HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 10-K
March 15, 2004
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2003

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 33-60134

HOLLIS-EDEN PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

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

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

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

None

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

Common stock, $.01 par value per share

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

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

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). YES x NO ¨

The aggregate market value of the voting stock held by nonaffiliates of the Registrant as of June 30, 2003, the end of Hollis-Eden Pharmaceuticals most recently completed second fiscal quarter, was approximately $148,875,838 based on the closing stock price of $12.43 for the Registrant s Common Stock as reported by the Nasdaq National Market.

As of March 5, 2004, there were outstanding 19,212,647 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 2004 Annual Meeting of Stockholders to be held during June 2004, are incorporated by reference into Part III of this Report.

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Hollis-Eden Pharmaceuticals, Inc.

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For the Fiscal Year Ended December 31, 2003

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. In particular, statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are contained or incorporated by reference in this 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 development efforts target radiation and chemotherapy induced immune suppression and immune dysregulation caused by infectious diseases such as HIV, malaria and tuberculosis. Our initial technology development efforts are primarily focused on a series of potent hormones and hormone analogs that we believe are key components of the body s natural regulatory system. We believe these immune regulating hormones (IRHs) can be used to reestablish host immunity in situations of dysregulation.

Preclinical and early clinical studies with these compounds indicate that they have the ability to significantly reduce a number of well known inflammatory mediators, while also increasing innate and adaptive immunity and reversing bone marrow suppression. In addition, these compounds have a very attractive safety profile to date, are cost-effective to manufacture and are unlikely to produce resistance.

We are currently developing several compounds in this series. NEUMUNE™ (HE2100) is a compound that we are developing in conjunction with the U.S. military to protect against the acute effects of radiation injury. IMMUNITIN™ (HE2000) is a Phase II clinical stage compound that has shown clinical activity in several infectious diseases, including HIV and malaria and, along with other IRHs that we are developing, is also being evaluated by a number of U.S. government agencies as a countermeasure for bioterrorism. A number of IRHs have also shown significant benefits in preclinical models of chemotherapy induced immune suppression, and we intend to clinically test one or more of these compounds in this setting. HE2200 has also been evaluated in several pilot phase II clinical studies and has shown an attractive safety profile. We are evaluating several formulation enhancements and chemical modifications that may improve its potential and make it a promising

candidate for further clinical development. In addition, compounds in this series have shown significant activity in preclinical models of a number of autoimmune conditions, and we are exploring the potential for second-generation compounds in the autoimmunity area. Lastly, in February 2004, we acquired Congressional Pharmaceutical Corporation, which is developing Phosphonol, a preclinical stage compound for treating the long-term effects of radiation injury.

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We are pursuing a partially integrated approach to building our business. As such, we are utilizing third parties for many of our activities. We believe by being involved in the design and supervision of these activities, but not the day-to-day execution, we can preserve our flexibility and limit our expenditures during the development phase. 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 class of hormones and analogs of hormones found in the body that we believe are important components of the body s regulatory system. These compounds have demonstrated significant preclinical activity in protecting the bone marrow from the damaging effects of radiation and chemotherapy. In addition, IRHs appear to reduce inflammation in a broad-spectrum fashion while also improving a number of components of the immune system in conditions of immune suppression. 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 immune regulating hormones revolves around their role in the hematopoietic system. Hematopoiesis is the process by which the body produces a number of key 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. Unfortunately, radiation and chemotherapy can significantly damage bone marrow, which can lead to life-threatening complications.

A number of preclinical studies with our immune regulating hormones indicate that these compounds can increase both neutrophils and platelets as well as other important immune cells following radiation injury or chemotherapy. In addition, those cells 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. In addition, the ability of IRHs to regulate reactive oxygen species may also contribute to preventing death of remaining bone marrow cells.

As a result of these actions, immune regulating hormones have the potential to be quite useful in treating a variety of conditions in which the bone marrow is damaged.

Role of Inflammation. Recently, the role of inflammation in disease pathogenesis has become increasingly recognized by the medical community. Chronic inflammation is generally believed to be caused by

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an over-stimulation of certain components of the immune system, such as reactive oxygen species, 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 now 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 more recently 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 more than 60 million 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 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 immune regulating hormones have been shown in *in vitro* systems to regulate a broad array of reactive oxygen species involved in inflammation and have been shown in animal models of numerous diseases to produce anti-inflammatory activities comparable to that historically seen with corticosteroids. In addition, our class of compounds has been shown in early clinical trials to produce long-lasting reductions in a number of key inflammatory mediators, including TNF-alpha, IL-1 beta and COX-2. Unlike most approaches to reducing inflammation, however, immune regulating hormones appear to boost a variety of immune responses in conditions of immune suppression, including innate and adaptive cell-mediated immunity and hematopoiesis.

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 system 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.

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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.

Unfortunately, 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 immune regulating hormones we are developing is a key determinant in whether appropriate levels of cytokines are produced to properly regulate immune responses. As we age, and under conditions of stress and chronic infections, levels of these immune regulating hormones 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.

As described above, certain pathogens have found ways to accelerate this process through natural selection. For example, in HIV, most patients cortisol levels rise (and counter-regulatory adrenal hormones fall) as the disease progresses from HIV to AIDS. This then leads to a corresponding increase in Th2 cytokines such as IL-10 relative to Th1 cytokines such as IFN gamma. As this situation continues, the immune system is dominated by Th2 cells unable to fight viral and other infections rather than the necessary cell-mediated Th1 cells. In this state of immune system dysregulation, the patient becomes highly susceptible to infection.

Certain HIV patients, however, maintain their ability to continue to produce high levels of Th1 cytokines and, in this small percentage of patients, HIV appears to take much longer to progress to AIDS. These patients are termed HIV long-term non-progressors. These observations have led to the belief that if patients can be brought from a predominant Th2 immune status back towards a Th1 dominant condition through drug therapy, the immune system may be able to contain or eliminate a number of such infectious pathogens that are plaguing millions of people around the world. This Th1/Th2 imbalance is seen not just with infectious disease, but also in cancer and autoimmune diseases. Thus, a drug that effectively corrects immune dysregulation could have the potential to address a wide variety of human ailments.

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.

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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 that is well down a very complex cascade of events is likely to be too simplistic 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.

Acquisition of Congressional Pharmaceutical Corporation

In February 2004, we acquired Congressional Pharmaceutical Corporation (CPC). CPC is a company that was formed to commercialize a series of compounds that have the potential to protect against DNA mutations that can occur as a result of radiation injury or chemotherapy. This DNA damage (mutagenesis) has been associated with an increased risk of a variety of different cancers and is believed to be a primary cause of the harmful long-term effects of radiation injury. CPC s lead compound, Phosphonol, has been licensed from the University of Chicago, and is in the preclinical stages of development.

PRODUCTS IN DEVELOPMENT

We are currently focusing our development activities on a series of immune regulating hormones as well as Phosphonol, the compound recently obtained through the acquisition of CPC. NEUMUNE is being co-developed with the U.S. military for use in protecting the body from acute radiation injury. This compound is being developed pursuant to a new rule enacted by the U.S. Food and Drug Administration (FDA) under which approval may be granted on the basis of efficacy in animals and safety in humans. Phosphonol is being developed to protect against the long-term effects of radiation injury and may be subject to the same rule. A number of IRHs have shown significant benefits in preclinical models of chemotherapy-induced immune suppression, and we intend to test one or more of these compounds in Phase I/II clinical trials in this indication. IMMUNITIN is our lead infectious disease compound and has shown activity in Phase II clinical trials in malaria, HIV and AIDS, and in a number of preclinical tuberculosis models. We are pursuing public/private partnerships with a number of organizations that may provide funding to allow us to conduct a Phase II/III clinical trial with IMMUNITIN in infectious disease. In addition, a number of U.S. government agencies are screening IMMUNITIN and other immune regulating hormones of ours as countermeasures against a number of pathogens that could be used as

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biowarfare agents. If these results are successful, IMMUNITIN, in a similar manner as NEUMUNE, could potentially be reviewed for approval under the new rule adopted by the FDA designed to provide an approval pathway for drugs to be used as countermeasures to weapons of mass destruction. We are also collaborating with the Cystic Fibrosis Foundation to study the effects of IMMUNITIN in treating cystic fibrosis. HE2200 has also been evaluated in several pilot phase II clinical studies and has shown an attractive safety profile. We are evaluating several formulation enhancements and chemical modifications that may improve its potential and make it a promising candidate for further clinical development. In addition, given the anti-inflammatory and immune stimulating effects seen with many of our IRHs, we are screening new IRHs in preclinical models of autoimmune conditions.

NEUMUNE

Published studies by the Armed Forces Radiobiology Research Institute (AFRRI) with our immune regulating hormone NEUMUNE have shown dramatic survival improvements in NEUMUNE-treated animals versus controls in models of radiation-induced immune suppression. The ability of NEUMUNE to stimulate both neutrophils and platelets as well as other components of innate immunity is believed to be the mechanism by which NEUMUNE exerted its protective effects in these studies. In light of recent world events, the need for a practical radioprotectant that can be used on a widespread basis in the event of a nuclear accident or event has been elevated significantly. We have initiated a collaboration with AFRRI to jointly develop NEUMUNE as a radioprotectant.

AFRRI is a leader in studying the short-term and long-term effects of radiation injury. A principal AFRRI 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 past several years, AFRRI, in concert with another Department of Defense project, has screened thousands of compounds in an effort to find an acute radioprotectant suitable for widespread use. Out of this screening and profiling effort, NEUMUNE has emerged as a leading candidate based on its significant efficacy in preclinical models to date, its safety profile, and the comparatively low-cost nature of its manufacturing process.

The FDA has informed us that NEUMUNE would qualify for review for radiation protection under a new rule adopted in 2002. Traditional drug development programs require large-scale clinical studies to establish efficacy in humans. However, pursuant to the new rule, in cases where traditional efficacy studies would be deemed unethical in evaluating a drug intended for use against lethal or permanently disabling toxic substances (such as in this situation, which would otherwise require healthy human volunteers to be exposed to potentially lethal effects of radiation), approval may be granted solely on the basis of proof of efficacy in relevant animal species and proof of safety in humans.

Given the accelerated potential development path for NEUMUNE and the significant and largely untapped market opportunity for compounds that can treat acute radiation injury, this program has become a top priority for us. We have demonstrated that NEUMUNE has significant activity in maintaining neutrophils and platelets in several non-human primate studies of acute radiation injury, and we are now finalizing the dose optimization work that we believe will allow us to initiate the pivotal large animal trials that will be necessary for formally establishing efficacy. In addition, we are collaborating with AFRRI to establish all of the manufacturing, toxicology and human safety data that will be needed to support a New Drug Application (NDA).

We believe the market opportunity for a drug that could be used to ameliorate the effects of acute radiation injury would be significant. Because the window of opportunity to treat radiation injury 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. In light of the current risk of terrorism, high-risk areas may include any military installation or theater of operations, any urban or 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. In addition, we believe similar market opportunities exist in Europe and

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Asia. The only drug that has been widely stockpiled for radiation injury is potassium iodide. Potassium iodide is only effective against the long-term risk of thyroid cancer, and does not protect the body from the acute effects on the bone marrow, which can lead to rapid fatalities. Despite this limitation, potassium iodide has been stockpiled broadly for years in Europe and Japan for civilians living within close proximity of nuclear power plants, and the U.S. has recently begun purchasing millions of doses of the drug for similar uses in this country. Given that NEUMUNE may be useful in protecting against the immediate life-threatening effects of radiation, we believe there may be strong interest by government agencies to adopt a similar stockpiling strategy if NEUMUNE is successfully developed.

As a result of the increased threat, the U.S. government is allocating significant funding for the stockpiling of drugs that act as medical countermeasures to weapons of mass destruction. In fact, as an incentive to industry to develop these countermeasures, the U.S. government is considering legislation that would provide a clear mechanism for placing large advance orders for investigational products in this area, even before they are approved. We are aggressively pursuing an advance order for NEUMUNE although we cannot guarantee that we will be successful in obtaining such an order.

IRHs in Chemotherapy Protection

As a result of our increasing knowledge of structure-activity relationships with this class of compounds, we have identified IRHs which appear to 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. Recent preclinical data in non-human primates with several of our immune regulating hormones in models of chemotherapy-induced immune suppression indicated that these compounds could significantly protect both neutrophils and platelets. We are preparing to select one of these compounds for clinical development in chemotherapy protection. Drugs that only stimulate neutrophils in this setting currently generate sales in excess of $2.5 billion annually, although we can not guarantee that our compounds, if approved, will generate significant sales.

Phosphonol

We acquired exclusive commercialization rights to Phosphonol in our recent acquisition of CPC. Like NEUMUNE, Phosphonol is being developed to protect 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 appears to have the potential to stabilize the genome after radiation injury, thus reducing genetic mutations. By reducing genetic mutations, Phosphonol may also reduce a variety of cancers that can occur seven to ten years after radiation injury.

We believe it may be possible to develop Phosphonol pursuant to the same animal efficacy rule we are following with NEUMUNE. We are now beginning to profile Phosphonol in a series of animal models designed to assess the safety, efficacy and oral bioavailability of the compound. We are also preparing to open discussions with the FDA about specific development objectives that would be required for marketing approval of the compound.

We believe that if Phosphonol can be successfully developed along with our product NEUMUNE, it would give us a compelling portfolio of products to treat the short- and long-term effects of radiation injury. We also believe that the experience and relationships we are building in both developing NEUMUNE and in attempting to secure advance stockpiling orders for the compound may be directly transferable to Phosphonol. Because Phosphonol addresses exposure to low levels of radiation, we believe the market opportunity for the compound may also include stockpiling for people who are exposed to inadvertent environmental radiation as well as for use in response to acts of terrorism and nuclear accidents,

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As with our immune regulating hormones, we also believe Phosphonol and related compounds may potentially play an important role in protecting against damage from chemotherapy.

IMMUNITIN in Infectious Disease

While the primary market opportunities for pharmaceuticals have traditionally been in the U.S., Europe and Japan, our immune regulating hormones have a number of attributes that make them potentially useful globally. Included in these attributes are the potential broad-spectrum activity in multiple infectious diseases, the attractive safety profile to date, the low likelihood of resistance and the relative ease of manufacture. Increasing focus on the crisis that infectious diseases such as HIV, malaria and tuberculosis have created in the developing world has led to a number of recent third party initiatives designed to provide funding for effective approaches to these diseases. If we are able to receive support from these initiatives for both development and commercialization, subject to obtaining regulatory approvals, marketing IMMUNITIN and our other compounds in developing countries could become commercially attractive. In addition, as described above, similar funding initiatives and incentives are now being proposed by the U.S. government to encourage the development of new drugs to serve as countermeasures against weapons of mass destruction, including nuclear, radiological, biological and chemical warfare. If these initiatives are enacted, there may be significant commercial opportunities to develop drugs that can be stockpiled to protect against these threats.

Viral. In addition to being an important world health problem and a potentially significant commercial opportunity, we believe HIV is a useful model system in which to study the effects of IMMUNITIN in immune dysregulation. HIV patients have high levels of chronic inflammation and also have many components of their immune systems that are compromised. We believe that if we can show clinical benefit in such a severe example of immune dysregulation, we may also be able to demonstrate benefit in a variety of other clinical situations in which the situation is not as severe.

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 all of these studies, IMMUNITIN treatment appeared to be generally well tolerated with mild to moderate pain at the injection site being the most common adverse event. In addition to assessing the safety profile of IMMUNITIN in the trials, we have also assessed the effect of IMMUNITIN on a wide variety of immune and inflammatory markers that are associated with disease progression.

Results from a study employing intermittent subcutaneous dosing of IMMUNITIN in 24 South African HIV patients receiving no other therapy were presented at the World AIDS Conference in July 2002. Prior to dosing with IMMUNITIN, these HIV patients had dramatically elevated transcript levels of inflammatory mediators, including TNF-alpha, COX-2, IL-1 beta and IL-6, relative to healthy South African volunteers. This indicated that these HIV-infected patients were experiencing broad-based systemic inflammatory immune dysregulation before treatment with IMMUNITIN. After dosing with IMMUNITIN, these same patients experienced statistically significant declines in transcripts for TNF-alpha, COX-2, IL-1 beta and IL-6 as well as other inflammatory mediators. The number of transcripts was reduced to levels close to those seen in healthy volunteers and remained significantly reduced for the entire treatment course despite only intermittent dosing.

A number of studies reported in the medical literature have shown that increases in inflammatory cytokines such as TNF-alpha, IL-1 beta and IL-6 and the enzyme COX-2 can lead to decreases in dendritic cells, which, in turn, lead to a progressive loss of innate and cell-mediated (Th1) immunity. This chronic inflammatory dysregulation and progressive loss of innate and cell-mediated immunity that is believed to be a major contributing factor to the ultimate progression to AIDS and the life-threatening opportunistic infections, cancers, wasting and dementia that compromise the patient. By quieting down this rampant systemic inflammation, we believe that IMMUNITIN has the potential to induce the immune system to mount appropriate innate and cell-mediated immune responses that will keep the virus in check and slow or prevent the progression to AIDS-related conditions.

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In this South African study, we also observed significant increases relative to placebo-treated patients in a wide variety of immune cell subsets associated with innate and cell-mediated immunity following dosing with IMMUNITIN. These increases appeared to be long lasting despite the fact that IMMUNITIN was only administered in intermittent treatment courses. A number of these cell types have been associated with delaying disease progression towards AIDS. In addition, patients receiving IMMUNITIN in this trial experienced a fall in virus levels over the course of the study, which reached a 0.6 log drop in the most effective dose group at the end of the 8-month monitoring period.

In 2003 we presented results from a study using IMMUNITIN as a monotherapy in 25 late-stage AIDS patients. Over this treatment course, patients in the placebo group experienced 67% more opportunistic infections than those treated with IMMUNITIN. The ability of IMMUNITIN to have an effect on a hard clinical end point like opportunistic infections on this late stage patient population indicates that improving host immune reponses to HIV can potentially lead to clear clinical benefit.

Parasitic. The ability of IMMUNITIN to reduce inflammation while stimulating innate and cell-mediated immunity seen in our HIV clinical trials also has possible implications for a number of other infectious diseases, including parasitic infections such as malaria. The medical literature indicates that high levels of the inflammatory mediator TNF-alpha are believed to be a cause of the pathology seen in malaria. In addition, both the innate and cell-mediated portions of the immune system are believed to be important in controlling the parasite.

As a result, we entered into a collaboration with the U.S. Navy on a preclinical program in malaria with IMMUNITIN. Based on favorable results in multiple preclinical studies with the compound, we then proceeded with two Phase II clinical studies 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 when the compound was delivered either by injection or as a buccal tablet.

Bacterial. We have 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 TB in this model system.

IMMUNITIN as a Countermeasure to Bioterrorism. The finding that IMMUNITIN appears active in humans in HIV and malaria and also appears to provide benefit preclinically against TB makes it a promising candidate against biowarfare agents. Government officials have expressed concern that if terrorists or rogue nations were to unleash a biowarfare agent, it may well be one that has been genetically engineered to be resistant to all known antibiotics. As such, the government is interested in developing compounds that are capable of boosting host immunity rather than attacking a specific pathogen. It is believed that such agents may provide protection against a number of different potential pathogens and would be unlikely to be affected by resistance issues.

IMMUNITIN appears to boost both innate and adaptive host immunity with an attractive safety profile. The compound has now shown broad-spectrum activity against viral (HIV), parasitic (malaria) and bacterial (TB) pathogens. In addition, it is easy to administer and cost-effective to produce, making it potentially suitable for large scale pharmaceutical stockpiling.

Because of these features, a number of government agencies have agreed to screen IMMUNITIN and our other immune regulating hormones as countermeasures against a series of pathogens that may be used as biowarfare agents. If these results are successful, we believe government grants may be available to fund further development in these indications. In addition, the U.S. government has recently proposed a series of sweeping incentives to encourage biotechnology and pharmaceutical companies to develop drugs for these threats. These incentives, if enacted, include guaranteed purchase contracts and other beneficial provisions. Depending on the

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nature of the pathogen, there may also be certain indications for which IMMUNITIN, if successfully developed, could be reviewed under the FDA s new animal efficacy rule described above.

Cystic Fibrosis and Other Autoimmune Indications

Given the anti-inflammatory and immune stimulating 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 diseases. To that end, we have entered into a collaboration with Cystic Fibrosis Foundation Therapeutics (CFFT), the non-profit drug discovery and development arm of the Cystic Fibrosis Foundation, to study IMMUNITIN in a Phase I/II clinical trial for the treatment of cystic fibrosis. CFFT has agreed to award up to $1.7 million in funding toward the development of this investigational drug candidate. The trial is anticipated to begin in 2004.

Hollis-Eden is also screening new IRHs in a number of preclinical models of autoimmunity and, if these results are successful, plans to enter one or more of these compounds into development for additional autoimmune indications.

Competition

Given the large market opportunities we are pursuing, most major pharmaceutical companies and a number of biotechnology companies have programs directed toward finding drugs to treat indications we are exploring. 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.

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. Other companies also have products in development to enhance hematopoiesis.

In the area of immune modulators for correcting immune dysregulation, a number of companies are targeting inhibition or enhancement of a single cytokine or other mediator. For example, Amgen s Enbrel targets TNF-alpha, as does Johnson & Johnson s Remicade. Vioxx from Merck and Celebrex from Pfizer/Pharmacia both target COX-2. While these targeted approaches have shown clinical benefit and have generated significant sales volumes, redundant mechanisms in the immune system limit their effectiveness. In addition, side effects and cost issues limit their global utility. In contrast, our immune regulating hormones appear to affect multiple cytokines and inflammatory mediators in a physiologic way that may make them more attractive drug candidates than currently available therapies.

In the area of infectious disease, 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 Hollis-Eden s proposed products and its research and development activities are and will continue to be subject to regulation by federal, state and local governmental authorities in the United States and other countries. In the United States, 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.

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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. The promising compound is subjected to extensive laboratory and animal testing to determine if the compound is biologically active and safe.

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

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

As described above, for several of the product opportunities we are pursuing, we may apply for approval based upon a new 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 efficacy 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 (NDA). Upon successful completion of Phase III clinical trials, the drug sponsor files an NDA 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 an NDA is approved, 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.

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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 United States, 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 over 100 issued U.S. and foreign patents and over 100 pending U.S. and foreign patent applications.

We consider the protection of our technology, whether owned or licensed, to the exclusion of use by others, to be vital to our business. While we intend to focus primarily on patented or patentable technology, we may also rely on trade secrets, unpatented property, know-how, regulatory exclusivity, patent extensions and continuing technological innovation to develop our competitive position. In the United States 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.

Patent applications in the United States are maintained in secrecy until patents issue. Publication of discoveries in the scientific or patent literature, if made, tends to lag behind actual discoveries by several months. 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.

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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 time. 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.

Relationship with Aeson Therapeutics, Inc.

During 2000 we acquired a 21% equity stake in Aeson Therapeutics, Inc., with an exclusive option to acquire the remainder of Aeson at a pre-determined price for a limited period of time. Aeson s lead compound is in Phase II clinical studies for the treatment of cardiovascular disease, as well as in preclinical studies for other indications. We exchanged $2 million in cash and 208,681 shares of Hollis-Eden common stock for our equity interest in Aeson. In 2002, in exchange for an extension of time to exercise our option to acquire the remainder of Aeson, we made an additional equity investment of $1.2 million in Aeson and now have approximately a 25% equity stake. All the payments were expensed as in-process R&D.

As a result of a decision to narrow the scope of our research and development activities in late 2002, we elected not to exercise our option to acquire the remainder of Aeson. We continue to hold our equity interest in the company.

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

In January 2000, we licensed technology from Dr. Henry Lardy and Humanetics Corporation. Through these relationships we have licensed a series of adrenal hormones and hormone analogs as well as related patents and patent applications in the areas of infectious diseases, oncology, radiation therapy, central nervous system disorders, metabolic conditions and inflammation related areas.

Also during January 2000, we entered into two new technology agreements with Patrick T. Prendergast, Colthurst Ltd. and Edenland, Inc. The first agreement, the Technology Assignment Agreement, replaced the Colthurst License Agreement dated May 18, 1994 among Hollis-Eden, Mr. Prendergast and Colthurst. This agreement assigned to us ownership of all patents, patent applications and current or future improvements of

the technology under the Colthurst License Agreement, including IMMUNITIN. Upon signing the agreement, we issued to Colthurst 132,000 shares of common stock, with an additional 528,000 shares and warrants to be issued over time upon the satisfaction of certain conditions. Because all of these conditions were not satisfied, we have not issued any additional shares or warrants to Colthurst, and we believe that we have no obligation to issue any

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additional shares or warrants. While we are confident in our analysis, if any dispute should arise in this matter, we cannot guarantee that, as a result of such dispute, additional equity will not be issued or that an additional accounting charge will not be made. The second agreement, the Sponsored Research and License Agreement, replaced both the Edenland License Agreement and the Research, Development and Option Agreement, each dated August 25, 1994, among Hollis-Eden, Mr. Prendergast and Edenland. Pursuant to the Sponsored Research and License Agreement, Edenland exclusively licensed to us a number of additional compounds, together with all related patents and patent applications.

In January 2002, we licensed technology from Dr. Henry Lardy and Humanetics Corporation. Through these relationships we have licensed a series of adrenal hormones and hormone analogs as well as related patents and patent applications in the areas of infectious diseases, oncology, radiation therapy, central nervous system disorders, metabolic conditions and inflammation related areas.

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. 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 is currently a scientific consultant to Hollis-Eden.

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 will issue 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 5, 2004, we had 51 full-time, non-union employees. We believe that our relations with our employees are good.

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Executive Officers and Senior Management

Our executive officers and senior management and their ages as of March 5, 2004 are as follows:

Name	Age	Position
Richard B. Hollis	51	Chairman of the Board, President and Chief Executive Officer
Daniel D. Burgess	42	Chief Operating Officer and Chief Financial Officer
James M. Frincke, Ph.D.	53	Chief Scientific Officer
Eric J. Loumeau	41	Vice President, Corporate General Counsel
Robert L. Marsella	51	Vice President, Business Development and Marketing
Christopher L. Reading, Ph.D.	56	Executive Vice President, Scientific Development
Dwight R. Stickney, M.D.	61	Vice President, Medical Affairs
Robert W. Weber	53	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 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 Pharmaceuticals, Inc. in August 1999. Mr. Burgess joined Hollis-Eden from Nanogen Inc., where he served as Vice President and Chief Financial Officer. Prior to joining Nanogen in 1998, Mr. Burgess spent ten years with Gensia Sicor, Inc. (acquired by Teva Pharmaceutical Industries Limited) and Gensia Automedics, Inc., a partially owned subsidiary of Gensia Sicor. He served as President and a director of Gensia Automedics, where he was responsible for all functional areas of this medical products company. In addition, he was Vice President and Chief Financial Officer of Gensia Sicor, where he was responsible for finance, investor relations, business development and other administrative functions. During his tenure with Gensia, Mr. Burgess helped transform the company from a research stage company with less than 50 employees into a fully integrated specialty pharmaceutical company with more than $150 million in annual revenues. Mr. Burgess was instrumental in helping Gensia raise over $400 million in various public and private financings and was a key figure in a number of acquisitions and in-licensing and out-licensing transactions. 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.

James M. Frincke, Ph.D. joined Hollis-Eden as Vice President, Research and Development in November 1997, was promoted to Executive Vice President in March 1999, and to Chief Scientific Officer in December 2001. Dr. Frincke joined Hollis-Eden from Prolinx, Inc., where he served as Vice President, Therapeutics Research and Development from 1995 to 1997. During his 20 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

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evaluation, pharmacology, manufacturing, and the management of regulatory and clinical matters of 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.

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. Mr. Marsella has more than 22 years of medical sales, marketing, and distribution experience. Prior to joining Hollis-Eden, Mr. Marsella acted as a distributor of various cardiac related hospital products for a number of years. In addition, he has also served as Regional Manager for Genentech and launched Activase™, t-pa (a biopharmaceutical drug) in the Western United States. Prior to joining Genentech, Mr. Marsella marketed intravenous infusion pumps for Imed Corporation for four years. Mr. Marsella began his career as a field sales representative and soon after was promoted to regional sales manager for U.S. Surgical Corporation, Auto Suture division. Mr. Marsella received his B.A. degree from San Diego State University.

Christopher L. Reading, Ph.D. became Vice President of Scientific Development in January 1999 and was promoted to Executive Vice President, Scientific Development in March 2002. Prior to joining Hollis-Eden, Dr. Reading was Vice President of Product and Process Development at Novartis Inc.-owned SyStemix Inc. During this time, he successfully filed three investigational new drug applications (INDs) in the areas of stem cell therapy technology and stem cell gene therapy for HIV/AIDS. Prior to joining SyStemix, Dr. Reading served on the faculty of the M.D. Anderson Cancer Center in Houston for nearly 13 years. His positions there included Associate and Assistant Professor of Medicine in the Departments of Hematology and Tumor Biology. During his career, Dr. Reading has given more than 25 national and international scientific presentations, published more than 50 peer-reviewed journal articles and 15 invited journal articles as well as written nearly 20 book chapters, and received numerous grants and contracts which supported his research activities. Dr. Reading has served on the National Science Foundation Advisory Committee for Small Business Innovative Research Grants (SBIR) as well as on the editorial boards of *Journal of Biological Response Modifiers* and *Molecular Biotherapy*. He holds a number of patents for his work with monoclonal antibodies and devices. Dr. Reading received his Ph.D. in Biochemistry at the University of California at Berkeley and completed postdoctoral study in tumor biology at The University of California at Irvine. He earned his B.A. in biology at the University of California at San Diego.

Dwight R. Stickney, M.D. was appointed Vice President, Medical Affairs in March 2003. He joined Hollis-Eden as Medical Director, Oncology in May 2000. Dr. Stickney joined Hollis-Eden from the Radiation Oncology Division of Radiological Associates of Sacramento Medical Group, Inc., in Sacramento, California, where he served as an oncologist since 1993. While at Radiological Associates, he served as Chairman of the Radiation Oncology Division from 1997 to 1999 and was a member of the Radiation Study section of the National Institute of Health s Division of Research Grants from 1993 to 1997. He also served as the Director of Radiation Research for Scripps Clinic and Research Foundation in La Jolla, California. Dr. Stickney has taught in medical academia as Associate Professor of Radiation Medicine at Loma Linda University School of Medicine and has served as Director of the International Order of Forresters Cancer Research Laboratory and on the Board of Directors of the American Cancer Society. Earlier in his career, Dr. Stickney held positions with the 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

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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 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.

Risk Factors

In evaluating our business, you should consider the following discussion of risks, in addition to other information contained in this annual report. 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 a variety of infectious diseases and immune system and metabolic disorders. However, all drug candidates require U.S. FDA and foreign government approvals before they can be commercialized. These regulations change from time to time and new regulations may be adopted. None of our drug candidates has been approved for commercial sale. We may incur significant additional operating losses over the next several years as we fund development, clinical testing and other expenses while seeking regulatory approval. 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 products, we will not be able to sell our products and will not generate revenues. If we receive regulatory approval of a product, such approval may impose limitations on the indicated uses for which we may market the product, which may limit our ability to generate significant revenues.

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 $107.1 million as of December 31, 2003. Our net losses for fiscal years 2003, 2002 and 2001 were $25.7 million, $17.5 million and $15.8 million, respectively. Many of our research and development programs are at an early stage. Potential drug candidates are subject to inherent risks of failure. These risks include the possibilities that no drug candidate will be found safe or effective, meet applicable regulatory standards or receive the necessary regulatory clearances. Even safe and effective drug candidates may never be developed into commercially successful drugs. If we are

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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 severe acute radiation injury 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 injury, 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 the U.S. and foreign governments. 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 the acute effects of radiation injury. Due to these uncertainties, we cannot guarantee that we will receive any stockpiling orders for NEUMUNE 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 United States and elsewhere. Because we are pursuing potentially large markets, our competitors include major, multinational pharmaceutical and chemical 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 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 research and development programs in these fields. 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 Amgen Inc. have developed or are developing products to boost neutrophils after chemotherapy.

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, 2003, our cash and cash equivalents totaled approximately $84.9 million. Based on our current plans, we believe these financial resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements at least well into 2006. 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,

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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 over 100 issued U.S. and foreign patents and over 100 pending U.S. and foreign patent applications. Our success will depend in part on our ability to obtain additional United States and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate 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 products, pharmaceuticals are either not patentable or have only recently become patentable. Past enforcement of intellectual property rights in many of these countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries may be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions. Our domestic patent position is also highly uncertain and involves complex legal and factual questions. The applicant or inventors of subject matter covered by patent applications or patents owned by or licensed to us may not have been the first to invent or the first to file patent applications for such inventions. Due to uncertainties regarding patent law and the circumstances surrounding our patent applications, the pending or future patent applications we own or have licensed may not result in the issuance of any patents. Existing or future patents owned by or licensed to us may be challenged, infringed upon, invalidated, found to be unenforceable or circumvented by others. Further, any rights we may have under any issued patents may not provide us with sufficient protection against competitive products 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. 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.

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In addition, if another party claims the same subject matter or subject matter overlapping with the subject matter that we have claimed in a United States patent application or patent, we may decide or be required to participate in interference proceedings in the United States 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.

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

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

Existing pricing regulations and reimbursement limitations may reduce our potential profits from the sale of our products.

The requirements governing product licensing, pricing and reimbursement vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after product-licensing approval is granted. As a result, we may obtain regulatory approval for a drug candidate in a particular country, but then be subject to price regulations that reduce our profits from the sale of the product. In some foreign markets pricing of prescription pharmaceuticals is subject to continuing government control even after initial marketing approval. In addition, certain governments may grant third parties a license to manufacture our product without our permission. Such compulsory licenses typically would be on terms that are less favorable to us and would 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. This 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 products currently pending, the decline in the size of the markets in which we may in the future sell commercial products could cause the perceived market value of our business and the price of our common stock to decline.

Our ability to commercialize our products successfully also will depend in part on the extent to which reimbursement for the cost of our products 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 potential products to the market, such products may not be considered cost effective and reimbursement may not be available or sufficient to allow us to sell such products 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 in the United States for the treatment of radiation exposure and chemotherapy protection;

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;

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

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

- we may not have the financial resources to continue research and development of any of our drug candidates; and
- we may not be able to enter into collaborative arrangements relating to any drug candidate subject to delay in regulatory filing.

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

- delays in enrolling volunteers;
- interruptions in the manufacturing of our drug candidates or other delays in the delivery of materials required for the conduct of our studies;
- lower than anticipated retention rate of volunteers in a trial;
- unfavorable efficacy results;
- serious side effects experienced by study participants relating to the drug candidate;
- new communications from regulatory agencies about how to best conduct these studies; or
- failure to raise additional funds.

If the manufacturers of our products do not comply with current Good Manufacturing Practices regulations, or cannot produce the amount of products we need to continue our development, we will fall behind on our business objectives.

An outside manufacturer, Hovione Soc. Química, S.A., is currently the primary producer of the active pharmaceutical ingredient for our drug candidate IMMUNITIN, and may produce other compounds for us in the future. 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 products.

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 clinical studies and prepare for commercialization of 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

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our products marketed and sold by others on attractive terms, it will impair our ability to commercialize our drug candidates and to enter new or existing markets. Our inability to effectively enter these markets would materially and adversely affect our ability to generate significant revenues.

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

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

We may face product liability claims related to the use or misuse of our products, 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 in an aggregate amount of $5 million. 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, have been highly volatile, especially recently. 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 clinical trials;
- unfavorable results from clinical trials;

unfavorable developments concerning patents or other proprietary rights; or

unfavorable domestic or foreign regulatory developments;

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 $5.00 to $36.25 between January 1, 2003 and March 5, 2004.

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

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instituted against that company. This type of litigation, if instituted, 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 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 14% of our outstanding common stock as of March 5, 2004. Assuming that Mr. Hollis exercises all of his outstanding warrants and options that vest within 60 days of March 5, 2004, Mr. Hollis would beneficially own approximately 20% of our outstanding common stock. As a result, Mr. Hollis may be able to significantly influence the management of Hollis-Eden 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 Hollis-Eden.

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 series 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 2. Properties

Our corporate headquarters are currently located at 4435 Eastgate Mall, Suite 400, San Diego, CA 92121, where we have leased approximately 22,000 square feet of office space through September 2004. In addition, we

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have leased, in San Diego, CA., 4,364 square feet of laboratory space through November 2005. We believe that our facilities are adequate for our current operations and we have lease extension options.

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. As of the date of this Annual Report on Form 10-K, we are not 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 2003.

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PART II

Item 5. Market for Registrant s Common Stock and Related Stockholder Matters

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, 2002 through March 5, 2004.

Common Stock	High	Low
2002		
First Quarter	$ 12.24	$ 5.71
Second Quarter	7.64	5.75
Third Quarter	6.94	4.02
Fourth Quarter	6.84	3.30
2003		
First Quarter	$ 6.70	$ 5.00
Second Quarter	17.50	5.78
Third Quarter	36.25	12.22
Fourth Quarter	22.30	9.41
2004		
January 1 March 5	$ 16.50	$ 11.00

On March 5, 2004, the closing price of our common stock as reported by the Nasdaq National Market System was $13.48 per share. There were approximately 5,500 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.

The following table provides information as of December 31, 2003 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,	Number of securities remaining available for future issuance under equity compensation plans

		warrants and rights	(excluding securities in the first column)
Stock option equity compensation plans approved by security holders	3,761,451	$ 8.88	552,265
Stock option equity compensation plans not approved by security holders	1,750,000	$ 6.50	
Warrant equity compensation plans not approved by security holders	690,620	$ 9.24	
Total	6,202,071		552,265

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.

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Changes in Securities

On February 25, 2003, we completed a private placement in which we issued $10.0 million aggregate principal amount of three-year convertible debentures, which were convertible into common stock at a price of $5.70 per share. Of these gross proceeds, $0.6 million was applied toward commissions to the placement agent, SG Cowan Securities Corporation. Expenses related to the offering were approximately $0.2 million. After deducting commissions and expenses, the Company received net proceeds of approximately $9.2 million. The investors were comprised of a group of qualified institutional buyers and institutional accredited investors. We also issued to the investors warrants to purchase up to 701,760 shares of common stock, one-half of which have an exercise price of $6.17 per share and the other half of which have an exercise price of $6.71 per share. In addition, as part of the placement agent fee, we issued to SG Cowen Securities Corporation a warrant to purchase up to 73,684 shares of common stock at an exercise price of $5.99 per share. During 2003, we issued a total of 9,070 shares of common stock in lieu of cash for interest payments due on the debentures. All of the debentures were converted into a total of 1,754,400 shares of common stock between June and August 2003.

In February 2003, we issued 50,000 shares of common stock to Humanetics Corporation as a milestone payment pursuant to the terms of that certain Exclusive License Agreement, entered into in January 2000.

In February 2003, we issued 118,921 shares of common stock to Pharmadigm, Inc. pursuant to the terms of that certain Sublicense Agreement, entered into in August 2002.

In March 2003, we amended a warrant previously issued to Jacmar/Viking, L.L.C. Pursuant to the amended warrant, the warrant is now exercisable into an aggregate of 250,000 shares of the Company s Common Stock at an exercise price of $10.00 per share. William H. Tilley, one of our directors, is a principal of Jacmar/Viking.

On June 19, 2003 we raised approximately $14.6 million in gross proceeds from the sale of 1,283,066 shares of common stock in a private placement at a price of $11.42 per share. Of these gross proceeds, $0.8 million was applied toward commissions to the placement agent, SG Cowan Securities Corporation. Expenses related to the offering were approximately $40,000. After deducting commissions and expenses, the Company received net proceeds of approximately $13.8 million. The investors are comprised of a group of qualified institutional buyers and institutional accredited investors. We also issued to the investors warrants to purchase up to 192,456 shares of common stock having an exercise price of $15.45 per share. In addition, as part of the placement agent fee, we issued to SG Cowan Securities Corporation a warrant to purchase up to 44,266 shares of common stock at an exercise price of $13.22 per share.

The sale and issuance of securities in the transactions described in the foregoing paragraphs were deemed to be exempt from registration under the Securities Act of 1933, as amended, by virtue of Section 4(2) and/or Regulation D promulgated under such Act. The recipients represented their intention to acquire the securities for investment only and not with a view to the distribution thereof. Appropriate legends are affixed to the securities issued in such transactions. All recipients either received adequate information about the Company or had access, through employment or other relationships, to such information.

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Item 6. Selected Financial Data

The following data summarizes certain selected financial data for each of the five years ended December 31, 2003 through 1999 and the period from inception (August 15, 1994) to December 31, 2003. 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).

	2003	2002	2001	2000	1999	Period from Inception (Aug. 15, 1994) to December 31, 2003
Statement of Operations Data:						
Research and development	$ 10,764	$ 13,083	$ 11,870	$ 17,933(3)	$ 5,731	$ 67,487
General and administrative	7,327(1)	4,787	5,091	4,157	11,940(4)	39,682
Total operating expenses	18,091	17,870	16,961	22,090	17,671	107,169
Other income (expense)	(7,580)(2)	368	1,199	2,575	2,351	78
Net loss	$ (25,671)	$ (17,502)	$ (15,762)	$ (19,515)	$ (15,320)	$ (107,091)
Net loss per share, basic and diluted	$ (1.67)	$ (1.35)	$ (1.35)	$ (1.74)	$ (1.41)	
Weighted average number of common shares outstanding, basic and diluted	15,381	12,932	11,654	11,240	10,861	
Balance Sheet Data:						
Cash and equivalents	$ 84,852	$ 13,087	$ 30,567	$ 34,298	$ 47,486	
Total assets	85,381	13,982	31,462	35,099	48,265	
Accounts payable and accrued expenses	3,329	2,950	3,602	2,636	1,640	
Stockholders equity	$ 82,052	$ 11,032	$ 27,860	$ 32,463	$ 46,625	

(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 we subsequently converted to common stock.

(3) 2000 Research and development expenses include $4.5 million for non-cash charges for the purchase of technology and in-process R&D.

(4) 1999 General and Administrative expenses include $7.7 million for non-cash charges, due to the acceleration of vesting of stock options for a former officer, the issuance of warrants for services, and the issuance of stock options to non-employees.

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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 development efforts target radiation and chemotherapy induced immune suppression and immune dysregulation caused by infectious diseases such as HIV, malaria and tuberculosis. Our initial technology development efforts are primarily focused on a series of potent hormones and hormone analogs that we believe are key components of the body s natural regulatory system. We believe these immune regulating hormones (IRHs) can be used to reestablish host immunity in situations of dysregulation.

We have been unprofitable since our inception and 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. 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 not generated any revenues for the period from August 15, 1994 (inception of Hollis-Eden Inc.) through December 31, 2003. 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, 2003, we have incurred expenses of approximately $67.5 million in research and development and $39.7 million in general and administrative expenses. We have incurred $0.1 million in net other income comprised of $7.6 million in deemed discount expense, $0.4 million in interest expense and $8.1 million in interest income. The combination of these resulted in a net loss of $107.1 million for the period from inception until December 31, 2003.

Research and development expenses were $10.8 million, $13.1 million and $11.9 million in 2003, 2002 and 2001, respectively. The research and development expenses relate primarily to the ongoing development, preclinical testing, and clinical trials for IMMUNITIN, NEUMUNE and HE2200, as well as our investment in Aeson Therapeutics, which has been expensed as in-process R&D. Research and development expenses decreased $2.3 million in 2003 compared to 2002. The decrease in research and development expenses was due mainly to reduced preclinical and clinical trial activities after streamlining our operations and focusing our research and development expenditures in the second half of 2002. Research and development expenses increased $1.2 million in 2002 compared to 2001 due to increased staffing, license fees and clinical trials

expenses, which was offset by reduced expenditures for preclinical work. We expect research and development expenses to increase in 2004 and beyond as our products move into the more expensive later stages of development.

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General and administrative expenses were $7.3 million, $4.8 million and $5.1 million in 2003, 2002 and 2001, respectively. General and administrative expenses relate to salaries and benefits, facilities, legal, investor relations, insurance and travel. General and administrative expenses increased $2.5 million in 2003 compared to 2002 primarily due to non-cash charges totaling $2.2 million for 2003. The non-cash charges are comprised of: $0.7 million in non-cash charges related to the issuance of a warrant and a change in the terms of a warrant to a service provider; $1.3 million in non-cash charges 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.

General and administrative expenses decreased $0.3 million in 2002 compared to 2001 due to decreased consulting fees and legal expenses that were partially offset by an increase in facilities and investor relations expenses. We expect general and administrative expenses to increase in 2004 and beyond as a result of the increased costs of compliance with new audit regulations, including section 404 of the Sarbanes Oxley Act, and costs associated with preparing for the potential launch of our products.

Other income and expenses were $(7.6) million, $0.4 million and $1.2 million in 2003, 2002 and 2001, respectively. For 2003, other income and expense was comprised of the following: an expense of $(7.6) million for the non-cash amortization of the deemed discount and deferred issuance costs on the convertible debentures issued and converted to common stock during 2003; interest income of $0.4 million; and interest expense on the convertible debentures totaling $(0.4) million. Other income and expense for 2002 and 2001 was interest income totaling $0.4 million and $1.2 million for each year respectively. The interest income declined in 2002 compared to 2001 due to lower cash balances and lower 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 addition, we have received a total of $17.3 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 principle amount of convertible debentures outstanding.

We became entitled to convert the outstanding debentures into common stock as of the close of market on Friday, August 8, 2003, at which point the volume weighted average price of our common stock had exceeded $14.25 for 15 consecutive trading days. 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.

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

	Payments Due by Period				
Contractual Obligations	Total	Less than one year	One to three years	Three to five years	More than Five years
Operating Leases	$ 1,045	$ 810	$ 213	$ 22	$

Our operations to date have consumed substantial capital without generating any revenues, 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. With the possible exception of sales of our NEUMUNE product for radiation treatment, 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 at least well into 2006. 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.

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

Critical Accounting Policies

Certain of our accounting policies require the application of judgment and estimates by management, which may be affected by different assumptions and conditions. These estimates are typically based on historical experience, terms of existing contracts, trends in the industry and information available from other outside sources, as appropriate. We believe the estimates and judgments associated with our reported amounts are appropriate in the circumstances. Actual results could vary from those estimates under different assumptions or conditions. Given the nature of our current operations, there are no other critical accounting policies that affect us.

Impact of Recently Issued Accounting Pronouncements

On December 31, 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. SFAS No. 148 amends SFAS No. 123, Accounting for Stock-Based Compensation, to provide alternative methods of transition to the fair value method of accounting for stock-based employee compensation under SFAS No. 123. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 and APB Opinion No. 28, Interim Financial Reporting, to require disclosure in the summary of significant accounting policies of the effects of an entity s accounting policy with respect to stock-based

employee compensation on reported earnings in annual and interim financial statements. While the Statement does not amend SFAS No. 123 to require companies to account for employee stock options using the fair value method, the disclosure provisions of SFAS No. 148 are applicable to all companies with stock-based employee compensation, regardless of whether the accounting for that compensation is using the fair value method of SFAS No. 123 or the intrinsic value method of Opinion 25. The company has elected to continue using the intrinsic value method and has incorporated these expanded disclosures into our Notes To Financial Statements.

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Item 7A. Quantitative and Qualitative Disclosures About Market Risk

At December 31, 2003, 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.

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Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Balance Sheets

	December 31,	
	2003	**2002**
	(In thousands)	
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 84,852	$ 13,087
Prepaid expenses	134	123
Deposits	27	87
Receivable from related party (Note 4)	18	
Total current assets	85,031	13,297
Property and equipment, net of accumulated depreciation of $434 and $327	282	398
Deposits	68	
Receivable from related party (Note 4)		274
Other receivable		13
Total assets	$ 85,381	$ 13,982
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,329	$ 2,950
Total current liabilities	3,329	2,950
Commitments and contingencies (Notes 6, 11, 12)		
Stockholders equity: (Notes 3, 7, 8, 9, 10)		
Preferred stock, no par value, 10,000 shares authorized; no shares outstanding		
Common stock, $.01 par value, 50,000 shares authorized; 19,272 and 12,972 shares issued, respectively	193	130
Paid-in capital	189,296	92,322
Cost of treasury stock (59 shares) as of December 31, 2003	(346)	
Deficit accumulated during development stage	(107,091)	(81,420)
Total stockholders equity	82,052	11,032
Total liabilities and stockholders equity	$ 85,381	$ 13,982

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

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Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Operations

	For the year ended December 31,			Period from Inception (Aug. 15, 1994) to December 31,
	2003	2002	2001	2003
	(In thousands, except per share amounts)			
Operating expenses:				
Research and development				
R & D operating expenses	$ 10,442	$ 13,017	$ 11,774	$ 61,823
R & D costs related to common stock and stock option grants for collaborations and technology purchases	322	66	96	5,664
Total research and development	10,764	13,083	11,870	67,487
General and administrative				
G & A operating expenses	5,161	4,523	4,804	27,475
G & A costs related to options / warrants granted	2,166	264	287	12,207
Total general and administrative	7,327	4,787	5,091	39,682
Total operating expenses	18,091	17,870	16,961	107,169
Other income (expense):				
Gain / loss on disposition of assets	(2)	(21)		(23)
Non-cash amortization of deemed discount and deferred Issuance costs on convertible debentures	(7,627)			(7,627)
Interest income	387	389	1,199	8,116
Interest expense	(338)			(388)
Total other income (expense)	(7,580)	368	1,199	78
Net loss	$ (25,671)	$ (17,502)	$ (15,762)	$ (107,091)
Net loss per share, basic and diluted	$ (1.67)	$ (1.35)	$ (1.35)	
Weighted average number of common shares outstanding	15,381	12,932	11,654	

The accompanying notes are an integral part of these financial statements

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Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Stockholders Equity

	Preferred stock at par value		Common stock at par value		Capital in excess of par	Cost of Repurchased Common Stock		Deferred	Deficit accumulated during development	
	shares	amount	shares	amount	value	shares	amount	compensation	stage	Total
					(In thousands)					
Contribution by stockholder		$		$	$ 103		$	$	$	$ 103
Common stock issued for cash			2,853		25					25
Common stock issued as consideration for the license agreements (Note 6)			543		5					5
Net loss									(1,277)	(1,277)
Balance at December 31, 1994			3,396		133				(1,277)	(1,144)
Common stock issued for cash			679		250					250
Common stock issued as consideration for amendments to the license agreements (Note 6)			76		28					28
Net loss									(672)	(672)
Balance at December 31, 1995			4,151		411				(1,949)	(1,538)
Common stock issued in conversion of debt (Note 7)			165		371					371
Common stock issued for cash, net of expenses (Note 7)			580		1,234					1,234
Common stock issued as consideration for termination of a finance agreement			15		34					34
Warrants issued to consultants for services rendered					24					24
Net loss									(692)	(692)
Balance at December 31, 1996			4,911		2,074				(2,641)	(567)
Recapitalization of Company upon the merger with Initial Acquisition Corp. (Note 3)			883	58	6,213					6,271
Warrants issued to a certain director upon the successful closure of the merger (Note 3)					570					570
Exercise of warrants, net of expenses			978	10	5,619					5,629
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
Options issued for services in lieu of cash (Note 9)					240				240
Amortization of deferred compensation								308	308
Net loss								(5,427)	(5,427)
Balance at December 31, 1998	4		8,592	86	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
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

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Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Stockholders Equity (Cont.)

	Preferred stock at par value		Common stock at par value		Capital in excess of par	Cost of Repurchased Common Stock		Deferred	Deficit accumulated during development	
	shares	amount	shares	amount	value	shares	amount	compensation	stage	Total
					(In thousands)					
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
			119	1	644					645

Common Stock issued for sublicense agreement (Note 6)									
Common Stock issued for milestone payment		50	1	281					282
Debt Conversion		1,755	17	9,983					10,000
Common Stock issued in lieu of cash/interest		9		142					142
Public Offering, net of expenses		2,500	25	58,576					58,601
Deemed discount on convertible debentures				6,470					6,470
Warrants issued for services				1,398					1,398
Amortization of non-employee options				128					128
Purchase of treasury stock					(59)	(346)			(346)
Net loss								(25,671)	(25,671)
Balance at December 31, 2003		$ 19,272	$ 193	$ 189,296	(59)	$ (346)	$	$ (107,091)	$ 82,052

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

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Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Cash Flows

	For the year ended December 31,			Period from Inception (Aug. 15, 1994) to December 31,
	2003	2002	2001	2003
	(In thousands)			
Cash flows from operating activities:				
Net loss	$ (25,671)	$ (17,502)	$ (15,762)	$ (107,091)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	118	122	131	576
Disposal of assets	2	21		30
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	223	137	96	519
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	552	271	176	2,692
Expense related to warrants issued as consideration to consultants	1,518	247	208	4,113
Expense related to warrants issued to a director for successful closure of merger				570
Expense related to stock options issued	561	17		5,718
Expense related to common stock issued for the purchase of technology				1,848
Common stock issued as consideration for In-Process R&D				2,000
Deferred compensation expense related to options issued				1,210
Changes in assets and liabilities:				
Prepaid expenses	(11)	46	(73)	(134)
Deposits	(8)	(60)		(95)
Other receivable	13	(13)		
Loan receivable from related party	3	3	(21)	(18)
Accounts payable and accrued expenses	1,024	(652)	966	3,974
Net cash used in operating activities	(14,049)	(17,363)	(14,279)	(76,394)
Cash flows provided by investing activities:				
Purchase of property and equipment	(4)	(119)	(132)	(887)
Payback of loan by a company officer	253			
Net cash provided by / used in investing activities	249	(119)	(132)	(887)
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	72,413		10,657	125,242
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
Net proceeds from warrants/options exercised	4,284	2	23	17,277
Net cash provided by financing activities	85,565	2	10,680	162,133
Net increase (decrease) in cash and equivalents	71,765	(17,480)	(3,731)	84,852
Cash and equivalents at beginning of period	13,087	30,567	34,298	
Cash and equivalents at end of period	$ 84,852	$ 13,087	$ 30,567	$ 84,852

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Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Cash Flows (Cont.)

	For the year ended December 31,			Period from Inception (Aug. 15, 1994) to December 31,
	2003	2002	2001	2003
			(In thousands)	
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		247	288	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.

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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 Phase II clinical studies. Our initial technology development efforts are focused on a series of potent hormones and hormone analogs that we believe are key components of the body s natural regulatory system. We believe these immune regulating hormones can be used to reestablish host immunity in situations of dysregulation. To date, the Company has not developed commercial products or generated sales for the period since inception (August 15, 1994) through December 31, 2003.

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, 2003, the Company s cash equivalents are approximately $84.9 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 of the assets (five and seven years) using the straight-line method.

Research and development

Research and development costs consist of license fee expenses related to license agreements, preclinical and clinical trial expenses, as well as research and development expenses with related parties. Such amounts paid to related parties aggregated $11.5 million in the form of cash and

stock for the period from inception (August 15, 1994) to December 31, 2003 (see Note 6, Colthurst, Edenland and Mr. Prendergast and Aeson Therapeutics). Such expenses are recognized as incurred.

Accounting for Stock-Based Compensation

During 1995, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards 123, Accounting for Stock-Based Compensation No. 123, which defines a fair-value-based method of accounting for stock compensation plans. However, it also allows an entity to continue to measure compensation cost related to employee stock compensation plans using the method of accounting prescribed by the Accounting Principles Board Opinion No. 25 (APB 25), Accounting for Stock Issued to Employees. Entities electing to follow APB 25 must make pro forma disclosures of net income, as if the fair-value-based method of accounting defined in SFAS 123 had been applied.

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HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (Continued)

If the Company had accounted for stock options issued to employees and directors in accordance with SFAS 123, the Company s net loss would have been reported as follows (in thousands, except per share amounts):

	Year ended December 31,		
	2003	2002	2001
Net loss As reported	$ (25,671)	$ (17,502)	$ (15,762)
Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards	(4,690)	(5,570)	(767)
Net loss Pro forma	$ (30,361)	$ (23,072)	$ (16,529)
Basic and diluted net loss per share As reported	$ (1.67)	$ (1.35)	$ (1.35)
Basic and diluted net loss per share Pro forma	$ (1.97)	$ (1.78)	$ (1.42)

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 generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Net loss per share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed in a manner consistent with basic net loss per share after giving effect to potentially dilutive securities. Potential common shares of 7,097,978, 6,254,853, and 6,297,364 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, 2003, 2002 and 2001 because their effect on net loss per share is anti-dilutive.

Recent accounting pronouncements

On December 31, 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. SFAS No. 148 amends SFAS No. 123, Accounting for Stock-Based Compensation, to provide alternative methods of transition to the fair value method of accounting for stock-based employee compensation under SFAS

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HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (Continued)

No. 123. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 and APB Opinion No. 28, Interim Financial Reporting, to require disclosure in the summary of significant accounting policies of the effects of an entity s accounting policy with respect to stock-based employee compensation on reported earnings in annual and interim financial statements. While the Statement does not amend SFAS No. 123 to require companies to account for employee stock options using the fair value method, the disclosure provisions of SFAS No. 148 are applicable to all companies with stock-based employee compensation, regardless of whether the accounting for that compensation is using the fair value method of SFAS No. 123 or the intrinsic value method of Opinion 25. The company has elected to continue using the intrinsic value method and has incorporated these expanded disclosures into these notes.

3. Recapitalization

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

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

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

4. Note 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 is at 4.5% per annum. Two payments totaling two-thirds of the note was paid by each of the due dates during April 2002 and 2003 and the remaining one third payment is due and payable on April 23 of 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 during May 2003.

5. Income Taxes

The Company has available a net operating loss carryforward of approximately $79 million at December 31, 2003 which may be carried forward as an offset to taxable income, if any, in future years through its expiration in 2012 to 2023. The Company has a net deferred tax asset of approximately $30 million at December 31, 2003 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.

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HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (Continued)

6. Related Party Licenses and other Agreements and Contingencies

Colthurst, Edenland and Mr. Prendergast

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

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

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

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HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (Continued)

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 replaces the Colthurst License Agreement. Pursuant to the Technology 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. The annual license fee of $500,000 and the royalty obligations under the Colthurst License Agreement were eliminated. In consideration for the foregoing, Hollis-Eden agreed to issue to Colthurst 660,000 shares of Common Stock and a warrant to purchase an aggregate of 400,000 shares of Common Stock at $25 per share. Only 132,000 of such shares of Common Stock were issued in 2000, with the remaining 528,000 shares to be issued over the next four years conditioned on continued compliance with the agreement and, in particular, satisfaction of the Conditions (as defined below). In addition, all of the shares under the warrant vest over four years conditioned on continued compliance with the agreement and, in particular, satisfaction of the Conditions (as defined below). The Sponsored Research and License Agreement replaces 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 agreed to fund additional preclinical research projects conducted by Edenland. Hollis-Eden will also have exclusive license rights to all results of such research and will have royalty obligations to Edenland on sales of new products, if any, resulting from such research.

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 agreement.

Because all of the Conditions have not been satisfied, Hollis-Eden has not issued any additional shares to Colthurst and believes it has no obligation to issue any additional shares and that the warrant will not vest as to any shares of Common Stock. While Hollis-Eden is confident in its analysis, if any dispute should arise in this matter, Hollis-Eden cannot guarantee that, as a result of such dispute, additional equity will not be issued or that an additional accounting charge will not be made.

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

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HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

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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.

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 additional milestone and royalty payments to Pharmadigm if we meet specified development and commercialization milestones for products covered by the patents. 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 is currently a scientific consultant to Hollis-Eden.

7. Common Stock

Reverse Stock Splits

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

Common Stock Financings

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

Company privately issued 580,005 shares of the Company s common stock at an offering price of $2.25 per share. Total proceeds from this offering aggregated $1,234,499.

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

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

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

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

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

8. Preferred Stock

During May 1998, as part of a private placement, the Company issued 4,000 shares of Convertible Preferred Stock for proceeds of $4.0 million. The proceeds of the offering is 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

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adjustment based on the future average stock price of the Company s common stock as described in Note 7. Upon conversion, all outstanding Preferred shares and Adjustable Common shares 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.

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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, 4,400,000 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 become exercisable immediately or generally are exercisable ratably over a three-year or four-year period beginning one-year from the date of the grant. The following table summarizes stock option activity under the Plan for 1997 through 2003 (in thousands, except per share amounts):

		Price Per Share	
	Shares	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
Outstanding, December 31, 2003	3,761	$ 2.25-17.83	$ 8.88

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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 2002 and 2003 the Company granted options to certain directors, officers and consultants, and will recognize $17,000 and $730,000, respectively, in expense related to these options over the vesting periods. Expenses related to options for consultants and directors were $96,000, $66,000 and $630,000 in 2001, 2002 and 2003, respectively. The remaining $144,000 charge for these options will be expensed over the vesting period of the options.

Non-Plan Options

During 1995 and 1996, the Company granted non-statutory stock options to purchase a total of 608,000 shares to directors, officers and consultants. As of December 31, 2003, options to purchase 250,000 shares were outstanding.

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 300,000 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.

In March 1999, the Company granted a non-statutory stock option to purchase 300,000 shares to an officer.

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NOTES TO FINANCIAL STATEMENTS (Continued)

The following table summarizes stock option activity not pursuant to the Plan for 1995 through 2003 (in thousands, except per share amounts):

		Price Per Share	
	Shares	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

Outstanding, December 31, 2002	1,915	$ 2.25-16.63	$ 6.23
Forfeited	165	2.25	2.25
Outstanding, December 31, 2003	1,750	$ 2.25-16.63	$ 6.60

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For various price ranges, weighted average characteristics of outstanding stock options at December 31, 2003 were as follows:

	Outstanding options			Exercisable options	
Range of Exercise Prices	Shares	Remaining life (years)	Weighted average price	Shares	Weighted average price
$ 2.25-$ 4.99	445,000	3.3	$ 2.39	433,417	$ 2.34
$ 5.00-$ 8.99	2,857,503	6.3	5.66	2,110,795	5.69
$ 9.00-$12.99	1,237,698	7.4	10.51	843,851	10.44
$13.00-$17.99	971,250	5.6	15.24	877,146	15.26

Pro Forma Disclosures of Net Income

The Company has elected to account for its stock-based compensation plans under APB 25; however, for pro forma disclosure purposes, the Company has computed the value of all options granted to employees during 2001 through 2003, using the Black-Scholes option pricing model with the following weighted average assumptions:

	2003	2002	2001
Risk free interest rate	3.27%	4.25%	4.66%
Expected dividend yield	0%	0%	0%
Expected lives	5 years	5 years	5 years
Expected volatility	122%	93%	137%

The stock options are assumed to be exercised in five years. The total value of warrants and options was computed to be the following approximate amounts, which would be amortized on the straight-line basis over the vesting period of the options (in thousands):

Year ended December 31, 2001	$ 767
Year ended December 31, 2002	5,570
Year ended December 31, 2003	4,690

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 2003, 2002 and 2001 were $6.31, $8.00 and $4.50 per share, respectively.

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HOLLIS-EDEN PHARMACEUTICALS, Inc.

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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 expires January 7, 2006.

IAC Management Warrants

During April 1994, the Company issued warrants, to existing shareholders and management, to purchase 160,000 units (the Units) at $10.00 per Unit, each unit to be identical to the Units issued as part of its initial public offering. Each Unit consists of (i) one share of common stock, $.01 par value per share and (ii) one Class A Warrants entitling the holder to purchase one share of common stock at a price of $9.00 per share. The warrants have expired except for one warrant to purchase 50,000 units, which expires March 18, 2005.

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

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.

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HOLLIS-EDEN PHARMACEUTICALS, Inc.

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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. The warrant extension did not result in an additional non-cash charge.

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.

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, an estimated value of approximately $80,000, and were issued in lieu of cash for services. The majority of these warrants have not been exercised.

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. Dr. Hollis is the brother of Richard B. Hollis.

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HOLLIS-EDEN PHARMACEUTICALS, Inc.

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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.

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 Warrants

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 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.

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.

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 expensed as a non-cash charge. This warrant has not been exercised.

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The following table summarizes stock warrant activity for 2001 through 2003 (in thousands, except per share amounts):

		Price Per Share	
	Shares	Range	Weighted Average
Outstanding, December 31, 2000	3,534	$ 9.00-25.00	$ 16.52
2001			
Issued	308	3.09-12.00	9.48
Forfeited	1,837	17.00-25.00	18.74
Outstanding, December 31, 2001	2,005	$ 3.09-20.50	$ 13.40
2002			
Issued	70	4.54-11.00	10.08
Forfeited	704	11.02-18.25	11.94
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

For various price ranges, the following table summarizes the weighted average prices of outstanding warrants as of December 31, 2003 (in thousands, except per share amounts):

	Outstanding Warrants		Exercisable Warrants	
Range of Exercise Prices	Shares	Weighted average price	Shares	Weighted average price
$ 3.00-$ 5.00	37	$ 3.78	37	$ 3.78
$ 5.01-$10.00	871	8.05	871	8.05

$10.01-$15.00	455	11.03	455	11.03
$15.01-$20.00	224	15.45	224	15.45

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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. On July 1, 2003, Mr. Hollis base salary was increased from $440,000 to $462,000. If Mr. Hollis employment is terminated without cause, for insufficient reason or pursuant to a change in control (as such terms are defined in the Hollis Employment Agreement), Mr. Hollis will receive as severance (i) an amount equal to five times his then current annual base salary plus five times the amount of the bonus awarded to him in the prior calendar year, (ii) immediate vesting of all unvested stock options of Hollis-Eden Pharmaceuticals (or the Surviving Corporation, 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 principally leased facilities under non-cancelable operating leases were approximately $754,000, $644,000 and $435,000 for 2003, 2002 and 2001 respectively. Future minimum payments for operating leases are as follows (in thousands):

	Operating Leases
2004	$ 827
2005	183
2006	13
2007	13
2008	9
Total minimum lease payments	$ 1,045

13. Subsequent Event

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 will issue 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 achieve 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. 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.

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HOLLIS-EDEN PHARMACEUTICALS, Inc.

(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (Continued)

14. Supplementary Financial Data

Interim Financial Information

(Unaudited)

	Quarter				Total Year
	March	June	September	December	
	(In thousands, except per share)				
Year Ended December 31, 2003					
R&D expenses	$ 2,305	$ 1,741	$ 2,619	$ 3,777	$ 10,442
G&A expenses	973	1,155	1,197	1,836	5,161
Non-cash charges	1,656	725	91	16	2,488
Net loss	5,197	4,731	10,328	5,415	25,671
Net loss per share	(0.40)	(0.36)	(0.66)	(0.28)	(1.67)
Cash and cash equivalents	19,424	32,796	29,720	84,852	84,852
Year Ended December 31, 2002					
R&D expenses	$ 2,916	$ 4,462	$ 3,572	$ 2,067	$ 13,017
G&A expenses	1,180	1,245	995	1,103	4,523
Non-cash charges	238	17	31	44	330
Net loss	4,218	5,616	4,515	3,153	17,502
Net loss per share	(0.33)	(0.43)	(0.35)	(0.24)	(1.35)
Cash and cash equivalents	25,523	20,484	16,441	13,087	13,087

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Report of Independent Public Accountants

To the Board of Directors and Stockholders of

Hollis-Eden Pharmaceuticals, Inc.:

We have audited the accompanying balance sheets of Hollis-Eden Pharmaceuticals, Inc. (a development stage company) as of December 31, 2003 and 2002 and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2003 and for the period from inception (August 15, 1994) to December 31, 2003. 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 auditing standards generally accepted in the 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, 2003 and 2002 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003 and for the period from inception (August 15, 1994) to December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ BDO Seidman, LLP

BDO Seidman, LLP

New York, NY

February 3, 2004 (except for Note 13 which is as of February 24, 2004)

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

Not applicable.

Item 9A. Controls and Procedures

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Operating Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures for the quarter ended December 31, 2003. Based on that evaluation, our management, including our Chief Executive Officer and Chief Operating Officer and Chief Financial Officer, concluded that our disclosure controls and procedures were effective and that there has been no change in our internal control over financial reporting during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 2004 Annual Meeting (the Proxy Statement).

Item 11. Executive Compensation

The information concerning executive compensation is set forth in the Proxy Statement under the heading Executive Compensation, which information is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information concerning security ownership of certain beneficial owners and management is set forth in the Proxy Statement under the heading Security Ownership of Certain Beneficial Owners and Management, which information is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions

The information concerning certain relationships and related transactions is set forth in the Proxy Statement 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, which information is incorporated herein by reference.

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PART IV

Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K

(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, 2003, 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.

(b) Reports on Form 8-K

None

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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, on March 12, 2004.

HOLLIS-EDEN PHARMACEUTICALS, INC.

By: /s/ RICHARD B. HOLLIS

Richard B. Hollis, Chairman of the Board of Directors, Chief Executive Officer, President and Director

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.

Signature	Title	Date
/s/ RICHARD B. HOLLIS **Richard B. Hollis**	Chairman of the Board of Directors, Chief Executive Officer, President And Director	March 12, 2004
/s/ DANIEL D. BURGESS **Daniel D. Burgess**	Chief Operating Officer/Chief Financial Officer (Principal Financial Officer)	March 12, 2004
/s/ ROBERT W. WEBER **Robert W. Weber**	Chief Accounting Officer and Vice President Controller (Principal Accounting Officer)	March 12, 2004
/s/ PAUL BAGLEY **Paul Bagley**	Director	March 12, 2004

/s/ BRENDAN R. MCDONNELL	Director	March 12, 2004
Brendan R. McDonnell		
/s/ THOMAS C. MERIGAN JR. M.D.	Scientific Advisor and Director	March 12, 2004
Thomas C. Merigan, Jr. M.D.		
/s/ WILLIAM H. TILLEY	Director	March 12, 2004
William H. Tilley		
/s/ SALVATORE J. ZIZZA	Director	March 12, 2004
Salvatore J. Zizza		

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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).

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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)).
*#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)).

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Exhibit Number	Description of Document
*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).
23.1	Consent of BDO Seidman, LLP.
24.1	Power of Attorney. Reference is made to signature page hereto
31.1	Rule 13a-14(a)/15d-14(a) Certification of Richard B. Hollis.
31.2	Rule 13a-14(a)/15d-14(a) Certification of Daniel D. Burgess.
32.1	Section 1350 Certifications of Richard B. Hollis and Daniel D. Burgess.

* Previously filed.
Management contract or compensatory plan, contract or arrangement to be filed as an exhibit pursuant to Item 14(c) of Form 10-K.
\# Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.