued receipt for one year of all employee benefit plans and programs in which Mr. Weber and his family were entitled to participate immediately prior to the date of termination. Under Mr. Weber's employment agreement, voluntary termination due to a change in duties or a change of control of the company will be considered the same as termination for any reason other than cause and shall entitle Mr. Weber to receive the benefits described in (i) through (v) above.

### *Severance and change in control benefits*

Mr. Weber, our Chief Financial Officer, has a provision in his employment agreement providing for certain severance benefits in the event of termination without cause, as well as a provision in his employment agreement providing for the acceleration of his then unvested options in the event of termination without cause following a change in control of the Company. These severance and acceleration provisions are described in the *Employment, Severance and Change of Control Agreements* section above, and certain estimates of these change of control benefits are provided in *Potential Payments Upon Termination or Change of Control* section below.

### *Other benefits*

Our named executive officers are eligible to participate in all of our employee benefit plans, such as medical, dental, vision, group life and disability insurance and our 401(k) plan, in each case on the same basis as our other employees. There were no special benefits or significant perquisites provided to any named executive officer in 2010.

**Table of Contents**

## Material tax and accounting implications of executive compensation policies

We account for the equity compensation expense for our employees under the rules of ASC 718, which requires us to estimate and record an expense for each award of equity compensation over the service period of the award. Accounting rules also require us to record cash compensation as an expense at the time the obligation is accrued. Unless and until we achieve sustained profitability, the availability to us of a tax deduction for compensation expense is not material to our financial position. We structure discretionary cash bonus compensation so that it is taxable to our employees at the time it becomes available to them. Federal income tax law prohibits publicly held companies from deducting certain compensation paid to a named executive officer that exceeds \$1 million during the tax year. To the extent that compensation is based upon the attainment of performance goals set by the Compensation Committee pursuant to plans approved by our stockholders, such compensation is not included in the computation of this limit. Although the Compensation Committee intends, to the extent feasible and where it believes it is in the best interests of the Company and our stockholders, to attempt to qualify executive compensation as tax deductible, it does not intend to permit this tax provision to dictate the Compensation Committee's development and execution of effective compensation plans.

**SUMMARY COMPENSATION TABLE**

The following table shows for the fiscal years ended December 31, 2008, 2009 and 2010, compensation awarded to or paid to, or earned by, our Chief Executive Officer, our Chief Financial Officer and our two other most highly compensated executive officers in 2010 (the Named Executive Officers ).

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)(1)	Option Awards (\$)(1)	All Other Compensation (\$)(2)	Total (\$)
Dr. James M. Frincke	2008	\$ 325,000		\$ 3,915	\$ 199,260	\$ 23,554(3)	\$ 551,729
Chief Executive Officer	2009	\$ 325,000		\$ 1,238		\$ 20,060(4)	\$ 346,298
	2010	\$ 325,000		\$ 574	182,768	\$ 17,738(5)	\$ 526,080
Dr. Christopher L. Reading	2008	\$ 270,508		\$ 1,630	\$ 40,500	\$ 7,801	\$ 320,439
Chief Scientific Officer	2009	\$ 270,508		\$ 516		\$ 21,307	\$ 279,275
	2010	\$ 270,508		\$ 239	\$ 8,251	84,871	\$ 363,869
Dwight R. Stickney, M.D.	2008	\$ 371,394		\$ 1,630	\$ 40,500	\$ 5,461	\$ 418,985
Chief Medical Officer	2009	\$ 371,394		\$ 516		\$ 37,365	\$ 379,611
	2010	\$ 371,394		\$ 239	84,871	\$ 7,998	\$ 464,502
Robert W. Weber	2008	\$ 235,000		\$ 1,630	\$ 154,148	\$ 16,719(6)	\$ 407,497
Chief Financial Officer	2009	\$ 235,000		\$ 516		\$ 39,008(7)	\$ 259,464
	2010	\$ 235,000		\$ 239	84,871	\$ 17,148(8)	\$ 337,258

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

- (1) Amounts are calculated utilizing the provisions of ASC (718), Share-based Payments . See Note 2 Summary of Accounting Policies of the financial statements in the Company's Annual Report on Form 10-K, for the year ended December 31, 2010 for a discussion of the assumptions underlying valuation of our equity awards.
- (2) Amounts shown in this column include company match for each Named Executive Officer's contributions to the Company's 401(k) plan as well as life insurance premiums paid on behalf of each Named Executive Officer.
- (3) The amount shown included a pay out of \$12,500 in accrued paid time off to Dr. Frincke as well as a company match of \$3,156 for Dr. Frincke's spouse.
- (4) The amount shown included a company match of \$2,487 for Dr. Frincke's spouse
- (5) The amount shown included a pay out of \$6,250 in accrued paid time off to Dr. Frincke as well as a company match of \$3,158 for Dr. Frincke's spouse.
- (6) The amount shown includes a pay out of \$9,038 in accrued paid time off to Mr. Weber.
- (7) The amount shown includes a pay out of \$15,817 in accrued paid time off to Mr. Weber.
- (8) The amount shown includes a pay out of \$9,038 in accrued paid time off to Mr. Weber.

**Table of Contents****Grants of Plan-Based Awards**

The following table shows for the fiscal year ended December 31, 2010, certain information regarding grants of plan-based awards to the Named Executive Officers:

**Grants of Plan-Based Awards in Fiscal 2010**

<b>Name</b>	<b>Grant Date</b>	<b>All Other Option Awards: Number of Securities Underlying Options (#)</b>	<b>Exercise or Base Price of Option Awards (\$/Share)</b>	<b>Grant Date Fair Value of Stock and Option Awards (\$ (1))</b>
James M. Frincke	01/29/2010	200,000	\$ 1.00	\$ 106,975
Christopher L. Reading	01/29/2010	100,000	\$ 1.00	\$ 53,488
Dwight R. Stickney	01/29/2010	100,000	\$ 1.00	\$ 53,488
Robert W. Weber	01/29/2010	100,000	\$ 1.00	\$ 53,488

- (1) Amounts are calculated utilizing the provisions of ACS (718), Share-based Payments. See Note 2 Summary of Accounting Policies of the financial statements in the Company's Annual Report on Form 10-K, for the year ended December 31, 2010, for a discussion of the assumptions underlying valuation of our equity awards.

**Table of Contents****Outstanding Equity Awards at Fiscal year-end.**

The following table shows for the fiscal year ended December 31, 2010, certain information regarding outstanding equity awards at fiscal year end for the Named Executive Officers.

**Outstanding Equity Awards At December 31, 2010**

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$) (6)
James M. Frincke	60,000		9.91	01/08/2012(3)		
	60,000		5.29	02/25/2013(3)		
	10,000		12.25	06/24/2013(4)		
	64,000		14.97	01/15/2014(3)		
	46,800		10.75	02/10/2015(3)		
	27,000		6.20	02/12/2016(3)		
	60,000		5.43	12/10/2016(3)		
	200,000		1.66	07/31/2017(2)		
	60,000		1.62	01/16/2018(7)		
	43,750	16,250	1.62	01/16/2018(3)		
3,000		1.62	01/16/2018(1)			
	145,833	54,167	1.00	01/28/2020(5)		
Christopher L. Reading	40,000		9.91	01/08/2012(3)		
	13,333		9.91	01/08/2012(1)		
	25,000		5.29	02/25/2013(3)		
	10,000		12.25	06/24/2013(4)		
	31,000		14.97	01/15/2014(3)		
	19,500		10.75	02/10/2015(3)		
	11,250		6.20	02/12/2016(3)		
	25,000		5.43	12/10/2016(3)		
	100,000		1.66	07/31/2017(2)		
	18,229	6,771	1.62	01/16/2018(3)		
	72,917	27,083	1.00	01/28/2020(5)		
Robert W. Weber	25,000		9.91	01/08/2012(3)		
	25,000		5.29	02/25/2013(3)		
	25,000		14.97	01/15/2014(3)		
	19,500		10.75	02/10/2015(3)		
	11,250		6.20	02/12/2016(3)		
	25,000		5.43	12/10/2016(3)		
	100,000		1.66	07/31/2017(2)		
	25,000		1.62	01/16/2018(7)		
	18,229	6,771	1.62	01/16/2018(3)		
	3,000		1.62	01/16/2018(1)		

Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

	30,350		2.25	02/26/2013(1)
	72,917	27,083	1.00	02/28/2020(5)
Dwight R. Stickney	36,000		6.90	05/28/2011(3)
	12,500		9.91	01/08/2012(3)
	12,500		5.29	02/25/2013(3)
	10,000		12.25	06/24/2013(3)
	1,000		12.20	06/25/2013(1)
	28,000		14.97	01/15/2014(3)
	6,000		10.69	12/02/2014(1)
	19,500		10.75	02/10/2015(3)
	11,250		6.20	02/12/2016(3)
	25,000		5.43	12/10/2016(3)
	100,000		1.66	07/31/2017(2)
	18,229	6,771	1.62	01/16/2018(3)
	72,917	27,083	1.00	01/28/2020(5)

(1) These grants vested immediately upon date of grant.

**Table of Contents**

- (2) These grants vest for 1/3rd of the total number of shares on the first year anniversary of the date of grant; 1/36th of the total shares vest each month thereafter.
- (3) These grants vest for 1/4th of the total number of shares on the first year anniversary of the date of grant; 1/48th of the total shares vest each month thereafter.
- (4) These grants vest for 1/4th of the total number of shares immediately upon the date of grant; 1/36th of the total shares vest each month thereafter.
- (5) These grants vest 1/2 the total number of shares upon the date of the grant, 1/24<sup>th</sup> of the total share vest each month thereafter.
- (6) The amounts reflected in this column represents the closing price of a share of our common stock on December 31, 2008, (\$0.68) multiplied by the number of shares that have not vested.
- (7) These grants vest and become exercisable in 12 equal monthly installments.

**Option Exercises and Stock Vested**

The following table provides information regarding the number of shares of common stock acquired and the value realized pursuant to the exercise of stock options, and all stock awards vested and the value realized pursuant to the vesting of stock awards, during 2010 by each of our Named Executive Officers.

Named Executive Officer	Option Awards		Stock Awards	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise (1) (\$)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting (2) (\$)
James M. Frincke			1,125	574
Christopher L. Reading			469	239
Dwight R. Stickney			469	239
Robert L. Marsella				
Robert W. Weber			469	239

- (1) The value realized on exercise is equal to the difference between the option exercise price and the closing price of our common stock on the date of exercise, multiplied by the number of shares subject to the option, without taking into account any taxes that may be payable in connection with the transactions.
- (2) The value realized on vesting is equal to the closing price of our common stock on the date of vesting, multiplied by the number of shares that vested.

None of our Named Executive Officers participates in or has account balances in qualified or non-qualified defined benefit plans sponsored by us. The Compensation Committee may elect to adopt qualified or non-qualified defined benefit plans in the future if the Compensation Committee determines that doing so is in our best interests.

**Nonqualified Deferred Compensation**

None of our Named Executive Officers participate in or have account balances in non-qualified defined contribution plans or other deferred compensation plans maintained by us. The Compensation Committee may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if the Compensation Committee determines that doing so

is in our best interests.

**Potential Payments upon Termination or Change-In-Control**

The summary below sets forth potential payments payable to certain of our current Named Executive Officers upon termination of employment or a change in control of the Company. The Compensation Committee may in its discretion, and with the approval of the applicable Named Executive Officer, revise, amend or add to these benefits in the future if it deems doing so advisable and in our best interests. Robert W. Weber, our Chief Financial Officer, is the only Named Executive Officer who has any severance and/or change of control arrangements.



**Table of Contents**

Under Mr. Weber's employment agreement, if Mr. Weber's employment is terminated without cause, Mr. Weber shall be entitled to the following: (i) base salary through date of termination, (ii) one year of severance pay at Mr. Weber's highest salary, (iii) an amount equal to the prior calendar year's bonus awarded to Mr. Weber, (iv) immediate vesting of all unvested stock options held by Mr. Weber, and the continuation of the exercise period of all stock options held by Mr. Weber until the final expiration of the original term of such stock options, and (v) continued receipt for one year of all employee benefit plans and programs in which Mr. Weber and his family were entitled to participate immediately prior to the date of termination. Currently, Mr. Weber's annual base salary is \$235,000. Assuming that Mr. Weber was terminated effective December 31, 2010, he would be entitled to receive an amount equal to his base salary of \$235,000, an amount equal to his 2010 discretionary cash bonus of \$0, the acceleration of the vesting of 33,854 shares of common stock subject to outstanding unvested stock options as of December 31, 2010 with an aggregate value equal to \$0 (based on the spread between the closing price of our common stock on December 31, 2010 of \$0.15 and the exercise price of the stock options) and continued employee benefits for he and his family for one year following such termination at an estimated aggregate cost of \$21,500. Under Mr. Weber's employment agreement, voluntary termination due to change in duties or change of control of the company will be considered the same as termination for any reason other than cause and shall entitle Mr. Weber to receive the same benefits described above.

**DIRECTOR COMPENSATION**

For 2010, each non-employee director received an annual retainer of \$15,000, a fee of \$2,500 per in-person board meeting attended, and a fee of \$1,000 per telephonic committee meeting attended if the duration of the committee meeting is expected to exceed one hour (including preparation time), with the applicable committee members determining at each such meeting whether such compensation is payable. Also, directors who serve as committee chairmen for board committees received an additional annual retainer of \$2,500 per year. During 2010, the chairman of the board received additional compensation of \$7,500 a month for his duties as chairman. We also grant discretionary stock options to non-employee members of our board of directors.

The following table shows for the fiscal year ended December 31, 2010, certain information with respect to the compensation of all non-employee directors of the Company:

**DIRECTOR COMPENSATION FOR FISCAL 2010**

Name	Fees Earned or Paid in		Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
	Cash	Awards						
	(\$)	(\$)		(\$)	(\$)		(\$)	(\$)
Jerome M. Hauer	19,500			14,426				33,926
Marc R. Sarni	26,000			14,426				40,426
Salvatore J. Zizza	103,500			22,201				125,701

- (1) Amounts are calculated utilizing the provisions of ASC 718, Share-based Payments. See Note 2, Summary of Accounting Policies, of the financial statements in the Company's Annual Report on Form 10-K, for the year ended December 31, 2010, for a discussion of the assumptions underlying valuation of our equity awards.



**Table of Contents****Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters**

The following table sets forth certain information regarding the ownership of our common stock as of January 31, 2011 by: (i) each director and nominee for director; (ii) each of the executive officers named in the compensation table; (iii) all of our executive officers and directors as a group; and (iv) all those known to us to be beneficial owners of more than five percent of our common stock. Except as otherwise shown, the address of each stockholder listed is in care of Harbor BioSciences at 9171 Towne Centre Drive, Suite 180, San Diego, California 92122.

Beneficial Owner	Beneficial Ownership <sup>(1)</sup>	
	Number of Shares	Percent of Total
James M. Frincke(2)	897,451	2.5%
Christopher L. Reading(3)	410,604	1.2%
Salvatore J. Zizza(4)	339,667	*
Dwight R. Stickney(5)	395,156	1.1%
Jerome M. Hauer(6)	108,750	*
Marc R. Sarni(7)	113,750	*
Robert W. Weber(8)	444,326	1.2%
All executive officers and directors as a group (7 persons)(9)	2,709,704	7.2%

Less than one percent.

- (1) This table is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and 13G filed with the Securities and Exchange Commission. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 35,465,838 shares outstanding on January 31, 2011, adjusted as required by rules promulgated by the Securities and Exchange Commission.
- (2) Includes 796,633 shares subject to options which are presently exercisable or will become exercisable within 60 days of January 31, 2011, and 36,604 shares held under our 401(k) plan in his name. Also includes 41,279 shares subject to options which are presently exercisable or will become exercisable within 60 days of January 31, 2011, and 15,060 shares held under our 401(k) plan in his spouse's name.
- (3) Includes 374,042 shares subject to options which are presently exercisable or will become exercisable within 60 days of January 31, 2011, and 33,749 shares held under our 401(k) plan.
- (4) Includes 209,667 shares subject to options which are presently exercisable or will become exercisable within 60 days of January 31, 2011. Also includes 1,500 shares held in trust in the name of his children, with respect to which Mr. Zizza disclaims beneficial ownership.
- (5) Includes 354,709 shares subject to options which are presently exercisable or will become exercisable within 60 days of January 31, 2011, and 35,697 shares held under our 401(k) plan.
- (6) Includes 108,750 shares subject to options which are presently exercisable or will become exercisable within 60 days of January 31, 2011.
- (7) Includes 108,750 shares subject to options which are presently exercisable or will become exercisable within 60 days of January 31, 2011.
- (8)

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

Includes 388,059 shares subject to options which are presently exercisable or will become exercisable within 60 days of January 31, 2011, and 32,517 shares held under our 401(k) plan.

- (9) Includes 2,381,889 shares subject to options which are presently exercisable or will become exercisable within 60 days of January 31, 2011, and 153,627 shares held under our 401(k) plan.

**Table of Contents**

The following table provides information as of December 31, 2010 with respect to all of our compensation plans under which we are authorized to issue equity securities of the company.

## Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities in the first column)
Stock option equity compensation plans approved by security holders	3,820,665	\$ 4.22	5,055,537
Stock option equity compensation plans not approved by security holders			
Warrant equity compensation plans not approved by security holders	50,000	\$ 5.52	
Total	3,870,665		5,055,537

The material features of each compensation plan or arrangement adopted without the approval of securities holders is included in Note 9 ( Stock Options Non-Plan Options ) and Note 10 ( Common Stock Purchase Warrants ) in our Notes to Financial Statements.

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

Dr. James Frincke's wife serves as our director of accounting. She earned \$109,828 in base salary during fiscal year 2010 and received 10,000 stock option grants at \$1.00 strike price in 2010.

In February 2003, Mr. Weber, our Chief Financial Officer was granted a fully vested and exercisable stock option to purchase a total of 40,000 shares of our common stock with an exercise price of \$2.25 per share with a five year exercise period expiring February 25, 2008. In January 2008, the compensation committee of our board of directors approved the extension of the expiration date of the exercise period for the remaining 30,350 shares underlying this stock option from February 25, 2008, to February 25, 2013, resulting in the deemed cancellation of the original stock option and the grant of a replacement stock option.

**Independence of the Board of Directors**

## Edgar Filing: Harbor BioSciences, Inc. - Form 10-K

After review of all relevant transactions and relationships between each director, or any of his or her family members, and us, our senior management and our independent registered public accounting firm, our board affirmatively has determined that Messrs. Sarni, Zizza and Hauer are independent directors within the meaning of the rules of the NASDAQ listing standards

Our Board has established three standing committees: the Audit Committee, the Compensation Committee, and the Nominating and Corporate Governance Committee. Each member of the Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee, respectively, meets the independence standards set forth in the rules of the NASDAQ listing standards.

**Table of Contents****Item 14. Principal Accountant Fees and Services**

## Independent Registered Public Accounting Firm Fees

The following table shows the fees incurred for services rendered by BDO USA, LLP, our independent registered public accounting firm in 2010 and 2009. All such services were pre-approved by the Audit Committee in accordance with the pre-approval policy described below.

	2010	2009
<b>Audit Fees</b>		
Annual financial statements and reviews of quarterly financial statements	\$ 76,000	\$ 76,000
Review of other documents filed with the SEC	\$ 5,000	\$ 5,000
Other Fees	\$ 7,554	\$ 5,687
<b>Subtotal Audit Fees</b>	<b>\$ 83,554</b>	<b>\$ 86,687</b>
<b>Audit Related Fees</b>	<b>-0-</b>	<b>-0-</b>
Tax Fees	\$ 8,000	\$ 8,000
All Other Fees	-0-	-0-
<b>Total</b>	<b>\$ 96,554</b>	<b>\$ 94,687</b>

## Pre-Approval Policies

The Audit Committee pre-approves all audit and permissible non-audit services provided by the independent registered public accounting firm. These services may include audit services, audit-related services, internal control services, tax services and other services. The Audit Committee has adopted a policy for the pre-approval of services provided by the independent registered public accounting firm, BDO USA, LLP. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of the Audit Committee's approval of the scope of the engagement of the independent registered public accounting firm or an individual explicit case-by-case basis before the independent registered public accounting firm is engaged to provide each service.

During the year, circumstances may arise when it may become necessary to engage the independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging the independent registered public accounting firm. The Audit Committee has delegated pre-approval authority to the Chairman of the Audit Committee for those instances. The Chairman must report on such approvals at the next scheduled Audit Committee meeting.

The Audit Committee has determined that the rendering of the non-audit services by BDO USA, LLP is compatible with maintaining the auditor's independence.

All fiscal year 2010 audit and non-audit services provided by the independent registered public accounting firm were pre-approved.

**Table of Contents**

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

(a) The following documents have been filed as part of this Annual Report on Form 10-K:

1. *Financial Statements*: The information required by this item is included in Item 8 of Part II of this report.
2. *Financial Statement Schedules*: Financial statement schedules required under the related instructions are not applicable for the three years ended December 31, 2010, and have therefore been omitted.
3. *Exhibits*: The exhibits listed in the Exhibit Index attached to this report are filed or incorporated by reference as part of this Annual Report.



Table of Contents

## SIGNATURES

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

HARBOR BIOSCIENCES, INC.

By: /s/ JAMES M. FRINCKE  
**James M. Frincke,**

**President and Chief Executive Officer**

Date: March 28, 2011

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints ROBERT W. WEBER as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substituted, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ JAMES M. FRINCKE <b>James M. Frincke</b>	President and Chief Executive Officer	March 28, 2011
/s/ ROBERT W. WEBER <b>Robert W. Weber</b>	Chief Financial Officer and Secretary	March 28, 2011
/s/ JEROME M. HAUER <b>Jerome M. Hauer</b>	Director	March 28, 2011
/s/ MARC R. SARNI <b>Marc R. Sarni</b>	Director	March 28, 2011
/s/ SALVATORE J. ZIZZA <b>Salvatore J. Zizza</b>	Director	March 28, 2011



**Table of Contents**

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Document</b>
*3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 4.1 to Registrant's Registration Statement on Form S-4 (No. 333-18725), as amended (the Form S-4)).
3.2	Bylaws of Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009)
*3.3	Certificate of Designation of Series B Junior Participating Preferred Stock (incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K dated November 15, 1999).
*3.4	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.4 to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.)
*3.5	Certificate of Ownership (incorporated by reference to Exhibit 3.1 to Registrant's Current Report on Form 8-K dated February 16, 2010)
*3.6	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Registrant's Current Report on Form 8-K dated June 2, 2010.
*4.1	Amended and Restated Rights Agreement (the Rights Agreement) between the Company and American Stock Transfer and Trust Company, LLC, as Rights Agent, amending and restating the Rights Agreement dated as of November 15, 1999 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K dated October 22, 2009).
* 10.1	Registrant's 1997 Incentive Stock Option Plan (the Option Plan) as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
* 10.2	Forms of Incentive Stock Options and Nonstatutory Stock Options under the Option Plan (incorporated by reference to Exhibit 10.5 to the Form S-4).
* 10.3	Form of Nonstatutory Stock Options outside the Option Plan (including Annex I, identifying the officers and directors who are holders of such options and their respective option amounts and exercise prices), (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
* 10.4	Employment Agreement by and between Registrant and Richard B. Hollis dated November 1, 1996 (incorporated by reference to Exhibit 10.6 to the Form S-4).
* 10.5	Employment Agreement by and between Registrant and Robert W. Weber dated March 16, 1996 (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998).
* 10.6	Nonstatutory Stock Option by and between Registrant and Terren S. Peizer effective as of February 6, 1997 (incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
* 10.7	Separation and Mutual Release Agreement by and between Registrant and Terren S. Peizer effective as of February 25, 1999 (incorporated by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999).
* 10.8	Nonstatutory Stock Option by and between Registrant and Richard B. Hollis effective as of January 1, 1999 (incorporated by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Document</b>
*10.9	Settlement and Mutual Release Agreement, dated January 20, 2000, among Registrant, Colthurst Limited, Edenland, Inc. and Patrick T. Prendergast (incorporated by reference to Exhibit 99.2 to Registrant's Current Report on Form 8-K dated January 20, 2000).
*10.10	Technology Assignment Agreement, dated January 20, 2000, among Registrant, Colthurst Limited and Patrick T. Prendergast (incorporated by reference to Exhibit 99.3 to Registrant's Current Report on Form 8-K dated January 20, 2000).
*10.11	Common Stock and Warrant Agreement, dated January 20, 2000, among Registrant and Colthurst Limited (incorporated by reference to Exhibit 99.4 to Registrant's Current Report on Form 8-K dated January 20, 2000).
*10.12	Warrant, dated January 20, 2000, issued to Colthurst Limited (incorporated by reference to Exhibit 99.5 to Registrant's Current Report on Form 8-K dated January 20, 2000).
*10.13	Indemnification Agreement among Registrant and Executive Officers and Directors (incorporated by reference to Exhibit 10.17 to Registrant's Registration Statement on Form S-1 (No. 333-69454).
*10.14	Securities Purchase Agreement, dated as of February 25, 2003, by and between The Company. and the purchasers identified therein (incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.15	Form of 7.5% Convertible Debenture issued to the purchasers listed on Schedule I attached thereto on February 25, 2003 (incorporated by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.16	Form of Stock Purchase Warrant issued to purchasers listed on Schedule I attached thereto on February 25, 2003 (incorporated by reference to Exhibit 10.29 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.17	Registration Rights Agreement, dated February 25, 2003, by and between The Company. and the purchasers identified therein (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.18	Warrant, dated February 25, 2003, issued to SG Cowen Securities Corporation (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.19	Warrant issued to SG Cowen Securities Corporation on June 19, 2003 (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-3 (No. 333-106835)).
*#10.20	Study Funding Agreement, dated as of June 17, 2003, between the Registrant and Cystic Fibrosis Foundation Therapeutics, Inc (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003).
*10.21	Amended 401(k) Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003).
*10.22	Form of Common Stock Purchase Warrant issued on June 1, 2005 (incorporated by reference to Exhibit 10.41 to the Registrant's Current Report on Form 8-K dated June 2, 2005).
*#10.23	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant entered into on December 3, 2003 (incorporated by reference to Exhibit 10.42 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Document</b>
*#10.24	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant entered into on February 17, 2004 (incorporated by reference to Exhibit 10.43 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
*#10.25	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated July 12, 2004 (incorporated by reference to Exhibit 10.44 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
*#10.26	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated October 19, 2004 (incorporated by reference to Exhibit 10.45 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
*#10.27	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated January 6, 2005 (incorporated by reference to Exhibit 10.46 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
*#10.28	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated May 16, 2005 (incorporated by reference to Exhibit 10.47 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
* 10.29	2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.30	Form of Option Agreement for use under 2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.31	Form of Restricted Stock Award Agreement for use under 2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.32	Form of Restricted Stock Unit Award Agreement for use under 2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.33	2005 Non-Employee Directors' Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.6 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.34	Form of Option Agreement for use under 2005 Non-Employee Directors' Equity Incentive Plan (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
*#10.35	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated November 30, 2005 (incorporated by reference to Exhibit 10.52 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005).
*10.36	Form of Stock Purchase Agreement dated as of February 2, 2006 (incorporated by reference to Exhibit 10.48 to Registrant's Current Report on Form 8-K dated February 2, 2006) (the February 2006 Purchase Agreement).

**Table of Contents**

<b>Exhibit Number</b>	<b>Description of Document</b>
*10.37	Form of Stock Purchase Warrant, issued pursuant to the February 2006 Purchase Agreement (incorporated by reference to the Current Report on Form 8-K dated February 2, 2006).
*10.38	Form of Stock Purchase Agreement dated as of November 7, 2006 (incorporated by reference to Exhibit 10.49 to Registrant's Current Report on Form 8-K dated November 7, 2006) (the November 2006 Purchase Agreement).
*10.39	Form of Common Stock Purchase Warrant, issued pursuant to the November 2006 Purchase Agreement (incorporated by reference to Exhibit 10.48 to Registrant's Current Report on Form 8-K dated November 7, 2006).
#10.40	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated December 11, 2006 (incorporated by reference to Exhibit 10.58 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2006).
* 10.41	Amendment to Employment Agreement dated as of December 7, 2007 between the Registrant and Richard B. Hollis (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K Dated December 10, 2007).
* 10.42	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated June 12, 2008 (incorporated by reference to Exhibit 10.61 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008).
*10.43	Placement Agent Agreement dated as of June 7, 2010 (incorporated by reference to Exhibit 1.1 to Registrant's Current Report on Form 8-K dated June 8, 2010).
*10.44	Form of Securities Purchase Agreement dated as of June 7, 2010 (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K dated June 8, 2010).
*10.45	Form of Common Stock Purchase Warrant dated as of June 7, 2010 (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K dated June 8, 2010).
10.46	License Agreement between China State Institute of Pharmaceutical Industry Registrant dated December 20, 2010 for HE2000.
10.47	License Agreement between China State Institute of Pharmaceutical Industry Registrant dated December 20, 2010 for Apoptone (HE3235)
10.48	License Agreement between China State Institute of Pharmaceutical Industry Registrant dated December 20, 2010 for Triolex (HE3286)
23.1	Consent of BDO USA, LLP.
31.1	Rule 13a-14(a)/15d-14(a) Certification of James M. Frincke.
31.2	Rule 13a-14(a)/15d-14(a) Certification of Robert W. Weber.
32.1	Section 1350 Certifications of James M. Frincke and Robert W. Weber.
*	Previously filed.
#	Management contract or compensatory plan, contract or arrangement to be filed as an exhibit pursuant to Item 14(c) of Form 10-K.
#	Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.