HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 10-K/A
March 20, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K/A

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

For the fiscal year ended December 31, 2007

OR

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

For the transition period from to

Commission File Number 000-24672

HOLLIS-EDEN PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**13-3697002**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4435 Eastgate Mall, Suite 400	
San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.01 per share	**The Nasdaq Stock Market**

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

None

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

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

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities 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 x NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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.YES ¨ NO x

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 x Non-accelerated filer ¨ Smaller Reporting Company ¨
Indicate by check mark whether the Registrant is a shell company (as defined in Exchange Act Rule 12b-2).YES ¨ NO x

The aggregate market value of the voting stock held by nonaffiliates of the Registrant as of June 29, 2007, the end of Hollis-Eden Pharmaceuticals most recently completed second fiscal quarter, was approximately $53,907,361 based on the closing stock price of $2.04 for the Registrant s Common Stock as reported by the Nasdaq National Market*.

As of March 12, 2008, there were outstanding 29,005,305 shares of the Registrant s Common Stock, $.01 par value per share.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of Registrant s definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after Registrant s fiscal year end December 31, 2007, are incorporated by reference into Part III of this Annual Report on Form 10-K.

*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, 2007. This calculation does not reflect a determination that such persons are affiliates for any other purposes.

This amendment is being filed to correct the dates on the following items Report of Independent Registered Public Accounting Firm , Consent of Independent Registered Public Accounting Firm and Item 1 of Exhibit 32.1 Certification for the Company s Annual Report on Form 10-K.

Hollis-Eden Pharmaceuticals, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2007

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve 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. We have based these forward-looking statements on our current expectations about future events. While we believe these expectations are reasonable, such forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. The actual future results for Hollis-Eden Pharmaceuticals, Inc. may differ materially from those discussed here for various reasons, including those discussed in this Annual Report in Part 1, 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. 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 and specifically decline any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments. When used in this Annual Report, unless otherwise indicated, we, our and us refers to Hollis-Eden Pharmaceuticals, Inc. and its subsidiaries.

PART I

Item 1. Business

GENERAL OVERVIEW

Hollis-Eden Pharmaceuticals, Inc., a development-stage pharmaceutical company, is engaged in the discovery, development and commercialization of products 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 believe these compounds are key components of the body s natural regulatory system that potentially can be useful in treating a wide variety of medical conditions.

Preclinical and early clinical studies to date with compounds being developed from this technology platform indicate that they have the ability to reduce non-productive inflammation, stimulate innate and adaptive immunity, and stimulate cell proliferation. These compounds have also been shown in these studies to play an important role in metabolism. Other of our compounds have shown activity in preclinical models of hormone sensitive cancers. In addition, these compounds have an attractive safety profile to date and are cost-effective to manufacture.

We are currently focused on the development of two clinical drug development candidates TRIOLEX (HE3286), a next-generation compound currently in a clinical trial for the treatment of metabolic disorders and cleared by U.S. Food and Drug Administration (FDA) for clinical trials in rheumatoid arthritis, and APOPTONE (HE3235), a next-generation compound selected for clinical development for cancer.

TRIOLEX is being initially developed for the treatment of type 2 diabetes, a disease affecting approximately 20 million Americans and over 160 million people worldwide. Preclinical studies to date with TRIOLEX suggest that it acts as an insulin sensitizer to improve the utilization of glucose without causing the undesirable side effect of weight gain associated with currently marketed insulin sensitizers. A Phase I clinical trial in healthy volunteers completed during 2007 demonstrated the compound 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 appeared to be safe and well tolerated in healthy volunteers with no reported drug related adverse side effects to date. TRIOLEX is currently in a multi-dose Phase I/II proof-of-concept clinical trial in obese, insulin resistant volunteers.

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TRIOLEX has also shown activity in several preclinical models of rheumatoid arthritis and we have received clearance from the FDA on our Investigational New Drug application (IND) to initiate clinical studies in this indication. In early 2008, we commenced an exploratory Phase I/II clinical study in ulcerative colitis patients with the objective of demonstrating activity in humans with a short treatment course of TRIOLEX and, in addition, to potentially optimize the design of our proposed clinical studies in rheumatoid arthritis. We also are continuing to profile both TRIOLEX and analogs of TRIOLEX in other preclinical models of autoimmunity.

APOPTONE is being developed initially for the treatment of prostate cancer. 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. In preclinical models of prostate and breast cancer conducted to date, APOPTONE has been shown to reduce the incidence, growth and progression of tumors. In February 2008, we filed an IND with the FDA seeking clearance to initiate Phase I/II clinical trials in hormone sensitive cancers, including prostate cancer.

In addition to the clinical development stage drug candidates described above, we also have two first-generation compounds in our pipeline of drug candidates, NEUMUNE® (HE2100) and IMMUNITIN (HE2000). While we have generated indications of activity in human clinical trials with these two compounds, neither is currently being actively developed due to changes in the respective markets for each of these compounds, as well as the fact that that we believe our next-generation drug candidates TRIOLEX and APOPTONE offer greater potential for commercialization.

NEUMUNE was under development as a treatment for acute radiation syndrome (ARS) a potentially fatal acute illness caused by high doses of radiation exposure over a significant portion of the body. We had been collaborating on the development of NEUMUNE for ARS with the U.S. military with the intent of securing procurement contracts with the Department of Health and Human Services (HHS) and the Department of Defense (DOD). However, in March 2007, HHS cancelled its solicitation for medical countermeasures to treat the effects of ARS in its entirety. In light of HHS s cancellation of its solicitation, we made the strategic decision to curtail further development of NEUMUNE and to focus our resources on TRIOLEX, APOPTONE and follow-on oral compounds for indications that have well defined clinical paths and large, well-established markets.

We also have an active research program that is generating new clinical leads that are being further evaluated in preclinical models of a number of different diseases including metabolic and autoimmune conditions, inflammatory diseases of the lung, bone metabolism and regenerative medicine.

Our principal executive offices are located at 4435 Eastgate Mall, Suite 400, San Diego, CA 92121, and our telephone number is (858) 587-9333. We are incorporated in Delaware.

Hollis-Eden Pharmaceuticals, HE3286, HE3235, HE2000, HE2100, TRIOLEX, APOPTONE, IMMUNITIN, NEUMUNE and the Hollis-Eden Pharmaceuticals stylized logo are trademarks of Hollis-Eden Pharmaceuticals, 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.holliseden.com. The reference to our website does not constitute incorporation by reference of the information contained on our website.

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TECHNOLOGY DESCRIPTION

Hormonal Signaling Technology Platform

Our primary technology development efforts are focused on a series of adrenal steroid hormones and hormone analogs that we believe are key components of the body s natural regulatory system and that potentially can be useful in treating a wide variety of medical conditions. In studies conducted to date, compounds being developed from our Hormone Signaling Technology Platform appear to reduce inflammation in a broad-spectrum fashion while also improving a number of components of the immune system in conditions of immune suppression. These compounds also appear to be important in regulating metabolism. Another compound APOPTONE, has been selected for development for cancer and hormone-sensitive cancers. In addition, our first generation compounds have demonstrated preclinical activity in protecting the bone marrow from the damaging effects of radiation and chemotherapy. These adrenal hormones are known to be depleted as we age, and this process can be accelerated as a result of infectious diseases and other chronic immune system disorders.

Inflammation

One of our initial focus areas for compounds developed from our technology platform is in the area of inflammation. The role of inflammation in disease pathogenesis has become increasingly recognized by the medical community. Chronic inflammation is generally believed to be caused by an over-stimulation of certain components of the immune system, such as reactive oxygen species and pro-inflammatory mediators, due to persistent low-grade infections or the body s inability to differentiate between certain cells or tissues in the body and foreign pathogens. Published studies have implicated chronic inflammation in a host of diseases ranging from autoimmune conditions, such as arthritis and psoriasis, to infectious diseases, including human immunodeficiency virus (HIV), malaria and tuberculosis, and to metabolic disease, including diabetes and cardiovascular disease as well as a number of different cancer types.

One of the most widely used classes of agent for treating inflammation is the corticosteroid class. Industry market research indicates that there are tens of millions of new prescriptions for corticosteroids issued by physicians in the U.S. each year for a wide range of conditions. While these drugs are very potent anti-inflammatory agents, their chronic use can lead to immune suppression and other side effects including bone loss.

Over the last decade, a number of new agents for treating inflammation have been introduced that are focused on inhibiting a specific component of the inflammatory cascade, such as agents that block specific inflammatory cytokines, including TNF-alpha and IL-1 beta, as well as drugs that inhibit specific enzymes, such as COX-2. These drugs have shown impressive activity in a number of clinical conditions such as arthritis, inflammatory bowel disease and psoriasis. However, by focusing on a specific mediator, these agents may not be able to overcome the redundancy built into the immune system and can also cause immune suppression and other side effects in certain patient populations. In addition, the cost of producing a number of these new agents is quite high.

Compounds we are developing have been shown in preclinical models to date to regulate a broad array of inflammatory mediators. For example, we have conducted preclinical studies which we believe indicate the ability of these compounds to regulate the nuclear transcription factor NF-kB pathway that may be central to the beneficial effects seen with these compounds in preclinical models of type 2 diabetes and rheumatoid arthritis. In addition, this class of compounds has been shown in early clinical trials to produce long-lasting reductions in a number of other key inflammatory mediators, including TNF-alpha, IL-1 beta and IL-6. Unlike most approaches to reducing inflammation, however, our compounds appear to either maintain or boost a variety of immune responses in conditions of immune suppression, including innate and adaptive cell-mediated immunity.

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Innate and Cell-Mediated Immunity

Humans have three lines of defense against infection. The physical barrier of our skin and mucosal surfaces provides our first line of defense. This effectively protects us from numerous pathogens found in our immediate surroundings. Should a microbe gain entry through a break in the skin, by ingestion or by other means, protection comes from the next two lines of defense innate and adaptive immunity.

Innate immunity refers to the all-purpose, immediate antimicrobial response that occurs regardless of the nature of the invader. For example, macrophages, granulocytes and natural killer cells roam our body and recognize and destroy foreign cells they encounter. This response serves to fight the infection after initial exposure, pending development of adaptive immunity.

The adaptive immune system mounts a highly sophisticated and specialized immune response to protect us against specific invaders, and provides long-term protection or immunity from subsequent exposure to those invaders. Adaptive immunity can be divided into two branches, the cellular or cell-mediated immune response, also known as Th1-type response, and the humoral immune response, also known as Th2-type response. These two interconnected immune functions work in concert through finely tuned checks and balances to mount an appropriate defense. In response to an intracellular pathogen, B-cells of the humoral arm (Th2) proliferate and produce large amounts of appropriate antibodies that flag invaders for elimination from the body. The cellular (Th1) immune response employs specialized T-cells to recognize and destroy host cells showing signs of infection by intracellular pathogens. The relative mobilization of each branch of the immune system depends on the specific disease or condition, and the nature of the response can be influenced by the pathogen itself and where it enters the body.

The balance between the cellular (Th1) and humoral (Th2) arms of the immune system is modulated by a highly integrated network of molecular and cellular interactions driven by cytokines. Cytokines are small proteins that act as intercellular chemical messengers. These cytokines, which are regulated by hormones generated by the endocrine system, can be classified as either Th1 or Th2 depending on their role. Th1 cytokines such as interleukin 2 (IL-2), interferon gamma (IFN-gamma) and interleukin 12 (IL-12) stimulate the cellular response and suppress the humoral response. Th2 cytokines, such as interleukin 10 (IL-10), interleukin 6 (IL-6) and interleukin 4 (IL-4), stimulate the humoral response and suppress the cellular response.

Generally, in healthy individuals the immune system is in homeostasis, or has balanced expression of Th1 and Th2 cytokines. If a foreign invader triggers an adaptive cellular or Th1-type response, the feedback mechanism within the immune system greatly reduces the humoral or Th2-type response. Once the invader is controlled or eliminated, a combination of hormones and cytokines act quickly to return the system to homeostasis through the same feedback mechanism.

Our therapeutic strategy is based on the observation that this complicated balance of cytokines is regulated by competing levels of certain adrenal hormones. In young, healthy adults, the balance between corticosteroids such as cortisol, which have immunosuppressive properties, and compounds we are developing is a key determinant in whether appropriate levels of cytokines are produced to properly regulate immune responses. As we age, and under conditions of stress, chronic infections or systemic inflammation, levels of these compounds that counteract the immunosuppressive effect of corticosteroids fall significantly, leading to a decline in the ability to fight off infections that would otherwise be contained by a well functioning immune system.

Hollis-Eden s Approach

With the advent of the technology revolution over the last several decades, scientists have been presented with a whole new series of tools that allow them to study very specific aspects of biological function. This led to a scientific approach that largely centered on how a certain drug

might interact with a specific signaling function or target for a specific disease. While this approach has resulted in a number of successful drugs, frequently these compounds are not as effective in clinical practice as anticipated and produce a number of unintended side effects due to the complexity of interactions amongst different systems in human biology.

The research community has increasingly begun to embrace the concept of a systems biology approach to drug development one that accounts for the complexity of interactions between cellular pathways. This approach recognizes that enhancing or inhibiting just one signal in this complicated cascade of events is likely to be too simplistic an approach to overcome many of the more intractable health problems facing medicine today. Researchers in this emerging field are attempting to integrate a number of different scientific disciplines, such as molecular biology, high speed computing and engineering, to understand these intricate interactions in immune and metabolic function and the dysregulation in these pathways that can lead to a very diverse set of diseases and conditions at an upstream level. The concept is that there may be common links between diseases such as arthritis, diabetes, HIV, Alzheimer s disease and cancer that can all benefit from an appropriate upstream re-regulation of immune and/or metabolic function.

While most researchers in this area are taking a *ground up* approach to understanding each specific component in these intricate cascades and how they relate to one another, and then trying to design drugs that can successfully intervene in correcting dysregulation across all of these pathways, our approach is more *top down*: identify the hormones that have been developed through millions of years of evolution to be the master signalers involved in initiating these cascades and look at conditions where their modulation is dysregulated. By then applying the latest tools of pharmaceutical development, our goal is to design compounds and routes of administration that deliver these signals when and where they are needed to intervene in this systemic dysregulation.

As factors such as chronic inflammation, innate and adaptive immunity, and metabolic function are implicated in a host of diseases, including virtually all diseases of aging, successfully applying this approach has potential utility for a number of important pharmaceutical markets. The hormone series that we are focused on is known to be involved in cell signaling at an upstream level, and these hormones are known to be depleted as we age. This depletion can be accelerated as a result of a number of the conditions we are pursuing. We believe that by starting with the lessons that evolutionary biology has taught us, the time to develop new therapeutics that target these systemic abnormalities will be shortened relative to the *ground up* approach being pursued by others.

PRODUCTS IN DEVELOPMENT

We are currently focusing our development activities on two compounds from our proprietary series. Our lead clinical drug development candidates are TRIOLEX (HE3286), a next-generation compound currently in clinical trials for the treatment of metabolic disorders and ulcerative colitis and being prepared for clinical trials in rheumatoid arthritis and APOPTONE (HE3235), a next-generation compound selected for clinical development in cancer.

Each of these compounds is described in more detail below. In addition, we have an active research program focused on adrenal hormones that is identifying additional clinical candidates for a wide range of medical conditions.

TRIOLEX (HE3286)

Type 2 Diabetes

Diabetes is a disease in which the body does not produce adequate quantities of, or properly use, insulin. Insulin is a hormone needed to carry glucose from the blood into cells, where it is converted to energy the cells need to perform properly. When insulin is not present in sufficient quantity or does not function correctly, the result is high levels of glucose in the blood. Over time, chronically elevated blood glucose 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, or juvenile onset, diabetes and type 2, or adult onset, diabetes.

TRIOLEX is a next-generation compound that we are developing for the treatment of type 2 diabetes. We believe that TRIOLEX may be the first in a new class of insulin sensitizers with a novel mechanism of action. The compound was discovered by our scientists in a pharmaceutical development program targeting metabolism.

TRIOLEX is currently in a multi-dose Phase I/II proof-of-concept clinical trial in obese, insulin resistant volunteers. The Phase I/IIa clinical trial is designed to evaluate the safety of TRIOLEX and the effect of the drug candidate on insulin sensitivity and whole-body glucose disposal. The initial dosing group is being evaluated by intravenous glucose tolerance test (IVGTT) and multiple biomarkers of insulin resistance, metabolic disorders and inflammation. Additional dosing groups will be evaluated through euglycemic/hyperinsulinemic clamps, a method widely used in the pharmaceutical industry and academia to test compounds as potential insulin sensitizers for the treatment of type 2 diabetes, and multiple biomarkers of insulin resistance, metabolic disorders and inflammation. A single-dose Phase I clinical trial conducted during 2007 demonstrated that the compound 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 adverse side effects to date.

Preclinical studies in rats fed with a diet containing the parent hormone of TRIOLEX showed a reduction in the expression levels of certain genes encoding key enzymes involved in glucose and cortisol metabolism (e.g., PEPCK or 11ß-HSD1), an effect which we believe could lessen the severity or impact of type 2 diabetes on insulin resistance. We believe this indicates that this hormone is potentially important to glucose metabolism. Through the application of medicinal chemistry, we have extended the inherent properties of that hormone into what we believe is a more pharmaceutically suitable compound, TRIOLEX, for the treatment of type 2 diabetes.

Data generated to support the use of TRIOLEX in this indication include the following:

- When administered orally to genetically obese mice prone to diabetes (*db/db* model), TRIOLEX, after 10 days, significantly ($p<0.02$) suppressed the progression of hyperglycemia typically observed in these animals.

- In an animal model of diet-induced insulin resistance, TRIOLEX significantly ($p<0.01$) improved glucose handling in an oral glucose tolerance test (OGTT) when compared to the control group and at the end of the study was superior ($p<0.003$) to the active control (rosiglitazone). In addition, TRIOLEX demonstrated a statistically significant ($p<0.006$) reduction in fasting glucose values when compared to controls at days 14 and 29 of the study, and the activity was similar to the active control (rosiglitazone) ($p<0.05$).

- Additional evidence of improvement in glucose disposal by TRIOLEX comes from a hyperinsulinemic/euglycemic clamp study, widely acknowledged as the gold standard preclinical model to measure insulin sensitivity *in vivo*. In this study, administration of TRIOLEX to diabetic *db/db* mice for 14 days markedly increased the glucose infusion rate (GIR) required to maintain normal levels of blood glucose following an intravenous infusion of a high dose of insulin. The GIR is a key parameter used to determine the degree of insulin sensitivity *in vivo*, and its increase following treatment with TRIOLEX indicates that this compound acts physiologically as an insulin sensitizer in the diabetic state.

In parallel experiments designed to elucidate the possible mechanism of action of TRIOLEX to produce these metabolic effects, it was observed that TRIOLEX may regulate the pro-inflammatory NF-kB pathway in cultured mouse macrophages and human monocytes. We believe this is an important finding because over the last several years, reports in the scientific literature suggest that chronic activation of inflammatory pathways such as NF-kB can also lead to insulin resistance and may play a role in the progression towards type 2 diabetes.

There are several pharmaceutical approaches to treating type 2 diabetes. These include drugs designed to increase insulin production by the pancreas, drugs designed to reduce glucose production by the liver and drugs designed to increase the body s sensitivity to insulin, thereby improving glucose disposal from the bloodstream. Frequently clinicians will combine drugs from these different approaches in an effort to achieve appropriate glucose control.

The only currently approved anti-diabetic agents that are known to act as insulin sensitizers are the glitazone class of drugs, which collectively represent 48% of the annual sales in the $12 billion per year global oral anti-

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diabetic market. Glitazones appear to act primarily through the activation of a nuclear hormone receptor, known as PPARgamma. While these agents can lower blood glucose, they have been associated with undesirable side effects such as weight gain. In contrast, preclinical studies with TRIOLEX to date indicate that it does not act on the PPARgamma receptor and does not have the undesirable effect of weight gain seen with the glitazone class. Therefore, we believe these preclinical studies suggest that TRIOLEX may represent the first of a new class of insulin sensitizing agents that could be used in controlling type 2 diabetes.

The need for new classes of agents such as TRIOLEX to treat type 2 diabetes is significant. There are approximately 20 million Americans with type 2 diabetes and over 160 million type 2 diabetics worldwide. These figures are increasing rapidly as a result of the aging population and the rising incidence of obesity, which is a common risk factor for the disease. Clinical data indicates only 36% of type 2 diabetics are currently able to achieve the American Diabetes Association maximum recommended HbA1c glucose level of 7.0. Large clinical studies have shown that failure to achieve these glucose targets can progressively lead to severe health consequences including neuropathy, blindness, amputation, heart attack, stroke and death.

Rheumatoid Arthritis

We have also been cleared to begin clinical development of TRIOLEX for the treatment of rheumatoid arthritis (RA), under an open IND with the FDA. According to the Centers for Disease Control and Prevention, or (CDCP), an estimated 46 million people were treated for some form of arthritis and other rheumatic conditions in 2003, the latest year for which data available, and an estimated 8 million more people will suffer from arthritis between 2005 and 2015. Rheumatoid arthritis is a type of chronic arthritis that occurs in joints on both sides of the body (such as hands, wrists or knees). In rheumatoid arthritis, the immune system attacks the joints and sometimes the other organs.

Once the immune system is triggered, immune cells migrate from the blood into the joints and produce substances that cause inflammation. The increased number of cells and inflammatory substances within the joint cause irritation, wearing down cartilage (cushioning material at the end of bones), swelling the joint lining (synovium) and causing the joint lining to produce fluid.

As the cartilage wears down, the space between the bones narrows. If the condition worsens, the bones could rub against each other. As the joint lining expands, it may invade into or erode the bone, resulting in irreversible damage to the bone.

Potential mechanisms of action for TRIOLEX include regulation of the NF-kB pathway and increasing the production of regulatory T cells (Treg cells). NF-kB is a well-known transcription regulator that controls the production of inflammatory cytokines such as TNF-alpha and Interferon-gamma. Treg cells are referred to in the scientific literature as the peacekeepers of the body. Their role is to keep the immune system from attacking the body itself. Recent studies of Treg cells indicate that they may play a broader role than simply preventing autoimmune conditions. The medical literature is now suggesting that the manipulations of these cells could offer new treatments for conditions ranging from diabetes to organ rejection.

In a preclinical collagen-induced arthritis model (CIA), TRIOLEX, when compared to placebo, significantly reduced the severity of disease and decreased disease over the course of the study. Moreover, histological analysis of joint tissue conducted at the end of the study indicated a marked reduction of tissue damage in the TRIOLEX-treated animals compared to placebo.

TRIOLEX has also shown a statistically significant reduction in disease in a rodent model of established arthritis. Mice were immunized to induce disease, and one week after disease onset were treated orally with TRIOLEX or placebo. While the severity of arthritis worsened steadily in the placebo-treated group, it nearly resolved or remained at a minimum in the TRIOLEX-treated group ($p \leq 0.001$). Treatment resulted in a

difference in arthritis severity that was on average 45% lower in the TRIOLEX-treated group than in the placebo-

treated group. The study was conducted in the DBA mouse model of collagen-induced arthritis, a model widely used in the pharmaceutical industry and academia to test new agents as potential treatments for rheumatoid arthritis.

In addition, in an animal model of collagen antibody induced arthritis (CAIA), TRIOLEX significantly reduced disease in a dose dependent fashion, with the highest dose completely eliminating disease. In the CAIA model, disease is induced by injecting animals with arthrogenic antibodies, a method that largely bypasses the animal s own cellular immune system. Severe joint inflammation occurs within hours after the injection of antibodies. TRIOLEX was highly effective in this model whether treatment began 1 day or 5 days after injection with antibodies. Benefit at the peak of disease was associated with a significant reduction of interleukin-6 (IL-6) and matrix metalloproteinase-3 (MMP-3) messenger RNA from the joints of TRIOLEX-treated animals when compared to placebo-treated controls. IL-6 and MMP-3 are thought to be among the most important drivers of disease and tissue destruction in human rheumatoid arthritis.

Ulcerative Colitis

In February 2008, we commenced a Phase I/II clinical trial with TRIOLEX in ulcerative colitis. This Phase I/II dose ranging study will evaluate the safety, tolerance, pharmacokinetics and activity of TRIOLEX when administered orally for 28 days to patients with active, mild-to-moderate ulcerative colitis. We believe that certain aspects of the pathology driving ulcerative colitis are similar to those driving rheumatoid arthritis. Therefore, data obtained in this ulcerative colitis study could potentially help support the design of our proposed clinical studies in rheumatoid arthritis.

In a preclinical model widely used by the pharmaceutical industry and academia to test agents as potential treatments for ulcerative colitis, TRIOLEX showed significant ($p < 0.05$) benefit. In that model, TRIOLEX-treated animals had significantly reduced disease, as judged by reduced colon weight and reduced area of necrosis, compared to the placebo-treated animals. TRIOLEX performed as well or better than Sulfazalazine, the standard of care used as a positive control in this model.

Pulmonary Diseases

Inflammation and infection in the lungs are common to many serious diseases, such as asthma, chronic obstructive pulmonary disease, and cystic fibrosis. Cystic fibrosis is a fatal genetic disease associated with chronic pulmonary infections and intense airway inflammation. The anti-inflammatory and immune regulating activity of some of our compounds has already shown benefit in several preclinical models of pulmonary infection and inflammation including the cystic fibrosis transmembrane conductance regulator (CFTR) mouse model of cystic fibrosis and the lipopolysaccharide (LPS) induced lung injury model. We are collaborating with Cystic Fibrosis Foundation Therapeutics (CFFT), the non-profit drug discovery and development arm of the Cystic Fibrosis Foundation, to develop a new anti-inflammatory agent for use in cystic fibrosis. In late 2007, CFFT selected TRIOLEX as a drug candidate for lung inflammation associated with cystic fibrosis under our existing collaboration agreement. As a result, we received additional milestone payments totaling $645,000 from CFFT. If we are able to successfully develop a compound for cystic fibrosis, there may also be opportunities to pursue other pulmonary indications for this type of drug.

Other Autoimmune Diseases

Given the anti-inflammatory and immune regulating effects seen with compounds from our technology platform in preclinical and early clinical trials, we are also interested in exploring the potential for new compounds from our technology platform in a variety of autoimmune indications.

These small molecule compounds are structurally similar to widely used corticosteroids, but unlike corticosteroids, they do not appear to date to cause immune suppression or bone loss two common side effects of corticosteroids. Statistically significant anti-inflammatory effects have been demonstrated with compounds

from our technology platform *in vivo* models of pleurisy, a model of lung inflammation, experimental autoimmune encephalomyelitis (EAE), a model of multiple sclerosis, and lipopolysaccharide challenge, a lethal model of endotoxic shock.

In addition to these anti-inflammatory properties, compounds from our technology platform have been shown to improve immune function (rather than suppress it as would be expected with corticosteroids) in a popliteal lymph node assay and were also shown to counteract corticosteroid-induced changes responsible for bone loss in *in vitro* studies. We are continuing to profile new compounds in a number of preclinical models of autoimmunity and, if these results are successful, may enter one or more of these compounds into development for additional autoimmune indications.

APOPTONE (HE3235)

Prostate Cancer

APOPTONE is a second-generation compound we have selected for clinical development in the area of hormone-driven cancers. In early 2008, we filed an IND for APOPTONE for clinical studies in hormone-sensitive cancers. Assuming clearance by the FDA, we plan to commence a Phase I/II clinical study in late-stage prostate cancer patients.

In our research effort for this program, we screened compounds from our library that inhibited adrenal androgen stimulated proliferation of human LnCaP prostate cancer cells *in vitro*. This system, designed to mimic late-stage prostate cancer in humans, was used to identify lead compounds that would then be tested in a well-accepted murine model for androgen independent prostate cancer that utilizes human tumor cell lines.

In preclinical models of prostate and breast cancer, treatment with APOPTONE significantly inhibited the incidence, growth and progression of tumors. In a commonly used preclinical model for androgen independent prostate cancer, treatment with APOPTONE reduced tumor incidence in a dose dependent fashion and, in the high-dose group, completely prevented tumor growth, compared to 92% tumor incidence in vehicle-treated animals. In a separate preclinical model, mice with rapidly growing prostate tumors were randomized to receive treatment with either APOPTONE or placebo, and tumors were then tracked for three weeks. At the end of the study, tumor volume in the animals receiving placebo was on average over seven times larger (370 mm^3) than their initial size. In contrast, tumor growth in the APOPTONE group was arrested at approximately 57 mm^3 ($p<0.001$), with two out of the nine treated animals becoming completely tumor free.

We believe the mechanism of APOPTONE in inhibiting prostate tumor growth in preclinical studies appears to be due to the tumor cells undergoing programmed cell death, or apoptosis. Analysis of gene expression from tumors in the preclinical studies indicate APOPTONE appears to act as a apoptotic agent, down regulating genes that protect tumor cells from apoptosis such as Bcl-2 while increasing the expression of pro-apoptotic genes such as caspases. APOPTONE appears to have good oral bioavailability in non-human primates. Preclinical findings also show that APOPTONE may increase the susceptibility of tumor cells to chemotherapeutic agents by down-regulating ABCG2, previously known as the Breast Cancer Resistance Protein (BCRP).

In addition to prostate cancer, we are exploring the potential of APOPTONE in other cancers. For example, data from preclinical breast cancer studies demonstrate that treatment with APOPTONE resulted in a reduced tumor burden for existing tumors that were present before treatment commenced compared to placebo treated animals ($p<0.001$). In addition, after the treatment period began, all placebo controls developed one or more additional tumors, while not a single new tumor arose in the animals treated with APOPTONE. This preventive action of HE3235 on the occurrence of new tumors reached statistical significance ($p<0.01$). During the five weeks of observation after dosing stopped, existing tumors in

the APOPTONE-treated animals from this preclinical model had still not progressed and no new tumors were reported, in contrast to the vehicle-treated animals in which tumors continued to proliferate.

Competition

Given the large market opportunities for products that treat the indications for which we are developing our compounds, most major pharmaceutical companies and many biotechnology companies have programs directed toward finding drugs to treat indications 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® from Takeda Pharmaceuticals and Avandia® from GlaxoSmithKline already approved for improving insulin sensitivity, and additional drugs are in development. While Actos® and Avandia® currently account for a significant share of the market for type 2 diabetes drugs, they are known to cause the unwanted side effects of weight gain and edema. In addition, both were recently given black box warnings by the FDA for heart failure related to drug treatment.

In the area of immune modulators for correcting immune dysregulation, a number of companies are targeting inhibition or enhancement of a single cytokine or other mediator. For example, Amgen s Enbrel® targets TNF-alpha, as does Johnson & Johnson s Remicade®. Other immune-modulating drugs such as Celebrex from Pfizer target COX-2. While these targeted approaches have shown clinical benefit and have generated significant sales volumes, redundant mechanisms in the immune system can limit their effectiveness. In addition, side effects and cost issues may limit their global utility. In contrast, we believe our compounds may affect multiple cytokines and inflammatory mediators in a physiologic way that may make them more attractive drug candidates than currently available therapies, assuming they are successfully developed and commercialized.

Government Regulation

General

The manufacturing and marketing of our proposed products 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 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.

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. IND status allows initiation of clinical investigation within 30 days of filing if the FDA does not respond with questions during the 30-day period.

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, all existing pharmacology and toxicology information on the product, ethical factors, the risk to human subjects and the potential benefits of therapy relative to 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 has 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 trials of a drug, consisting of wide-scale studies on patients with the same disease, 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 all information that has been gathered. The NDA must include the chemical composition of the drug, scientific rationale, purpose, animal and laboratory studies, results of human tests, formation and production details, and proposed labeling.

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.

The testing and approval process is likely to require substantial time and effort, 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 the conduct of clinical trials, product licensing, pricing and reimbursements vary widely from country to country.

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 use.

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 standards. 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 quality control and manufacturing 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 a number of licenses to 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, pharmaceuticals 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 licensor of its intellectual property was the first to invent certain 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 infringe the patent 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.

Technology Agreements

In December 1999, we entered into a license agreement with Dr. Roger M. Loria, a Professor of Microbiology and Immunology at Virginia Commonwealth University. Under this agreement Dr. Loria exclusively licensed to us all rights in and to his patents and patent applications for certain uses of androstenediol and androstenetriol. This agreement was amended on April 9, 2002 and on December 12, 2006. We terminated our license agreement with Dr. Loria effective November 19, 2007.

In January 2000, we entered into an agreement with Patrick T. Prendergast, Colthurst Ltd. and Edenland, Inc., which assigned to us ownership of all patents, patent applications and current or future improvements relating to IMMUNITIN™ (HE2000) one of our first generation drug candidates not currently in development.

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. 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 the 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 us from 1999 to mid-2003.

In February 2004, we acquired Congressional Pharmaceutical Company, or 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 we issued approximately 50,000 shares of our common stock to the former stockholders of CPC. In addition, if we achieve certain development milestones, we 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 we 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. Furthermore, upon regulatory approval and commercialization of products covered by the licensed intellectual property, we 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 us in the fields of hematopoiesis and radiation and chemotherapy exposure.

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.

Employees

As of March 10, 2008, we had 56 full-time, 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 arch 10, 2008 are as follows:

Name	Age	Position
Richard B. Hollis	55	Chairman of the Board, President and Chief Executive Officer
James M. Frincke, Ph.D.	57	Chief Operating Officer
Robert L. Marsella	55	Sr. Vice President, Business Development and Marketing
Christopher L. Reading, Ph.D.	60	Chief Scientific Officer
Dwight R. Stickney, M.D.	65	Chief Medical Officer
Robert W. Weber	57	Interim Chief Financial Office, Chief Accounting Officer and Vice President, Operations

Richard B. Hollis founded Hollis-Eden in August 1994. Mr. Hollis currently serves as our Chairman, President and Chief Executive Officer. Mr. Hollis has served as a member of our board of directors since our inception. Mr. Hollis has over 25 years experience in the health care industry, has a proven track record of launching and marketing important new medical products, and a distinguished career of managing the growth and operations of companies in a variety of senior management positions. Prior to founding Hollis-Eden, Mr. Hollis served as Chief Operating Officer of Bioject Medical from 1991 to 1994 and as Vice President Marketing and Sales/General Manager for Instromedix from 1989 to 1991. From 1986 to 1989, Mr. Hollis served as a general manager of the Western business unit of Genentech, Inc., a manufacturer of biopharmaceuticals. Prior to joining Genentech, Mr. Hollis served as a divisional manager of Imed Corporation, Inc., a manufacturer of drug delivery systems. Mr. Hollis began his career in the health care industry with Baxter Travenol. Mr. Hollis received his B.A. in Psychology from San Francisco State University.

James M. Frincke, Ph.D. joined Hollis-Eden 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 and to Chief Operating Officer in February 2008. Dr. Frincke joined Hollis-Eden 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 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.

Robert L. Marsella became Vice President of Business Development and Marketing of Hollis-Eden in September 1997, and was promoted to Senior Vice President of Business Development and Marketing in December 2004. Mr. Marsella has more than 26 years of medical sales, marketing, and distribution experience. Prior to joining Hollis-Eden, Mr. Marsella acted as a distributor of various cardiac related hospital products for a number of years. In addition, he has also served as Regional Manager for Genentech and launched Activase™, t-pa (a biopharmaceutical drug) in the Western United States. Prior to joining Genentech, Mr. Marsella marketed intravenous infusion pumps for Imed Corporation a division of Warner Lambert for a number of years. Mr. Marsella began his career as a field sales representative and soon after was promoted to regional sales manager for U.S. Surgical Corporation, Auto Suture division. Mr. Marsella received his B.A. degree from San Diego State University.

Christopher L. Reading, Ph.D. became 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. Prior to joining Hollis-Eden, Dr. Reading was Vice President of Product and Process

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

Dwight R. Stickney, M.D. joined Hollis-Eden 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 Hollis-Eden from the Radiation Oncology Division of Radiological Associates of Sacramento Medical Group, Inc., in Sacramento, California, where he served as an 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 Forresters 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 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 Hollis-Eden in March 1996 and currently serves as the Interim Chief Financial Officer and Chief Accounting Officer and was promoted to the additional title of Vice President Operations in February 2008. Mr. Weber has thirty years of experience in financial management. Mr. Weber 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 Vice President Finance 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 Vice President Finance and 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, investor relations, private and venture financing, corporate legal matters, acquisitions/divestitures as well as information services and computer automation. 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 report 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.

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

Our principal development efforts are currently centered around a proprietary class of small compounds which we believe shows promise for the treatment of several diseases and disorders. However, all drug candidates require approval by the FDA before they can be commercialized in the U.S. as well as approval by various foreign government agencies before they can commercialized in other countries. These regulations change from time to time and new regulations may be adopted. None of our drug candidates have been approved for commercial sale. We may incur significant additional operating losses for the foreseeable future as we fund development, preclinical and clinical testing and other expenses in support of regulatory approval of our drug candidates. 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 these 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. 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.

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 $214.6 million as of December 31, 2007. Our net losses for fiscal years 2007, 2006 and 2005 were approximately $23.1 million, $30.2 million and $29.4 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 and universities and other research institutions. Several of these entities have already successfully marketed and commercialized products that will compete with our products, assuming that our products gain regulatory approval. A large number of companies including Merck & Company, Inc., GlaxoSmithKline, TAP Pharmaceutical Products, Inc., 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 & Company, Inc., Pfizer Inc., Johnson & Johnson Inc. and Amgen Inc., are developing and marketing new drugs for the treatment of chronic inflammatory conditions.

Many 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 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. 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.

We may 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, 2007, our cash and cash equivalents totaled approximately $43.2 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 for at least the next 12 months. 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 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.

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

We own or have obtained a license to numerous 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 products. 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.

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.

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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 pricing regulations and reimbursement limitations may reduce 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.

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Delays in the conduct or completion of our preclinical or clinical studies or the analysis of the data from our 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 drug candidates is set forth below. We have either completed or are in the midst of:

- Phase I clinical trial with TRIOLEX (HE3286) in the United States under an IND for the treatment of metabolic diseases;
- Phase I/II clinical trial with TRIOLEX (HE3286) in the United States under an IND for the treatment of metabolic diseases
- Phase I/II clinical trial with TRIOLEX (HE3286) in the United States under an IND for ulcerative colitis
- Open IND to begin clinical trials with TRIOLEX (HE3286) for the treatment of rheumatoid arthritis; and
- Pending IND for APOPTONE to initiate Phase I/II clinical trials for the treatment of hormone-sensitive cancers including prostate cancer.

We may encounter problems with some or all of our completed or ongoing studies that may cause us or regulatory authorities to delay or suspend our ongoing studies or delay the analysis of data from our completed or ongoing studies. We rely, in part, on third parties to assist us in managing and monitoring our preclinical and clinical studies. We generally do not have control over the amount and timing of resources that our business partners devote to our drug candidates. Our reliance on these third parties may result in delays in completing or failure to complete studies if third parties fail to perform their obligations to us. If the results of our ongoing and planned studies for our drug candidates are not available when we expect or if we encounter any delay in the analysis of the results of studies of our drug candidates:

- we may not have the financial resources to continue research and development of any of our drug candidates;
- we may not be able to enter into collaborative arrangements relating to any drug candidate subject to delay in regulatory filing;
- we may lose any competitive advantage associated with early market entry; and
- our ability to generate revenues may be delayed.

Any of the following reasons, among others, could delay or suspend the completion of our ongoing and 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;

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 obtaining our required quantity and quality of supply, we could experience significant delays in our development programs and regulatory process.

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.

If we were to lose the services of Richard B. Hollis, 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 highly upon our Chief Executive Officer, Richard B. Hollis. The loss of Mr. Hollis services could impede the achievement of our objectives. We also highly depend on our ability to hire and retain qualified scientific and technical personnel. The competition for these employees is intense. Thus, we may not be able to continue to hire and retain the qualified personnel needed for our business. Loss of the services of or the failure to recruit key scientific and technical personnel could adversely affect our business, operating results and financial condition.

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.

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

The market prices for securities of life sciences companies, particularly those that are not profitable, are highly volatile. 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

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 $1.42 to $10.25 between September 30, 2005 and March 10, 2008.

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 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 our 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.

We may be delisted from The Nasdaq Global Market, which could materially limit the trading market for our common stock.

Our common stock is quoted on The Nasdaq Global Market. In order to continue to be included in The Nasdaq Global Market, a company must meet Nasdaq s maintenance criteria. We may not be able to continue to meet these listing criteria. Failure to meet Nasdaq s maintenance criteria may result in the delisting of our common stock from The Nasdaq Global Market. If our common stock is delisted, in order to have our common stock relisted on The Nasdaq Global Market we would be required to meet the criteria for initial listing, which are more stringent than the maintenance criteria. Accordingly, if we were delisted we may not be able to have our common stock relisted on The Nasdaq Global Market. If our common stock is removed from listing on The Nasdaq Global Market, it may become more difficult for us to raise funds and may materially limit the trading market of our common stock.

Because stock ownership is concentrated, you and other investors will have minimal influence on stockholders decisions.

Assuming that outstanding warrants and options have not been exercised, Richard B. Hollis, our Chief Executive Officer, owns approximately 7.9% of our outstanding common stock as of December 31, 2007. Assuming that Mr. Hollis exercises all of his outstanding warrants and options that vest within 60 days of December 31, 2007, Mr. Hollis would beneficially own approximately 12.4% of our outstanding common stock. As a result, Mr. Hollis may be able to significantly influence our management and all matters requiring stockholder approval, including the election of directors. Such concentration of ownership may also have the effect of delaying or preventing a change in control of our company.

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

Future sales of substantial amounts of our common stock, including shares that we may issue upon exercise of options and warrants, 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 a 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.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate headquarters are currently located at 4435 Eastgate Mall, Suite 400, San Diego, CA 92121, where we have leased approximately 22,000 square feet of office space through December 2009. In addition, we have leased approximately 13,000 square feet of laboratory and office space in San Diego, CA. through November 2009. 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. Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of security holders during the fourth quarter of 2007.

PART II

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

Our common stock is traded on the Nasdaq Global Market under the symbol HEPH.

The following table sets forth the quarterly high and low sales prices for our common stock from January 1, 2006 through March 10, 2008.

2006		
First Quarter	$ 7.93	$ 4.44
Second Quarter	6.16	4.52
Third Quarter	7.25	4.09
Fourth Quarter	7.49	5.16
2007		
First Quarter	$ 6.24	$ 2.46
Second Quarter	3.10	1.90
Third Quarter	2.64	1.42
Fourth Quarter	2.87	1.48
2008		
January 1 March 10	$ 2.09	$ 1.50

Performance Measurement Comparison[1]

The following graph compares changes through December 31, 2007, in the cumulative total return on our common stock, a broad market index, namely the NASDAQ Composite Index (the NASDAQ Index), and an industry index, namely the NASDAQ Biotechnology Index (the Industry Index). The Industry Index comprises all companies listed on the NASDAQ Stock Market under SIC 283. All values assume reinvestment of the full amount of all dividends as of December 31 of each year.

(1) *The material in this section is not soliciting material is not deemed filed with the SEC, and is not to be incorporated by reference into any filing of the Company under the 1933 or 1934 Act.*

On March 10, 2008, the closing price of our common stock as reported by the Nasdaq Global Market was $1.74 share. There were approximately 11,000 shareholders 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 the fourth quarter 2007.

We made no repurchases of our securities during the year ended December 31, 2007.

Item 6. Selected Financial Data

The following data summarizes certain selected financial data for each of the five years ended December 31, 2007 through 2003 and the period from inception (August 15, 1994) to December 31, 2007. 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).

	2007	2006	2005	2004	2003	Period from Inception (Aug. 15, 1994) to December 31, 2007
Statement of Operations Data:						
Contract revenues	$ 645	$ 444	$ 56	$ 63	$	$ 1,208
Research and development	18,319(3)	23,764(3)	18,342	18,488	10,306	144,629
General and administrative	8,150(3)	9,644(3)	9,777	7,216	7,785(1)	76,240
Settlement of Dispute			3,000			3,000
Total operating expenses	26,469	33,408	31,119	25,704	18,091	223,869
Interest income (expense)	2,781	2,741	1,622	917	49	15,789
Other income (expense)	(78)	(8)		(33)	(7,629)(2)	(7,769)
Net loss	$ (23,121)	$ (30,231)	$ (29,441)	$ (24,757)	$ (25,671)	$ (214,641)
Net loss per share, basic and diluted	$ (0.80)	$ (1.20)	$ (1.46)	$ (1.28)	$ (1.67)	
Weighted average number of common Shares outstanding, basic and diluted	28,955	25,131	20,125	19,267	15,381	
Balance Sheet Data:						
Cash and equivalents	$ 43,215	$ 67,135	$ 45,130	$ 61,991	$ 84,852	
Total assets	45,123	68,512	46,582	63,242	85,381	
Total current liabilities	3,018	6,734	7,708	5,008	3,329	
Stockholders equity	$ 42,105	$ 61,778	$ 38,874	$ 58,234	$ 82,052	

(1) 2003 General and administrative expenses include $2.3 million for non-cash charges related to options and warrants issued and term changes.

(2) 2003 Other expense includes $7.6 million for non-cash amortization of deemed discount and deferred issuance costs on convertible debentures that was subsequently converted to common stock.

(3) 2006 and 2007 Research and development and general and administrative expenses include the expense for stock-based compensation under SFAS 123R. Stock-based compensation expense was not included in financial results for previous years. (See Accounting for Stock-Based Compensation in the Notes to Financial Statements).

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, development and commercialization of products 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 believe these compounds are key components of the body s natural regulatory system that potentially can be useful in treating a wide variety of medical conditions.

We have been unprofitable since our inception. As of December 31, 2007, we had an accumulated deficit of approximately $214.6 million. We expect to incur substantial additional operating losses and capital expenditures for the foreseeable future as we increase expenditures on research and development and begin to allocate significant and increasing resources to clinical testing and other activities in support of the development of our drug candidates. In addition, during the next few years, 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.

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, 2007, we have incurred approximately $144.6 million in research and development expenses, $76.2 million in general and administrative expenses, and $3.0 million in a settlement of dispute. From inception through December 31, 2007 we have generated approximately $1.2 million in revenues (which resulted from providing research and development services under our Study Funding Agreement with Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT)). We have earned $8.0 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 $0.1 million loss on disposal of assets . These expenses have been offset by $16.1 million in interest income. The combination of these resulted in a net loss of $214.6 million for the period from inception until December 31, 2007.

Research and development and general and administrative expenses include the expense for stock-based compensation for the years ended December 31, 2007 and 2006, while stock-based compensation expense was not included in our financial results for 2005 (See Accounting for Stock-Based Compensation in the Notes to Financial Statements).

Research and development expenses were $18.3 million, $23.8 million and $18.3 million in 2007, 2006 and 2005, respectively. The research and development expenses relate primarily to the ongoing development, preclinical testing and clinical trials for our drug candidates. Research and development expenses decreased $5.4 million in 2007 compared to 2006. The decrease in research and development expenses was due mainly to the

discontinuation of our NEUMUNE (HE2100) research and development program. The increase of $5.5 million in research and development expenses in 2006 compared to 2005 was due primarily to the growth in our laboratory operations, stock-based compensation, as well as preclinical and clinical activities and personnel associated with advancing our drug candidates through development.

General and administrative expenses were $8.1 million, $9.6 million and $9.8 million in 2007, 2006 and 2005, 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 $1.5 million in 2007 compared to 2006. General and administrative expenses decreased due mainly to a decrease in executive head count and in legal costs and consulting fees. General and administrative expenses decreased $0.1 million in 2006 compared to 2005 primarily as a result of reduced legal expenses offset by the impact of stock-based compensation expense related to the adoption of SFAS No. 123R in 2006. Legal fees were $0.3 million and $2.9 million in 2006 and 2005, respectively while stock-based compensation expense was $2.3 million and $0 in 2006 and 2005, respectively. Also, an additional operating expense of $3.0 million was incurred in 2005 due to settlement of a dispute.

Other income and expenses were $2.7 million, $2.7 million and $1.6 million in 2007, 2006 and 2005, respectively. During 2007 and 2006, we earned interest income totaling $2.8 million and $2.7 million, respectively. The interest income increase in 2007 compared to 2006 was due to higher interest rates.

Liquidity and Capital Resources

We have financed our operations since inception primarily through the sale of shares of common stock. During the year ended December 31, 1995, we received cash proceeds of $250,000 from the sale of securities. In May 1996, we completed a private placement of shares of common stock, from which we received aggregate gross proceeds of $1.3 million. In March 1997, the Merger of IAC and Hollis-Eden, Inc. provided us with $6.5 million in cash and other receivables. In May 1998, we completed a private placement of common stock and warrants, from which we received gross proceeds of $20 million. During January 1999, we completed two private placements of common stock raising approximately $25 million. In December 2001, we completed a private placement of common stock and warrants, from which we received gross proceeds of $11.5 million. In February 2003, we completed a private placement of convertible debentures and warrants, from which we received gross proceeds of $10.0 million. In June 2003, we completed a private placement of common stock and warrants, from which we received gross proceeds of $14.7 million. In October 2003 we completed a public offering of our common stock from which we received $62.5 million in gross proceeds. In June 2005, we completed a sale of shares of our common stock and warrants from which we received $10.0 million in gross proceeds. During 2006 (in February and in November), we completed two sales of shares of our common stock and warrants from which we received, in the aggregate gross proceeds of approximately $52.0 million. In addition, we have received a total of $17.8 million from the exercise of warrants and stock options from inception.

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.

We became entitled to convert the outstanding debentures into common stock in August 2003 and 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.

A summary of our current contractual obligations is as follows (in thousands):

		Payments Due by Period			
Contractual Obligations	**Total**	**Less than one year**	**One to three years**	**Three to five years**	**More than Five years**
Operating Leases	$ 2,342	$ 1,173	$ 1,167	$ 2	$

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 Cystic Fibrosis Foundation Therapeutics, Inc. 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, together with interest thereon, will be sufficient to meet our operating expenses and capital requirements for at least the next 12 months. 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, 2007, our cash and cash equivalents totaled approximately $43.2 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 may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

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 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 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 2007, 2006 or 2005.

In December 2006, the Financial Accounting Standards Board (the FASB) issued FASB Staff Position) No. EITF 00-19-2, *Accounting for Registration Payment Arrangements (FSP EITF 00-19-2).* FSP EITF 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration

under a registration payment arrangement, whether issued as separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5, *Accounting for Contingencies.* The guidance in FSP EITF 00-19-2 amends FASB Statement No. 133, *Accounting for Derivative Financial Instruments and Hedging Activities* , and No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* and FIN 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* to include scope exceptions for registration payment arrangements. This FSP is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issuance of this FSP. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of this FSP, this guidance shall be effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. We have adopted EITF 00-19-2 as of December 31, 2006 and it did not have a material impact on our financial statements.

As of January 1, 2006, we account for stock-based compensation in accordance with SFAS No. 123-R, *Share-Based Payment* . Under the fair value recognition provisions of this statement, share-based compensation 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 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. We have chosen to utilize the safe harbor expected life for our options. Because stock-based compensation 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. SFAS No. 123-R 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 SFAS No. 123-R, 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, the Financial Accounting Standards Board issued Interpretation No. 48, *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 the FASB s Interpretation No. 48, and it has had no material impact on its financial statements.

Impact of Recently Issued Accounting Pronouncements

At its December 2007 meeting, the FASB ratified the consensus reached by the EITF 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property.* The EITF concluded that a collaborative arrangement is one in which the participants are actively involved and are exposed to significant risks and rewards that depend on the ultimate commercial success of the endeavor. Revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, and other accounting literature. Payments to or from collaborators would be evaluated and presented based on the nature of the arrangement and its terms, the nature of the entity s business and whether those payments are within the scope of other accounting literature. The nature and purpose of collaborative arrangements are to be disclosed along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however, required disclosure under EITF 07-1 applies to the entire collaborative agreement. This issue is effective for fiscal years beginning after December 15, 2008, and is

to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The Company is currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, which replaces SFAS No. 141, *Business Combinations*, and requires an acquirer to recognize the assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions. This Statement also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the non-controlling interest in the acquiree, at the full amounts of their fair values. SFAS 141(R) makes various other amendments to authoritative literature intended to provide additional guidance or to confirm the guidance in that literature to that provided in this Statement. This Statement applies to business combinations for which the acquisition date is in fiscal years beginning after December 15, 2008. The Company is currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51*. SFAS No. 160 establishes accounting and reporting standards that require the ownership interests in subsidiaries held by parties other than the parent to be clearly identified, labeled and presented in the consolidated statement of financial position within equity, but separate from the parent s equity. This Statement also requires the amount of consolidated net income attributable to the parent and to the noncontrolling interest to be clearly identified and presented on the face of the consolidated statement of income. Changes in a parent s ownership interest while the parent retains its controlling financial interest in its subsidiary must be accounted for consistently, and when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary must be initially measured at fair value. The gain or loss on the deconsolidation of the subsidiary is measured using the fair value of any noncontrolling equity investment. The Statement also requires entities to provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. This Statement is effective for fiscal years beginning after December 15, 2008. The Company is currently in the process of evaluating the impact of adopting this pronouncement.

In June 2007, the EITF reached a consensus on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received to Be Used in Future Research and Development Activities*. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided. This Issue is effective for fiscal years beginning after December 15, 2007, and earlier application is not permitted. The pronouncement is not expected to have a material effect on the Company s financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements.* SFAS No. 157 establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new circumstances. In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Liabilities.* SFAS No. 157 and 159 are effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, FASB deferred the effective date of SFAS No. 157 for one year for non-financial assets and non-financial liabilities that are recognized or disclosed at fair value in the financial statements on a non recurring basis. In addition, FASB issued a staff position that SFAS No. 157 does not apply under SFAS No. 13 Accounting for Leases and other accounting pronouncements that address fair value measurements for purposes of lease classifications under SFAS No. 13. The Company is currently analyzing the effects of the new standards, and its potential impact on its financial statements.

In February 2007, the FASB issued SFAS No. 159 *The Fair Value Option for Financial Assets and Financial Liabilities* to permit all entities to choose to elect, at specified election dates, to measure eligible

financial instruments at fair value. An entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date, and recognize upfront costs and fees related to those items in earnings as incurred and not deferred. SFAS 159 applies to fiscal years beginning after November 15, 2007 with early adoption permitted for an entity that has also elected to apply the provisions of SFAS 157*, Fair Value Measurements*. An entity is prohibited from retrospectively applying SFAS 159, unless it chooses early adoption. SFAS 159 also applies to eligible items existing at November 15, 2007 (or early adoption date). The Company has not yet determined the impact, it any, of adopting SFAS 159 on its consolidated financial statements.

Off-Balance Sheet Arrangements

Hollis Eden Pharmaceuticals, Inc. currently does not have any off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

At December 31, 2007, our investment portfolio included only cash and money market accounts and did not contain fixed-income securities, with the exception of a small amount held in a restricted CD. 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.

Item 8. Financial Statements and Supplementary Data

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Balance Sheets

	December 31, 2007	2006
	(In thousands, except par value)	
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 43,215	$ 67,135
Prepaid expenses	269	188
Deposits	7	39
Other receivable	645	
Receivable from related party		4
Total current assets	44,136	67,366
Property and equipment, net of accumulated depreciation of $1,213 and $990	892	1,051
Deposits	61	61
Restricted cash	34	34
Total assets	$ 45,123	$ 68,512
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable	$ 455	$ 625
Accrued expenses	2,563	$ 6,109
Total current liabilities	3,018	6,734
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, 50,000 shares authorized; 29,064 and 28,971 shares issued and 29,005 and 28,913 outstanding respectively	291	290
Paid-in capital	256,801	253,354
Cost of treasury stock (59 shares)	(346)	(346)
Deficit accumulated during development stage	(214,641)	(191,520)
Total stockholders equity	42,105	61,778
Total liabilities and stockholders equity	$ 45,123	$ 68,512

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

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Operations

	For the year ended December 31,			Period from Inception (Aug.15, 1994) to December 31, 2007
	2007	2006	2005	
	(In thousands, except per share amounts)			
Revenue:				
Contract R&D revenue	$ 645	$ 444	$ 56	$ 1,208
Total revenue	645	444	56	1,208
Operating expenses:				
Research and development				
R & D operating expenses	17,074	22,177	18,342	136,130
R & D costs related to common stock and stock option grants for collaborations and technology purchases	1,245	1,587		8,499
Total research and development	18,319	23,764	18,342	144,629
General and administrative				
G & A operating expenses	6,160	7,365	9,746	59,599
G & A costs related to options / warrants granted	1,990	2,279	31	16,641
Total general and administrative	8,150	9,644	9,777	76,240
Settlement of dispute			3,000	3,000
Total operating expenses	26,469	33,408	31,119	223,869
Other income (expense):				
Loss on disposition of assets	(78)	(8)		(142)
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures				(7,627)
Interest income	2,781	2,741	1,622	16,177
Interest expense				(388)
Total other income, net	2,703	2,733	1,622	8,020
Net loss	$ (23,121)	$ (30,231)	$ (29,441)	$ (214,641)
Net loss per share, basic and diluted	$ (0.80)	$ (1.20)	$ (1.46)	
Weighted average number of common shares outstanding, basic and diluted	28,955	25,131	20,125	

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

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Stockholders Equity

	Preferred stock at par value		Common stock at par value		Capital in excess of	Cost of Repurchased Common Stock		Deficit accumulated during development	
	Shares	Amount	Shares	Amount	par value	Shares	Amount	stage	Total
					(In thousands)				
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

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Stockholders Equity (Continued)

	Preferred stock at par value		Common stock at par value		Capital in excess of	Cost of Repurchased Common Stock		Deficit accumulated during	
	Shares	Amount	Shares	Amount	par value	Shares	Amount	development stage	Total
					(In thousands)				
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
Amortization of deferred compensation					308				308
Net loss								(5,427)	(5,427)
Balance at December 31, 1998	4		8,592	86	37,538			(13,321)	24,303
Exercise of warrants			755	8	5,136				5,144
Exercise of stock options			10		75				75
Private Placement, net of expenses (Note 7)			1,368	14	24,759				24,773
Preferred Stock Conversion (Note 7,8)	(4)		346	3	(3)				
Deferred compensation-Options forfeited (Note 9)					51				51
Amortization of non-employee options					559				559
Warrants issued for services in lieu of cash (Note 10)					2,140				2,140
Options accelerated vesting (Note 9)					4,900				4,900
Net loss								(15,320)	(15,320)
Balance at December 31, 1999			11,071	111	75,155			(28,641)	46,625
Exercise of warrants			133	2	758				760
Exercise of stock options			1		5				5
Common Stock issued for 401k/401m plan			6		63				63
Common Stock issued for In-Process R&D (Note 6)			209	2	1,998				2,000
Options granted for license fee			38		598				598
Amortization of non-employee options					79				79
Common Stock issued for purchase of technology			132	1	1,847				1,848
Net loss								(19,515)	(19,515)
Balance at December 31, 2000			11,590	116	80,503			(48,156)	32,463
Exercise of stock options			10		22				22
Common Stock issued for 401k/401m plan			16		96				96
Private Placement, net of expenses (Note 7)			1,280	13	10,644				10,657
Warrants issued for services in lieu of cash (Note 10)					80				80
Amortization of non-employee options					96				96
Warrants issued for services					208				208
Net loss								(15,762)	(15,762)

Balance at December 31, 2001	12,896	129	91,649	(63,918)	27,860

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Stockholders Equity (Continued)

	Preferred stock at par value		Common stock at par value		Capital in excess of	Cost of Repurchased Common Stock		Deficit accumulated during	
	Shares	Amount	Shares	Amount	par value	Shares	Amount	development stage	Total
					(In thousands)				
Exercise of stock options					2				2
Common Stock issued for 401k/401m plan			26		137				137
Common Stock issued for sublicense agreement (Note 6)			50	1	204				205
Common Stock issued to consultants					17				17
Amortization of non-employee options					66				66
Warrants issued for services					247				247
Net loss								(17,502)	(17,502)
Balance at December 31, 2002			12,972	130	92,322			(81,420)	11,032
Common Stock issued for 401k/401m 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	189,296	(59)	(346)	(107,091)	82,052
Common Stock issued for 401k			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	190,235	(59)	(346)	(131,848)	58,234
Common Stock issued for 401k			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

Hollis-Eden Pharmaceuticals, 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	Shares	Amount	(In thousands)	Shares	Amount		
Amortization of non-employee options					30				30
Net loss								(29,441)	(29,441)
Balance at December 31, 2005			20,782	208	200,301	(59)	(346)	(161,289)	38,874
Common Stock issued for 401k			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
Amortization of FAS 123R employee options					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 401k			96	1	192				193
Exercise of stock options			9		20				20
Amortization of FAS 123R employee options					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

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

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Cash Flows

	2007	2006	2005	Period from Inception (Aug. 15, 1994) to December 31, 2007
		(In thousands)		
Cash flows from operating activities:				
Net loss	$ (23,121)	$ (30,231)	$ (29,441)	$ (214,641)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	309	294	303	1,699
Disposal of assets	85	8		156
Compensation expense related to equity awards	3,128	3,534		6,662
Compensation expense related to restricted stock	90	93		183
Amortization of deemed discount on convertible debentures				6,470
Amortization of deferred issuance cost				1,157
Common stock issued for 401k/401m plan	192	225	151	1,235
Common stock issued as consideration for amendments to the license agreements				33
Common stock issued as consideration for termination of a finance agreement				34
Common stock and options issued as consideration for license fees, milestone payment, interest and services			30	2,859
Expense related to warrants issued as consideration to consultants	17	239		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		180		2,809
Deferred compensation expense related to options issued				1,210
Changes in assets and liabilities:				
Prepaid expenses	(81)	16	(28)	(269)
Deposits	32	14	(8)	(68)
Other receivable	(645)	8	1	(645)
Other Receivable from related party	4	7	(11)	
Accounts payable	(170)	341	(161)	1,146
Accrued expenses	(3,546)	(1,315)	2,861	2,516
Net cash used in operating activities	(23,706)	(26,587)	(26,303)	(174,949)
Cash flows provided by investing activities:				
Purchase of property and equipment	(234)	(237)	(458)	(2,746)
Net cash provided by (used in) investing activities	(234)	(237)	(458)	(2,746)
Cash flows from financing activities:				
Restricted Cash		(34)		(34)
Contributions from stockholder				104
Net proceeds from sale of preferred stock				4,000
Net proceeds from sale of common stock		48,777	9,515	183,534
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	20	86	385	17,796
Net cash provided by financing activities	20	48,829	9,900	220,910
Net increase (decrease) in cash and equivalents	(23,920)	22,005	(16,861)	43,215

Cash and equivalents at beginning of period	67,135	45,130	61,991	
Cash and equivalents at end of period	$ 43,215	$ 67,135	$ 45,130	$ 43,215
Supplemental disclosure of cash flow information:				
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.

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements

1. The Company

Hollis-Eden Pharmaceuticals, Inc. (Hollis-Eden or the Company), a development stage pharmaceutical company, is engaged in the discovery, development and commercialization of products for the treatment of diseases and disorders in which the body is unable to mount an appropriate immune response. 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 multiple clinical studies. The Company s technology development efforts are focused on a series of potent hormones and hormone analogs that the Company believes are key components of the body s natural regulatory system. Beginning in the second quarter of 2004, the Company has been generating a small amount of revenue. This revenue resulted from providing research and development services under the Company s Study Funding Agreement with Cystic Fibrosis Foundation Therapeutics, Inc. To date, the Company has not developed commercial products or generated any product sales for the period since inception (August 15, 1994 through December 31, 2007).

2. Summary of Accounting Policies

Cash Equivalents

The Company considers any liquid investments with a maturity of three months or less when purchased to be cash equivalents. At December 31, 2007 the Company s cash equivalents are approximately $43.2 million and are deposited primarily in a money market account with a large 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. Leasehold improvements are amortized over the lesser of the lease term or the useful life. The cost of major additions and improvements is capitalized, 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		
	2007	2006	Lives
	(in thousands)		
Leasehold improvements	$ 23	$ 11	3 years

Machinery, equipment and information systems	1,864	1,812	5-7 years
Furniture and fixtures	218	218	5-7 years
Total	2,105	2,041	
Less: Accumulated depreciation	(1,213)	(990)	
	$ 892	$ 1,051	

Depreciation expense associated with property and equipment was approximately $309,000, $294,000 and $303,000 in 2007, 2006, and 2005, respectively.

In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS 144), 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

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

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 is 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 2007.

Accrued Expenses

Accrued expenses include approximately $0.5 million and $0.5 million in accrued vacation expense, $0.7 million and $1.0 million in accrued salary / bonus expense and $1.3 million and $4.5 million in other research and development / general and administrative expenses as of December 31, 2007 and 2006, respectively.

Revenue Recognition

In December 2003, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 104 Revenue Recognition (SAB 104), 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 SAB 104.

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 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 2007, 2006 or 2005.

Accounting for Stock-Based Compensation

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 January 1, 2006, we applied Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for options. 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

HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

the option equaled or exceeded the market price of the stock on the date of the grant. As a result, under APB No. 25 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, 2007 the Plan has 7,429,139 shares of common stock reserved for issuance.

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards (SFAS) No. 123 (Revised 2004), Share-Based Payment (123R), 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 SFAS 123R; accordingly, results from prior periods have not been restated. Under this transition method, stock-based compensation expense for the fiscal year ended December 31, 2007 and 2006 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 SFAS 123, *Accounting for Stock-Based Compensation*, 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 SFAS 123R.

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 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 SFAS 123R, the effect of forfeitures on the pro forma expense amounts was not recognized. SFAS 123R 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.

Black-Scholes Option Valuation Assumptions(1)

	Fiscal year Ended		
	December 31, 2007	**December 31, 2006**	**December 31, 2005**
Risk-free interest rate	4.75%	4.75%	4.02%
Expected dividend yield	0%	0%	0%
Expected life(2)	6.25 years	6.25 years	5 years
Expected volatility(3)	76%	84%	86%

(1) Forfeitures are estimated as 5.05% for 2007, 2% for 2006 and 0% for 2005, based on historical experience.
(2)

The 2007 and 2006 expected life is based on the safe-harbor method as described in SEC Staff Accounting Bulletin No. 107. The 2005 expected life was estimated at the time.

(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.

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In November 2005, the FASB issued SFAS 123R-3, *Transition Election to Accounting for the Tax Effects of Share-Based Payment Awards* . This requires an entity to follow either the transition guidance (long method) for the additional-paid-in-capital pool, or the alternative transition (simplified method) as described in the pronouncement. We have decided to use the alternative transition (simplified method) for accounting for the tax effects of our share-based payment awards.

For stock options granted prior to the adoption of SFAS No. 123-R, if expense for stock-based compensation had been determined under the fair value method of the original SFAS 123 for the year ended December 31, 2005, our net loss per common share would have been adjusted to the following pro forma amount.

		Year ended December 31, 2005
Net loss As reported	$	(29,441)
Add: Stock-based employee compensation expense included in reported net loss		-0-
Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards		(3,926)
Net loss Pro forma	$	(33,367)
Basic and diluted net loss per share As reported	$	(1.46)
Basic and diluted net loss per share Pro forma	$	(1.66)

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 $192,000, $199,000 and $179,000 in 2007, 2006 and 2005, respectively.

Income Taxes

The Company provides for income taxes under the principles of SFAS 109 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.

On July 13, 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), 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 the FASB s Interpretation No. 48, and it has had no material impact on its financial statements.

Financial Instruments

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

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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 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 balances are generally substantially in excess of the amounts insured by the Federal Deposit Insurance Corporation.

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 9,702,428, 9,939,430 and 8,253,374 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, 2007, 2006 and 2005 because their effect on net loss per share is anti-dilutive.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements.* SFAS No. 157 establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new circumstances. In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Liabilities* SFAS No. 157 and 159 are effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, FASB deferred the effective date of SFAS No. 157 for one year for non-financial assets and non-financial liabilities that are recognized or disclosed at fair value in the financial statements on a non recurring basis. In addition, FASB issued a staff position that SFAS No. 157 does not apply under SFAS No. 13 Accounting for Leases and other accounting pronouncements that address fair value measurements for purposes of lease classifications under SFAS No. 13. The Company is currently analyzing the effects of the new standard and its potential impact on its financial statements.

In February 2007, the FASB issued SFAS No. 159 *The Fair Value Option for Financial Assets and Financial Liabilities* to permit all entities to choose to elect, at specified election dates, to measure eligible financial instruments at fair value. An entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date, and recognize upfront costs and fees related to those items in earnings as incurred and not deferred. SFAS 159 applies to fiscal years beginning after November 15, 2007 with early adoption permitted for an entity that has also elected to apply the provisions of SFAS 157*, Fair Value Measurements*. An entity is prohibited from retrospectively applying SFAS 159, unless it chooses early adoption. SFAS 159 also applies to eligible items existing at November 15, 2007 (or early adoption date). The Company has not yet determined the impact, it any, of adopting SFAS 159 on its consolidated financial statements.

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At its December 2007 meeting, the FASB ratified the consensus reached by the EITF 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property.* The EITF concluded that a collaborative arrangement is one in which the participants are actively involved and are exposed to significant risks and rewards that depend on the ultimate commercial success of the endeavor. Revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, and other accounting literature. Payments to or from collaborators would be evaluated and presented based on the nature of the arrangement and its terms, the nature of the entity s business and whether those payments are within the scope of other accounting literature. The nature and purpose of collaborative arrangements are to be disclosed along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however, required disclosure under EITF 07-1 applies to the entire collaborative agreement. This issue is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The Company is currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, which replaces SFAS No. 141, *Business Combinations*, and requires an acquirer to recognize the assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions. This Statement also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the non-controlling interest in the acquiree, at the full amounts of their fair values. SFAS 141(R) makes various other amendments to authoritative literature intended to provide additional guidance or to confirm the guidance in that literature to that provided in this Statement. This Statement applies to business combinations for which the acquisition date is in fiscal years beginning after December 15, 2008. The Company is currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51*. SFAS No. 160 establishes accounting and reporting standards that require the ownership interests in subsidiaries held by parties other than the parent to be clearly identified, labeled and presented in the consolidated statement of financial position within equity, but separate from the parent s equity. This Statement also requires the amount of consolidated net income attributable to the parent and to the noncontrolling interest to be clearly identified and presented on the face of the consolidated statement of income. Changes in a parent s ownership interest while the parent retains its controlling financial interest in its subsidiary must be accounted for consistently, and when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary must be initially measured at fair value. The gain or loss on the deconsolidation of the subsidiary is measured using the fair value of any noncontrolling equity investment. The Statement also requires entities to provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. This Statement is effective for fiscal years beginning after December 15, 2008. The Company is currently in the process of evaluating the impact of adopting this pronouncement.

In June 2007, the EITF reached a consensus on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received to Be Used in Future Research and Development Activities*. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer

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expected to be provided. This Issue is effective for fiscal years beginning after December 15, 2007, and earlier application is not permitted. The pronouncement is not expected to have a material effect on the Company s financial statements.

Reclassifications

Certain reclassifications have been made to the 2005 and Inception-to-date financial statements to conform to the current presentation.

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.) remains the continuing legal entity and registrant for Securities and Exchange Commission reporting purposes. The 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.

4. 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.

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 $175.4 million and $131.1 million at December 31, 2007 and 2006, respectively, which may be carried forward as an offset to taxable income, if any, in future years through its expiration for California in 2017 and for federal in 2027. The Company has a net federal and state deferred tax asset of approximately $68.3 million and $14.3 million, at December 31, 2007 and 2006, respectively, comprised of research and development credits and the net

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operating loss carryforward. 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 SFAS 109. 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 2007 and 2006, the tax effects of stock compensation under FAS 123R.

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.

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.

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

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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, Hollis-Eden 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 Hollis-Eden ownership of all patents, patent applications and current or future improvements of the technology under the Colthurst License Agreement, including IMMUNITIN, Hollis-Eden 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, Hollis-Eden agreed to issue to Colthurst 660,000 shares of Common Stock and 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 Hollis-Eden a number of compounds, together with all related patents and patent applications, and Hollis-Eden funded additional preclinical research projects conducted by Edenland. Hollis-Eden 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 Hollis-Eden 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 Emerging Issues Task Force No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, 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, Hollis-Eden 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 IMMUNITIN) that was assigned to the Company under the Assignment Agreement.

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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 shareholders granted the Company an exclusive option to acquire the remainder of Aeson at a predetermined price.

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. Hollis-Eden 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. Hollis-Eden 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 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 Hollis-Eden 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 Tas