

HOLLIS EDEN PHARMACEUTICALS INC /DE/

Form 10-K

March 16, 2006

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2005

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
of incorporation or organization)

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

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

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:

None

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

Common stock, \$.01 par value per share

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.

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

The aggregate market value of the voting stock held by nonaffiliates of the Registrant as of June 30, 2005, the end of Hollis-Eden Pharmaceuticals' most recently completed second fiscal quarter, was approximately \$170,660,049 based on the closing stock price of \$9.42 for the Registrant's Common Stock as reported by the Nasdaq National Market.

As of March 1, 2006, there were outstanding 24,804,085 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 pursuant to Regulation 14A in connection with the solicitation of proxies for our 2006 Annual Meeting of Stockholders to be held on June 9, 2006, are incorporated by reference into Part III of this Report.

Table of Contents

Hollis-Eden Pharmaceuticals, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2005

INDEX

	Page
<u>PART I</u>	
Item 1 <u>Business</u>	3
Item 1A <u>Risk Factors</u>	19
Item 1B <u>Unresolved Staff Comments</u>	26
Item 2 <u>Properties</u>	26
Item 3 <u>Legal Proceedings</u>	26
Item 4 <u>Submission of Matters to a Vote of Security Holders</u>	27
<u>PART II</u>	
Item 5 <u>Market for Registrant's Common Stock and Related Stockholder Matters</u>	28
Item 6 <u>Selected Financial Data</u>	29
Item 7 <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	30
Item 7A <u>Quantitative and Qualitative Disclosures About Market Risk</u>	33
Item 8 <u>Financial Statements and Supplementary Data</u>	34
Item 9 <u>Changes In and Disagreements with Accountants on Accounting and Financial Disclosure</u>	63
Item 9A <u>Controls and Procedures</u>	63
Item 9B <u>Other Information</u>	65
<u>PART III</u>	
Item 10 <u>Directors and Executive Officers of the Registrant</u>	66
Item 11 <u>Executive Compensation</u>	66
Item 12 <u>Security Ownership of Certain Beneficial Owners and Management</u>	66
Item 13 <u>Certain Relationships and Related Transactions</u>	67
Item 14 <u>Principal Accountants Fees and Services</u>	67
<u>PART IV</u>	
Item 15 <u>Exhibits and Financial Statement Schedules</u>	68
<u>Signatures</u>	69

Table of Contents

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 response. Our initial technology development efforts are primarily focused on a series of hormones and hormone analogs that we have labeled immune regulating hormones, or IRHs. We believe these natural 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 IRHs indicate that they have the ability to reverse bone marrow suppression, reduce non-productive inflammation and stimulate innate and adaptive immunity. In addition, these IRHs have a very attractive safety profile to date and are cost-effective to manufacture.

The initial commercial application we are pursuing with this class of compounds is focused on protecting the body from the acute effects of radiation injury. Our lead compound in this area is NEUMUNE (HE2100), which is being co-developed with the U.S. military. Because of the potential to use such an agent in Homeland Defense, there are a number of unique features in the development and commercialization process that we believe make NEUMUNE a particularly attractive initial commercial opportunity for us.

Specifically, unlike drug candidates for traditional medical indications, NEUMUNE may be reviewed for regulatory approval by the U.S. Food and Drug Administration, or 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, in addition to the potential to supply the U.S. military with NEUMUNE, we are pursuing an advance purchase contract under Project BioShield to provide NEUMUNE to the Strategic National Stockpile, or SNS, for use by first responders and civilians who may be at risk of radiation injury. Project BioShield is legislation which has allocated \$6 billion towards advance government purchase contracts for development stage compounds that may be useful as medical

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

countermeasures to weapons of mass destruction such as radiological or nuclear weapons. We believe that supplying NEUMUNE to the U.S. government under this program would also allow us initially to have significantly less commercial infrastructure than would be necessary to launch a new drug for a traditional indication.

We have generated a substantial amount of data regarding the safety and activity of NEUMUNE in the setting of radiation injury. This data indicates that NEUMUNE mitigates neutropenia (loss of white blood cells)

Table of Contents

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 FDA and have conducted three Phase I human clinical trials with NEUMUNE in the U.S. and The Netherlands indicating that NEUMUNE has an attractive safety profile. NEUMUNE also demonstrated statistically significant increases in both neutrophils and platelets in these human studies. We have also commenced work on scaling-up the manufacturing of NEUMUNE for potential commercial use.

Because of the attractive aspects of the market opportunity for drugs to treat radiation injury, in February 2004, we acquired an additional, non-IRH development-stage compound for radiation protection with our acquisition of Congressional Pharmaceutical Corporation, or CPC, and its lead product candidate, PHOSPHONOL (a phosphothioate). PHOSPHONOL is being evaluated for protection against the long-term complications of radiation exposure, such as genetic mutations that can lead to cancer.

Like exposure to radiation, many current cancer therapies can also cause damage to the bone marrow. As a result, we believe there may be a significant market opportunity for compounds similar to NEUMUNE in the area of protecting against the damaging effects of cancer chemotherapy. While this indication would require a more traditional and lengthy drug development, regulatory and commercialization process, we believe the market opportunity in this area is significant. We are currently conducting preclinical studies with second-generation compounds that we believe may be well suited for development in this indication.

We have also generated a large amount of preclinical data indicating that IRHs have a potential role to play in treating autoimmune conditions such as multiple sclerosis, asthma and arthritis. We are continuing to profile second-generation compounds in preclinical models for further development in autoimmune diseases. In addition, these IRHs may be useful in treating certain pulmonary diseases, as well as a range of metabolic conditions.

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

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. For certain therapeutic indications or geographic regions, we anticipate establishing strategic collaborations to commercialize these opportunities.

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. We maintain a website at www.holliseden.com. The reference to our worldwide web address does not constitute incorporation by reference of the information contained on our website.

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.

TECHNOLOGY DESCRIPTION

Immune Regulating Hormones

Our primary technology development efforts are focused on a series of 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, among other things, demonstrated significant preclinical activity in protecting the bone

Table of Contents

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. These 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 key 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.

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 initial results from a Hollis-Eden sponsored preclinical study. 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 cytokines, 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 cardiovascular disease and 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.

In the last several years 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

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

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 reactive oxygen species and pro-inflammatory cytokines involved in inflammation. In addition, our class of compounds has been shown in early clinical trials to

Table of Contents

produce long-lasting reductions in a number of key inflammatory mediators, including TNF-alpha, IL-1 beta and IL-6. Unlike most approaches to reducing inflammation, however, IRHs appear to 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, 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, 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.

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

As we age, and under conditions of stress and chronic infections, 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.

Table of Contents

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.

In the last several years, 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 complex 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, cardiovascular disease, 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. NEUMUNE is being co-developed with the U.S. military for use in protecting the body from Acute Radiation Syndrome, or ARS. A number of IRHs have shown significant benefits in preclinical models of chemotherapy-induced immune suppression, and we intend to test one of these compounds in Phase I/II clinical trials in this indication. In the infectious disease area, IMMUNITIN has shown activity in Phase II clinical trials in malaria, HIV and AIDS, and in a number of preclinical tuberculosis models. Furthermore, given the anti-inflammatory and immune regulating effects seen with many of our IRHs, we are screening second-generation IRHs in preclinical models of autoimmune conditions, pulmonary diseases and metabolic disorders. In addition, PHOSPHONOL, a non-IRH candidate, is being evaluated for protection against DNA mutations from radiation exposure and chemotherapy treatment.

NEUMUNE

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

NEUMUNE is being developed as a treatment for 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

Table of Contents

of radiation exposure over a significant portion of the body. This exposure results in the depletion of HSPCs, in the bone marrow, resulting in thrombocytopenia, loss of key clotting elements known as platelets, and severe neutropenia, loss of white blood cells known as neutrophils. Thrombocytopenia increases the risk of uncontrolled bleeding, while severe 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 exposure. Anemia or loss of oxygen carrying red blood cells can also contribute to morbidity and mortality from ARS. 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 are co-developing NEUMUNE with the Armed Forces Radiobiology Research Institute, or AFRRRI, an agency within the U.S. Department of Defense. AFRRRI is a leader in studying the effects of radiation injury. A principal AFRRRI mission is the development of pharmaceutical agents that can be used to prevent injury from radiation caused by a nuclear accident or event. Over the years, AFRRRI, has screened thousands of compounds in an effort to find a radioprotectant for ARS suitable for widespread use. Published studies by AFRRRI with NEUMUNE in rodents have shown dramatic survival improvements in NEUMUNE-treated animals versus controls in models of radiation-induced immune suppression, leading AFRRRI to identify NEUMUNE as its lead ARS candidate.

We are developing NEUMUNE as a countermeasure to ARS under the FDA Animal Rule, adopted in 2002 for approval of medical countermeasures to weapons of mass destruction. Traditional drug development programs require large-scale clinical studies to establish efficacy in humans in order 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 radiation injury, 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 ARS as well as on survival. To date, these studies indicate that NEUMUNE can provide benefit in monkey 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 monkeys exposed to 4 Gy of total body irradiation showed protection with NEUMUNE doses ranging from 2.5 to 42.5 mg/kg. Representative data from these studies, giving the compound once per day for 5 days by intramuscular injection at a dose of 15 mg/kg, showed a reduction in the number of days of severe neutropenia were reduced from 12 to 3. In this study thrombocytopenia and severe anemia were eliminated.

High-dose radiation models were also conducted with and without supportive clinical support such as antibiotics, IV fluids and platelet transfusions. In the studies conducted without supportive care, 32.5% of the control animals died versus only 12.5% of the NEUMUNE treated animals. Animals receiving NEUMUNE experienced reductions in neutropenia, thrombocytopenia and anemia in both models. 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.

In Phase I human safety studies conducted in the U.S. and The Netherlands, as of December 2005, a total of 111 volunteers had been enrolled, with 39 volunteers having completed the 5-day treatment course. 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 volunteers also experienced a dose dependent, increase in neutrophils and platelets during the 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.

Table of Contents

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. As a result of the increased terrorist threat, the U.S. government is allocating funding for the stockpiling of drugs that act as medical countermeasures to weapons of mass destruction.

As an incentive to industry to develop these countermeasures, the U.S. government enacted Project BioShield, legislation that provides a mechanism for placing advance orders for investigational products in this area, which are contingent on FDA approval. A total of \$6 billion has been allocated to purchase medical countermeasures under this legislation. Project BioShield also contains provisions enabling the Department of Health and Human Services, or HHS, to begin purchasing new medical countermeasures for the Strategic National Stockpile, or SNS, in advance of formal FDA approval. This provision, known as an Emergency Use Authorization, or EUA, has already been implemented for other development stage medical countermeasures to weapons of mass destruction.

In late 2005, HHS issued an initial Request for Proposal, or RFP for therapeutics to treat ARS. The request specifically sought 100,000 treatment courses of therapies that could mitigate neutropenia sufficiently to improve survival following exposure to 2 to 6 Gy of total body irradiation. The RFP also placed an added value on candidates that could protect against additional components of ARS such as thrombocytopenia and anemia. Furthermore, the RFP requires products to be available within two years under an EUA, and gives additional consideration to products that can be supplied to the SNS within 12 months of a contract award. In February 2006, we filed our formal response to this RFP detailing the potential for NEUMUNE in this indication.

We believe the next step in the procurement process for countermeasures to ARS will be the awarding of advance purchase contracts. There can be no assurance when or if HHS will grant awards under this procurement process and whether we will be awarded such a contract. Our development plans and timelines may vary substantially depending on whether we receive such a commitment and the size of such commitment, if any.

While we responded to the initial HHS RFP for an ARS countermeasure with the objective of securing an advance purchase contract for NEUMUNE, we believe that the number of treatment courses, and the therapeutic approach inherent in the initial RFP, are insufficient to address a mass casualty nuclear scenario. A February 2002 study published in the *British Medical Journal* estimated that a 12.5-kiloton nuclear bomb detonated in New York City would cause 50,000 deaths immediately from the explosion, and hundreds of thousands would be potentially exposed to life threatening ARS.

Because the window of opportunity to treat ARS is short, we believe any drug to treat this condition will need to be stockpiled on a local level to be appropriately available for high-risk populations. High-risk areas may include any military installation or theater of operations, any metropolitan area that is at risk of a radiological attack, and a 10 to 50 mile radius around any nuclear power plant or spent fuel facility. Such a definition would encompass a large portion of the highly populated areas in the U.S., and require the procurement and stockpiling of significantly higher quantities of ARS therapies than the 100,000 treatment courses sought in the initial HHS RFP.

Current treatment protocols for ARS recommend hospitalization for two to three weeks, the administration of multiple platelet transfusions and the use of antibiotics, in addition to costly growth factors to replenish neutrophils. Unfortunately, such a treatment regimen is unlikely to be available for most victims of a mass casualty event. Part of the challenge with such a mass casualty scenario is the lack of hospital beds and the supply of platelets for transfusions.

For example, in New York State, on average there are only 20,000 to 25,000 hospital beds available on a given day, and the average hospital carries only a one-day supply of platelets. Furthermore, platelets have a very short shelf life and can not be stockpiled in large quantities. In the

type of mass casualty scenario that could occur following a nuclear or radiological event, local hospitals and treatment facilities are likely to be completely overwhelmed and treatment would likely be unavailable for the vast majority of victims.

Table of Contents

The critical importance of mitigating thrombocytopenia was demonstrated in studies of victims of Hiroshima and Nagasaki showing that bleeding from ARS was a major cause of mortality. The significance of thrombocytopenia in ARS was also revealed in our studies in rhesus monkeys, where the number of days of thrombocytopenia by day 14 after total body irradiation was the strongest predictor of survival. These findings would appear to indicate that therapies to protect platelet levels are at least as important as therapies to protect neutrophils in the setting of ARS.

Use of a therapy such as NEUMUNE, we believe, would prove effective even without hospitalization of victims in a mass casualty scenario, offering the potential to treat a much larger percentage of victims than a hospital-based approach. As discussed above, NEUMUNE has been shown to reduce the duration of both neutropenia and thrombocytopenia following radiation exposure, and has demonstrated a survival advantage in a model of radiation injury in rhesus monkeys where similar to a mass casualty scenario, the animals were not provided any supportive care.

Furthermore, in a hospital setting, NEUMUNE potentially could stretch supplies of existing antibiotics and blood products across a much larger number of patients. NEUMUNE has also shown an attractive safety profile to date and is cost-effective in quantities appropriate for a mass casualty scenario, such that it could potentially be forward deployed to multiple locations across the nation and self-administered without physician supervision.

In addition to a possible BioShield procurement under the initial ARS RFP issued by HHS, we believe there are multiple other significant market opportunities for NEUMUNE. Among these is a potential procurement of a countermeasure such as NEUMUNE by the Department of Defense, which has been seeking an ARS therapy since the 1960s and considers NEUMUNE its lead product candidate for ARS. The Department of Defense has issued a Sources Sought Notice, or SSN, for an ARS therapy for use by U.S. forces, and we responded to that SSN in January 2006.

The Department of Defense also indicated in a letter to us that it will be issuing by mid-year 2006 its own RFP for an ARS therapy for the military. In that letter, we were highly encouraged by the Defense Department to respond to this RFP.

We also believe state and local governments, foreign governments and civilians may be interested in stockpiling NEUMUNE for ARS, if the compound is approved for this indication.

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

Recent findings also show the ability of NEUMUNE to increase CD34+ HSPCs, which could lead to additional market opportunities for NEUMUNE and our other IRHs. For example, loss of CD34+ cells is implicated in many diseases of aging. We are now exploring the potential for IRHs in additional clinical indications.

PHOSPHONOL

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

In February 2004, we acquired exclusive commercialization rights to PHOSPHONOL in our acquisition of Congressional Pharmaceutical Corporation, or CPC. Like NEUMUNE, PHOSPHONOL is being evaluated for protection against the effects of radiation injury. However, whereas NEUMUNE addresses the short-term effects of radiation injury, PHOSPHONOL is designed to treat the long-term effects of radiation exposure. PHOSPHONOL may have the potential to decrease genetic mutations after radiation injury, thus reducing genetic mutations. By reducing genetic mutations, PHOSPHONOL may also reduce a variety of cancers that can occur a number of years after radiation injury.

Table of Contents

We believe it may be possible to develop PHOSPHONOL pursuant to the same animal efficacy rule we are following with NEUMUNE. We have begun profiling PHOSPHONOL and other compounds in this series in preclinical models designed to assess safety, efficacy and oral bioavailability.

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 very 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 innovative, 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

As a result of our increasing knowledge of structure-activity relationships with this class of compounds, we are now profiling second-generation IRHs which 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. Assuming our profiling efforts are successful, we plan to select one of these IRHs for clinical development in chemotherapy protection. Drugs that only stimulate neutrophils in this setting currently generate sales in excess of \$3.0 billion

annually, although we can not guarantee that our compounds, if approved, will generate significant sales.

IRHs in Autoimmune Disease

Given the anti-inflammatory and immune regulating effects seen with IMMUNITIN and other IRHs in preclinical and early clinical trials, we are also interested in exploring the potential for IRHs in autoimmune

Table of Contents

diseases. First-generation immune regulating hormones such as IMMUNITIN have been shown in preclinical and early clinical studies to provide broad-spectrum anti-inflammatory activity.

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 (LPS), challenge, or lipopolysaccharide, 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. Compounds profiled in one or more of these studies included first-generation IRHs as well as a series of new second-generation IRHs that were able to demonstrate more potent activity than the first-generation IRHs. We are continuing to profile these and other new IRHs in a number of preclinical models of autoimmunity and, if these results are successful, plan to 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 new drug.

IRHs in Metabolic Disorders

There is significant preclinical literature describing benefits of IRHs in animal models of metabolic disorders, including glucose, cholesterol and triglyceride regulation and obesity. We are currently screening promising second-generation IRHs in preclinical models of metabolic disorders. If successful, we may initiate clinical trials in one or more of these disorders.

Competition

Given the large market opportunities for products that treat the indications for which we are developing our IRHs, most major pharmaceutical companies and a number of 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.

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

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. 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

Table of Contents

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 diseases such as HIV, and many other drugs candidates are in development.

Government Regulation

General

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

Approval Process

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

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

Investigational New Drug, or IND. Before human tests can start, the drug sponsor must file an IND application with the FDA, showing how the drug is made and the results of animal testing. IND status allows initiation of clinical investigation within 30 days of filing if the FDA does not respond with questions during the 30-day period.

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

relative to risk.

Phase I clinical trials, studies usually are conducted on healthy volunteers or, in the case of certain terminal illnesses such as AIDS, 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

Table of Contents

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 several of the product opportunities we are pursuing, 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 product 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 product 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

Table of Contents

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 product 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. Dr. Loria is a Professor of Microbiology and Immunology at Virginia Commonwealth University. He is a leading expert in the field of IRHs and is a scientific consultant to Hollis-Eden.

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

Table of Contents

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. 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, 2006, we had 64 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, 2006 are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Richard B. Hollis	53	Chairman of the Board, President and Chief Executive Officer
Daniel D. Burgess	44	Chief Operating Officer and Chief Financial Officer
James M. Frincke, Ph.D.	55	Chief Scientific Officer
Steven A. Gordziel, Ph.D.	59	Vice President, Product Development
Jessie R. Groothuis	59	Vice President, Clinical Affairs
Eric J. Loumeau	43	Vice President, Corporate General Counsel

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

Robert L. Marsella	53	Sr. Vice President, Business Development and Marketing
Christopher L. Reading, Ph.D.	58	Executive Vice President, Scientific Development
Dwight R. Stickney, M.D.	63	Vice President, Medical Affairs
Robert W. Weber	55	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

Table of Contents

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 Sicom, Inc. (acquired by Teva Pharmaceutical Industries Limited) and Gensia Automedics, Inc., a partially owned subsidiary of Gensia Sicom. 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 Sicom, 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 Board 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 Prolixin, 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.

Jessie R. Groothuis M.D. joined Hollis-Eden in 2004 as Vice President, Clinical Affairs. Before joining Hollis-Eden, Dr. Groothuis was Global Medical Director, Immunoscience Development at Abbott Laboratories, where she managed the global clinical trials and strategy for her division. Most recently at Abbott, Dr. Groothuis

Table of Contents

managed a 20-member team, oversaw large multi-site global clinical trials, and was responsible for the registration and launch of Synagis, a monoclonal antibody, in a number of international markets. Throughout her seven-year tenure with Abbott, she managed all phases of development for multiple drug candidates, and was lead investigator for four separate drugs in Abbott's pipeline. Prior to Abbott, Dr. Groothuis was Director of the *Neonatal High Risk Follow Up Clinic* and Professor of Pediatrics at the University of Colorado School of Medicine and The Children's Hospital, Department of Pediatrics. In this position she was lead clinical investigator on a number of large clinical trials in the area of immunology. Dr. Groothuis is board certified by the American Board of Pediatrics and the National Board of Medical Examiners. She received her B.S. from Stanford University, her M.D. from the University of Chicago and post-doctoral training at Vanderbilt University.

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

Table of Contents

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 Diplomat of the American Board of Internal Medicine and Hematology and a Diplomat of the American Board of Radiology, Therapeutic Radiology.

Robert W. Weber joined Hollis-Eden in March 1996 and currently serves as 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 immune regulating hormones, a class of drug candidates 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

Table of Contents

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 operating revenues and have never commercially introduced a product. Our accumulated deficit was approximately \$161.3 million as of December 31, 2005. Our net losses for fiscal years 2005, 2004 and 2003 were approximately \$29.4 million, \$24.8 million and \$25.7 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.

We do not believe any drug has ever been approved and commercialized for the treatment of severe acute radiation injury. 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 Acute Radiation Syndrome (ARS), is approved by the FDA, we cannot predict with any certainty the size of this market. The 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 (DHHS) issued a Request for Proposal (RFP) which specified an initial potential stockpiling order of up to 100,000 treatment regimens, which is substantially lower than we had anticipated. While we have responded to the RFP, we cannot guarantee that we will be able to meet the requirements set forth in the RFP or that we will receive any resulting stockpiling orders. A decision by any department of the U.S. Government to enter into a commitment to purchase NEUMUNE, whether before or after FDA approval, is largely out of our control. Our development plans and timelines may vary substantially depending on whether we receive such a commitment and the size of such commitment, if any. 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 after chemotherapy. A large number of companies, including Merck & Company, Pfizer Inc., Johnson & Johnson Inc. and Amgen Inc. are also developing and marketing new drugs for the treatment of chronic inflammatory conditions. Companies such as GlaxoSmithKline, Merck & Company, 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.

Table of Contents

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 to continue our business.

As of December 31, 2005, our cash and cash equivalents totaled approximately \$45.1 million. In February 2006, we completed an offering of common stock and warrants to purchase common stock, pursuant to which we received net proceeds of approximately \$24.4 million. Based on our current plans, we believe these financial resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements for at least the next 12 months. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We may require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

we may not obtain additional financial resources when necessary or on terms favorable to us, if at all; and

any available additional financing may not be adequate.

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

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

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

Table of Contents

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.

Table of Contents

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 payors 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;

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

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

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

Table of Contents

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 the 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.

Table of Contents

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.

Trading in 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 \$4.44 to \$16.50 between January 1, 2004 and March 1, 2006.

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 National Market, which could materially limit the trading market for our common stock.

Our common stock is quoted on The Nasdaq National Market. In order to continue to be included in The Nasdaq National Market, a company must meet Nasdaq's maintenance criteria. We may not be able to continue

Table of Contents

to meet these listing criteria. Failure to meet Nasdaq's maintenance criteria may result in the delisting of our common stock from The Nasdaq National Market. If our common stock is delisted, in order to have our common stock relisted on The Nasdaq National 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 National Market. If our common stock is removed from listing on The Nasdaq National Market, it may become more difficult for us to raise funds through the sale of our common stock or securities convertible into 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 11% of our outstanding common stock as of December 31, 2005. Assuming that Mr. Hollis exercises all of his outstanding warrants and options that vest within 60 days of December 31, 2005, Mr. Hollis would beneficially own approximately 18% 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

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

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 2007. In addition, we have leased, in San Diego, CA., 7,876 square feet of laboratory and office space through November 2006. 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

Table of Contents

these matters, as of the date of this Annual Report on Form 10-K, 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 2005.

Table of Contents**PART II****Item 5. Market for Registrant's Common Equity and Related Stockholder Matters and Issuer Purchases of 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, 2004 through March 1, 2006.

Common Stock	High	Low
2004		
First Quarter	\$ 16.50	\$ 8.46
Second Quarter	13.27	6.51
Third Quarter	14.40	7.87
Fourth Quarter	12.20	8.50
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		
January 1 - March 1	\$ 7.93	\$ 4.44

On March 1, 2006, the closing price of our common stock as reported by the Nasdaq National Market System was \$6.42 share. There were approximately 9,000 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 2005.

We made no repurchases of our securities during the year ended December 31, 2005.

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

The following data summarizes certain selected financial data for each of the five years ended December 31, 2005 through 2001 and the period from inception (August 15, 1994) to December 31, 2005. 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>2005</u>	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2001</u>	<u>Period from Inception (Aug. 15, 1994) to December 31, 2005</u>
Statement of Operations Data:						
Contract revenues	\$ 56	\$ 63	\$	\$	\$	\$ 119
Research and development	18,710	18,918	10,764	13,083	11,870	105,115
General and administrative	9,409	6,786	7,327(1)	4,787	5,091	55,877
Settlement of Dispute	3,000					3,000
Total operating expenses	31,119	25,704	18,091	17,870	16,961	163,992
Interest Income (Expense)	1,622	917	49	389	1,199	10,267
Other income (expense)		(33)	(7,629)(2)	(21)		(7,683)
Net loss	\$ (29,441)	\$ (24,757)	\$ (25,671)	\$ (17,502)	\$ (15,762)	\$ (161,289)
Net loss per share, basic and diluted	\$ (1.46)	\$ (1.28)	\$ (1.67)	\$ (1.35)	\$ (1.35)	
Weighted average number of common shares outstanding, basic and diluted	20,125	19,267	15,381	12,932	11,654	
Balance Sheet Data:						
Cash and equivalents	\$ 45,130	\$ 61,991	\$ 84,852	\$ 13,087	\$ 30,567	
Total assets	46,582	63,242	85,381	13,982	31,462	
Total Current Liabilities	7,708	5,008	3,329	2,950	3,602	
Stockholders' equity	\$ 38,874	\$ 58,234	\$ 82,052	\$ 11,032	\$ 27,860	

- (1) 2003 General and administrative expenses include \$2.2 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.

Table of Contents

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

The following discussion contains forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements" above. This discussion and analysis should be read in conjunction with the financial statements and notes included elsewhere in this report.

General

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 response. Our initial technology development efforts are primarily focused on a series of 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.

We have been unprofitable since our inception, with the possible exception of revenues to be received under government contracts for our drug candidate NEUMUNE, we expect to incur substantial additional operating losses for at least the next few years as we increase expenditures on research and development and begin to allocate significant and increasing resources to clinical testing and other activities. 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 must 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 until December 31, 2005, we have incurred approximately \$105.1 million in research and development expenses and \$55.9 million in general and administrative expenses and \$3.0 million in a settlement of dispute. From inception through December 31, 2005 we have generated approximately \$0.1 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 \$2.6 million in other expenses. This loss is comprised of \$7.6 million in deemed discount expense and \$0.4 million in interest expense. These expenses have been offset by \$10.6 million in interest income. The combination of these resulted in a net loss of \$161.3 million for the period from inception until December 31, 2005.

Research and development expenses were \$18.7 million, \$18.9 million and \$10.8 million in 2005, 2004 and 2003, respectively. The research and development expenses relate primarily to the ongoing development, preclinical testing, and clinical trials for NEUMUNE, IMMUNITIN and other immune regulating hormones. Research and development expenses decreased \$0.2 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. Research and development expenses increased \$8.1

million in 2004 compared to 2003. The increase in research and development expenses was due mainly to the advancement of NEUMUNE into later stages of development as well as growth in our laboratory operations, other preclinical activities, consulting and personnel. Research and development also increased as a result of the purchase of CPC in 2004.

Table of Contents

General and administrative expenses were \$9.4 million, \$6.8 million and \$7.3 million in 2005, 2004 and 2003, respectively. General and administrative expenses relate to salaries and benefits, facilities, legal, accounting/auditing, investor relations, consultants, insurance and travel. 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 an settlement of dispute. General and administrative expenses decreased \$0.5 million in 2004 compared to 2003 primarily due to non-cash charges totaling \$2.2 million related to the issuance of a warrant to a director and issuance of stock options to an officer and a director; and \$0.2 million in non-cash charges related to stock options issued to consultants. Excluding the non-cash charges in 2004 and 2003, general and administrative expenses increased \$1.7 million in 2004 compared to 2003. The increase is due mainly to increases in consulting, travel and accounting/audit fees (including costs associated with complying with Section 404 of the Sarbanes-Oxley Act of 2002), as well as increases in personnel and recruiting.

Other income and expenses were \$1.6 million, \$0.9 million and \$(7.6) million in 2005, 2004 and 2003, respectively. During 2005 and 2004, we earned interest income totaling \$1.6 million and \$0.9 million, respectively. For 2003, other income and expense included \$0.4 million of interest income and \$(8.0) million in expense for items associated with convertible debentures converted to common stock that year. This \$(8.0) million is comprised of the following charges: an expense of \$(7.6) million for the non-cash amortization of the deemed discount and deferred issuance costs on the convertible debentures, plus interest expense on the convertible debentures totaling \$(0.4) million. The interest income increase in 2005 compared to 2004 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. In addition, we have received a total of \$17.7 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.

Table of Contents

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	\$ 1,624	\$ 926	\$ 689	\$ 9	\$

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 amounts received under the CFFT collaboration in 2004 and 2005, and 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, 2005, our cash and cash equivalents totaled approximately \$45.1 million. In February 2006, we raised an additional \$24.4 million in net proceeds from the sale of common stock and warrants.

Our future capital requirements will depend upon many factors, including progress with preclinical testing and clinical trials, whether we receive an advance purchase contract from the U.S. government for NEUMUNE, 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 or 2005.

Table of Contents

Impact of Recently Issued Accounting Pronouncements

In December 2004, SFAS No. 123(R), *Share-Based Payment*, which addresses the accounting for employee stock options, was issued. SFAS 123(R) revises the disclosure provisions of SFAS 123 and supersedes APB Opinion No. 25. SFAS 123(R) requires that the cost of all employee stock options, as well as other equity-based compensation arrangements, be reflected in the financial statements based on the estimated fair value of the awards. This statement is effective for all public entities as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. We expect the adoption of SFAS 123R to increase our reported net loss and earnings per share. The Company has not elected to early implement SFAS 123(R) for the year ended December 31, 2005.

In December 2004, the FASB issued SFAS 153, *Exchanges of Nonmonetary Assets*, an amendment of APB Opinion No. 29 (SFAS 153). The guidance in APB Opinion No. 29, *Accounting for Nonmonetary Transactions*, is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in APB Opinion No. 29, however, included certain exceptions to that principle. SFAS 153 amends APB Opinion No. 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS 153 is effective for nonmonetary asset exchanges in fiscal periods beginning after June 15, 2005. We do not believe that the adoption of SFAS 153 will have a material impact on our results of operations or financial position.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

At December 31, 2005, our investment portfolio included only cash and money market accounts and does not contain fixed-income securities. There would be no material impact to our investment portfolio, in the short term, associated with any change in interest rates, and any decline in interest rates over time will reduce our interest income, while increases in interest rates over time will increase our interest income.

Table of Contents

Item 8. Financial Statements and Supplementary Data

	Page
<u>Balance Sheets as of December 31, 2005 and 2004</u>	35
<u>Statements of Operations for the Fiscal Years Ended December 31, 2005, December 31, 2004, December 31, 2003 and the Period From Inception (August 15, 1994) to December 31, 2005</u>	36
<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 and December 31, 2005</u>	37
<u>Statements of Cash Flow for the Fiscal Years Ended December 31, 2005, December 31, 2004, December 31, 2003 and the Period from Inception (August 15, 1994) to December 31, 2005</u>	40
<u>Notes to Financial Statements</u>	41
<u>Report of Independent Registered Public Accounting Firm</u>	62

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

	December 31,	
	2005	2004
	(In thousands,	
	except par value)	
ASSETS:		
Current assets:		
Cash and cash equivalents	\$ 45,130	\$ 61,991
Prepaid expenses	204	176
Deposits	52	44
Other receivable	8	9
Receivable from related party	7	
	<u>45,401</u>	<u>62,220</u>
Total current assets	45,401	62,220
Property and equipment, net of accumulated depreciation of \$740 and \$462	1,116	961
Receivable from related party	4	
Deposits	61	61
	<u>46,582</u>	<u>63,242</u>
Total assets	\$ 46,582	\$ 63,242
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable and accrued expenses	\$ 7,515	\$ 5,008
Deferred revenue	193	
	<u>7,708</u>	<u>5,008</u>
Total current liabilities	7,708	5,008
Commitments and contingencies (Notes 6, 11, 12)		
Stockholders' equity: (Notes 3, 7, 8, 9, 10,13)		
Preferred stock, \$.01 par value, 10,000 shares authorized; no shares outstanding		
Common stock, \$.01 par value, 50,000 shares authorized; 20,782 and 19,347 shares issued and 20,723 and 19,288 outstanding respectively	208	193
Paid-in capital	200,301	190,235
Cost of treasury stock (59 shares)	(346)	(346)
Deficit accumulated during development stage	(161,289)	(131,848)
	<u>38,874</u>	<u>58,234</u>
Total stockholders' equity	38,874	58,234
Total liabilities and stockholders' equity	\$ 46,582	\$ 63,242

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

Table of Contents**Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Statements of Operations**

	For the year ended December 31,			Period from
	2005	2004	2003	Inception (Aug. 15, 1994) to December 31, 2005
	(In thousands, except per share amounts)			
Revenue:				
Contract R&D revenue	\$ 56	\$ 63	\$	\$ 119
Total revenue	56	63		119
Operating expenses:				
Research and development				
R & D operating expenses	18,710	18,915	10,442	99,448
R & D costs related to common stock and stock option grants for collaborations and technology purchases		3	322	5,667
Total research and development	18,710	18,918	10,764	105,115
General and administrative				
G & A operating expenses	9,378	6,653	5,161	43,506
G & A costs related to options / warrants granted	31	133	2,166	12,371
Total general and administrative	9,409	6,786	7,327	55,877
Settlement of Dispute	3,000			3,000
Total operating expenses	31,119	25,704	18,091	163,992
Other income (expense):				
Loss on disposition of assets		(33)	(2)	(56)
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures			(7,627)	(7,627)
Interest income	1,622	917	387	10,655
Interest expense			(338)	(388)
Total other income (expense), net	1,622	884	(7,580)	2,584
Net loss	\$ (29,441)	\$ (24,757)	\$ (25,671)	\$ (161,289)
Net loss per share, basic and diluted	\$ (1.46)	\$ (1.28)	\$ (1.67)	
Weighted average number of common shares outstanding, basic and diluted	20,125	19,267	15,381	

The accompanying notes are an integral part of these financial statements

Table of Contents**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 Common Stock		Deferred compensation	Deficit accumulated during development stage	Total
	at par value	at par value	at par value	at par value		Shares	Amount			
	Shares	Amount	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)					1,848			(1,848)		
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	16,325			(1,566)	(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
					240					240

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

Options issued for services in lieu of cash (Note 9)

Amortization of deferred compensation								308		308		
Net loss									(5,427)	(5,427)		
Balance at December 31, 1998	4	\$	8,592	\$	86	\$	38,796	\$	(1,258)	\$	(13,321)	\$ 24,303
Exercise of warrants			755		8		5,136					5,144
Exercise of stock options			10				75					75
Private Placement, net of expenses (Note 7)			1,368		14		24,759					24,773
Preferred Stock Conversion (Note 7,8)	(4)		346		3		(3)					
Deferred compensation-Options forfeited (Note 9)							(1,207)		1,258			51
Amortization of non-employee options							559					559
Warrants issued for services in lieu of cash (Note 10)							2,140					2,140

Table of Contents

	Preferred stock at par value		Common stock at par value		Capital in excess of par value	Cost of Repurchased Common Stock		Deferred compensation	Deficit accumulated during development stage	Total
	Shares	Amount	Shares	Amount		Shares	Amount			
(In thousands)										
Options accelerated vesting (Note 9)					4,900					4,900
Net loss									(15,320)	(15,320)
Balance at December 31, 1999			11,071	111	75,155				(28,641)	46,625
Exercise of warrants			133	2	758					760
Exercise of stock options			1		5					5
Common Stock issued for 401k/401m plan			6		63					63
Common Stock issued for In-Process R&D (Note 6)			209	2	1,998					2,000
Options granted for license fee			38		598					598
Amortization of non-employee options					79					79
Common Stock issued for purchase of technology			132	1	1,847					1,848
Net loss									(19,515)	(19,515)
Balance at December 31, 2000			11,590	116	80,503				(48,156)	32,463
Exercise of stock options			10		22					22
Common Stock issued for 401k/401m plan			16		96					96
Private Placement, net of expenses (Note 7)			1,280	13	10,644					10,657
Warrants issued for services in lieu of cash (Note 10)					80					80
Amortization of non-employee options					96					96
Warrants issued for services					208					208
Net loss									(15,762)	(15,762)
Balance at December 31, 2001			12,896	129	91,649				(63,918)	27,860
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
			9		142					142

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

Common Stock issued in lieu of cash / interest								
Public Offering, net of expenses	2,500	25	58,576					58,601
Deemed discount on convertible debentures			6,470					6,470
Warrants issued for services			1,398					1,398
Amortization of non-employee options			128					128
Purchase of treasury stock				(59)	(346)			(346)
Net loss							(25,671)	(25,671)
Balance at December 31, 2003	19,272	193	189,296	(59)	(346)		(107,091)	82,052
Common Stock issued for 401k/401m plan	17		147					147
Exercise of warrants	6		11					11
Exercise of stock options	4		16					16
Common Stock issued for In-Process R&D (Note 6)	48		629					629
Amortization of non-employee options			136					136
Net loss							(24,757)	(24,757)

Table of Contents

	Preferred stock at par value		Common stock at par value		Capital in excess of par value	Cost of Repurchased Common Stock		Deferred compensation	Deficit accumulated during development stage	Total
	Shares	Amount	Shares	Amount		Shares	Amount			
(In thousands)										
Balance at December 31, 2004			19,347	\$ 193	\$ 190,235	(59)	\$ (346)		\$ (131,848)	\$ 58,234
Common Stock issued for 401k/401m plan			25		151					151
Exercise of warrants			42	1	260					261
Exercise of stock options			35	1	123					124
Public Offering, net of expenses (Note 7)			1,333	13	9,502					9,515
Amortization of non-employee options					30					30
Net loss									(29,441)	(29,441)
Balance at December 31, 2005			20,782	\$ 208	200,301	(59)	\$ (346)		\$ (161,289)	\$ 38,874

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

Table of Contents**Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Statements of Cash Flows**

	2005	2004	2003	Period from Inception (Aug. 15, 1994) to December 31, 2005
	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>2005</u>
(In thousands)				
Cash flows from operating activities:				
Net loss	\$ (29,441)	\$ (24,757)	\$ (25,671)	\$ (161,289)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	303	218	118	1,096
Disposal of assets		33	2	63
Amortization of deemed discount on convertible debentures			6,470	6,470
Amortization of deferred issuance cost			1,157	1,157
Common stock issued for 401k/401m plan	151	147	223	817
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	552	2,859
Expense related to warrants issued as consideration to consultants			1,518	4,113
Expense related to warrants issued to a director for successful closure of merger				570
Expense related to stock options issued			561	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		629		2,629
Deferred compensation expense related to options issued				1,210
Changes in assets and liabilities:				
Prepaid expenses	(28)	(42)	(11)	(204)
Deposits	(8)	(10)	(8)	(113)
Other receivable	1	(9)	13	(8)
Other Receivable from related party	(11)	18	3	(11)
Accounts payable, accrued expenses, and deferred revenue	2,700	1,679	1,024	8,352
Net cash used in operating activities	(26,303)	(21,958)	(14,049)	(124,656)
Cash flows provided by investing activities:				
Purchase of property and equipment	(458)	(930)	(4)	(2,275)
Payback of loan by a company officer			253	
Net cash provided by (used in) investing activities	(458)	(930)	249	(2,275)
Cash flows from financing activities:				
Contributions from stockholder				104
Net proceeds from sale of preferred stock				4,000
Net proceeds from sale of common stock	9,515		72,413	134,757
Net proceeds from issuance of convertible debentures and warrants			9,214	9,214
Purchase of treasury stock			(346)	(346)
Proceeds from issuance of debt				371
Net proceeds from recapitalization				6,271

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

Net proceeds from warrants/options exercised	385	27	4,284	17,690
Net cash provided by financing activities	9,900	27	85,565	172,061
Net increase (decrease) in cash and equivalents	(16,861)	(22,861)	71,765	45,130
Cash and equivalents at beginning of period	61,991	84,852	13,087	
Cash and equivalents at end of period	\$ 45,130	\$ 61,991	\$ 84,852	\$ 45,130
Supplemental disclosure of cash flow information:				
Interest paid	\$	\$	\$ 338	\$ 388
Conversion of debt to equity			10,000	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	371

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

Table of Contents

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. The Company believes these immune regulating hormones can be used to reestablish host immunity in situations of dysregulation. 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, 2005).

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, 2005 the Company's cash equivalents are approximately \$45.1 million and are deposited primarily in a money market mutual fund with a large financial institution.

Property and Equipment

Property and equipment is stated at cost and depreciated over the estimated useful lives (five and seven years) or the remaining lease term of the assets using the straight-line method.

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 reasonable 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, 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

Table of Contents**Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

December 31, 2003 (see Note 6, Colthurst, Edenland and Mr. Prendergest and Aeson Therapeutics). No such related party expenses were incurred in 2004 or 2005.

Accounting for Stock-Based Compensation

The Company has elected to follow Accounting Principles Board Opinion No. 25 (APB 25), *Accounting for Stock Issued to Employees*, and related interpretations in accounting for its employee stock options rather than the alternative fair value accounting provided for under SFAS No. 123, *Accounting and Disclosure for Stock-Based Compensation*. The Company has also adopted the pro forma disclosure requirements of SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123*. In accordance with APB 25, compensation cost relating to stock options granted by the Company is measured as the excess, if any, of the market price of the Company's stock at the date of grant over the exercise price of the stock options. This expense is recognized over the vesting period of the stock options.

As required by SFAS No. 148 and SFAS No. 123, the Company provides pro forma net (loss) and pro forma net (loss) per common share disclosures for stock-based awards made during the periods presented as if the fair-value-based method defined in SFAS No. 123 had been applied.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period (See Note 9). The Company's net loss would have been reported as follows (in thousands, except per share amounts):

	Year ended December 31,		
	2005	2004	2003
Net loss As reported	\$ (29,441)	\$ (24,757)	\$ (25,671)
Add: Stock-based employee compensation expense included in reported net loss			122
Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards	(4,910)	(5,203)	(4,865)
Net loss Pro forma	\$ (34,351)	\$ (29,960)	\$ (30,414)
Basic and diluted net loss per share As reported	\$ (1.46)	\$ (1.28)	\$ (1.67)
Basic and diluted net loss per share Pro forma	\$ (1.71)	\$ (1.55)	\$ (1.98)

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

Table of Contents

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 8,253,374, 7,813,643, and 7,097,978 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, 2005, 2004 and 2003 because their effect on net loss per share is anti-dilutive.

Recent Accounting Pronouncements

In December 2004, SFAS No. 123(R), Share-Based Payment, which addresses the accounting for employee stock options, was issued. SFAS 123(R) revises the disclosure provisions of SFAS 123 and supersedes APB Opinion No. 25. SFAS 123(R) requires that the cost of all employee stock options, as well as other equity-based compensation arrangements, be reflected in the financial statements based on the estimated fair value of the awards. This statement is effective for all public entities that file as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. The Company expects the adoption of SFAS 123R to increase our reported net loss and earnings per share. The Company has not elected to early implement SFAS 123(R) for the year ended December 31, 2005.

In December 2004, the FASB issued SFAS 153, Exchanges of Nonmonetary Assets, an Amendment of APB Opinion No. 29 (SFAS 153). The guidance in APB Opinion No. 29, Accounting for Nonmonetary Transactions, is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in APB Opinion No. 29, however, included certain exceptions to that principle. SFAS 153 amends APB Opinion No. 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has

commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS 153 is effective for nonmonetary asset exchanges in fiscal periods beginning after June 15, 2005. The adoption of SFAS 153 has not had a material impact on our results of operations or financial position.

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.

Table of Contents

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 \$131 million at December 31, 2005 which may be carried forward as an offset to taxable income, if any, in future years through its expiration in 2012 to 2025. The Company has a net deferred tax asset of approximately \$52 million at December 31, 2005 comprised of capitalized start-up costs, 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. If certain substantial changes in the Company's ownership should occur, there would potentially be an annual limitation on the amount of the carryforwards, which could be utilized in a tax year. The Company has not

performed a section 382 change in control test to date. Until this test is performed, the Company cannot be certain of the use of the loss carryforwards.

6. Related Party Licenses and other Agreements and Contingencies

Colthurst, Edenland and Mr. Prendergast

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

Pursuant to a license agreement dated May 18, 1994 (Colthurst License Agreement) with related parties, Patrick T. Prendergast, a significant stockholder at the time, and with Colthurst Limited, a company controlled by

Table of Contents

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

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.

During November 1999, the Company filed two separate requests for arbitration with Mr. Prendergast, Colthurst and Edenland. The first arbitration sought clarification of certain operational issues with respect to roles and responsibilities set forth in the license agreement covering IMMUNITIN. The second arbitration sought to rescind both of the agreements with Edenland covering future potential drug candidates other than IMMUNITIN.

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

On January 20, 2000, Hollis-Eden reached a settlement on its pending arbitrations with Mr. Prendergast, Colthurst and Edenland. The Settlement and Mutual Release Agreement completely disposed of all of the matters that were at issue in the pending arbitrations. In addition, the parties entered into two new technology agreements, the Technology Assignment Agreement and the Sponsored Research and License Agreement.

The Technology Assignment Agreement (Assignment Agreement) replaced the Colthurst License Agreement. Pursuant to the Assignment Agreement, Mr. Prendergast and Colthurst assigned to Hollis-Eden ownership of all patents, patent applications and current or future improvements of the technology under the Colthurst License Agreement, including IMMUNITIN, Hollis-Eden's lead clinical compound at the time. The annual license fee of \$500,000 and the royalty obligations under the Colthurst License Agreement were eliminated. In consideration for the foregoing, Hollis-Eden agreed to issue to Colthurst 660,000 shares of Common Stock and a warrant to purchase an aggregate of 400,000 shares of Common Stock at \$25 per share.

Table of Contents

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

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), including (i) support of Hollis-Eden's actions by Mr. Prendergast and Colthurst, by voting their shares of Hollis-Eden stock in favor of management and (ii) Mr. Prendergast and his affiliated companies not conducting research and development activities relating to the transferred technology. 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.

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

Table of Contents

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

option to acquire the remainder of Aeson to September 30, 2002. Hollis-Eden also received additional equity securities as a result of its \$1.2 million payment and now has approximately a 25% equity stake in Aeson. 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. Accordingly, the option to acquire Aeson has now expired. The Company continues to hold a 25% equity interest in Aeson which is accounted for under the equity method.

Pharmadigm

In August 2002, we entered into a Sublicense Agreement with Pharmadigm, 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 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.

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 is performing work on multiple task orders that were issued under a collaboration with the Armed Forces Radiobiology Research Institute (AFRRI). Under these task orders, the Company is conducting radiation studies with a subcontractor. The task orders commit AFRRI to reimburse the Company for \$2.0 million in subcontractor fees. The reimbursement amounts from AFRRI will be recorded in the same timeline as the subcontractor fees, resulting in no impact on the statement of operations. The company has received

Table of Contents

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

reimbursements by AFRRRI in excess of payments to subcontractors in the amount of \$585,000 as of December 31, 2005. This amount was recorded as a liability.

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, and the Company has a liability of \$193,531 recorded as deferred revenue as of December 31, 2005.

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,

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

the debt financing, plus accrued interest, was converted into 164,962 shares of common stock at a price of \$2.25 per share. In April 1996, the Company privately issued 580,005 shares of the Company's common stock at an offering price of \$2.25 per share. Total proceeds from this offering aggregated \$1,234,499.

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

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

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.

Table of Contents

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.

8. Preferred Stock

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

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

Table of Contents

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

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

1997 Stock Option Plan

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.

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

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

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

Table of Contents**Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

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

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

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
	<u> </u>	<u> </u>	<u> </u>
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
	<u> </u>	<u> </u>	<u> </u>
Outstanding, December 31, 2005	4,646	\$ 2.25-17.83	\$ 9.57

Table of Contents**Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

The Company entered into stock option agreements with certain directors, officers and consultants. These options became exercisable according to a schedule of vesting as determined by the Board of Directors. During 2003, 2004 and 2005 the Company granted options to certain directors, officers, and consultants, of which some are at exercise prices below market value at the date of grant, and will recognize \$730,000, \$100,800, and zero, respectively, in expense related to these options over the vesting periods. Expenses related to options for consultants and directors were \$630,000, \$34,000, and \$25,000 in 2003, 2004 and 2005, respectively. The remaining \$30,000 charge for these options will be expensed over the remaining vesting period of the options.

As of December 31, 2005, the total remaining shares of common stock available for grant under the 2005 Equity Plan is 850,050 (which includes 100,000 shares under the inducement pool).

2005 Non-Employee Directors Equity Incentive Plan

The 2005 Non-Employee Directors Equity Incentive Plan (the Non-Employee Directors Plan) was approved by the Company's stockholders at the June 17, 2005 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 optionholder's continued service period. 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

Non-Plan Options

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

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 2004, the Company granted non-statutory stock options to purchase a total of 170,000 shares to directors and officers. In 2005, the Company did not grant any non-statutory stock options to directors or officers.

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

Table of Contents

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

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.

Table of Contents**Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

The following table summarizes stock option activity not pursuant to the Plan for 1995 through 2005 (in thousands, except per share amounts):

	Shares	Price Per Share	
		Range	Weighted Average
1995			
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
1998			
Exercised	53	2.25-5.30	2.93
Forfeited	50	2.25	2.25
Outstanding, December 31, 1998	2,855	\$ 2.25-7.95	\$ 4.58
1999			
Granted	300	16.63	16.63
Exercised	10	7.95	7.95
Forfeited	1,220	2.25-5.00	4.95
Outstanding, December 31, 1999	1,925	\$ 2.25-16.63	\$ 6.16
Outstanding, December 31, 2000	1,925	\$ 2.25-16.63	\$ 6.16
2001			
Exercised	10	2.25	2.25
Outstanding, December 31, 2001	1,915	\$ 2.25-16.63	\$ 6.23

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

Outstanding, December 31, 2002	1,915	\$ 2.25-16.63	\$ 6.23
2003			
Forfeited	165	2.25	2.25
	<u> </u>	<u> </u>	<u> </u>
Outstanding, December 31, 2003	1,750	\$ 2.25-16.63	\$ 6.60
2004			
Granted	170	\$ 10.79-11.75	\$ 11.51
	<u> </u>	<u> </u>	<u> </u>
Outstanding, December 31, 2004	1,920	\$ 2.25-16.63	\$ 7.04
2005			
Granted	28	\$ 6.39-7.59	\$ 7.00
Exercised	22	2.25	2.25
	<u> </u>	<u> </u>	<u> </u>
Outstanding, December 31, 2005	1,926	\$ 2.25-16.63	\$ 7.09

Table of Contents**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, 2005 were as follows:

Range of Exercise Prices	Outstanding options			Exercisable options	
	Shares	Remaining life (years)	Weighted average price	Shares	Weighted average price
\$ 2.25-\$ 4.99	418,200	1.3	\$ 2.38	418,200	\$ 2.38
\$ 5.00-\$ 8.99	2,956,310	4.5	5.74	2,666,175	5.69
\$ 9.00-\$12.99	1,857,809	6.6	10.66	1,309,527	10.55
\$13.00-\$17.99	1,369,500	5.0	15.15	1,106,313	15.21
Balance as of 12/31/2005	6,601,819	5.0	\$ 8.87	5,500,215	\$ 8.51

Options exercisable at December 31, 2005, 2004 and 2003 were \$5,500,215, \$4,867,670 and \$4,265,209 at weighted average exercise prices of \$8.51, \$8.14 and \$8.29, respectively.

Pro Forma Disclosures of Net Loss

The Company has elected to account for its stock-based compensation plans under APB 25 (see Note 2); however, for pro forma disclosure purposes, the Company has computed the value of all options granted to employees during 2003 through 2005, using the Black-Scholes option pricing model with the following weighted average assumptions:

	2005	2004	2003
Risk free interest rate	4.02%	3.34%	3.27%
Expected divided yield	0%	0%	0%
Expected lives	5 years	5 years	5 years
Expected volatility	136%	180%	122%

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.

The weighted average, estimated fair values of employee stock options granted during fiscal 2005, 2004 and 2003 were \$6.42, \$11.49, and \$6.31 per share, respectively.

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.

Table of Contents

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

IAC Management Warrants

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

Representatives Warrants

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

Investor Relations Warrant

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

1998 Private Placement Warrants

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

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

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. 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.

Table of Contents

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

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. 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. 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. The warrants have no vesting period and were issued in lieu of cash for services. An estimated value for these warrants of approximately \$80,000 was expensed. The majority of these warrants have not been exercised. The unexercised warrants have expired.

2001 Private Placement Warrants

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

As a finders fee, the Company issued two warrants with an expiration date of December 11, 2006 to the placement agent for a total of 112,640 shares of common stock. One warrant has an exercise price of \$9.00 and the other an exercise price of \$12.00. 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 have not been exercised.

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.

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

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 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.

Table of Contents

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

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.

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. These warrants expire June 19, 2007. These 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. 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.

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.

Table of Contents**Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

The following table summarizes stock warrant activity for 2003 through 2005 (in thousands, except per share amounts):

	Shares	Price Per Share	
		Range	Weighted Average
Outstanding, December 31, 2002	1,371	\$ 3.09-20.50	\$ 13.97
2003			
Issued	1,262	5.99-15.45	8.73
Exercised	467	3.09-15.45	7.49
Forfeited	579	3.09-20.50	19.26
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

For various price ranges, the following table summarizes the weighted average prices of outstanding warrants as of December 31, 2005 (in thousands, except per share amounts):

Range of Exercise Prices	Outstanding Warrants		Exercisable Warrants	
	Shares	Weighted average price	Shares	Weighted average price
\$ 3.00-\$ 5.00	21	\$ 3.09	21	\$ 3.09

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

\$ 5.01-\$10.00	993	8.51	993	8.51
\$10.01-\$15.00	459	11.26	459	11.26
\$15.01-\$20.00	179	15.45	179	15.45
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Balance as of 12/31/2005	1,652	\$ 9.96	1,652	\$ 9.96

The weighted average fair value of warrants issued in fiscal years 2005, 2004 and 2003 were \$9.96, \$9.82 and \$9.79, respectively.

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, 2005, Mr. Hollis' base salary was increased from \$485,000 to \$500,000. If Mr. Hollis' employment is terminated without cause,

Table of Contents**Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)**

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 \$888,000, \$902,000, and \$754,000 for 2005, 2004 and 2003 respectively. Future minimum payments for operating leases are as follows (in thousands):

	Operating Leases

2006	\$ 926
2007	666
2008	23
2009	9

Total minimum lease payments	\$ 1,624

13. Subsequent Event

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 an exercise 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.

On January 9, 2006, the Company entered into a Settlement Agreement and General Release of Claims with certain former warrant holders of the Company who had made various allegations against the Company in connection with warrants that expired in January 2002. Although the Company denied all such allegations, the Company agreed to settle all disputes between the parties. As part of the Settlement Agreement, the former warrant holders received compensation from the Company and the Company's insurance carrier. The Company's portion of such settlement is \$540,000, which is accrued for at December 31, 2005 and will be paid by the Company prior to April 9, 2006.

Table of Contents**Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Notes to Financial Statements (Continued)****14. Supplementary Financial Data (Unaudited)****Interim Financial Information****(Unaudited)**

	<u>March</u>	<u>June</u>	<u>September</u>	<u>December</u>	<u>Year</u>
	(In thousands, except per share)				
Year Ended December 31, 2005					
R&D operating expenses	\$ 5,344	\$ 4,173	\$ 4,152	\$ 5,041	\$ 18,710
G&A operating expenses	1,776	2,736	1,957	2,909	9,378
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
Year Ended December 31, 2004					
R&D operating expenses	\$ 4,665	\$ 3,425	\$ 4,259	\$ 6,566	\$ 18,915
G&A operating expenses	1,429	1,693	1,483	2,048	6,653
Non-cash charges	12	15	71	38	136
Net loss	5,901	4,879	5,586	8,391	24,757
Net loss per share	(0.31)	(0.25)	(0.29)	(0.44)	(1.28)
Cash and cash equivalents	79,215	73,116	68,177	61,991	61,991

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.

Fourth Quarter Adjustments

In the fourth quarter of fiscal 2005, the Company recorded a \$3,000,000 accrual relating to a settlement of a dispute, which is shown separately on the statement of operations (see Note 6). In addition, the Company recorded a \$540,000 accrual related to a Settlement Agreement and General Release of Claims with certain former warrant holders, which is included in general and administrative operating expenses (See Note 13).

Table of Contents

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 balance sheets of Hollis-Eden Pharmaceuticals, Inc. (the Company) (a development stage company) as of December 31, 2005 and 2004 and the related statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2005 and for the period from inception (August 15, 1994) to December 31, 2005. 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. An audit also includes 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, 2005 and 2004, and the results of its operations and cash flows for each of the years in the three year period ended December 31, 2005 and for the period from inception (August 15, 1994) to December 31, 2005, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2005, 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 10, 2006 expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Costa Mesa, California

March 10, 2006

Table of Contents

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 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

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

provide reasonable assurance as to the detection of fraud.

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

Management has assessed the effectiveness of Hollis-Eden's internal control over financial reporting as of December 31, 2005, 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, 2005.

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, 2005. Its report is included herein.

Table of Contents

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, 2005, 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, 2005, 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, 2005, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

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

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, 2005 and 2004 and the related statements of operations, stockholders' equity and cash flows for each of the years in the three year period ended December 31, 2005 and for the period from inception (August 15, 1994) to December 31, 2005, and our report dated March 10, 2006 expressed an unqualified opinion on those financial statements.

/s/ BDO Seidman, LLP

Costa Mesa, California

March 10, 2006

Table of Contents***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, 2005 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 February 13, 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>2006 Base Salary</u>	<u>2005 Bonus</u>
Richard B. Hollis	\$ 512,500	\$ 250,000
Chairman of the Board, President and Chief Executive Officer		
Dwight R. Stickney, M.D.	343,375	40,000
Vice President, Medical Affairs		
Daniel D. Burgess	330,050	40,000
Chief Operating Officer and Chief Financial Officer		
James M. Frincke, Ph.D.	287,000	40,000
Chief Scientific Officer		
Eric J. Loumeau	261,375	35,000
Vice President, Corporate General Counsel		

Table of Contents**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 to be filed with the Commission pursuant to Regulation 14A in connection with the Hollis-Eden's 2006 Annual Meeting (the "Proxy Statement").

Item 11. Executive Compensation

The information required by this item is incorporated by reference to the disclosures under the heading "Executive Compensation" in the Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information regarding certain beneficial owners and management required by this item is incorporated by reference to the disclosures under the heading "Security Ownership of Certain Beneficial Owners and Management" in the Proxy Statement.

The following table provides information as of December 31, 2005 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	4,676,119	\$ 9.58	870,050
Stock option equity compensation plans not approved by security holders	1,925,700	\$ 7.09	

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

Warrant equity compensation plans not approved by security holders	796,386	\$	10.17
Total	7,398,205		870,050

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 or year ended December 31, 2005.

Table of Contents

Item 13. Certain Relationships and Related Transactions

The information required by this item is incorporated by reference to the disclosures under the heading Certain Transactions, which information is incorporated herein by reference.

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.

Table of Contents

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents have been filed as part of this Annual Report 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, 2005, and have therefore been omitted.
3. *Exhibits:* The exhibits listed in the Exhibit Index attached to this report are filed or incorporated by reference as part of this Annual Report.

Table of Contents

SIGNATURES

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

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, 2006

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, 2006
/s/ DANIEL D. BURGESS <hr/> Daniel D. Burgess	Chief Operating Officer/Chief Financial Officer (Principal Financial Officer)	March 10, 2006
/s/ ROBERT W. WEBER <hr/> Robert W. Weber	Chief Accounting Officer and Vice President Controller (Principal Accounting Officer)	March 10, 2006
/s/ PAUL BAGLEY <hr/> Paul Bagley	Director	March 10, 2006

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

<i>/s/</i> JEROME M. HAUER	Director	March 10, 2006
<hr/>		
Jerome M. Hauer		
<i>/s/</i> BRENDAN R. McDONNELL	Director	March 10, 2006
<hr/>		
Brendan R. McDonnell		
<i>/s/</i> THOMAS C. MERIGAN, JR. M.D.	Director	March 10, 2006
<hr/>		
Thomas C. Merigan, Jr. M.D.		
<i>/s/</i> MARC R. SARNI	Director	March 10, 2006
<hr/>		
Marc R. Sarni		
<i>/s/</i> SALVATORE J. ZIZZA	Director	March 10, 2006
<hr/>		
Salvatore J. Zizza		

Table of Contents**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).

Table of Contents

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)).

Table of Contents

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)).
*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 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 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.
*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).

Table of Contents

Exhibit Number	Description of Document
*#10.40	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Company 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).
*#10.41	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Company 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 Company 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 Company 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 Company 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 Company 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
* 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.
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.

Table of Contents

- * 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.