

HOLLIS EDEN PHARMACEUTICALS INC /DE/  
Form 10-K  
March 16, 2007

---

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

WASHINGTON, D.C. 20549

---

**FORM 10-K**

---

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

**For the fiscal year ended December 31, 2006**

**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**  
**(State or other jurisdiction)**

**13-3697002**  
**(I.R.S. Employer)**

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

(of incorporation or organization)

(Identification No.)

4435 Eastgate Mall, Suite 400

San Diego, CA  
(Address of principal executive offices)

92121  
(Zip Code)

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

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

Common stock, \$.01 par value per share

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

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

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

Indicate by check mark 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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Exchange Act Rule 12b-2).

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  NO

## Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

The aggregate market value of the voting stock held by nonaffiliates of the Registrant as of June 30, 2006, the end of Hollis-Eden Pharmaceuticals' most recently completed second fiscal quarter, was approximately \$106,854,156 based on the closing stock price of \$4.79 for the Registrant's Common Stock as reported by the Nasdaq National Market\*.

As of March 1, 2007, there were outstanding 28,918,901 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, 2006, are incorporated by reference into Part III of this Report.

\*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, 2006. This calculation does not reflect a determination that such persons are affiliates for any other purposes.

---

Hollis-Eden Pharmaceuticals, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2006

INDEX

	<u>Page</u>
<u>PART I</u>	
Item 1 <u>Business</u>	3
Item 2 <u>Properties</u>	29
Item 3 <u>Legal Proceedings</u>	29
Item 4 <u>Submission of Matters to a Vote of Security Holders</u>	29
<u>PART II</u>	
Item 5 <u>Market for Registrant's Common Stock and Related Stockholder Matters</u>	30
Item 6 <u>Selected Financial Data</u>	32
Item 7 <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	33
Item 7A <u>Quantitative and Qualitative Disclosures About Market Risk</u>	36
Item 8 <u>Financial Statements and Supplementary Data</u>	37
Item 9 <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	70
Item 9A <u>Controls and Procedures</u>	70
Item 9B <u>Other Information</u>	72
<u>PART III</u>	
Item 10 <u>Directors and Executive Officers of the Registrant</u>	73
Item 11 <u>Executive Compensation</u>	73
Item 12 <u>Security Ownership of Certain Beneficial Owners and Management</u>	73
Item 13 <u>Certain Relationships and Related Transactions</u>	73
Item 14 <u>Principal Accountants Fees and Services</u>	74
<u>PART IV</u>	
Item 15 <u>Exhibits and Financial Statement Schedules</u>	75
<u>Signatures</u>	76

---

## 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 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 report 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 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 the 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. Our initial technology development efforts are primarily focused on a series of adrenal hormones and hormone analogs that we have labeled immune regulating hormones, or IRHs, that are derived from our hormonal signaling technology platform. We believe these IRHs 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 with these compounds indicate that they have the ability to reverse bone marrow suppression, reduce non-productive inflammation and stimulate innate and adaptive immunity. These compounds have also been shown in these studies to play an important role in metabolism and, more recently, in preclinical studies of hormonally driven cancers. In addition, these IRHs have a very attractive safety profile to date and are cost-effective to manufacture.

We have generated a substantial amount of data regarding the safety and activity of NEUMUNE® (HE2100) in the setting of acute radiation syndrome (ARS). This data indicates that NEUMUNE mitigates neutropenia (loss of white blood cells known as neutrophils), thrombocytopenia (loss of key clotting elements known as platelets) and anemia (loss of red blood cells). NEUMUNE has also been shown to increase survival versus placebo in rhesus monkeys after exposure to high levels of radiation. In 2005 we filed an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA, and we have conducted four Phase I human clinical trials with NEUMUNE in the U.S. and The Netherlands. These studies indicate that NEUMUNE has an attractive safety profile and that the compound can increase both neutrophils and platelets in young and elderly healthy humans.

Because of the potential to use such an agent as a medical countermeasure to a weapon of mass destruction, there are a number of unique features applicable to the development and commercialization process of NEUMUNE for ARS. Specifically, unlike drug candidates for traditional medical indications, NEUMUNE may be reviewed for regulatory approval in ARS by the FDA, on the basis of efficacy in animals and safety in humans. This potentially avoids the need to conduct large and expensive studies typically required by the FDA to establish efficacy

in humans. Further, because the compound could be stockpiled by government agencies, the

cost of distribution could potentially be significantly less than for traditional pharmaceuticals. We have been collaborating on the development of NEUMUNE for ARS with the U.S. military. Our intent had been to secure procurement contracts with both the Department of Health and Human Services (HHS) and the Department of Defense (DOD). However, in March 2007, after being notified on multiple occasions that we were in the competitive range for an active Request for Proposal (RFP), we were informed by HHS that NEUMUNE did not meet the technical requirements for this RFP. HHS then cancelled the solicitation in its entirety. While we believe DOD remains interested in procuring a drug candidate like NEUMUNE for bone marrow damage from ARS, they have not yet issued a RFP for this indication. Therefore, it is uncertain whether or when a market for NEUMUNE in ARS will materialize and, as a result, we have curtailed our development activities in this indication until such time as the market opportunity becomes more clear.

In addition to the potential role for NEUMUNE in ARS, we believe there is also an opportunity for the compound in preventing or mitigating infections acquired in the healthcare setting. Numerous published preclinical studies indicate that NEUMUNE can significantly improve survival from lethal infections when administered prior to infectious challenge. While we have an open IND for the compound in this indication, in light of HHS cancellation of its RFP described above, we have made the strategic decision to curtail further development of NEUMUNE and will focus our resources on HE3286, HE3235 and follow-on oral compounds for indications that have well defined clinical paths and large, well-established markets. If Congressional intervention or procurement activities by the Department of Defense improve the opportunity for NEUMUNE in the very short term we may revisit this decision. We will also consider licensing or selling the compound to third parties for further development.

We are also in the process of preparing and filing an IND on our lead compound, HE3286, which is being developed initially for type 2 diabetes, a disease affecting approximately 20 million Americans and over 160 million people worldwide. Preclinical studies with the compound indicate that it acts as an insulin sensitizer to improve the utilization of glucose without causing the side effects seen with currently marketed insulin sensitizers.

HE3286 has also shown activity in several preclinical models of rheumatoid arthritis and we anticipate filing an IND in this area if additional preclinical studies are successful. We are continuing to profile both HE3286 and analogs of HE3286 in other preclinical models of autoimmunity.

We have recently identified another compound from our hormonal signaling technology platform, HE3235, that has shown activity in preclinical models of prostate cancer and breast cancer. This compound has now been selected for clinical development, and assuming toxicology studies and manufacturing scale-up activities are successful, we anticipate filing an IND for this compound as well.

Another one of our drug candidates, IMMUNITIN (HE2000), is a Phase II stage IRH that has shown clinical activity in infectious diseases, including HIV, malaria, and preventing reactivation of tuberculosis in AIDS patients. IMMUNITIN may be a candidate for further development as a compound to be used in treating global infectious disease epidemics.

In addition to the four clinical development stage drug candidates described above, we have an active research program that is generating new clinical leads. These new leads are being further evaluated in preclinical models of a number of different diseases including chemotherapy induced bone marrow suppression, autoimmune conditions, inflammatory diseases of the lung, glucose and bone metabolism and regenerative medicine.

We are pursuing a partially integrated approach to building our business. As such, we are utilizing third parties for many of our activities. If we are able to successfully develop our investigational drug candidates, we anticipate marketing them directly in the U.S. and potentially elsewhere in indications for which only a small sales force is required. For certain therapeutic indications or geographic regions that require a larger sales force to successfully commercialize a product, we anticipate establishing strategic collaborations with larger organizations which have the

resources to compete effectively in these settings.



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, HE2000, HE2100, HE2200, HE2300, HE2400, IMMUNITIN, NEUMUNE, PHOSPHONOL, REVERSIONEX 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](http://www.holliseden.com). The reference to our website does not constitute incorporation by reference of the information contained on our website.

## **TECHNOLOGY DESCRIPTION**

### ***Immune Regulating Hormones***

Our primary technology development efforts are focused on a series of adrenal hormones and hormone analogs that we have labeled immune regulating hormones, or IRHs. We believe these IRHs are key components of the body's natural regulatory system that potentially can be useful in treating a wide variety of medical conditions. To date, these IRHs have demonstrated preclinical activity in protecting the bone marrow from the damaging effects of radiation and chemotherapy. In addition, IRHs 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. Further, based on preclinical results these compounds appear to be important in regulating metabolism and hormonally driven cancers. 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.

### ***Hematopoiesis***

One of our initial focus areas for these IRHs revolves around their role in the hematopoietic system. Hematopoiesis is the process by which the body produces a number of key blood cell types, including neutrophils and platelets. Neutrophils are white blood cells that are critical early responders used in combating foreign pathogens. When they are depleted, the host becomes highly susceptible to life-threatening infections. Similarly, a significant loss of platelets, which are key clotting elements in the blood, can lead to life-threatening bleeding episodes. Platelets have also recently been recognized as an important component of innate immunity.

Neutrophils and platelets are produced by the bone marrow. Radiation and chemotherapy can significantly damage bone marrow, which can lead to life-threatening complications.

A number of preclinical studies and initial clinical studies with our IRHs indicate that these compounds can increase both neutrophils and platelets. In addition, preclinical studies indicate the neutrophils that are produced following treatment with IRHs appear to be more effective at killing pathogens than untreated cells.

Mechanistically, IRHs appear both to increase the proliferative potential of residual bone marrow cells after injury and accelerate the rate at which new cells are generated. We believe this recovery of bone marrow cells may be attributable to the ability of NEUMUNE to increase CD34+ hematopoietic stem and progenitor cells, or HSPCs, as demonstrated in results from a Hollis-Eden sponsored preclinical study in rhesus monkeys. In addition, the ability of IRHs to regulate reactive oxygen species and reduce systemic inflammation may also contribute to preventing death of remaining bone marrow cells.

Because of these characteristics, IRHs have the potential to be quite useful in treating a variety of conditions in which the bone marrow is damaged.

### ***Role 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 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.

Our IRHs have been shown to regulate a broad array of inflammatory mediators. For example, we have conducted preclinical studies which indicate the ability of IRHs to regulate the nuclear transcription factor NF-kB that may be central to the beneficial effects seen with these compounds in preclinical models of type 2 diabetes and rheumatoid arthritis. In addition, our 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, IRHs appear to either maintain or boost a variety of immune responses in conditions of immune suppression, including innate and adaptive cell-mediated immunity.

### ***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 back towards homeostasis through the same feedback mechanism.

A wide variety of viruses including HIV, certain parasites such as malaria, and bacteria such as tuberculosis, have evolved ways of evading destruction by the immune system by causing the body to overproduce Th2 cytokines and underproduce Th1 cytokines. This in turn leads to a corresponding overproduction of cells unable to fight these pathogens and an underproduction of cells that can. A key element in this dysregulation is believed to be a state of chronic inflammation that is produced in these conditions.

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 the IRHs 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 IRHs 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 of 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 our proprietary series of IRHs. We have already generated indications of activity in human clinical trials with two of these compounds, NEUMUNE and IMMUNITIN, and two other compounds, HE3286 and HE3235, have now been selected for clinical development. 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 host of medical conditions.

In addition to the potential role for NEUMUNE in ARS, we believe there is also an opportunity for the compound in preventing or mitigating infections acquired in the healthcare setting. Numerous published preclinical studies indicate that NEUMUNE can significantly improve survival from lethal infections when administered prior to infectious challenge. While we have an open IND for the compound in this indication, in light of HHS' cancellation of its RFP described above, we have made the strategic decision to curtail further development of NEUMUNE and will focus our resources on HE3286, HE3235 and follow-on oral compounds for indications that have well defined clinical paths and large, well-established markets. If Congressional intervention or procurement activities by the Department of Defense improve the opportunity for NEUMUNE in the very short term we may revisit this decision. We will also consider licensing or selling the compound to third parties for further development.

### **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.



HE3286 is a next generation IRH that we are developing for the treatment of type 2 diabetes. The compound was discovered by our scientists in a pharmaceutical development program targeting metabolism.

Studies in rats fed with a diet containing the parent hormone of HE3286 showed a reduction in the expression levels of certain genes encoding key enzymes involved in glucose and cortisol metabolism (e.g. PEPCK or 11 $\beta$ -HSD1), an effect which should lessen the severity or impact of type 2 diabetes on insulin resistance. This indicates that this hormone is potentially central to glucose metabolism. Through the application of medicinal chemistry, we have extended the inherent properties of that hormone into a more pharmaceutically suitable compound, HE3286, for the treatment of type 2 diabetes.

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

When administered orally to genetically obese mice prone to diabetes (*db/db* model), HE3286, 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, HE3286 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, HE3286 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 HE3286 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 HE3286 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 HE3286 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 HE3286 to produce these metabolic effects, it was found that HE3286 regulates the pro-inflammatory NF- $\kappa$ B pathway in cultured mouse macrophages or 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- $\kappa$ B can also lead to insulin resistance and may play a role in the progression towards type 2 diabetes. The January 2007 issue of *Diabetologia* includes a new third party study regarding this pathway, which concludes that moderate inhibition of NF- $\kappa$ B improves glucose tolerance in animals and is a suitable therapeutic target for the treatment of 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-diabetic market. Glitazones appear to act primarily through the activation of a nuclear hormone receptor known as PPAR $\gamma$ . While these agents can lower blood glucose, they have been associated with undesirable side effects such as weight gain. In contrast, preclinical studies with HE3286 indicate that it does not act on the PPAR $\gamma$  receptor and does not have the undesirable effect of weight gain seen with the glitazone class. Therefore, these preclinical studies suggest that HE3286 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 HE3286 to treat type 2 diabetes is clear. 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.

HE3286 has demonstrated good oral bioavailability in non-human primates. In addition, preliminary results of GLP toxicology studies indicate the compound is well tolerated. Based on these findings, Hollis-Eden is preparing to file an Investigational New Drug application (IND) with the FDA for HE3286 for the treatment of type 2 diabetes.

### ***Rheumatoid Arthritis***

HE3286 is also being evaluated for clinical development in the treatment of rheumatoid arthritis. According to the Centers for Disease Control and Prevention, or CDCP, an estimated 46.1 million people were treated for 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 HE3286 include regulation of NF- $\kappa$ B and increasing the production of regulatory T cells (Treg cells). NF- $\kappa$ B 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 collagen-induced arthritis model (CIA), HE3286, 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 HE3286-treated animals compared to placebo.

HE3286 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 HE3286 or placebo. While the severity of arthritis worsened steadily in the placebo-treated group, it nearly resolved or remained at a minimum in the HE3286-treated group ( $p \leq 0.001$ ). Treatment resulted in a difference in arthritis severity that was on average 45% lower in the HE3286-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 industry and academia to test new agents as potential treatments for

rheumatoid arthritis.

### **HE3235**

We recently selected a new compound, HE3235, for clinical development in the area of hormone driven cancers. HE3235 appears to have good oral bioavailability in non-human primates. The lead indication we are pursuing is for hormone refractory prostate cancer (HRPC).

The incidence of HRPC is estimated at approximately 90,000 in the U.S., resulting in an estimated 36,000 deaths each year. Hormone therapy that blocks production of testosterone can effectively control prostate disease for a period of time. However, hormone therapy will eventually fail and the prostate cancer will continue to grow and spread. HRPC is a disease state represented by tumors that develop the ability to grow despite low levels of testosterone. HRPC cells appear to be able to utilize other endogenously produced adrenal steroids as tumor growth factors.

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 HRPC in humans, was used to identify lead compounds that would then be tested in a well accepted murine model for HRPC that utilizes human tumor cell lines.

In this mouse model, HE3235 reduced tumor incidence in a dose dependent fashion and, in the high-dose group, completely prevented tumor uptake (0/11), compared to 92% tumor incidence (11/12) in vehicle-treated animals.

These findings have now been extended into animals with established tumors. In this prostate model, mice with rapidly growing prostate tumors were randomized to receive treatment with either HE3235 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 7 times larger (370 mm<sup>3</sup>) than their initial size. In contrast, tumor growth in the HE3235 group was arrested at approximately 57 mm<sup>3</sup> ( $p < 0.001$ ), with 2 out of the 9 treated animals becoming completely tumor free.

Preliminary results from the first in a series of breast cancer studies further support the concept that HE3235 can block adrenal hormones that stimulate tumor growth. Rats were given the potent carcinogen N-methyl-N-nitrosourea to induce multiple breast tumors. Later in the experiment, animals with detected tumors were randomized to receive one of two strengths of HE3235 or to be assigned to a placebo control group. Treatment with HE3235 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 6 placebo controls developed one or more additional tumors, while not a single new tumor arose in the 10 animals treated with HE3235. This preventive action of HE3235 on the occurrence of new tumors also reached statistical significance ( $p < 0.01$ ).

In addition to further profiling HE3235 in cancer models, we have begun scaling up the manufacturing process in anticipation of conducting IND-enabling toxicology studies. Assuming results of these activities are successful, we anticipate filing an IND for HE3235 in late 2007 or early 2008.

### **NEUMUNE**

NEUMUNE has been under development as a treatment for acute radiation syndrome, or ARS, a condition for which there are no approved therapeutics. ARS, also referred to as radiation sickness, is a potentially fatal acute illness caused by high doses of radiation exposure over a significant portion of the body. This exposure results in the depletion of hematopoietic stem and progenitor cells in the bone marrow, which then leads to thrombocytopenia (loss of key clotting elements known as platelets), and neutropenia (loss of white blood cells known as neutrophils).

Thrombocytopenia increases the risk of uncontrolled bleeding, while neutropenia can significantly increase an individual's susceptibility to life threatening infections. Either of these conditions can

lead to death, which usually occurs in the first thirty to sixty days following radiation exposure. ARS also causes anemia (loss of oxygen carrying red blood cells) which can contribute to morbidity and mortality. If an individual can survive this initial period of insult, the bone marrow will generally return to normal production of these critical blood cell components.

We licensed certain patents related to NEUMUNE from Dr. Roger Loria, a professor of microbiology and immunology at Virginia Commonwealth University. We have been developing the compound in collaboration with the Armed Forces Radiobiology Research Institute, or AFRRI, an agency within the U.S. Department of Defense. AFRRI is a leader in studying the effects of radiation injury. Published studies by AFRRI with NEUMUNE in rodents have shown dramatic survival improvements in NEUMUNE-treated animals versus controls in models of radiation-induced immune suppression, leading AFRRI to identify NEUMUNE as its lead ARS candidate.

We have been developing NEUMUNE as a countermeasure to ARS under the FDA Animal Rule, which was adopted in 2002 for review of medical countermeasures to weapons of mass destruction. Traditional drug development programs require large-scale clinical studies to establish efficacy in humans in order for a drug candidate to be granted FDA approval. Under the Animal Rule, however, for indications in which it would be unethical to conduct efficacy studies in humans, as is the case with ARS, approval may be granted on the basis of efficacy in relevant animal species and safety in humans.

Pursuant to the Animal Rule, we have designed and conducted multiple efficacy studies in rhesus monkeys to assess the effect of NEUMUNE on mitigating the hematopoietic effects of ARS as well as on survival. To date, these studies indicate that NEUMUNE can provide benefit in non-human primate models across a wide range of radiation exposures, including lethal exposures, and in settings where no other medical support is administered, as well as in settings where supportive care can be provided.

In a sublethal model, studies conducted in rhesus monkeys exposed to 4 Gy of total body irradiation showed protection with NEUMUNE at doses ranging from 2.5 to 42.5 mg/kg. Published data from one of these studies, giving the compound once per day for 5 days by intramuscular injection at a dose of 15 mg/kg, showed the number of days of severe neutropenia were reduced from 12 to 3. In this study severe thrombocytopenia and severe anemia were eliminated.

High-dose radiation models were also conducted in rhesus monkeys with and without clinical support such as antibiotics, IV fluids and platelet transfusions. In the studies conducted without supportive care, 32.5% of the 40 control animals died versus only 12.5% of the 40 NEUMUNE treated animals. NEUMUNE-treated animals also required fewer platelet and blood transfusions and fewer antibiotic courses than placebo treated animals in the model where such supportive care was provided when needed. Animals receiving NEUMUNE experienced reductions in neutropenia, thrombocytopenia and anemia in both models.

In Phase I human safety studies conducted in the U.S. and The Netherlands, as of January 2007, a total of 129 volunteers had been enrolled including 57 in multi-dose studies designed to mimic the anticipated therapeutic regimen. One of these multi-dose studies included a separate cohort of healthy elderly subjects. An analysis of results from these studies indicates that the compound is generally well tolerated, with pain and swelling at the injection site being the most commonly reported adverse event. These healthy young and elderly volunteers also experienced a dose dependent increase in neutrophils and platelets during the multi-dose study. The magnitude of the increase in platelets and neutrophils in healthy volunteers was generally consistent with that seen in unirradiated monkeys when given doses of NEUMUNE that led to protection in radiation studies.

In light of the current risk of a terrorist attack with a nuclear or radiological weapon, we believe the market opportunity for a drug that could be used to ameliorate the effects of ARS could be significant. Further, because the compound could be stockpiled by government agencies, the cost of distribution could potentially be significantly less than for traditional pharmaceuticals. Our intent had been to secure procurement contracts for





NEUMUNE with both the Department of Health and Human Services (HHS) and the Department of Defense (DOD). However, in March 2007, after being notified on multiple occasions that we were in the competitive range for an active Request for Proposal (RFP), we were informed by HHS that NEUMUNE did not meet the technical requirements for this RFP. HHS then cancelled the solicitation in its entirety. While we believe DOD remains interested in procuring a drug candidate like NEUMUNE for bone marrow damage from ARS, they have not yet issued a RFP for this indication. Therefore, it is uncertain whether or when a market for NEUMUNE in ARS will materialize and as a result, we have curtailed our development activities in this indication until such time as the market opportunity becomes more clear.

If an agency within the federal government does ultimately decide to procure NEUMUNE, we also believe state and local governments, foreign governments and civilians may be interested in stockpiling the compound, if it is approved by the FDA for this indication.

We believe that a successful pivotal registration efficacy study in monkeys and a successful pivotal registration safety study in humans will be required prior to the submission of a New Drug Application, or NDA, for FDA approval. Accordingly, we would plan to meet with the FDA and other appropriate government agencies to gain concurrence on final protocol design for those studies prior to initiating any such activities.

### ***IMMUNITIN***

IMMUNITIN is a clinical-stage IRH that we have tested as a monotherapy in a number of infectious disease studies. Specifically, IMMUNITIN has been tested in a series of Phase I/II and Phase II clinical trials in HIV/AIDS patients in the U.S. and South Africa. In over 200 patients, IMMUNITIN treatment demonstrated an attractive safety profile. Results from studies in HIV-infected patients included long-lasting, statistically significant declines in a number of key inflammatory mediators, including TNF-alpha, IL-1 and IL-6, compared to placebo-treated patients, while increasing a wide variety of immune cell subsets associated with innate and cell-mediated immunity. In addition, patients receiving IMMUNITIN experienced a reduction in viral load.

In late-stage AIDS patients, IMMUNITIN-treated patients experienced a reduction in the number of opportunistic infections such as tuberculosis compared to those treated with placebo. We have also shown in a series of preclinical studies in models of tuberculosis that IMMUNITIN is effective when given as a monotherapy in either the acute or chronic phase of this bacterial infection. In addition, IMMUNITIN appears to have an additive effect when combined with the current three-drug regimen standard of care of antibiotic treatment for tuberculosis in this model system.

Based on favorable results in multiple preclinical malaria studies with the U.S. Navy with IMMUNITIN, we also undertook two Phase II clinical studies with the compound in malaria patients in Thailand. Results from these studies indicated that IMMUNITIN was effective at reducing parasite count and cleared malarial parasites in most patients within seven days.

The growing prevalence of infectious diseases such as HIV, malaria and tuberculosis in the developing world has created a significant need for affordable, effective therapies. While we believe our IRHs have a number of attributes that make them potentially useful globally, significant geo-political barriers-to-entry exist that make investment in this area difficult to justify currently. These barriers include compulsory licensing and lack of sufficient third party funding for research and development. Recently, a number of third party initiatives designed to provide funding for effective approaches to these diseases have appeared to gain momentum. If we are able to receive support from these initiatives for both development and commercialization, subject to obtaining regulatory approvals, marketing IMMUNITIN in developing countries could become commercially attractive.

### ***IRHs in Chemotherapy Protection***

Based on our knowledge of structure-activity relationships with this class of compounds, we are profiling next-generation IRHs that we believe may be well suited for use in chemotherapy protection in cancer patients. As with radiation injury, chemotherapy can damage the bone marrow, causing depletion of neutrophils and platelets, which can be life-threatening. Preclinical data in rhesus monkeys with IRHs in models of chemotherapy-induced immune suppression indicate that these IRHs could significantly protect both neutrophils and platelets.

### ***Additional IRHs in Other Autoimmune Disease***

Given the anti-inflammatory and immune regulating effects seen with IRHs in preclinical and early clinical trials, we are also interested in exploring the potential for new IRHs in rheumatoid arthritis as well as other autoimmune indications.

These small molecule drug candidates are structurally similar to widely used corticosteroids, but unlike corticosteroids they do not appear to cause immune suppression or bone loss two common side effects of corticosteroids. Statistically significant anti-inflammatory effects have been demonstrated with our IRHs in *in vivo* models of pleurisy, a model of lung inflammation, experimental autoimmune encephalomyelitis, (EAE), which is a model of multiple sclerosis, and lipopolysaccharide challenge, a lethal model of endotoxic shock.

In addition to these anti-inflammatory properties, IRHs were 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 IRHs 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.

### ***IRHs in Pulmonary Diseases***

Inflammation and infection in the lungs are common to many serious diseases, such as asthma, chronic obstructive pulmonary disease, or COPD, and cystic fibrosis, or CF. CF is a fatal genetic disease associated with chronic pulmonary infections and intense airway inflammation. The anti-inflammatory and immune regulating activity of IRHs has already shown benefit in several preclinical models of pulmonary infection and inflammation including the CFTR mouse model of CF and the LPS induced lung injury model. We are collaborating with Cystic Fibrosis Foundation Therapeutics, the non-profit drug discovery and development arm of the Cystic Fibrosis Foundation, to develop a new anti-inflammatory agent for use in CF. If we are able to successfully develop a compound for CF, there may also be opportunities to pursue other pulmonary indications for this type of drug.

### **Competition**

Given the large market opportunities for products that treat the indications for which we are developing our IRHs, most major pharmaceutical companies and many biotechnology companies have programs directed toward finding drugs to treat indications we are exploring. In the field of hematopoiesis, the leading products on the market designed to enhance the production of neutrophils in patients receiving chemotherapy treatment are Neupogen and Neulasta from Amgen and Leukine from Schering. Other companies also have products either on the market or in development to enhance hematopoiesis.

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, our immune regulating hormones appear to affect multiple cytokines and inflammatory mediators in a physiologic way that may make them more attractive drug candidates than currently available therapies.

In infectious disease, most current approaches are targeted at creating pathogen-specific compounds rather than drugs that target correcting dysregulations in the immune system. As described above, while these approaches have had success, their limitations in the areas of side effects, resistance and cost have become increasingly recognized. In addition, we believe they can be expected to have different profiles than our compounds and may therefore be complementary to our efforts. Companies like GlaxoSmithKline, Merck and Abbott have developed drugs for treating infectious diseases such as HIV, and many other drugs candidates are in development.

In metabolism and type 2 diabetes, there are a number of drugs such as Actos<sup>®</sup> from Takeda Pharmaceuticals and Avandia<sup>®</sup> from GlaxoSmithKline already approved for improving insulin sensitivity, and additional drugs are in development. While, based on preclinical study results, we have identified certain potential advantages of HE3286 over currently marketed drugs in this area, there can be no assurance that these advantages will be observed in human clinical trials. Even if these advantages are found in humans, there can be no assurance our compound can be successfully developed or marketed.

## **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.

## Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

*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.

As described above, for NEUMUNE in the setting of Acute Radiation Syndrome, we may apply for approval based upon a rule adopted by the FDA in 2002, titled *Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible* (Part 314, Subpart I), which is also referred to as the Animal Rule. Pursuant to this new rule, in situations where it would be unethical to conduct traditional Phase II and Phase III efficacy studies in humans, as is the case with countermeasures to a number of weapons of mass destruction, the FDA will review new drugs for approval on the basis of safety in humans and efficacy in relevant animal models.

*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 license to numerous U.S. and foreign patents and foreign 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 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 license technology designed around such patents or 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. We may need to acquire licenses under patents belonging to others for technology potentially useful or necessary to us. If any such licenses are required, we cannot be certain that they will be available on terms acceptable to us, if at all. 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. Dr. Loria exclusively licensed to us all rights to NEUMUNE and HE2200, together with all related patents and patent applications. This agreement was amended on April 9, 2002 and on December 12, 2006. Dr. Loria is a Professor of Microbiology and Immunology at Virginia Commonwealth University.

In January 2000, we entered into two agreements with Patrick T. Prendergast, Colthurst Ltd. and Edenland, Inc. The first agreement assigned to us ownership of all patents, patent applications and current or future improvements of the IMMUNITIN (HE2000) technology. Under the second agreement, the Sponsored Research and License Agreement, Edenland exclusively licensed to us a number of additional compounds, together with all related patents and patent applications. In connection with a recent settlement of a dispute, the Sponsored Research and License Agreement was terminated, and all technology previously licensed thereunder, (which does not include IMMUNITIN or any other IRH s being developed by us), reverted back to Edenland.

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 to Hollis-Eden from 1999 to mid-2003.

In February 2004, we acquired 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, which are currently in the preclinical stages of development 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.

## Employees

As of March 1, 2007, we had 66 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 March 1, 2007 are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Richard B. Hollis	54	Chairman of the Board, President and Chief Executive Officer
Daniel D. Burgess	45	Chief Operating Officer and Chief Financial Officer
James M. Frincke, Ph.D.	56	Chief Scientific Officer
Steven A. Gordziel, Ph.D.	60	Vice President, Product Development
Eric J. Loumeau	44	Vice President, Corporate General Counsel
Robert L. Marsella	54	Sr. Vice President, Business Development and Marketing
Christopher L. Reading, Ph.D.	59	Executive Vice President, Scientific Development
Dwight R. Stickney, M.D.	64	Vice President, Medical Affairs
Robert W. Weber	56	Chief Accounting Officer and Vice President Controller

**Richard B. Hollis** founded Hollis-Eden in August 1994. Mr. Hollis currently serves as our Chairman, President and Chief Executive Officer. 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.

**Daniel D. Burgess** became Chief Operating Officer and Chief Financial Officer of Hollis-Eden in August 1999. Mr. Burgess joined Hollis-Eden from Nanogen Inc., where he served as Vice President and Chief Financial Officer. Prior to joining Nanogen in 1998, Mr. Burgess spent ten years with Gensia Sicor, Inc. (acquired by Teva Pharmaceutical Industries Limited) and Gensia Automedics, Inc., a partially owned subsidiary of Gensia Sicor. He served as President and a director of Gensia Automedics, where he was responsible for all functional areas of this medical products company. In addition, he was Vice President and Chief Financial Officer of Gensia Sicor, where he was responsible for finance, investor relations, business development and other administrative functions. Prior to joining Gensia, Mr. Burgess held positions at Castle & Cooke, Inc. and Smith Barney, Harris Upham and Company. He received a degree in Economics from Stanford University and an MBA from Harvard Business School. Mr. Burgess is a member of the Boards of Directors of Santarus, Inc. and Metabasis Therapeutics, Inc.

**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, and to Chief Scientific Officer in December 2001. 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.

**Steven A. Gordziel, Ph.D.**, joined Hollis-Eden in 2004 as Vice President, Product Development. Prior to joining Hollis-Eden, Dr. Gordziel was Vice President of Pharmaceutical Development at Penwest Pharmaceutical Company from 2002 to 2004. At Penwest, he managed a team of 30 members responsible for formulation development, analytical development and validation, stability evaluation, scale up and process development and preparation of clinical supplies for regulatory filings and clinical studies. Previously, Dr. Gordziel was Vice President, Development Research, for the Wallace Pharmaceuticals Division of Carter Wallace, Inc. where he was employed from 1979 to 2002. With Carter Wallace for more than 20 years, Dr. Gordziel had the opportunity to build the company's product development capabilities and assume increasing management responsibility in all aspects of product development. During this time Dr. Gordziel was heavily involved in numerous Investigational New Drug (IND) and New Drug Application (NDA) submissions. Dr. Gordziel began his career at Ortho Pharmaceuticals and Wyeth Laboratories as a formulations scientist. He earned a B.S. in Pharmacy from the Philadelphia College of Pharmacy, and his Ph.D. in Pharmaceutical Chemistry from the University of Connecticut, Storrs.

**Eric J. Loumeau** became Vice President, Corporate General Counsel in September 1999. Mr. Loumeau joined Hollis-Eden from the law firm of Cooley Godward LLP, where he had primary responsibility for Hollis-Eden's account for the previous four years. As a partner at Cooley Godward, Mr. Loumeau represented a number of private and public companies in corporate and securities law matters. He joined the firm in 1995 from Skadden, Arps, Slate, Meagher and Flom, where he was an associate for four years. Mr. Loumeau attended Harvard Law School and the University of California, Berkeley, Boalt Hall School of Law, where he received a J.D. degree. He holds a B.S. degree in Business Administration with an emphasis in finance from Brigham Young University.

**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 25 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 for four 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 and was promoted to Executive Vice President, Scientific Development in March 2002. Prior to joining Hollis-Eden, Dr. Reading was Vice President of Product and Process Development at Novartis Inc.-owned SyStemix Inc. During this time, he successfully filed three investigational new drug applications (INDs) in the areas of stem cell therapy technology and stem cell gene therapy for HIV/AIDS. Prior to joining SyStemix, Dr. Reading served on the faculty of the M.D. Anderson Cancer Center in Houston for nearly 13 years. His positions there included Associate and Assistant Professor of Medicine in the Departments of Hematology and Tumor Biology. During his career, Dr. Reading has given more than 25 national and international scientific presentations, published more than 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.** was appointed Vice President, Medical Affairs in March 2003. He joined Hollis-Eden as Medical Director, Oncology in May 2000. 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 Forrester's Cancer Research Laboratory and on the Board of Directors of the California Division of the American Cancer Society. Earlier in his career, Dr. Stickney held positions with Burroughs Wellcome and the Centers for Disease Control, and academic teaching appointments at The University of California at Los Angeles and The University of California at Riverside. He has also served as a consultant for a number of biotechnology companies on the design and conduct of clinical trials. Dr. Stickney 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 Diplomate of the American Board of Internal Medicine and Hematology and a Diplomate of the American Board of Radiology, Therapeutic Radiology.

**Robert W. Weber** joined Hollis-Eden in March 1996 and currently serves as Chief Accounting Officer and Vice President–Controller. Mr. Weber has over twenty-five 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 diseases and disorders in which the body is unable to mount an appropriate immune response. 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 be 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. 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. 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 \$191.5 million as of December 31, 2006. Our net losses for fiscal years 2006, 2005 and 2004 were approximately \$30.2 million, \$29.4 million and \$24.8 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 safe and effective drug candidates may never be developed into commercially successful drugs. If we are unable to develop safe, commercially viable drugs, we may never achieve profitability. If we become profitable, we may not remain profitable.

*The market for treating acute radiation syndrome is uncertain as are our development plans and timelines for NEUMUNE.*

We do not believe any drug has ever been approved and commercialized for the treatment of acute radiation syndrome. In addition, the incidence of large-scale exposure to nuclear or radiological events has been low. Accordingly, even if NEUMUNE, our lead drug candidate to treat ARS, is approved by the FDA, we cannot predict with any certainty the size of this market. The initial potential market for NEUMUNE is largely dependent on the size of stockpiling orders, if any, procured by government agencies. While a number of governments have historically stockpiled drugs to treat indications such as smallpox, anthrax exposure, plague, tularemia and certain long-term effects of radiation exposure, we are unaware of any significant stockpiling orders for drugs to treat ARS. On December 9, 2005, the U.S. Department of Health and Human Services (HHS) issued a Request for Proposal (RFP), which specified an initial potential stockpiling order of up to 100,000 treatment courses, which is substantially lower than we had anticipated. We responded to the RFP in February 2006, and were informed in March 2007 that NEUMUNE was no longer in the competitive range for this RFP and that the RFP had been cancelled in its entirety. As a result of the decision by HHS to cancel the RFP, our development plans and timelines for NEUMUNE are uncertain and may not continue at all. In addition, even if NEUMUNE is approved by regulatory authorities, we cannot guarantee that we will receive any stockpiling orders for NEUMUNE, that any such order would be profitable to us or that NEUMUNE will achieve market acceptance by the general public.

*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. Companies such as Amgen Inc. have developed or are developing products to boost neutrophils or platelets after chemotherapy. A large number of companies, including Merck & Company, Inc., Pfizer Inc., Johnson & Johnson Inc. and Amgen Inc., are also developing and marketing new drugs for the treatment of chronic inflammatory conditions. A large number of

companies including Merck & Company, Inc., GlaxoSmithKline, TAP Pharmaceutical Products, Inc., and Eli Lilly and Co. are also developing and marketing new drugs for the treatment of type 2 diabetes. Companies such as GlaxoSmithKline, Merck & Company, Inc., Roche Pharmaceuticals, Pfizer Inc. and Abbott Laboratories have significant market share for the treatment of a number of infectious diseases such as HIV. In addition, biotechnology companies such as Gilead Sciences Inc., Chiron Corporation and Vertex Pharmaceuticals Inc., as well as many others, have marketed products or research and development programs in these fields.

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, 2006, our cash and cash equivalents totaled approximately \$67.1 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.***

## Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

We own or have obtained a license to numerous U.S. and foreign patents and foreign 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 on 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.

***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.

***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:

animal efficacy studies with NEUMUNE for the treatment of radiation exposure;

Phase I clinical trials with NEUMUNE in the United States and the Netherlands;

## Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Phase II clinical trials with IMMUNITIN in South Africa and Phase I/II clinical trials with IMMUNITIN in the United States for the treatment of HIV/AIDS; and

Phase II clinical trials with IMMUNITIN in Thailand for the treatment of malaria

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 our studies for our drug candidates:

we may not have the financial resources to continue research and development of any of our drug candidates; and

we may not be able to enter into collaborative arrangements relating to any drug candidate subject to delay in regulatory filing.

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 trial;

unfavorable efficacy results;

serious side effects experienced by study participants relating to the drug candidate;

new communications from regulatory agencies about how to conduct these studies; or

failure to raise additional funds.

***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.

***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 may have a significant impact on the market price of our common stock. 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; or

broader economic, industry and market trends unrelated to our performance

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 \$2.67 to \$16.50 between January 1, 2004 and March 9, 2007.

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 9% of our outstanding common stock as of December 31, 2006. Assuming that Mr. Hollis exercises all of his outstanding warrants and options that vest within 60 days of December 31, 2006, Mr. Hollis would beneficially own approximately 14% 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 2006.

---

**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 National Market System under the symbol HEPH.

The following table sets forth the quarterly high and low bid quotations and/or selling prices for our common stock from January 1, 2005 through March 9, 2007.

2005		
First Quarter	\$ 9.62	\$ 6.65
Second Quarter	8.62	6.50
Third Quarter	11.17	6.11
Fourth Quarter	6.17	4.53
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		
January 1 - March 9	\$ 6.24	\$ 2.67

**Performance Measurement Comparison<sup>(1)</sup>**

The following graph compares changes through December 31, 2006, 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 and 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 9, 2007, the closing price of our common stock as reported by the Nasdaq National Market System was \$2.83 share. There were approximately 12,000 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 sales of unregistered equity securities in the fourth quarter 2006.

We made no repurchases of our securities during the year ended December 31, 2006.

**Item 6. Selected Financial Data**

The following data summarizes certain selected financial data for each of the five years ended December 31, 2006 through 2002 and the period from inception (August 15, 1994) to December 31, 2006. 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).

	<u>2006</u>	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>Period from Inception (Aug. 15, 1994) to December 31, 2006</u>
<b>Statement of Operations Data:</b>						
Contract revenues	\$ 444	\$ 56	\$ 63	\$	\$	\$ 563
Research and development	23,764(3)	18,342	18,488	10,306	12,895	126,310
General and administrative	9,644(3)	9,777	7,216	7,785(1)	4,975	68,090
Settlement of dispute		3,000				3,000
Total operating expenses	33,408	31,119	25,704	18,091	17,870	197,400
Interest Income (Expense)	2,741	1,622	917	49	389	13,008
Other income (expense)	(8)		(33)	(7,629)(2)	(21)	(7,691)
Net loss	\$ (30,231)	\$ (29,441)	\$ (24,757)	\$ (25,671)	\$ (17,502)	\$ (191,520)
Net loss per share, basic and diluted	\$ (1.20)	\$ (1.46)	\$ (1.28)	\$ (1.67)	\$ (1.35)	
Weighted average number of common Shares outstanding, basic and diluted	25,131	20,125	19,267	15,381	12,932	
<b>Balance Sheet Data:</b>						
Cash and equivalents	\$ 67,135	\$ 45,130	\$ 61,991	\$ 84,852	\$ 13,087	
Total assets	68,512	46,582	63,242	85,381	13,982	
Total Current Liabilities	6,734	7,708	5,008	3,329	2,950	
Stockholders' equity	\$ 61,778	\$ 38,874	\$ 58,234	\$ 82,052	\$ 11,032	

- (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 income 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 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 report. This discussion and analysis should be read in conjunction with the financial statements and notes included elsewhere in this report.*

**General**

We are a development-stage pharmaceutical company engaged in developing a proprietary new class of small molecule compounds based on our hormonal signaling technology platform. These compounds, metabolites or synthetic analogs of adrenal steroid hormones, are designed to restore the biological activity of cellular signaling pathways disrupted by disease and aging. In investigational studies, they have been demonstrated in humans to possess several properties with potential therapeutic benefit: they regulate innate and adaptive immunity, reduce nonproductive inflammation, and stimulate cell proliferation.

We have been unprofitable since our inception. As of December 31, 2006, we had an accumulated deficit of approximately \$191.5 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 (the "Merger"), 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, 2006, we have incurred approximately \$126.3 million in research and development expenses, \$68.1 million in general and administrative expenses, and \$3.0 million in a settlement of dispute. From inception through December 31, 2006 we have generated approximately \$0.6 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 \$5.3 million in other income. The other income and expense is comprised of \$7.6 million in deemed discount expense and \$0.4 million in interest expense. These expenses have been offset by \$13.4 million in interest income. The combination of these resulted in a net loss of \$191.5 million for the period from inception until December 31, 2006.

Research and development and general and administrative expenses include the expense for stock-based compensation for the year ended December 31, 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).

## Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Research and development expenses were \$23.8 million, \$18.3 million and \$18.5 million in 2006, 2005 and 2004, respectively. The research and development expenses relate primarily to the ongoing development, preclinical testing, clinical trials for our drug candidates, and patent expenses. Research and development expenses increased \$5.4 million in 2006 compared to 2005. The increase in research and development expenses



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 candidate, NEUMUNE, through development. Research and development expenses decreased \$0.1 million in 2005 compared to 2004. The decrease in research and development expenses was mainly due to our investment in Congressional Pharmaceutical Corporation (CPC), which was expensed as in-process R&D in the first quarter of 2004, and there was no such investment in 2005.

General and administrative expenses were \$9.6 million, \$9.8 million and \$7.2 million in 2006, 2005 and 2004, respectively. General and administrative expenses relate to salaries and benefits, facilities, legal, accounting/auditing, investor relations, consultants, insurance and travel. 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. General and administrative expenses increased \$2.6 million in 2005 compared to 2004 primarily as a result of increased legal fees associated with certain legal proceedings. 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, \$1.6 million and \$0.9 million in 2006, 2005 and 2004, respectively. During 2006 and 2005, we earned interest income totaling \$2.7 million and \$1.6 million, respectively. The interest income increase in 2006 compared to 2005 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):

Contractual Obligations	Payments Due by Period				
	Total	Less than one year	One to three years	Three to five years	More than five years
Operating Leases	\$ 3,428	\$ 1,089	\$ 2,327	\$ 12	\$

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 small amount received under the CFFT collaboration. 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, 2006, our cash and cash equivalents totaled approximately \$67.1 million.

Our future capital requirements will depend upon many factors, including progress with preclinical testing and clinical trials, whether there are changes in our development plans and timelines for our drug candidate NEUMUNE as a result of HHS's decision to exclude our proposal from the competitive range and cancel the RFP in its entirety, 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 2004, 2005 or 2006.

In December 2006, the FASB issued FASB Staff Position ( FSP ) No. EITF 00-19-2, *Accounting for Registration Payment Arrangements*. This FSP 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 this FSP 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.

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

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 is currently analyzing the effects of the new standard and its potential impact on its 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. The Company is currently analyzing the effects of the new standards, and its potential impact on its financial statements.

#### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

At December 31, 2006, 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**

	<u>Page</u>
<u>Balance Sheets as of December 31, 2006 and 2005</u>	38
<u>Statements of Operations for the Fiscal Years Ended December 31, 2006, December 31, 2005, December 31, 2004 and the Period From Inception (August 15, 1994) to December 31, 2006</u>	39
<u>Statements of Stockholders' Equity for the Fiscal Years Ended December 31, 1994, December 31, 1995, December 31, 1996, December 31, 1997, December 31, 1998, December 31, 1999, December 31, 2000, December 31, 2001, December 31, 2002, December 31, 2003, December 31, 2004, December 31, 2005, and December 31, 2006</u>	40
<u>Statements of Cash Flow for the Fiscal Years Ended December 31, 2006, December 31, 2005, December 31, 2004 and the Period from Inception (August 15, 1994) to December 31, 2006</u>	43
<u>Notes to Financial Statements</u>	44
<u>Report of Independent Registered Public Accounting Firm</u>	69

**Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Balance Sheets**

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(In thousands,</b>	
	<b>except par value )</b>	
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 67,135	\$ 45,130
Prepaid expenses	188	204
Deposits	39	52
Other receivable		8
Receivable from related party	4	7
	<u>67,366</u>	<u>45,401</u>
Total current assets	67,366	45,401
Property and equipment, net of accumulated depreciation of \$990 and \$740	1,051	1,116
Receivable from related party		4
Deposits	61	61
Restricted cash	34	
	<u>68,512</u>	<u>46,582</u>
Total assets	\$ 68,512	\$ 46,582
<b>LIABILITIES AND STOCKHOLDERS EQUITY:</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,734	\$ 7,515
Deferred revenue		193
	<u>6,734</u>	<u>7,708</u>
Total current liabilities	6,734	7,708
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; 28,971 and 20,782 shares issued and 28,913 and 20,723 outstanding respectively	290	208
Paid-in capital	253,354	200,301
Cost of treasury stock (59 shares)	(346)	(346)
Deficit accumulated during development stage	(191,520)	(161,289)
	<u>61,778</u>	<u>38,874</u>
Total stockholders' equity	61,778	38,874
Total liabilities and stockholders' equity	\$ 68,512	\$ 46,582

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
	2006	2005	2004	Inception (Aug. 15, 1994) to December 31, 2006
	( In thousands, except per share amounts)			
Revenue:				
Contract R&D revenue	\$ 444	\$ 56	\$ 63	\$ 563
Total revenue	444	56	63	563
Operating expenses:				
Research and development				
R & D operating expenses	22,177	18,342	18,485	119,056
R & D costs related to common stock and stock option grants for collaborations and technology purchases	1,587		3	7,254
Total research and development	23,764	18,342	18,488	126,310
General and administrative				
G & A operating expenses	7,365	9,746	7,083	53,439
G & A costs related to options / warrants granted	2,279	31	133	14,651
Total general and administrative	9,644	9,777	7,216	68,090
Settlement of dispute		3,000		3,000
Total operating expenses	33,408	31,119	25,704	197,400
Other income (expense):				
Loss on disposition of assets	(8)		(33)	(64)
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures				(7,627)
Interest income	2,741	1,622	917	13,396
Interest expense				(388)
Total other income, net	2,733	1,622	884	5,317
Net loss	\$ (30,231)	\$ (29,441)	\$ (24,757)	\$ (191,520)
Net loss per share, basic and diluted	\$ (1.20)	\$ (1.46)	\$ (1.28)	
Weighted average number of common shares outstanding, basic and diluted	25,131	20,125	19,267	

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		Common stock		Capital in excess of par value	Cost of Repurchased		Total
	at par value		at par value			Common Stock	Deficit accumulated during development stage	
	Shares	Amount	Shares	Amount				
( 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
Deferred compensation stock options (Note 9)								
Amortization of deferred compensation					282			282
Exercise of stock options					1			1
Net loss							(5,253)	(5,253)
Balance at December 31, 1997			6,772	68	14,759		(7,894)	6,933
Exercise of warrants			399	4	1,196			1,200
Exercise of stock options			53	1	155			156
Private Placement, net of expenses (Note 7)	4		1,329	13	19,877			19,890
Warrants issued for services in lieu of cash (Note 10)					408			408
Stock issued for license fee (Note 6)			33		500			500
Stock issued for services in lieu of cash			6		95			95
Options issued for services in lieu of cash (Note 9)					240			240
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

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

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)

## Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

## Statements of Stockholders Equity (Continued)

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

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Net loss							(25,671)	(25,671)
Balance at December 31, 2003		19,272	193	189,296	(59)	(346)	(107,091)	82,052

## Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

## Statements of Stockholders Equity (Continued)

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

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

## Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

## Statements of Cash Flows

	2006	2005	2004	Period from Inception (Aug. 15, 1994) to December 31, 2006
	<u>2006</u>	<u>2005</u>	<u>2004</u>	<u>2006</u>
Cash flows from operating activities:				
Net loss	\$ (30,231)	\$ (29,441)	\$ (24,757)	\$ (191,520)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	294	303	218	1,390
Disposal of assets	8		33	71
Compensation expense related to equity awards	3,627			3,627
Amortization of deemed discount on convertible debentures				6,470
Amortization of deferred issuance cost				1,157
Common stock issued for 401k/401m plan	225	151	147	1,042
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	136	2,859
Expense related to warrants issued as consideration to consultants	239			4,352
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		629	2,809
Deferred compensation expense related to options issued				1,210
Changes in assets and liabilities:				
Prepaid expenses	16	(28)	(42)	(188)
Deposits	14	(8)	(10)	(99)
Other receivable	8	1	(9)	
Other receivable from related party	7	(11)	18	(4)
Accounts payable, accrued expenses, and deferred revenue	(974)	2,700	1,679	7,378
	<u>(26,587)</u>	<u>(26,303)</u>	<u>(21,958)</u>	<u>(151,243)</u>
Net cash used in operating activities				
Cash flows provided by investing activities:				
Purchase of property and equipment	(237)	(458)	(930)	(2,512)
	<u>(237)</u>	<u>(458)</u>	<u>(930)</u>	<u>(2,512)</u>
Net cash provided by (used in) investing activities				
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	86	385	27	17,776
	<u>48,829</u>	<u>9,900</u>	<u>27</u>	<u>220,890</u>
Net cash provided by financing activities				
Net increase (decrease) in cash and equivalents	22,005	(16,861)	(22,861)	67,135
Cash and equivalents at beginning of period	45,130	61,991	84,852	
	<u>45,130</u>	<u>61,991</u>	<u>84,852</u>	



Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Cash and equivalents at end of period	\$ 67,135	\$ 45,130	\$ 61,991	\$ 67,135
	<b>_____</b>	<b>_____</b>	<b>_____</b>	<b>_____</b>
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 initial 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, 2006).

**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, 2006 the Company's cash equivalents are approximately \$67.1 million and are deposited primarily in a money market account with a large financial institution.

*Property and Equipment*

Property, plant 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, plant and equipment balances and corresponding lives were as follows:

<u>December 31</u>		
2006	2005	Lives

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

	(in thousands)		
Leasehold improvements	11	45	3 years
Machinery, equipment and information systems	1,812	1,593	5-7 years
Furniture and fixtures	218	218	5-7 years
<b>Total</b>	<b>2,041</b>	<b>1,856</b>	
Less: Accumulated depreciation	(990)	(740)	
	<b>\$ 1,051</b>	<b>\$ 1,116</b>	

Depreciation expense associated with property, plant and equipment was approximately \$294,000, \$303,000, and \$218,000, in 2006, 2005, and 2004 respectively.

**HOLLIS-EDEN PHARMACEUTICALS, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

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 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 2006.

***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 2006, 2005 or 2004.

***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

## Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

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, 2006 the Plan has 5,925,763 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, 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, 2006	December 31, 2005	December 31, 2004
Risk-free interest rate	4.75%	4.02%	3.34%
Expected dividend yield	0%	0%	0%
Expected life(2)	6.25 years	5 years	5 years
Expected volatility(3)	84%	86%	88%

## Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

- (1) Forfeitures are estimated as 2% based on historical experience.
- (2) The 2006 expected life is based on the safe-harbor method as described in SEC Staff Accounting Bulletin No. 107. The 2005 and 2004 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.

**HOLLIS-EDEN PHARMACEUTICALS, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

In November 2005, the Financial Accounting Standards Board 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 and 2004, our net loss per common share would have been adjusted to the following pro forma amounts.

	Year ended December 31,	
	2005	2004
Net loss As reported	\$ (29,441)	\$ (24,757)
Add: Stock-based employee compensation expense included in reported net loss	0	0
Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards	(3,926)	(4,241)
Net loss Pro forma	\$ (33,367)	\$ (28,998)
Basic and diluted net loss per share As reported	\$ (1.46)	\$ (1.28)
Basic and diluted net loss per share Pro forma	\$ (1.66)	\$ (1.51)

**401K 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 \$199,000, \$179,000, and \$147,000 in 2006, 2005 and 2004, 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.



*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.

*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

**HOLLIS-EDEN PHARMACEUTICALS, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

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

***Concentrations of Risk***

Financial instruments, which potentially expose the Company to concentrations of credit risk, consist primarily of cash and cash equivalents. The Company places its cash with high quality financial institutions. Cash 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 9,939,430, 8,253,374, and 7,813,643 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, 2006, 2005 and 2004 because their effect on net loss per share is anti-dilutive.

***Recent Accounting Pronouncements***

On July 13, 2006, the Financial Accounting Standards Board issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), 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. At this time the company does not anticipate that the affects of FIN 48 will be material to the 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. The Company is currently analyzing the effects of the new standard and its potential impact on its financial statements.

*Reclassifications*

Certain reclassifications have been made to the 2005, 2004 and Inception-to-date financial statements to conform to the current year's 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.

**HOLLIS-EDEN PHARMACEUTICALS, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

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 is being repaid on a bi-monthly basis.

**5. Income Taxes**

The Company has available a net operating loss carryforward of approximately \$156.7 million at December 31, 2006 which may be carried forward as an offset to taxable income, if any, in future years through its expiration in 2012 to 2026. The Company has a net deferred tax asset of approximately \$61 million at December 31, 2006 comprised of research and development credits and the net operating loss carryforward. The net deferred tax asset has 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 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 and for 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.

**HOLLIS-EDEN PHARMACEUTICALS, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

**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 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

**HOLLIS-EDEN PHARMACEUTICALS, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

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 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.

***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.



Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

In March 2002, the Company amended certain of its agreements with Aeson. Under the amendments, the Company paid Aeson \$1.2 million, which extended the initial date by which the Company could exercise its option to acquire the remainder of Aeson to September 30, 2002. Hollis-Eden also received additional equity

**HOLLIS-EDEN PHARMACEUTICALS, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

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 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 Task Force No. 99-12. In addition, if the Company achieves certain development milestones, it will be required to issue additional shares of our common stock to the former stockholders of CPC. In the event all of the milestones are achieved, the total number of additional shares that the Company would be required to issue to the former stockholders of CPC is 275,000, more than half of which would be issued only upon FDA approval of CPC's product. No such milestone has been met to date. Furthermore, upon regulatory approval and commercialization of products covered by the licensed intellectual property, the Company may be required to pay royalties to the former stockholders of CPC and the University of Chicago. Following the acquisition, Dr. Grdina agreed to an exclusive consulting arrangement with the Company in the fields of hematopoiesis and radiation and chemotherapy exposure.

*AFRRI Collaboration*

The Company performed work on two task orders that were issued under a collaboration with the Armed Forces Radiobiology Research Institute ( AFRRI ). Under these task orders, the Company conducted radiation studies with a subcontractor. The task orders committed AFRRI to reimburse the Company for \$2.0 million in subcontractor fees. The reimbursement amounts from AFRRI were recorded in the same timeline as the subcontractor fees, resulting in no impact on the statement of operations.

**HOLLIS-EDEN PHARMACEUTICALS, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

***Study Funding Agreement***

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

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

Revenue is recognized under this agreement on a percentage of completion method for each distinct agreed-upon event.

**7. Common Stock**

***Reverse Stock Splits***

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

***Common Stock Financings***

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

During May 1998, the Company completed a private financing totaling \$20.6 million in gross proceeds. The Company issued 1,329,201 shares of common stock, (of which 192,061 shares were subject to adjustment based on future average stock price ( Adjustable Common Stock )), 4,000

## Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

shares of 5% Series A Convertible Preferred Stock and warrants to purchase 1,437,475 shares of common stock in the financing. The warrants entitled the holders to purchase up to a total of 1,437,475 shares of common stock at a price of \$17.00 per share.

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

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

**HOLLIS-EDEN PHARMACEUTICALS, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

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

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

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

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

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

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

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

On June 7, 2006 the Company issued 35,000 shares of the Company's common stock to Aeson Therapeutics, Inc. (Aeson) in connection with the purchase of substantially all of Aeson's assets, resulting in an expense of \$180,000. Upon certain events, the Company may be obligated to issue an additional 165,000 shares.

**HOLLIS-EDEN PHARMACEUTICALS, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

The acquisition was expensed as in-process research and development. The company has not achieved any of the development milestones.

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

**8. Preferred Stock**

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

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

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

**9. Stock Options and Restricted Stock**

*Stock Options*

*1997 Stock Option Plan*



## Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

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

**HOLLIS-EDEN PHARMACEUTICALS, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)*****2005 Equity Incentive Plan***

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

On March 18, 2006 the Board of Directors amended and restated the 2005 Equity Plan to reserve an additional 500,000 shares for issuance, for a total of 6,000,000 reserved shares and 100,000 inducement shares. The amendment was approved by the Company's stockholders at the June 9, 2006 Annual Meeting of Stockholders. The approval of the amendment allows the Company to continue to grant stock options and other awards at levels determined appropriate by our Board of Directors. The following table summarizes stock option activity under the Plan and the 2005 Equity Plan for 1997 through 2006 (in thousands, except per share amounts):

	Shares	Price Per Share	
		Range	Weighted Average
1997			
Granted	518	\$ 6.75-8.70	\$ 7.13
Outstanding, December 31, 1997	518	\$ 6.75-8.70	\$ 7.13
1998			
Granted	341	13.25-16.75	14.52
Forfeited	100	8.70	8.70
Outstanding, December 31, 1998	759	\$ 6.75-16.75	\$ 10.24
1999			
Granted	776	10.56-16.63	12.70
Forfeited	61	14.06-14.63	14.63

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Outstanding, December 31, 1999	1,474	\$ 6.75-16.75	\$ 11.36
2000			
Granted	774	6.50-15.06	8.18
Exercised	1	6.75	6.75
Forfeited	24	6.75-15.13	14.22
	<u>          </u>	<u>          </u>	<u>          </u>
Outstanding, December 31, 2000	2,223	\$ 6.50-16.75	\$ 10.22

**HOLLIS-EDEN PHARMACEUTICALS, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

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

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

	<u>Shares</u> (in thousands)	<u>Weighted- Average Exercise Price per Share</u>	<u>Weighted- Average Remaining Contractual Term</u> (in years)	<u>Aggregate Intrinsic Value</u> (in thousands)
Outstanding, December 31, 2006	5,538	\$ 8.93	5.4	\$ 519
Exercisable on December 31, 2006	4,194	\$ 9.44	4.2	\$ 507

As of December 31, 2006, the total remaining shares of common stock available for grant under the 2005 Equity Plan is 387,313 (which includes 100,000 shares under the inducement pool).

**HOLLIS-EDEN PHARMACEUTICALS, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)****2005 Non-Employee Directors Equity Incentive Plan**

The 2005 Non-Employee Directors Equity Incentive Plan (the Non-Employee Directors Plan ) was approved by the Company s stockholders at the June 9, 2006 Annual Meeting of Stockholders. Under the Non-Employee Directors Plan, 150,000 shares of common stock have been reserved for issuance to non-employee directors and provides for the grant of nonstatutory stock options, stock appreciation rights, stock purchase awards, restricted stock awards, restricted stock unit awards, and other forms of equity compensation. The Board of Directors determines terms of the stock awards, including vesting requirements. The exercise price of all options granted under the Non-Employee Directors Plan must equal at least the fair market value on the date of grant. The options expire not later than ten years from the date of the grant and generally are exercisable ratably during the option holder s continued service period.

On March 18, 2006 the Board of Directors amended and restated the 2005 Directors Plan to reserve an additional 150,000 shares for issuance for a total of 300,000 shares reserved. The amendment was approved by the Company s stockholders at the June 9, 2006 Annual Meeting of Stockholders, and it allows the Company to continue to grant stock options and other awards at levels determined appropriate by the Board of Directors. The following table summarizes stock option activity under the Non-Employee Directors Plan for 2005 (in thousands, except per share amounts):

	Shares	Price Per Share	
		Range	Weighted Average
2005			
Granted	30	\$ 10.75	\$ 10.75
Outstanding, December 31, 2005	30	\$ 10.75	\$ 10.75
2006			
Granted	253	\$ 5.43-11.75	\$ 7.55
Outstanding, December 31, 2006	283	\$ 5.43-11.75	\$ 7.89

Shares (in thousands)	Weighted- Average Exercise Price per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
--------------------------	--	--	---------------------------------

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Outstanding, December 31, 2006	283	\$ 7.89	8.9	\$ 0
Exercisable on December 31, 2006	82	\$ 11.57	7.6	\$ 0

As of December 31, 2006, the total remaining shares of common stock available for grant under the 2006 Non-Employee Directors Equity Incentive Plan is 17,000 shares.

*Non-Plan Options*

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

In February 1997, as part of an employment agreement, the Company granted a non-statutory stock option to an executive to purchase 2,400,000 shares of the Company's common stock at a price of \$5.00 per share, which vested ratably over a six-year period. The intrinsic value of the options was \$1,848,000. As a result, the

**HOLLIS-EDEN PHARMACEUTICALS, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

Company recorded as deferred compensation a non-cash charge of \$1,848,000, which was being amortized ratably over the six-year vesting period. Through February 1999, the Company had amortized a total of \$641,333. In March 1999, the Company announced the resignation of this executive, at which time the Company and the executive agreed that the option would remain outstanding for a total of 1,200,000 shares, including the acceleration of vesting of 400,000 shares. This acceleration is considered to be a new grant of options and, as such, the Company took a one-time non-cash charge of \$4.9 million during the first quarter of 1999. No change was made to the terms of the option for the remaining 800,000 shares.

In March 1999, the Company granted a non-statutory stock option to purchase 300,000 shares to an officer at an exercise price of \$16.63.

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

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

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

The following table summarizes stock option activity not pursuant to the Plan for 1995 through 2006 (in thousands, except per share amounts):

	Shares	Price Per Share	
		Range	Weighted Average
1995			



Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

Granted	38	\$ 2.65-7.95	\$ 4.64
Outstanding, December 31, 1995	38	\$ 2.65-7.95	\$ 4.64
1996			
Granted	570	2.25	2.25
Outstanding, December 31, 1996	608	\$ 2.25-7.95	\$ 2.40
1997			
Granted	2,400	5.00	5.00
Forfeited	50	2.25	2.25
Outstanding, December 31, 1997	2,958	\$ 2.25-7.95	\$ 4.51

**HOLLIS-EDEN PHARMACEUTICALS, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

	Shares	Price Per Share	
		Range	Weighted Average
<b>1998</b>			
Exercised	53	\$ 2.25-5.30	\$ 2.93
Forfeited	50	2.25	2.25
	<u>          </u>	<u>          </u>	<u>          </u>
Outstanding, December 31, 1998	2,855	\$ 2.25-7.95	\$ 4.58
<b>1999</b>			
Granted	300	16.63	16.63
Exercised	10	7.95	7.95
Forfeited	1,220	2.25-5.00	4.95
	<u>          </u>	<u>          </u>	<u>          </u>
Outstanding, December 31, 1999	1,925	\$ 2.25-16.63	\$ 6.16
Outstanding, December 31, 2000	1,925	\$ 2.25-16.63	\$ 6.16
<b>2001</b>			
Exercised	10	2.25	2.25
	<u>          </u>	<u>          </u>	<u>          </u>
Outstanding, December 31, 2001	1,915	\$ 2.25-16.63	\$ 6.23
Outstanding, December 31, 2002	1,915	\$ 2.25-16.63	\$ 6.23
<b>2003</b>			
Forfeited	165	2.25	2.25
	<u>          </u>	<u>          </u>	<u>          </u>
Outstanding, December 31, 2003	1,750	\$ 2.25-16.63	\$ 6.60
<b>2004</b>			
Granted	90	10.79-11.70	11.30
	<u>          </u>	<u>          </u>	<u>          </u>
Outstanding, December 31, 2004	1,840	\$ 2.25-16.63	\$ 6.83
<b>2005</b>			
Granted	28	6.39-7.59	7.00
Exercised	22	2.25	2.25
	<u>          </u>	<u>          </u>	<u>          </u>
Outstanding, December 31, 2005	1,846	\$ 2.25-16.63	\$ 6.89
<b>2006</b>			
Exercised	28	\$ 2.25	\$ 2.25
Forfeited	220	2.25-11.70	3.10
	<u>          </u>	<u>          </u>	<u>          </u>
Outstanding, December 31, 2006	1,598	\$ 5.00-16.63	\$ 7.49

	Shares (in thousands)	Weighted- Average Exercise Price per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2006	1,598	\$ 7.49	2.2	\$ 312
Exercisable on December 31, 2006	1,562	\$ 7.46	2.1	\$ 312

**HOLLIS-EDEN PHARMACEUTICALS, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

For various price ranges, weighted average characteristics of outstanding stock options at December 31, 2006 were as follows:

Range of Exercise Prices	Outstanding options			Exercisable options	
	Shares	Remaining life (years)	Weighted average price	Shares	Weighted average price
\$ 2.25-\$ 5.29	1,850,600	2.9	\$ 4.82	1,811,710	\$ 4.81
\$ 5.30-\$ 6.50	1,775,543	7.6	\$ 5.89	671,783	\$ 6.28
\$ 6.75-\$10.56	1,625,807	3.8	\$ 8.94	1,532,925	\$ 8.99
\$10.69-\$14.97	1,647,708	5.8	\$ 12.83	1,306,867	\$ 12.98
\$15.06-\$17.83	519,500	2.2	\$ 16.53	513,626	\$ 16.53
Balance as of 12/31/2006	7,419,158	4.8	\$ 8.58	5,836,911	\$ 8.94

Options exercisable at December 31, 2006, 2005 and 2004 were 5,836,911, 5,500,215 and 4,867,670 at weighted average exercise prices of \$8.94, \$8.51 and \$8.14, respectively.

The weighted average, estimated fair values of employee stock options granted during the fiscal years ended December 31, 2006 and December 31, 2005 were \$4.22 and \$5.21 per share, respectively.

The total stock-based compensation expense included in our statement of operations for the fiscal years ended December 31, 2006 and December 31, 2005 was \$3.6 million and \$-0-, respectively. Of the \$3.6 million stock-based compensation expense, \$2.8 million relates to awards granted prior to January 1, 2006.

As of December 31, 2006, the unrecognized stock-based compensation expense related to non-vested options and restricted shares was approximately \$7.8 million which is expected to be recognized over a weighted average period of approximately 2.7 years. During the fiscal year ended December 31, 2006 the total intrinsic value of the stock options exercised was \$145,000. The total fair value of options vested during the fiscal years ended December 31, 2006 and December 31, 2005 were \$4.5 million and \$4.6 million, respectively. The Company issues new shares of common stock upon the exercise of stock options.

Cash proceeds and the intrinsic value related to stock options exercised during the fiscal years 2006 and 2005 to date, are provided in the following table (in thousands):

	Fiscal year Ended December 31,		
	2006	2005	2004
Proceeds from stock options exercised	\$ 86	\$ 124	\$ 16
Tax benefit related to stock options exercised(1)	NA	NA	NA
Intrinsic value of stock options exercised(2)	\$ 145	\$ 176	\$ 35

- (1) SFAS 123R requires that the excess tax benefits received related to stock option exercises be presented as financing cash inflows. We currently do not receive a tax benefit related to the exercise of stock options due to the Company's net operating losses.
- (2) The intrinsic value of stock options exercised is the amount by which the market price of the stock on the date of exercise exceeded the market price of the stock on the date of grant.

**HOLLIS-EDEN PHARMACEUTICALS, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)*****Restricted Stock***

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

<u>(Shares in thousands)</u>	<u>Shares</u>	<u>Weighted- Average Grant Date Fair Value</u>
Outstanding at beginning of year		
Granted	68	\$ 6.20
Vested		
Forfeited	4	\$ 6.20
	<u>        </u>	<u>        </u>
Outstanding December 31, 2006, nonvested	64	\$ 6.20

The market price of the common stock on the date of the grant was initially recorded as deferred compensation within the stockholders' equity section of the Company's balance sheet and subsequently is being amortized over the 4-year vesting period. During the fiscal year ended December 31, 2006, \$93,000 of compensation expense was amortized and is included in general and administrative and research and development expense in the statement of operations.

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

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

***IAC Management Warrants***

## Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

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

### *Representatives Warrants*

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

**HOLLIS-EDEN PHARMACEUTICALS, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

***Investor Relations Warrant***

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

***1998 Private Placement Warrants***

In connection with the May 1998 private placement, the Company issued warrants to purchase 1,437,475 shares of common stock at an exercise price of \$17.00 per share. The warrants were exercisable until May 2001. Of the warrants issued, 157,000 were issued as finders fees, and 1,280,475 were issued to the private placement investors. These warrants have expired.

***1999 Agent Warrants***

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

***1999 Consulting Warrant***

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

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



*2001 Consulting Warrants*

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

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

**HOLLIS-EDEN PHARMACEUTICALS, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

***2001 Private Placement Warrants***

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

As a finders fee, the Company issued two warrants to the placement agent for a total of 112,640 shares of common stock. One warrant has an exercise price of \$9.00 per share and the other an exercise price of \$12.00 per share. The value ascribed to these warrants based on the Black-Scholes pricing model was \$1.5 million and was included as a charge to equity. These warrants to purchase 68,329 shares of our common stock were previously exercised and the remaining unexercised warrants expired December 11, 2006.

***2002 Consulting Warrants***

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

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

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

***2003 Convertible Note and Warrants***

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

## Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

common stock which are exercisable at a price per share of \$6.71, subject to adjustment. The warrants are exercisable until February 25, 2007. Approximately half of these warrants have been exercised.

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

The placement agent received a warrant to purchase 73,684 shares of common stock having an exercise price of \$5.99 per share. This warrant is exercisable until February 25, 2008. The value ascribed to this warrant based on the Black-Scholes pricing model was \$0.4 million and was expensed as a non-cash charge. This warrant has not been exercised.

**HOLLIS-EDEN PHARMACEUTICALS, Inc.**

**(A Development Stage Company)**

**Notes to Financial Statements (Continued)**

***2003 Private Placement Warrants***

In connection with the June 2003 private placement, the Company issued warrants to purchase 192,456 shares of common stock to investors with an exercise price of \$15.45 per share. These warrants expire June 19, 2007. Approximately 13,000 warrants have been exercised and the remaining warrants have not been exercised.

As a finders fee, the Company issued a warrant with an expiration date of June 19, 2008 to the placement agent, for a total of 44,266 shares of common stock with an exercise price of \$13.22 per share. The value ascribed to this warrant based on the Black-Scholes pricing model was \$0.5 million and was charged to equity. This warrant has not been exercised.

***2004 Consulting Warrants***

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

The 2004 warrants were valued at a total of \$108,280 using the Black-Scholes pricing model. The value of the warrants is amortized according to the vesting period which approximates the period over which the services are performed. In 2004, \$102,860 was expensed and is included in the 2004 operating expenses. The additional \$5,420 was expensed in 2005, over the remaining vesting period.

***2005 Financing Warrants***

In connection with the June 2005 subscription agreement with a single institutional investor, the Company issued a four-year warrant to purchase up to an additional 266,667 shares of common stock at an exercise price of \$10.00 per share. The value ascribed to this warrant based on the Black-Scholes pricing model was \$1.8 million and was charged to equity. This warrant has not been exercised.

***2006 Financing Warrants***

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

issuance, and none have been exercised.

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

*2006 Consulting Warrants*

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

The 2006 warrants were valued at a total of \$40,320 using the Black-Scholes pricing model. The value of the warrants is amortized according to the vesting period which approximates the period over which the services are performed. In 2006, \$11,120 was expensed and is included in the 2006 operating expenses.

**HOLLIS-EDEN PHARMACEUTICALS, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

In December 2006, the Company issued a consulting warrant to purchase up to a total of 50,000 shares of the Company's common stock at an exercise price of \$5.52. The warrant was issued for consulting services performed for the Company. The warrants were valued at a total of \$215,000 using the Black-Scholes pricing model. The warrant vested immediately and was expensed in 2006. The expense is included in the 2006 operating expenses.

The following table summarizes stock warrant activity for 2004 through 2006 (in thousands, except per share amounts):

	Shares	Price Per Share	
		Range	Weighted Average
Outstanding, December 31, 2003	1,587	\$ 3.09-15.45	\$ 9.85
2004			
Issued	12	10.15-11.75	11.22
Exercised	6	4.72-10.10	5.15
Forfeited	6	4.72-10.10	6.99
Outstanding, December 31, 2004	1,587	\$ 3.09-15.45	\$ 9.82
2005			
Issued	267	10.00	10.00
Exercised	42	6.17	6.17
Forfeited	160	4.54-11.00	9.66
Outstanding, December 31, 2005	1,652	\$ 3.09-15.45	\$ 9.96
2006			
Issued	1,664	5.52-8.75	8.63
Exercised	10	3.09-6.23	3.22
Forfeited	787	3.09-12.00	10.25
Outstanding, December 31, 2006	2,519	\$ 5.52-15.45	\$ 9.02

For various price ranges, the following table summarizes the weighted average prices of outstanding warrants as of December 31, 2006 (in thousands, except per share amounts):

**Outstanding Warrants****Exercisable Warrants**

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

<u>Range of Exercise Prices</u>	<u>Shares</u>	<u>Weighted average price</u>	<u>Shares</u>	<u>Weighted average price</u>
\$ 5.01-\$10.00	2,296	8.43	2,296	8.43
\$10.01-\$15.00	44	13.22	44	13.22
\$15.01-\$20.00	179	15.45	179	15.45
Balance as of 12/31/2006	2,519	\$ 9.02	2,519	\$ 9.02

The weighted average fair value of warrants issued in fiscal years 2006, 2005 and 2004 were \$9.02, \$9.96 and \$9.82, respectively.

**HOLLIS-EDEN PHARMACEUTICALS, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)****11. Employment Agreement**

Pursuant to an employment agreement between Hollis-Eden and Mr. Richard B. Hollis entered into in November 1996 (the Hollis Employment Agreement), Mr. Hollis' annual base salary was increased to \$225,000 upon the consummation of the Merger, with bonuses, future salary increases and equity compensation as determined by the Hollis-Eden Pharmaceuticals Board of Directors. Effective January 1, 2006, Mr. Hollis' base salary was increased from \$500,000 to \$512,000. If Mr. Hollis' employment is terminated without cause, for insufficient reason or pursuant to a change in control (as such terms are defined in the Hollis Employment Agreement), Mr. Hollis will receive as severance (i) an amount equal to five times his then current annual base salary plus five times the amount of the bonus awarded to him in the prior calendar year, (ii) immediate vesting of all unvested stock options of Hollis-Eden Pharmaceuticals (or the surviving corporation in a change in control, if applicable) held by him and (iii) continued benefits under all employee benefit plans and programs for a period of three years. All of such payments are to be made in one lump sum within 30 days of termination. If Mr. Hollis' employment is terminated with cause or if Mr. Hollis resigns other than for sufficient reason, Mr. Hollis' compensation and benefits will cease immediately and Mr. Hollis will not be entitled to severance benefits.

**12. Leases**

Rental expenses for principal leased facilities under non-cancelable operating leases were approximately \$958,000, \$888,000, and \$902,000 for 2006, 2005 and 2004 respectively. Future minimum payments for operating leases are as follows (in thousands):

	<b>Operating Leases</b>
2007	\$ 1,089
2008	1,170
2009	1,157
2010	10
2011	2
<b>Total minimum lease payments</b>	<b>\$ 3,428</b>



**HOLLIS-EDEN PHARMACEUTICALS, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)****13. Supplementary Financial Data (Unaudited)****Interim Financial Information****(Unaudited)**

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

	<u>March</u>	<u>June</u>	<u>September</u>	<u>December</u>	<u>Year</u>
	(In thousands, except per share)				
<b>Year Ended December 31, 2006</b>					
R&D operating expenses	\$ 4,186	\$ 6,175	\$ 5,543	\$ 6,273	\$ 22,177
G&A operating expenses	2,105	1,688	1,370	2,202	7,365
Non-cash charges	1,294	1,012	1,094	465	3,865
Net loss	(6,919)	(8,117)	(7,265)	(7,930)	(30,231)
Net loss per share	(0.30)	(0.33)	(0.29)	(0.29)	(1.20)
Cash and cash equivalents	60,513	53,446	47,445	67,135	67,135
<b>Year Ended December 31, 2005</b>					
R&D operating expenses	\$ 5,298	\$ 4,022	\$ 4,050	\$ 4,972	\$ 18,342
G&A operating expenses	1,822	2,887	2,059	2,978	9,746
Non-cash charges	12	6	6	7	31
Net loss	(6,812)	(6,538)	(5,661)	(10,430)	(29,441)
Net loss per share	(0.35)	(0.33)	(0.27)	(0.50)	(1.46)
Cash and cash equivalents	54,198	55,908	51,451	45,130	45,130

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Hollis Eden Pharmaceuticals, Inc.

San Diego, California

We have audited the accompanying consolidated statements of financial condition of Hollis-Eden Pharmaceuticals Inc. (the Company) (a development stage company) as of December 31, 2006 and 2005, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Hollis-Eden Pharmaceuticals Inc. as of December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123R (SFAS No. 123R) Share-Based Payment, which addresses the accounting for stock-based payment transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Hollis-Eden Pharmaceuticals Inc.'s internal control over financial reporting as of December 31, 2006, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 5, 2007 expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Costa Mesa, California

March 5, 2007



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

Not applicable.

**Item 9A. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures*

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

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

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

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

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

pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;

provide reasonable assurance that transactions are recorded properly to allow for the preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and the Board of Directors of the Company;

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements; and

provide reasonable assurance as to the detection of fraud.

## Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

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

Management has assessed the effectiveness of Hollis-Eden's internal control over financial reporting as of December 31, 2006, based on the criteria for effective internal control described in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2006.

BDO Seidman LLP, the independent registered public accounting firm that audited the financial statements included in this Annual Report on Form 10-K, was engaged to attest to and report on management's assessment of the effectiveness of Hollis-Eden's internal control over financial reporting as of December 31, 2006. Its report is included herein.

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of

Hollis-Eden Pharmaceuticals, Inc.

San Diego, California

We have audited management's assessment, included in the accompanying *Management's Report on Internal Control over Financial Reporting*, that Hollis-Eden Pharmaceuticals, Inc. (the Company) maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A Company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the financial statements as of December 31, 2006 and 2005 and the related statements of operations, stockholders' equity and cash flows for each of the years in the three year period ended December 31, 2006 and for the period from inception (August 15, 1994) to December 31, 2006, and our report

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-K

dated March 5, 2007 expressed an unqualified opinion on those financial statements.

/s/ BDO Seidman, LLP

Costa Mesa, California

March 5, 2007

**Changes in Internal Control over Financial Reporting**

There were no changes in Hollis-Eden's internal controls over financial reporting that occurred during the quarter ended December 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

At its meeting on December 11, 2006, the Compensation Committee of the Board of Directors took the following actions with respect to the compensation of the Company's named executive officers (as defined in Regulation S-K item 402(a)(3)):

<u>Executive Officer</u>	<u>2007 Base Salary</u>	<u>2006 Bonus</u>
Richard B. Hollis	\$ 532,480	\$ 385,000
Chairman of the Board, President and Chief Executive Officer		
Daniel D. Burgess	343,252	66,010
Chief Operating Officer and Chief Financial Officer		
James M. Frincke, Ph.D.	298,480	57,400
Chief Scientific Officer		
Eric J. Loumeau	271,830	52,275
Vice President, Corporate General Counsel		
Christopher L. Reading, Ph.D.	260,104	50,020
Executive Vice President, Scientific Development		



---

**PART III**
**Item 10. Directors and Executive Officers of the Registrant**

See the section entitled "Executive Officers and Senior Management" in Part I, Item 1 hereof for information regarding executive officers and senior management.

The other information required by this item is incorporated by reference from Hollis-Eden's definitive Proxy Statement which is expected to be filed with the Commission pursuant to Regulation 14A in connection with the Hollis-Eden's 2007 Annual Meeting (the "Proxy Statement") not later than 120 days after the end of our fiscal year ended December 31, 2006.

**Item 11. Executive Compensation**

The information required by this item is incorporated by reference to the Proxy Statement.

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

The information regarding certain beneficial owners and management required by this item is incorporated by reference to the Proxy Statement.

The following table provides information as of December 31, 2006 with respect to all of our compensation plans under which we are authorized to issue equity securities of the company.

**Equity Compensation Plan Information**

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities in the first column)
Stock option equity compensation plans approved by security holders	5,821,450	\$ 8.89	404,249
Stock option equity compensation plans not approved by security holders	1,597,708	\$ 7.49	
Warrant equity compensation plans not approved by security holders	64,000	\$ 5.56	

Total	7,483,158	404,249
-------	-----------	---------

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

*Unregistered Sales of Equity Securities and Use of Proceeds*

We made no unregistered sales of securities or repurchases of our securities during the quarter ended December 31, 2006.

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

The information required by this item is incorporated by reference to the Proxy Statement.

**Item 14. Principal Accountant Fees and Services**

The information concerning Principal Accountant Fees and Services is set forth in the Proxy Statement under the heading "Ratification of Selection of Independent Auditors" in the Proxy Statement which information is incorporated herein by reference.

**PART IV**

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

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

1. *Financial Statements*: The information required by this item is included in Item 8 of Part II of this report.
2. *Financial Statement Schedules*: Financial statement schedules required under the related instructions are not applicable for the three years ended December 31, 2006, and have therefore been omitted.
3. *Exhibits*: The exhibits listed in the Exhibit Index attached to this report are filed or incorporated by reference as part of this Annual Report.

## SIGNATURES

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

HOLLIS-EDEN PHARMACEUTICALS, INC.

By: /s/ RICHARD B. HOLLIS  
Richard B. Hollis,

Chairman of the Board of Directors,

Chief Executive Officer, President and Director

Date: March 10, 2007

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ RICHARD B. HOLLIS <hr/> Richard B. Hollis	Chairman of the Board of Directors, Chief Executive Officer, President And Director	March 10, 2007
/s/ DANIEL D. BURGESS <hr/> Daniel D. Burgess	Chief Operating Officer/Chief Financial Officer (Principal Financial Officer)	March 10, 2007
/s/ ROBERT W. WEBER <hr/> Robert W. Weber	Chief Accounting Officer and Vice President Controller (Principal Accounting Officer)	March 10, 2007
/s/ JEROME M. HAUER <hr/> Jerome M. Hauer	Director	March 10, 2007
/s/ BRENDAN R. McDONNELL	Director	March 10, 2007

---

**Brendan R. McDonnell**

*/s/* THOMAS C. MERIGAN, JR. M.D.

Director

March 10, 2007

---

**Thomas C. Merigan, Jr. M.D.**

*/s/* MARC R. SARNI

Director

March 10, 2007

---

**Marc R. Sarni**

*/s/* SALVATORE J. ZIZZA

Director

March 10, 2007

---

**Salvatore J. Zizza**

INDEX TO EXHIBITS

Exhibit Number	Description of Document
*3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 4.1 to Registrant's Registration Statement on Form S-4 (No. 333-18725), as amended (the Form S-4)).
*3.2	Bylaws of Registrant (incorporated by reference to Exhibit 4.2 to the Form S-4).
*3.3	Certificate of Designation of Series B Junior Participating Preferred Stock (incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K dated November 15, 1999).
*3.4	Certificates of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.4 to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.)
*4.1	Rights Agreement dated as of November 15, 1999 among Registrant and American Stock Transfer and Trust Company (incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K dated November 15, 1999).
* 10.1	Registrant's 1997 Incentive Stock Option Plan (the Option Plan) as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
* 10.2	Forms of Incentive Stock Options and Nonstatutory Stock Options under the Option Plan (incorporated by reference to Exhibit 10.5 to the Form S-4).
* 10.3	Form of Nonstatutory Stock Options outside the Option Plan (including Annex I, identifying the officers and directors who are holders of such options and their respective option amounts and exercise prices), (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
* 10.4	Employment Agreement by and between Registrant and Richard B. Hollis dated November 1, 1996 (incorporated by reference to Exhibit 10.6 to the Form S-4).
* 10.5	Employment Agreement by and between Registrant and Robert W. Weber dated March 16, 1996 (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998).
* 10.6	Consulting Agreement and Warrant by and between Registrant and William H. Tilley and Jacmar/Viking, L.L.C. dated March 8, 1999 (incorporated by reference to Exhibit 10.5 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999).
* 10.7	Amendments to Consulting Agreement and Warrant by and between Registrant and William H. Tilley and Jacmar/Viking L.L.C. dated March 12, 2001 (incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
* 10.8	Nonstatutory Stock Option by and between Registrant and Terren S. Peizer effective as of February 6, 1997 (incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
* 10.9	Separation and Mutual Release Agreement by and between Registrant and Terren S. Peizer effective as of February 25, 1999 (incorporated by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999).
* 10.10	Nonstatutory Stock Option by and between Registrant and Richard B. Hollis effective as of January 1, 1999 (incorporated by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).

Exhibit Number	Description of Document
* 10.11	Promissory Note, as amended, by and between Registrant and Richard B. Hollis dated May 22, 1998 (incorporated by reference to Exhibit 10.11 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
* 10.12	Hollis-Eden Pharmaceuticals, Inc. Series A Warrant Agreement dated May 20, 1997, by and between Registrant and Richard B. Hollis, as amended on May 5, 2000 (incorporated by reference to Exhibit 10.12 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
* 10.13	Employment Agreement by and between Registrant and Daniel D. Burgess dated July 9, 1999 (incorporated by reference to Exhibit 10.10 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999).
* 10.14	Employment Agreement by and between Registrant and Eric J. Loumeau dated September 15, 1999 (incorporated by reference to Exhibit 10.11 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999).
* 10.15	Hollis-Eden Pharmaceuticals Unit Warrant, dated April 23, 1994, by and between Registrant and Salvatore J. Zizza, as amended on March 18, 2002 (incorporated by reference to Exhibit 10.15 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002).
*10.16	Settlement and Mutual Release Agreement, dated January 20, 2000, among Registrant, Colthurst Limited, Edenland, Inc. and Patrick T. Prendergast (incorporated by reference to Exhibit 99.2 to Registrant's Current Report on Form 8-K dated January 20, 2000).
*10.17	Technology Assignment Agreement, dated January 20, 2000, among Registrant, Colthurst Limited and Patrick T. Prendergast (incorporated by reference to Exhibit 99.3 to Registrant's Current Report on Form 8-K dated January 20, 2000).
*10.18	Common Stock and Warrant Agreement, dated January 20, 2000, among Registrant and Colthurst Limited (incorporated by reference to Exhibit 99.4 to Registrant's Current Report on Form 8-K dated January 20, 2000).
*10.19	Warrant, dated January 20, 2000, issued to Colthurst Limited (incorporated by reference to Exhibit 99.5 to Registrant's Current Report on Form 8-K dated January 20, 2000).
*10.20	Indemnification Agreement among Registrant and Executive Officers and Directors (incorporated by reference to Exhibit 10.17 to Registrant's Registration Statement on Form S-1 (No. 333-69454).
*10.21	Hollis-Eden Pharmaceuticals, Inc. Discretionary Contribution Plan and Trust Agreement (incorporated by reference to Exhibit 99.2 to Registrant's Registration Statement on Form S-8 (No. 333-92185)).
*10.22	Form of Stock and Warrant Purchase Agreement, dated as of December 11, 2001, between the Registrant and the purchasers listed on Schedule I attached thereto (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-3 (No. 333-75860)).
*10.23	Form of Warrant, dated December 11, 2001, issued to the purchasers listed on Schedule I thereto (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-3 (No. 333-75860)).
*10.24	Form of Warrant issued to H.C. Wainwright & Co., Inc. in the amounts and on the dates listed on Schedule I attached thereto (incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-3 (No. 333-75860)).



Exhibit Number	Description of Document
*#10.25	Patent License Agreement between the Registrant and Dr. Roger M. Loria (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-3 (No. 333-75860)). (the Loria License )
*10.26	Sublease dated December 19, 2001 between Cooley Godward LLP and Registrant (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001).
*10.27	Securities Purchase Agreement, dated as of February 25, 2003, by and between Hollis-Eden Pharmaceuticals, Inc. and the purchasers identified therein (incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.28	Form of 7.5% Convertible Debenture issued to the purchasers listed on Schedule I attached thereto on February 25, 2003 (incorporated by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.29	Form of Stock Purchase Warrant issued to purchasers listed on Schedule I attached thereto on February 25, 2003 (incorporated by reference to Exhibit 10.29 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.30	Registration Rights Agreement, dated February 25, 2003, by and between Hollis-Eden Pharmaceuticals, Inc. and the purchasers identified therein (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.31	Warrant, dated February 25, 2003, issued to SG Cowen Securities Corporation (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002).
*10.32	Registration Rights Agreement dated June 19, 2003, by and between Hollis-Eden Pharmaceuticals, Inc. and the purchasers identified therein. (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-3 (No. 333-106835)).
*10.33	Form of Stock Purchase Warrant issued to purchasers listed on Schedule I attached thereto on June 19, 2003 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-3 (No. 333-106835)).
*10.34	Warrant issued to SG Cowen Securities Corporation on June 19, 2003 (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-3 (No. 333-106835)).
*#10.35	Study funding Agreement, dated as of June 17, 2003, between the Registrant and Cystic Fibrosis Foundation Therapeutics, Inc (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003).
*10.36	Amendments to Consulting Agreement and Warrant by and between the Registrant and William H. Tilley and Jacmar/Viking, L.L.C. dated March 11, 2003 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003).
*10.37	Amended 401(k) Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003).
*10.38	First Amendment to Sublease dated December 19, 2001 between Cooley Godward LLP and Registrant (incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2004).
*10.39	Form of Common Stock Purchase Warrant issued on June 1, 2005 (incorporated by reference to Exhibit 10.41 to the Registrant's Current Report on Form 8-K dated June 2, 2005).
*#10.40	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant entered into on December 3, 2003 (incorporated by reference to Exhibit 10.42 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).

Exhibit Number	Description of Document
*#10.41	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant entered into on February 17, 2004 (incorporated by reference to Exhibit 10.43 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
*#10.42	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated July 12, 2004 (incorporated by reference to Exhibit 10.44 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
*#10.43	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated October 19, 2004 (incorporated by reference to Exhibit 10.45 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
*#10.44	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated January 6, 2005 (incorporated by reference to Exhibit 10.46 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
*#10.45	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated May 16, 2005 (incorporated by reference to Exhibit 10.47 to the Registrant's Amendment No. 1 on Form 10-Q/A to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005).
* 10.46	2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.47	Form of Option Agreement for use under 2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.48	Form of Restricted Stock Award Agreement for use under 2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.49	Form of Restricted Stock Unit Award Agreement for use under 2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.50	2005 Non-Employee Directors' Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.6 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
* 10.51	Form of Option Agreement for use under 2005 Non-Employee Directors' Equity Incentive Plan (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (No. 333-130670), filed December 23, 2005).
*#10.52	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Company dated November 30, 2005 (incorporated by reference to Exhibit 10.52 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005).
*10.53	Form of Stock Purchase Agreement dated as of February 2, 2006 (incorporated by reference to the Current Report on Form 8-K dated February 2, 2006) (the February 2006 Purchase Agreement).
*10.54	Form of Stock Purchase Warrant, issued pursuant to the February 2006 Purchase Agreement (incorporated by reference to the Current Report on Form 8-K dated February 2, 2006).

Exhibit Number	Description of Document
*10.55	Form of Stock Purchase Agreement dated as of November 7, 2006 (incorporated by reference to the Current Report on Form 8-K dated November 7, 2006) (the November 2006 Purchase Agreement ).
*10.56	Form of Common Stock Purchase Warrant, issued pursuant to the November 2006 Purchase Agreement (incorporated by reference to the Registrant's Current Report on Form 8-K dated November 7, 2006).
#10.58	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated December 11, 2006.
#10.59	Amendment to the Loria License dated December 12, 2006.
23.1	Consent of BDO Seidman, LLP.
31.1	Rule 13a-14(a)/15d-14(a) Certification of Richard B. Hollis.
31.2	Rule 13a-14(a)/15d-14(a) Certification of Daniel D. Burgess.
32.1	Section 1350 Certifications of Richard B. Hollis and Daniel D. Burgess.
*	Previously filed. Management contract or compensatory plan, contract or arrangement to be filed as an exhibit pursuant to Item 14(c) of Form 10-K.
#	Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.