HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 10-K405
February 25, 2002

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2001

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 of incorporation or organization)	**(I.R.S. Employer Identification No.)**

9333 Genesee Avenue, Suite 200, San Diego, CA 92121
(Address of principal executive offices) (Zip Code)

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

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. x

The aggregate market value of the voting stock held by nonaffiliates of the Registrant as of February 19, 2002 totaled $87,441,417 based on the closing stock price of the Registrant s Common Stock as reported by the Nasdaq National Market.

As of February 19, 2002, 12,922,037 shares of the Registrant s Common Stock, $.01 par value per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of Registrant s Annual Report to Stockholders for the fiscal year ended December 31, 2001, are incorporated by reference into Part II of this report. Registrant s definitive proxy statement to be filed with the Securities and Exchange Commission, pursuant to regulation 14A in connection with the 2002 Annual Meeting of Stockholders to be held during June 2002, is incorporated by reference into Part III of this Report.

HOLLIS-EDEN PHARMACEUTICALS, INC.
FORM 10-K

For the Fiscal Year Ended December 31, 2001

INDEX

PART I

		Page
Item 1	Business	3
Item 2	Properties	23
Item 3	Legal Proceedings	23
Item 4	Submission Of Matters To A Vote Of Security Holders	23
PART II		
Item 5	Market For Registrant's Common Stock And Related Stockholder Matters	24
Item 6	Selected Financial Data	25
Item 7	Management's Discussion And Analysis Of Results Of Operations And Financial Condition	25
Item 7A	Quantitative and Qualitative Disclosures About Market Risk	27
Item 8	Financial Statements And Supplementary Data	27
Item 9	Changes In And Disagreements With Accountants On Accounting And Financial Disclosures	27
PART III		
Item 10	Directors And Executive Officers Of The Registrant	28
Item 11	Executive Compensation	28
Item 12	Security Ownership Of Certain Beneficial Owners And Management	28
Item 13	Certain Relationships And Related Transactions	28
PART IV		
Item 14	Exhibits, Financial Statement Schedules And Reports On Form 8-K	29
	Signatures	30

This Annual Report on Form 10-K contains certain forward-looking statements that involve risks and uncertainties. The actual future results for Hollis-Eden Pharmaceuticals, Inc. may differ materially from those discussed here. Additional information concerning factors that could cause or contribute to such differences can be found in this Annual Report on Form 10-K in Part I, Item 1 under the caption Risk Factors, Part II, Item 7 entitled Management s Discussion and Analysis of Results of Operations and Financial Condition and elsewhere throughout this Annual Report.

PART I

Item 1. ***Business***

GENERAL

Hollis-Eden Pharmaceuticals, Inc., a development-stage pharmaceutical company, is engaged in the discovery, development and commercialization of products for the treatment of infectious diseases and other conditions resulting from immune system disorders and hormonal imbalances. 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 compounds can be used as a hormone replacement therapy to reestablish balance to the immune system 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.

This type of pharmaceutical profile has the potential to be useful in the treatment of a broad array of diseases. As a result, we are studying the compounds in a series of different clinical settings. Based on the results of these studies, we will choose the most attractive potential clinical indications to pursue for the pivotal clinical trials that are necessary for commercial approval.

Our lead compound in this series, HE2000, is currently in Phase II clinical trials in HIV, malaria and, most recently, in hepatitis B. Our preliminary findings in clinical studies in HIV and malaria are encouraging. Another immune regulating hormone, HE2200, is now entering Phase II trials in a trial designed to test the ability of the compound to improve response to vaccination in elderly individuals. Through our relationship with Aeson Therapeutics, Inc. (Aeson), we have a right to acquire significant additional intellectual property in this field, including the rights to a compound in this class that is in Phase II clinical trials for the treatment of cardiovascular disease. Given the profile seen to date with these compounds, clinical trials are also being planned in certain autoimmune conditions. In addition, we have entered into a collaboration with the U.S. military to develop another of our compounds, HE2100, for use as a radioprotectant. This compound and other compounds in this series may also be useful in reversing radiation and chemotherapy induced immune suppression in cancer patients.

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.

TECHNOLOGY OVERVIEW

Our 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 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. Our approach is designed to replace these depleted hormones, allowing reestablishment of proper functions across a number of theses important regulatory pathways, thus allowing the body s immune system to potentially control progression of a number of different diseases.

Role of Inflammation

In the last several years, the role of inflammation in disease pathogenesis has become increasingly recognized by the medical community. Chronic inflammation is generally believed to be caused by an over-stimulation of certain components of the immune system caused by a persistent low grade infection 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 (e.g. arthritis and psoriasis) to infectious diseases (e.g. HIV, malaria, and hepatitis) 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 immunosuppression 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 animal models of numerous diseases to produce anti-inflammatory activities comparable to that historically seen with corticosteroids. In addition, our compounds have 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 engulf and digest 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 bacterial invasion, 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 cancer or infection by viruses or parasites. The relative mobilization of each branch of the immune system depends on the specific disease or condition, and the nature of the response can be influenced by the pathogen itself and where it enters the body.

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

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

Unfortunately, a wide variety of viruses including HIV and hepatitis B and C, certain parasites such as malaria, and a number of different tumor cells have evolved ways of evading destruction by the immune system by causing the body to overproduce Th2 cytokines and under produce 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. In the setting of HIV, this generally results in an immune system that progressively loses its ability to combat infections.

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 . Similarly, in hepatitis C, a small percentage of patients are able to mount a strong Th1 response and in these patients the immune system is able to successfully clear the virus. 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.

Hematopoiesis

Another component of immune dysfunction that can occur as a result of infectious diseases or radiation or chemotherapy induced immune suppression is a loss of a number of hematopoetic elements including neutrophils and platelets. Neutrophils are white blood cells that are critical early responders used in combating foreign pathogens. When they are depleted, as occurs in response to many cancer therapies, 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.

Preclinical and early clinical studies with immune regulating hormones indicate these compounds have the potential to boost both neutrophils and platelets in settings where these cell numbers are compromised. This finding has important potential implications in the area of radioprotection, both in the event of a nuclear accident or event and also as an adjunct to cancer therapy.

Hollis-Eden s Approach

Our approach is designed to interact at what is believed to be the trigger point of this dysregulation, the loss of key immune regulating hormones, offering a hormone replacement therapy that potentially will lead to a correction of immune dysregulation in many diseases.

We are employing the latest tools of the genomics revolution to further our understanding of the mechanism of action and our expertise in adrenal hormone biochemistry, signal transduction, receptor biology and gene transcription for this important class of compounds. We are seeking to identify and develop compounds that are highly potent and that avoid androgenic and other side effects.

PRODUCTS IN DEVELOPMENT

Our lead immune regulating hormone is HE2000, with which we are currently conducting Phase II clinical trials in HIV/AIDS, malaria and hepatitis B. We are also planning to conduct clinical trials with HE2000 in hepatitis C. In addition, we have begun clinical trials in the United States with HE2200, another immune regulating hormone drug candidate. This compound also has the potential to be useful in a number of conditions associated with immune dysregulation, including autoimmunity and vaccine potentiation in the elderly. Another immune regulating hormone, HE2100, has shown impressive preclinical activity in models of radiation protection and is being prepared for clinical trials in collaboration with the U.S. Armed Forces for this indication. Through our relationship with Aeson, we also have rights to acquire an additional compound in this class, HE2500, with which Aeson is currently conducting Phase II clinical trials for the treatment of cardiovascular disease and which has shown preclinical activity in a number of autoimmune indications.

HE2000 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 and dosing. Increasing focus on the crisis that infectious diseases such as HIV and malaria 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, subject to obtaining regulatory approvals, marketing HE2000 and our other compounds in developing countries could become commercially feasible.

HIV

In addition to being an important world health problem and a significant commercial opportunity, we believe HIV is an ideal model system in which to study the effects of our lead compound 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. We are testing HE2000 in a series of Phase I/II and Phase II clinical trials in HIV/AIDS patients in the U.S. and South Africa. In addition to assessing the safety profile of HE2000 in the trials, we are also assessing the effect of HE2000 on a wide variety of immune and inflammatory markers.

The results presented to date have been from studies employing intermittent dosing utilizing three different routes of administration (intramuscular and subcutaneous injections and buccal tablets) in South African HIV patients receiving no other therapy. In these studies HE2000 treatment appears to be generally well tolerated. To date, the only drug-related serious adverse events with HE2000 have been pain and swelling at the injection site in a small percentage of patients with an intramuscular formulation of this compound. To date the subcutaneous formulation is less irritating than the intramuscular formulation, and the buccal formulation has been well tolerated.

Clinical data also has been presented on the anti-inflammatory effects of HE2000 in HIV patients. The primary results presented were from a preliminary analysis through the first five months of dosing of HE2000 administered subcutaneously as a monotherapy to HIV patients in South Africa. The study, conducted in 24 patients, compared to placebo two different doses of HE2000 administered once per day for five days every six weeks. Prior to dosing with HE2000, 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 HE2000. After dosing with HE2000, these same patients experienced 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 five-month 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, IL-6 and the enzyme COX-2 can lead to decreases in dendritic cells and hematopoiesis, which, in turn, lead to a progressive loss of innate and cell-mediated (Th1) immunity. It is this chronic inflammatory dysregulation and progressive loss of innate and cell-mediated immunity that is believed to ultimately lead 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 immune regulating hormones have 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. Chronic elevations in these same inflammatory mediators have been shown in the medical literature to be associated with AIDS-related wasting, dementia, cancers, and ultimately mortality.

We have also observed significant increases relative to baseline in a wide variety of immune cell subsets associated with innate and cell-mediated immunity following dosing with HE2000 during the studies in South Africa. These increases appeared to be long lasting despite the fact that HE2000 was only administered in

intermittent treatment courses. A number of these cell types have been associated with delaying disease progression towards AIDS.

HE2000 also had a significant effect on the hematopoetic system in the clinical trials in South Africa. Administration of HE2000 led to pronounced increases (versus baseline) in a number of hematopoetic cell types including neutrophils and platelets.

We are currently optimizing the dosing regimen of HE2000 to maximize the potential impact of the compound before we proceed to the potential pivotal clinical trials that would be necessary for approval.

We believe HE2000 has the potential to play an important role in treating HIV/AIDS in both the developed and developing world. In the U.S. and Europe, where more than 1 million people are estimated to be infected, we believe that if we can demonstrate clinically that HE2000 restores or improves immune system activity, the compound may be useful for long-term control of viral replication and delaying or preventing the progression to AIDS, as well as preventing or clearing opportunistic infections. At a minimum, we believe HE2000 could prove very useful in treating patients who cannot tolerate other therapies and in salvage patients for whom other drug therapies have failed and whose immune systems have been ravaged by HIV.

In the developing world, where more than 35 million people are estimated to be infected, HE2000 may be particularly attractive for the following reasons: 1) it shows the potential to turn HIV positive patients into long-term non-progressors, at the same time reducing opportunistic infections; 2) we believe it will avoid resistance issues; 3) the dosing administration and monitoring are simple; 4) it has demonstrated no significant toxicity to date; and 5) it can be manufactured easily and at low cost. We are presenting our data to health authorities in South Africa and in other countries around the world that are challenged with managing the HIV epidemic, and we plan to work with them in designing and conducting the further human clinical trials necessary to establish patient safety and benefit required for regulatory approvals.

Malaria

The potential ability of HE2000 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 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 began collaborating with the U.S. Navy on a preclinical program in malaria with HE2000. Based on favorable results in multiple preclinical studies with the compound, we then proceeded with clinical trials in malaria patients in a Phase II clinical study in Thailand. Preliminary results from this study indicated that HE2000 was very successful at reducing parasite count and completely cleared malarial parasites in most patients within two days. Based on these favorable results we are now planning to conduct additional studies in malaria to further optimize the route of administration and dosing schedule. Additional studies may also examine the potential benefit of HE2000 when used in combination with other anti-malarial drugs, as well as potentially as a prophylactic agent.

Market research indicates that 300-500 million people per year suffer from malaria. This parasite is responsible for more than 1 million deaths annually, most of them children. Most cases of malaria occur in the developing world but, as a result of increased global travel and other factors, the incidence of malaria in the developed world is increasing. Historically, therapies with quinalone-based drugs such as chloroquine have been used to treat this condition. Recently, however, strains have developed that are resistant to chloroquine and other quinalones, making these drugs ineffective in many parts of the world. As a result, finding new approaches to the treatment of malaria has become a major priority of the U.S. military and health officials in many countries.

Hepatitis

As mentioned previously, in hepatitis B and hepatitis C a small percentage of patients are able to clear the virus by mounting a strong cell-mediated (Th1) response. Given the preclinical and early clinical data with HE2000 that demonstrates the ability of HE2000 to stimulate a strong Th1 response, we have begun a Phase II trial with HE2000 in Singapore in hepatitis B patients and are also planning to conduct studies with the compound in hepatitis C.

Existing therapies for hepatitis have proven to be effective in only a portion of the patients treated. In addition, side effects of existing therapies can be significant and the regimen is very expensive. As with HIV, resistance is a serious problem in treating the disease. Also as with HIV, cost and other aspects of existing therapies make them largely impractical in the developing world.

The World Health Organization (WHO) reported in 2000 that more than 350 million people have chronic hepatitis B infection and more than 1 million die from the disease each year. The Center for Disease Control (CDC) estimates that more than 1 million people in the United States are chronically infected with the disease. Hepatitis B can lead to liver abnormalities and the disease is believed to be the leading cause of liver cancer.

In October 2000, the WHO also reported that 3% of the world s population, an estimated 170 million people, are chronic carriers of hepatitis C, including an estimated 4 million in the U.S. Of those afflicted with hepatitis C, 10% to 20% are at risk of developing cirrhosis of the liver and 1% to 5% may develop liver cancer.

HE2200

We also have commenced human clinical trials in the United States with HE2200, another immune regulating hormone drug candidate. HE2200 has been shown in animal studies to increase responsiveness to vaccines in aged animals and to improve hematopoiesis in radiation-induced models of immune suppression. We licensed this compound from Roger Loria, Ph.D., a leading researcher in the field of immune regulating hormones and a Professor of Microbiology and Immunology at Virginia Commonwealth University.

The initial Phase I clinical trial is testing HE2200 in healthy adults and healthy elderly volunteers, with the primary endpoint of the trial being safety and tolerance. Other objectives of the trial are to evaluate changes in a number of key immune markers and pharmacokinetic data in both groups of volunteers. Based on results to date in our Phase I trial, we are initiating a Phase II study in the elderly to assess the ability of HE2200 to improve response to vaccination in this patient population. We are also planning to conduct Phase II studies with HE2200 in additional indications.

Preclinical studies with HE2200 and initial clinical results with HE2000, our lead immune regulating hormone in development, indicate that this class of compounds may improve defects in cell mediated (Th1) immunity. Deficiency of cell-mediated immunity has been strongly correlated with an immune system s inability to effectively fight a number of infectious diseases and cancer types. Laboratory tests with HE2200 have shown that the compound can reverse the loss of cell-mediated immunity seen in aged animals and that correcting this dysregulation with HE2200 treatment allows these animals to respond better to vaccination. The potential for correcting immune dysregulation in a similar way in elderly humans is significant. The loss of ability to mount a strong cell-mediated immune response seen in the elderly is believed to be a primary reason patients in this age group have difficulty recovering from infectious diseases such as the flu and pneumonia and also why vaccines in this population tend to be less effective. For example, medical literature indicates the influenza vaccine is only 30-70% effective in preventing hospitalization for pneumonia and influenza in the elderly.

HE2500 and Aeson Therapeutics, Inc.

During 2000 we obtained the right to acquire an additional immune regulating hormone, which we refer to as HE2500 (See Relationship with Aeson Therapeutics, Inc. below). Aeson is conducting a Phase II study

using an oral form of HE2500 for the treatment of cardiovascular patients with a particular lipid profile. Phase I human clinical studies indicate HE2500 is generally well tolerated. Aeson is also conducting preclinical studies using HE2500 in a number of other potential indications, including a collaboration with the National Cancer Institute to explore the use of HE2500 in the treatment of cancer.

HE2200 and HE2500 in Autoimmune Indications

Recent clinical trial results and preclinical studies also indicate immune regulating hormones have potential in a wide variety of other indications associated with chronic inflammatory dysregulation. Drugs designed to inhibit a single inflammatory mediator have been shown in clinical trials to be effective agents in treating a variety of autoimmune conditions, including arthritis, inflammatory bowel disease and psoriasis. As an example, monoclonal antibody drugs, which inhibit only TNF-alpha, are projected to generate sales in excess of $1 billion in 2001, and sales of drugs that inhibit only COX-2 are projected to approach $5 billion annually this year.

As described above, our immune regulating hormones appear to affect multiple mediators (including TNF-alpha and COX-2) involved in the inflammatory cascade in patients with systemic inflammation, and appear to do so without causing immunosuppression, a problem with many current anti-inflammatory drugs. Immune regulating hormones, particularly HE2200 and HE2500, have shown impressive preclinical activity in models of a number of autoimmune conditions including arthritis, psoriasis, lupus, inflammatory bowel disease and multiple sclerosis. Additional preclinical studies are currently being conducted, and we anticipate initiating clinical studies in one or more of these conditions in 2002.

HE2100

Recently published studies by the Armed Forces Radiobiology Research Institute (AFRRI) with another immune regulating hormone, HE2100, have shown dramatic survival improvements in HE2100 treated animals versus controls in models of radiation-induced immune suppression. The ability of HE2100 to stimulate both neutrophils and platelets as well as other components of innate immunity are believed to be the mechanism by which HE2100 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 HE2100 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 prophylactically 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 a radioprotectant suitable for widespread use. Out of this screening and profiling effort, HE2100 has emerged as a leading candidate based on its striking efficacy in preclinical models to date, its safety profile, and the comparatively low-cost nature of its manufacturing process.

Representatives from AFRRI were informed by the U.S. Food and Drug Administration (FDA) in November 2001 that HE2100 will qualify for review for radiation protection under a proposed new rule published in the Federal Register of October 5, 1999 vol. 64, no. 192, if this rule is finalized. Traditional drug development programs require large-scale clinical studies to establish efficacy in humans. However, pursuant to the proposed 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 several animal species and proof of safety in humans.

The activities seen in radiation models also have potential implications for use in conjunction with cancer therapy. Immune suppression induced by radiation therapy and chemotherapy limits the effective dose of these

treatments that can be given. Drugs that only stimulate neutrophils in this setting currently generate sales well in excess of $1 billion annually.

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. Most of these approaches in infectious disease are targeted at creating new antiviral compounds rather than drugs that target correcting dysregulations in the immune system. As described above, while these approaches have had success, their limitations as it relates to side effects, resistance and cost have become increasingly recognized. In addition, they will be expected to have different profiles than our compounds and may be complementary to our efforts.

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, Immunex 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, 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 field of hematopoiesis, the leading product on the market designed to enhance the production of neutrophils in patients receiving chemotherapy treatment is Neupogen from Amgen. Other companies also have products in development to enhance hematopoiesis.

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.

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 (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 but, in the case of certain terminal illnesses such as AIDS, are conducted on patients with disease that usually 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 trial or trials for FDA approval. Phase III normally involves the pivotal trials of a drug, consisting of wide scale studies on patients with the same disease, in order to evaluate the overall benefits and risks of the drug for the treated disease compared with other available therapies. The FDA continually reviews the clinical trial plans and results and may suggest design changes or may discontinue the trials at any time if significant safety or other issues arise.

New Drug Application (NDA). Upon successful completion of Phase III, 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.

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 its 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 in-house by ourselves, 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 80 issued U.S. and foreign patents and over 130 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.

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 obtained an exclusive worldwide sublicense to three additional issued patents in the area of adrenal hormones and hormone analogs from Aeson Therapeutics, Inc. In addition, we acquired a 21% equity

stake in Aeson, which is developing molecules that are analogs with similar biological properties to HE2000. Aeson s lead compound, which we refer to as HE2500, 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. The cash portion of the investment is being used by Aeson to fund specific studies with HE2500 as well as other compounds in its pipeline. As part of the transaction, Aeson and its shareholders have granted us an exclusive option to acquire the remainder of Aeson including the rights to HE2500 at a pre-determined price at any time through April 11, 2003.

Aeson is a privately held company that was formed to commercialize the discoveries of Dr. Arthur Schwarz, a professor at Temple University and a world leader in the field of adrenal hormones. Dr. Schwarz has identified and patented numerous compounds in this series and has shown preclinical activity with these compounds in a broad array of infectious disease, autoimmune and oncology models. Phase I human clinical studies indicate HE2500 is generally well tolerated. Aeson is conducting a pilot Phase II clinical study for the treatment of actinic keratosis, a dermatologic condition, using HE2500 in a topical form. Aeson has also initiated a Phase II study using an oral form of HE2500 for the treatment of cardiovascular patients with a particular lipid profile. Aeson is also conducting preclinical studies using HE2500 in a number of other potential indications, including a collaboration with the National Cancer Institute to explore the use of HE2500 in cancer.

Technology Agreements

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 HE2000, our lead clinical compound. 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 have not been satisfied, we have not issued any additional shares or warrants to Colthurst, and we believe that we have no obligation to issue any 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.

We have also licensed technology from Dr. Roger Loria, Dr. Henry Lardy and Humanetics Corporation, and have made an equity investment in Aeson Therapeutics, Inc. (described above). 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.

Employees

As of February 19, 2002, we had 44 full-time employees. We believe that our relations with our employees are good.

Executive Officers and Senior Management

Our executive officers and senior management and their ages as of February 19, 2002 are as follows:

Name	Age	Position
Richard B. Hollis	49	Chairman of the Board, President and Chief Executive Officer
Daniel D. Burgess	40	Chief Operating Officer and Chief Financial Officer
James M. Frincke, Ph.D.	51	Chief Scientific Officer
Eric J. Loumeau	39	Vice President, Corporate General Counsel
Robert L. Marsella	49	Vice President, Business Development and Marketing
Thomas C. Merigan, Jr., M.D.	68	Scientific Advisor and Director
Christopher L. Reading, Ph.D.	54	Executive Vice President, Scientific Development
Dwight R. Stickney, M.D.	59	Medical Director, Oncology
Robert W. Weber	51	Chief Accounting Officer Vand 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, Mr. Burgess spent ten years with Gensia Sicor, Inc. (now Sicor, Inc.) 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, Research and Development 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 (acquired by Novartis). In various capacities, he has been responsible for all aspects of pharmaceutical development including early stage research programs, product evaluation, pharmacology, manufacturing, and the management of regulatory and clinical matters 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 of Hollis-Eden in September 1999. Mr. Loumeau joined Hollis-Eden from the law firm of Cooley Godward LLP, where he had been primarily responsible 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 had been 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 in 1991. He holds a Bachelor 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 20 years of medical sales, marketing, and distribution experience. From 1994 Mr. Marsella was President of RLM Cardiac Products, an exclusive distributor in the Southwestern United States of various cardiac related hospital products. From 1990 to 1994, he marketed and distributed implantable pacemakers and defibrillators for Telectronics Pacing Systems. From 1987 to 1990, Mr. Marsella served as Regional Manager for Genentech, Inc. 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 in 1980 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 in 1975.

Thomas C. Merigan, Jr., M.D. became Scientific Advisor and a director of Hollis-Eden in March 1996 and acts as the Company s Medical Director for Infectious Diseases. Dr. Merigan has been George E. and Lucy Becker Professor of Medicine at Stanford University School of Medicine from 1980 to the present. Dr. Merigan has also been the Principal Investigator, NIAID Sponsored AIDS Clinical Trials Unit, from 1986 to the present and has been Director of Stanford University s Center For AIDS Research from 1988 to the present. Dr. Merigan is a member of various medical and honorary societies, has lectured extensively within and outside the United States, and authored numerous books and articles and has chaired and edited symposia relating to infectious diseases, including anti-viral agents, HIV and other retroviruses, and AIDS. From 1990 to the present, Dr. Merigan has been Chairman, Editorial Board of *HIV: Advances in Research and Therapy*. He is also a member of the editorial boards of *Aids Research and Human Retroviruses* (since 1983), *International Journal of Anti-Microbial Agents* (since 1990), and *The Aids Reader* (since 1991), among others. He is a co-recipient of ten patents, which, among other things, relate to synthetic polynucleotides, modification of hepatitis B virus infection, treatment of HIV infection, purified cytomegalovirus protein and composition and treatment for herpes simplex. Dr. Merigan has been Chair, Immunology Aids Advisory Board, Bristol Myers Squibb Corporation (1989 1995) and Chair, Scientific Advisory Board, Sequel Corp. (1993 1996). In 1994, Stanford University School of Medicine honored him with the establishment of the Annual Thomas C. Merigan Jr. Endowed Lectureship in Infectious Diseases, and, in 1996, Dr. Merigan was elected Fellow, American Association for the Advancement of Science. From 1966 to 1992, Dr. Merigan was Head, Division of Infectious Diseases, at Stanford School of Medicine. Dr. Merigan received his B.A. (with honors) from the University of California at Berkeley and his M.D. from the University of California at San Francisco.

Christopher L. Reading, Ph.D. became Vice President of Scientific Development in January 1999 and was promoted to Executive Vice President, Scientific Development in December 2001. Prior to joining Hollis-Eden, Dr. Reading was Vice President of Product and Process Development at Novartis Inc.-owned, SyStemix Inc., a Bay area biotechnology company. 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 world-renowned M.D. Anderson Cancer Center in Houston for nearly 13 years. His positions have 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 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 Clinical 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 Burroughs Wellcome, the Centers for Disease Control and academic teaching appointments at The University of California at Los Angeles and The University of California at Riverside. He has also served as a consultant for a number of biotechnology companies on the design and conduct of clinical trials. Dr. Stickney holds a Bachelor of Science in Microbiology, a Masters of Science in Immunology, and a M.D. from Ohio State University. In addition, he is certified as a Diplomat of the American Board of Internal Medicine, 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 twenty-five years of experience in financial management. Mr. Weber has been employed at executive levels by multiple start-up companies and contributed to the success of several turnaround situations. He previously served as Vice President of Finance at Prometheus Products, a subsidiary of Sierra Semiconductor (now PMC Sierra), from 1994 to 1996, and Vice President Finance and Chief Financial Officer for Amercom, a personal computer telecommunications software publishing company, from 1993 to 1994. From 1988 to 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

An investment in Hollis-Eden shares involves a high degree of risk. You should consider the following discussion of risks, in addition to other information contained in this annual report. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially adversely affected. This annual report also contains forward-looking statements that involve risks and uncertainties.

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 disorders. However, all drug candidates require U.S. FDA and foreign government approvals before they can be commercialized. None of our drug candidates have been approved for commercial sale. We expect to 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 to date produced favorable results, 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 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 $63.9 million through December 31, 2001. Our net losses for fiscal years 2001, 2000 and 1999 were $15.8 million, $19.5 million and $15.3 million, respectively. Many of our research and development programs are at an early stage. Potential drug candidates are subject to inherent risks of failure. These risks include the possibilities that no drug candidate will be found safe or effective, meet applicable regulatory standards or receive the necessary regulatory clearances. Even safe and effective drug candidates may never be developed into commercially successful drugs. If we are unable to develop safe, commercially viable drugs, we may never achieve profitability. If we become profitable, we may not remain profitable.

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 Glaxo Wellcome Inc., 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, and Schering AG and Roche Pharmaceuticals are current leaders in hepatitis therapies. 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., Pharmacia Corporation, Johnson & Johnson Inc. and Immunex Corporation are also developing and marketing new drugs for the treatment of chronic inflammatory conditions.

Many of these competitors have greater financial and other resources, larger research and development staffs and more effective marketing and manufacturing organizations than we do. In addition, academic and

government institutions have become increasingly aware of the commercial value of their research findings. These institutions are now more likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to develop and market commercial products.

Our competitors may succeed in developing or licensing technologies and drugs that are more effective or less costly than any we are developing. Our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates before we do. If competing drug candidates prove to be more effective or less costly than our drug candidates, our drug candidates, even if approved for sale, may not be able to compete successfully with our competitors existing products or new products under development. If we are unable to compete successfully, we may never be able to sell enough products at a sufficient price that would permit us to generate profits.

We will need to raise additional money before we expect to achieve profitability; if we fail to raise additional money, it would be difficult to continue our business.

As of December 31, 2001 our cash and cash equivalents totaled approximately $30.6 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 well into 2003. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We will require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We intend to 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 would not be able to continue to develop our drug candidates.

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

As of the date of this prospectus, we own or have obtained a license to over 80 issued U.S. and foreign patents and over 130 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. Our patent position is 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, and fail to successfully defend an infringement action or to have infringing patents declared invalid, we may:

incur substantial money damages;

encounter significant delays in bringing our drug candidates to market; and/or

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.

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

In addition, if another party claims the same subject matter or subject matter overlapping with the subject matter that we have claimed in a 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 profits.

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 competitive basis.

Delays in the conduct or completion of our clinical trials or the analysis of the data from our clinical trials 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 as follows:

- we are conducting Phase II clinical trials with HE2000 in South Africa and Phase I/II clinical trials with HE2000 in the United States for the treatment of HIV/AIDS;
- we are conducting Phase II clinical trials with HE2000 in Thailand for the treatment of malaria;
- we are conducting Phase II clinical trials with HE2000 in Singapore for the treatment of Hepatitis B;
- we are conducting Phase I safety clinical trials with HE2200 in the United States; and
- we have the right to acquire rights to HE2500, a compound that Aeson Therapeutics is studying in Phase II clinical trials in the United States for the treatment of cardiovascular disease and actinic keratosis.

We may encounter problems with some or all of our completed or ongoing clinical studies that may cause us or regulatory authorities to delay or suspend our ongoing clinical studies or delay the analysis of data from our completed or ongoing clinical studies. If the results of our ongoing and planned clinical studies for our clinical candidates are not available when we expect or if we encounter any delay in the analysis of our clinical studies for our clinical 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 product subject to delay in regulatory filing.

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

- delays in enrolling volunteers;
- lower than anticipated retention rate of volunteers in a trial;
- unfavorable efficacy results; or
- serious side effects experienced by study participants relating to the drug candidate.

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 our primary producer of our drug candidates. Manufacturers producing our products must follow current Good Manufacturing Practices regulations

enforced by the FDA and foreign equivalents. If a manufacturer of our products 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 our drug candidates. If we fail to establish a sufficient marketing and sales force or to make alternative arrangements to have 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;

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 $2.12 to $19.25 between January 1, 2000 and February 19, 2002.

These broad market fluctuations may adversely affect the ability of a stockholder to dispose of his shares at a price equal to or above the price at which the shares were purchased. In addition, in the past, following periods of volatility in the market price of a company s securities, securities class-action litigation has often been instituted against those companies. 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.

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 21% of our outstanding common stock as of February 19, 2002. Assuming the exercise of our outstanding warrants and options, Mr. Hollis would own approximately 21% of our outstanding common stock as of February 19, 2002. 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.

Item 2. ***Properties***

Our corporate headquarters are currently located at 9333 Genesee Avenue, Suites 110 and 200, San Diego, California 92121, where we lease approximately 16,000 square feet. These leases expire in August 2002. We will be relocating to 4435 Eastgate Mall, Suite 400, San Diego, CA 92121, where we have leased approximately 22,000 square feet through September 2004. We believe that our facilities are adequate for our current operations.

Item 3. ***Legal Proceedings***

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. 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 2001.

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 securities from January 1, 2000 through February 19, 2002.

Common Stock	High	Low
2000		
First Quarter	$ 19.250	$ 10.125
Second Quarter	17.438	7.750
Third Quarter	13.375	7.719
Fourth Quarter	9.188	4.000
2001		
First Quarter	$ 6.125	$ 2.750
Second Quarter	7.990	2.125
Third Quarter	7.360	4.010
Fourth Quarter	14.250	6.000
2002		
January 1 February 19	$ 12.240	$ 6.800

On February 19, 2002, the closing price of our Common Stock as reported by the Nasdaq National Market System was $8.77 per share. There were approximately 5,000 shareholders of record and beneficial stockholders of our Common Stock as of such date. We have not paid cash dividends on our common stock and do not intend to do so in the foreseeable future.

On December 13, 2001 we 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. Of these gross proceeds, $806,000 was applied toward commissions to the placement agent, H.C. Wainwright & Co., Inc. Expenses related to the offering are estimated to be $56,000. After deducting commissions and expenses, the Company received net proceeds of approximately $10.6 million. The investors are comprised of a group of qualified institutional buyers and institutional accredited investors. We 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, we issued two warrants to our placement agent 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.

The sale and issuance of the securities in the transaction described in the foregoing paragraph was 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 distribution thereof. Appropriate legends are affixed to the securities issued in such transaction.

Item 6. ***Selected Financial Data***

The following data summarizes certain selected financial data for each of the five years ended December 31, 2001 and the period from inception (August 15, 1994) to December 31, 2001. 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).

	As of or for the Year Ended December 31,					Period from Inception (Aug 15, 1994) to December 31, 2001
	2001	2000	1999	1998	1997	
Statement of Operations Data:						
Research and development	$ 11,870	$ 17,933(1)	$ 5,731	$ 2,777	$ 3,488	$ 43,640
General and administrative	5,091	4,157	11,940(2)	3,577	2,044	27,568
Total operating expenses	16,961	22,090	17,671	6,354	5,532	71,208
Other income	1,199	2,575	2,351	927	280	7,290
Net loss	$ (15,762)	$ (19,515)	$ (15,320)	$ (5,427)	$ (5,253)	$ (63,918)
Net loss per share, basic and diluted	$ (1.35)	$ (1.74)	$ (1.41)	$ (0.69)	$ (0.85)	
Weighted average number of common shares outstanding	11,654	11,240	10,861	7,851	6,193	
Balance Sheet Data:						
Cash and equivalents	$ 30,567	$ 34,298	$ 47,486	$ 24,190	$ 7,103	
Total assets	31,462	35,099	48,265	24,524	7,400	
Accounts payable and accrued expenses	3,602	2,636	1,640	222	467	
Stockholders equity	$ 27,860	$ 32,463	$ 46,625	$ 24,303	$ 6,933	

(1) 2000 Research and Development expenses include $4.5 million for non-cash charges for the purchase of technology and in-process R&D.

(2) 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.

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

The forward-looking comments contained in the following discussion involve risks and uncertainties. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to such differences can be found in the following discussion and elsewhere throughout this Annual 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 infectious diseases and other conditions resulting from immune system disorders and hormonal imbalances. 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 compounds can be used as a hormone replacement therapy to reestablish balance to the immune system 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) through December 31, 2001. We have devoted substantially all of our resources to the payment of research and development expenses, licensing fees plus general and administrative expenses. From inception until December 31, 2001, we have incurred expenses of approximately $43.6 million in research and development and $27.6 million in general and administrative expenses, which have been partially offset by $7.3 million in net interest income resulting in a loss of $63.9 million for the period.

Research and development expenses were $11.9 million, $17.9 million and $5.7 million in 2001, 2000 and 1999, respectively. The research and development expenses relate primarily to the ongoing development, preclinical testing, and clinical trials for our first drug candidate, HE2000. Research and development expenses decreased $6.0 million in 2001 compared to 2000. This decrease is due to the $6.5 million (of which $4.5 million was non-cash) expense that was related to the acquisition of technology and in-process research and development during 2000. There were no comparable expenses in 2001. Research and development expenses increased in 2000 compared to 1999 due to increased staffing, preclinical activity, and clinical trials. We expect these expenses to increase in 2002.

General and administrative expenses increased $0.9 million in 2001 compared to 2000 due to increased consulting fees, travel expenses, legal fees and annual report expenses. General and administrative expenses remained flat in 2000 compared to 1999 excluding the non-cash charges in 1999 of $7.7 million. The $7.7 million of non-cash charges was due to the acceleration of vesting of stock options for a former officer of Hollis-Eden, the issuance of warrants for services, as described below, and the issuance of stock options to non-employees.

During 1999, we announced the resignation of an executive officer and accelerated the vesting of 300,000 stock options previously granted to him. This acceleration was considered to be a new grant of options and therefore we expensed a one-time non-cash charge of $4.9 million. We also entered into a three-year agreement with a financial consulting organization affiliated with a director of Hollis-Eden. We agreed to issue, as compensation for services, warrants to purchase 500,000 shares of our common stock with an exercise price of $20.50 per share. The warrants were estimated to have a value of approximately $2.1 million, which was expensed as a non-cash charge.

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 shares and warrants, from which we received gross proceeds of $20 million. During January 1999, we completed two private placements raising approximately $25 million. In December 2001, we completed a private placement of shares and warrants, from which we received gross proceeds of $11.5 million. In addition, we have received a total of $13 million from the exercise of warrants and stock options from inception.

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. 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 is expected to 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 well into 2003. 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 expect to continue to incur increasing negative cash flows and net losses for the foreseeable future.

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

Not applicable.

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

The information required by this item is provided in a separate section beginning on page F-1.

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

Not applicable.

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 information required by this item with respect to directors is incorporated by reference from the information under the heading Election of Directors, contained in Hollis-Eden s definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the Hollis-Eden s 2002 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.

PART IV

Item 14. ***Exhibits, Financial Statement Schedules and Reports on Form 8-K***

(a) List of documents filed as part of this Annual Report to Stockholders on Form 10-K:

1. *Financial Statements*: The financial statements of Hollis-Eden Pharmaceuticals are included as Appendix F of this report. See Index to Financial Statements on page F-1.

2. *Financial Statement Schedules*: Financial statement schedules required under the related instructions are not applicable for the three years ended December 31, 2001, and have therefore been omitted.

3. *Exhibits*: The exhibits which are filed with this Report or which are incorporated herein by reference are set forth in the Exhibit Index on page E-1.

(b) Reports on Form 8-K

On December 18, 2001, we filed a report on Form 8-K dated December 13, 2001 with the SEC announcing that we completed a private placement of our common stock and warrants to purchase shares of our common stock.

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 February 21, 2002.

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	February 21, 2002
/s/ DANIEL D. BURGESS **Daniel D. Burgesss**	Chief Operating Officer/ Chief Financial Officer (Principal Financial Officer)	February 21, 2002
/s/ ROBERT W. WEBER **Robert W. Weber**	Chief Accounting Officer and Vice President Controller (Principal Accounting Officer)	February 21, 2002
/s/ PAUL BAGLEY **Paul Bagley**	Director	February 21, 2002
/s/ LEONARD MAKOWKA **Leonard Makowka**	Director	February 21, 2002
/s/ BRENDAN R. MCDONNELL **Brendan R. McDonnell**	Director	February 21, 2002

Signature	Title	Date
/s/ THOMAS C. MERIGAN JR. M.D. **Thomas C. Merigan, Jr. M.D.**	Scientific Advisor and Director	February 21, 2002
/s/ WILLIAM H. TILLEY **William H. Tilley**	Director	February 21, 2002
/s/ SALVATORE J. ZIZZA **Salvatore J. Zizza**	Director	February 21, 2002

APPENDIX E

HOLLIS-EDEN PHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K

EXHIBIT INDEX

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 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.
*10.1	Registrant s 1997 Incentive Stock Option Plan (the Option Plan) (incorporated by reference to Exhibit 10.3 to the Form S-4).
*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	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).
*10.4	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).
*10.5	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).
*10.6	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).
*10.7	Employment Agreement by and between Registr ant 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).
* 10.8	Employment Agreement by and between Registrant and Eric J. Loumeau dated September 15, 1999 (incorporated by reference to Exhibit 10.10 to Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 1999).
10.9	Settlement and Mutual Release Agreement, dated January 20, 2000, among Registrant, Colthurst Limited, Edenland, Inc. and Patrick T. Prendergast(incorporated by reference to Exhibit 99.2 to Registrant s Current Report on Form 8-K dated January 20, 2000).
10.10	Technology Assignment Agreement, dated January 20, 2000, among Registrant, Colthurst Limited and Patrick T. Prendergast (incorporated by reference to Exhibit 99.3 to Registrant s Current Report on Form 8-K dated January 20, 2000).

Exhibit Number	Description of Document
10.11	Common Stock and Warrant Agreement, dated January 20, 2000, among Registrant and Colthurst Limited (incorporated by reference to Exhibit 99.4 to Registrant s Current Report on Form 8-K dated January 20, 2000).
10.12	Warrant, dated January 20, 2000, issued to Colthurst Limited (incorporated by reference to Exhibit 99.5 to Registrant s Current Report on Form 8-K dated January 20, 2000).
10.13	Sponsored Research and License Agreement, dated January 20, 2000, among Registrant, Edenland, Inc., Colthurst Limited and Patrick T. Prendergast (incorporated by reference to Exhibit 99.6 to Registrant s Current Report on Form 8-K dated January 20, 2000).
10.14	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)).
10.15	Patent License Agreement between the Registrant and Dr. Roger M. Loria (incorporated by reference to Exhibit 10.1 to the Registrant s Registration Statement on Form S-3 (No. 333-75860).+
10.16	Sublease dated December 19, 2001 between Cooley Godward LLP and Registrant.
23.1	Consent of BDO Seidman, LLP.
24.1	Power of Attorney. Reference is made to signature page hereto.

* 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.

APPENDIX F

HOLLIS-EDEN PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

	Page
Report of Independent Certified Public Accountants	F-2
Balance Sheets as of December 31, 2001 and 2000	F-3
Statements of Operations for the Fiscal Years Ended December 31, 2001, December 31, 2000, December 31, 1999 and the Period From Inception (August 15, 1994) to December 31, 2001	F-4
Statements of Stockholders Equity for the Fiscal Years Ended December 31, 1994, December 31, 1995, December 31, 1996, December 31, 1997, December 31, 1998, December 31, 1999, December 31, 2000, December 31, 2001	F-5
Statements of Cash Flow for the Fiscal Years Ended December 31, 2001, December 31 2000, December 31, 1999 and the Period from Inception (August 15, 1994) to December 31, 2001	F-7
Notes to Financial Statements	F-9

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

To the Board of Directors and Stockholders of
Hollis-Eden Pharmaceuticals, Inc.
San Diego, CA

We have audited the accompanying balance sheets of Hollis-Eden Pharmaceuticals, Inc. (a development stage company) as of December 31, 2001 and 2000 and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2001 and for the period from inception (August 15, 1994) to December 31, 2001. 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, 2001 and 2000 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001 and for the period from inception (August 15, 1994) to December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ BDO
SEIDMAN,
LLP

New York, NY
January 24, 2002

HOLLIS-EDEN PHARMACEUTICALS, INC.
(A Development Stage Company)

BALANCE SHEETS

	December 31,	
	2001	**2000**
	(In thousands)	
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 30,567	$ 34,298
Prepaid expenses	169	96
Deposits	27	27
Total current assets	30,763	34,421
Property and equipment, net of accumulated depreciation of $335 and $204	422	422
Receivable from related party (Note 5)	277	256
Total assets	$ 31,462	$ 35,099
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,602	$ 2,636
Total current liabilities	3,602	2,636
Commitments and contingencies (Notes 8, 13, 14)		
Stockholders equity: (Notes 3, 4, 7, 9, 10, 11, 12)		
Preferred stock, no par value, 10,000 shares authorized; no shares outstanding		
Common stock, $.01 par value, 50,000 and 30,000 shares authorized respectively; 12,896 and 11,590 shares issued and outstanding, respectively	129	116
Paid-in capital	91,649	80,503
Deficit accumulated during development stage	(63,918)	(48,156)
Total stockholders equity	27,860	32,463
Total liabilities and stockholders equity	$ 31,462	$ 35,099

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

HOLLIS-EDEN PHARMACEUTICALS, INC.
(A Development Stage Company)

STATEMENTS OF OPERATIONS

	For the year ended December 31,			Period from Inception (Aug.15, 1994) to December 31, 2001
	2001	2000	1999	
	(In thousands, except per share amounts)			
Operating expenses:				
Research and development				
R&D operating expenses	$ 11,774	$ 13,407	$ 5,731	$ 38,364
R&D costs related to common stock and stock option grants for collaborations and technology purchase	96	4,526		5,276
Total research and development	11,870	17,933	5,731	43,640
General and administrative				
G&A operating expenses	4,804	4,157	4,279	17,791
G&A costs related to options/warrants granted	287		7,661	9,777
Total general and administrative	5,091	4,157	11,940	27,568
Total operating expenses	16,961	22,090	17,671	71,208
Other income (expense):				
Interest income	1,199	2,575	2,351	7,340
Interest expense				(50)
Total other income	1,199	2,575	2,351	7,290
Net loss	$ (15,762)	$ (19,515)	$ (15,320)	$ (63,918)
Net loss per share, basic and diluted	$ (1.35)	$ (1.74)	$ (1.41)	
Weighted average number of common shares outstanding	11,654	11,240	10,861	

The accompanying notes are an integral part of these financial statements

HOLLIS-EDEN PHARMACEUTICALS, INC.
(A Development Stage Company)

STATEMENTS OF STOCKHOLDERS EQUITY

	Preferred stock at par value		Common stock at par value		Capital in excess of par value	Deferred compensation	Deficit accumulated during development stage	Total
	shares	amount	shares	amount				
					(in thousands)			
Contribution by stockholder		$		$	$ 103	$	$	$ 103
Common stock issued for cash			2,853		25			25
Common stock issued as consideration for the license agreements (Note 8)			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 8)			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 10)			165		371			371
Common stock issued for cash, net of expenses (Note 10)			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 12)					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 10)	4		1,329	13	19,877			19,890
Warrants issued for services in lieu of cash (Note 9)					408			408
Stock issued for license fee (Note 8)			33		500			500
Stock issued for services in lieu of cash			6		95			95
Options issued for services in lieu of cash (Note 12)					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 10)			1,368	14	24,759			24,773
Preferred Stock Conversion (Note 10,11)	(4)		346	3	(3)			
Deferred compensation Options forfeited (Note 12)					(1,207)	1,258		51
Amortization of non-employee options					559			559
Warrants issued for services in lieu of cash (Note 9)					2,140			2,140
Options accelerated vesting (Note 12)					4,900			4,900
Net loss							(15,320)	(15,320)
Balance at December 31, 1999			11,071	111	75,155		(28,641)	46,625
Exercise of warrants			133	2	758			760
Exercise of stock options			1		5			5
Common Stock issued for 401k/401m plan			6		63			63

	Preferred stock at par value		Common stock at par value		Capital in excess of par value	Deferred compensation	Deficit accumulated during development stage	Total
	shares	amount	shares	amount				
					(in thousands)			
Common Stock issued for In-Process R&D (Note 8)			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 4)			1,280	13	10,644			10,657
Warrants issued for services in lieu of cash (Note 9)					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

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

HOLLIS-EDEN PHARMACEUTICALS, INC.
(A Development Stage Company)

STATEMENTS OF CASH FLOWS

	2001	2000	1999	Period from Inception (Aug. 15, 1994) to December 31, 2001
		(In thousands)		
Cash flows from operating activities:				
Net loss	$ (15,762)	$ (19,515)	$ (15,320)	$ (63,918)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	131	107	68	335
Common stock issued for 401k/401m plan	96	63		159
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 and services	176	677		1,870
Expense related to warrants issued as consideration to consultants	208		2,140	2,348
Expense related to warrants issued to a director for successful closure of merger				570
Expense related to stock options issued			4,900	5,140
Expense related to common stock issued for the purchase of technology		1,848		1,848
Common stock issued as consideration for In-Process R&D		2,000		2,000
Deferred compensation expense related to options issued			620	1,210
Changes in assets and liabilities:				
Prepaid expenses	(73)	19	(89)	(169)
Deposits			(18)	(27)
Loan receivable from related party	(21)	(12)	(38)	(277)
Accounts payable and accrued expenses	1,047	916	909	3,102
Wages payable	(81)	81	500	500
Disposal of assets			7	7
Net cash used in operating activities	(14,279)	(13,816)	(6,321)	(45,235)
Cash flows provided by investing activities:				
Purchase of property and equipment	(132)	(137)	(375)	(764)
Net cash used in investing activities	(132)	(137)	(375)	(764)
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	10,657		24,773	52,829
Proceeds from issuance of debt				371
Net proceeds from recapitalization				6,271
Net proceeds from warrants/options exercised	23	765	5,219	12,991
Net cash from financing activities	10,680	765	29,992	76,566
Net increase (decrease) in cash and equivalents	(3,731)	(13,188)	23,296	30,567
Cash and equivalents at beginning of period	34,298	47,486	24,190	
Cash and equivalents at end of period	$ 30,567	$ 34,298	$ 47,486	$ 30,567
Supplemental disclosure of cash flow information:				
Interest paid	$	$	$	$ 50
Conversion of debt to equity				371
Warrants issued to consultants in lieu of cash, no vesting	288			312
Warrants issued in lieu of cash, commissions on private placement			600	733

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

HOLLIS-EDEN PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO FINANCIAL STATEMENT

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 infectious diseases and immune system disorders. 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 several human clinical trials. The Company is focusing its initial development efforts on a potent series of immune regulating hormones and hormone analogs. The lead compound in this series, HE2000, is currently in Phase II clinical studies in a number of different indications. To date, the Company has not developed commercial products or generated sales for the period since inception (August 15, 1994) through December 31, 2001.

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. Because of the short maturities of these investments, the carrying amount is a reasonable estimate of fair value. At December 31, 2001, the Company s cash equivalents are approximately $30.6 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 or payable to related parties aggregated zero in both 2001 and 2000, and $0.5 million for the year ended December 31, 1999, and $6.3 million for the period from inception (August 15, 1994) to December 31, 2001. Such expenses are recognized as incurred.

During October 2000, the Company incurred an expense of $4.0 million comprised of $2.0 million in cash and 208,681 shares of Hollis Eden Common Stock for a 21% equity stake in Aeson Therapeutics and an exclusive worldwide sublicense to three issued patents (see Note 8, Aeson Therapeutics).

Income Taxes

The Company provides for income taxes under the principles of Statement of Financial Accounting Standards No. 109 (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.

HOLLIS-EDEN PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENT (Continued)

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

Net loss per share is presented as basic earnings based upon the weighted average number of common shares. Diluted earnings per share have not been presented as the common stock equivalents and their effect on earnings per share is anti-dilutive.

Recent accounting pronouncements

In June 2001, the Financial Accounting Standards Board finalized FASB Statements No. 141, *Business Combinations* (SFAS 141), and No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). SFAS 141 requires the use of the purchase method of accounting and prohibits the use of the pooling-of-interests method of accounting for business combinations initiated after June 30, 2001. SFAS 141 also requires that the Company recognize acquired intangible assets apart from goodwill if the acquired intangible assets meet certain criteria. SFAS 141 applies to all business combinations initiated after June 30, 2001 and for purchase business combinations completed on or after July 1, 2001. It also requires, upon adoption of SFAS 142, that the Company reclassify the carrying amounts of intangible assets and goodwill based on the criteria in SFAS 141.

SFAS 142 requires, among other things, that companies no longer amortize goodwill, but instead test goodwill for impairment at least annually. In addition, SFAS 142 requires that the Company identify reporting units for the purposes of assessing potential future impairments of goodwill, reassess the useful lives of other existing recognized intangible assets, and cease amortization of intangible assets with an indefinite useful life. An intangible asset with an indefinite useful life should be tested for impairment in accordance with the guidance in SFAS 142. SFAS 142 is required to be applied in fiscal years beginning after December 15, 2001 to all goodwill and other intangible assets recognized at that date, regardless of when those assets were initially recognized. SFAS 142 requires the Company to complete a transitional goodwill impairment test six months from the date of adoption. The Company is also required to reassess the useful lives of other intangible assets within the first interim quarter after adoption of SFAS 142. The adoption of these statements is not expected to effect the Company s financial condition.

In October 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long Lived Assets*. SFAS No. 144 requires that those long lived assets be measured at the lower of carrying amount or fair value less cost to sell, whether reported in continuing operations or discontinued operations. Therefore discontinued operations will no longer be measured at net realizable value or include amounts for operating losses that have not yet occurred. SFAS No. 144 is effective for financial statements issued for fiscal years beginning after December 14, 2001 and generally, is to applied prospectively. The adoption of these statements is not expected to effect the Company s financial condition.

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.)

HOLLIS-EDEN PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENT (Continued)

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. Financing

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 are comprised of 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.

5. 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. A third of the note is due and payable on April 23 of 2002, 2003 and 2004.

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

6. Income Taxes

The Company has available a net operating loss carryforward of approximately $50 million at December 31, 2001 which may be carried forward as an offset to taxable income, if any, in future years through its expiration in 2012 to 2021. The Company has a net deferred tax asset of approximately $18 million at December 31, 2001 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.

7. Reverse Stock Splits

In March 1996, a 1 for 2.65 split of the Company s common stock was effected. Also, on February 13, 1995 there was a 3 for 5 split of the Company s common stock. All stock splits have been retroactively reflected for all periods presented.

HOLLIS-EDEN PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENT (Continued)

8. Related Party Licenses and other Agreements and Commitments 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 HE2000. The second arbitration sought to rescind both of the agreements with Edenland covering future potential drug candidates other than HE2000.

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

HOLLIS-EDEN PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENT (Continued)

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 HE2000, 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 were 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) for approximately $4 million 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 have granted the Company an exclusive option to acquire the remainder of Aeson at a predetermined price. If the Company elects to not exercise the option by April 11, 2002, the Company, at its option, can fund an additional $2.0 million to Aeson for development work and extend the purchase option date until April 11, 2003. Regardless of whether the Company elects to exercise this option, the Company will retain its exclusive sublicense to the three patents.

HOLLIS-EDEN PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENT (Continued)

9. 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 7, 2002, except for one warrant for 393,250 shares which expires January 7, 2006.

Series B warrants

During February 1995, the Company issued 37,736 Series B Warrants to Edenland, Inc. in consideration for an amendment to the Edenland License Agreement. The warrants were exercisable until February 5, 2000, to purchase the same number of shares of common stock at a price of $15.90 per share. These warrants have expired.

Placement agent warrants

During May 1996, the Company issued to the placement agent, for the completion of the private placement in April 1996 (see Note 10), a warrant to purchase an aggregate of up to 445,000 shares of common stock, at an exercise price of $2.475 per share. The fair value of the 445,000 options was deducted from the net proceeds of the private placement as a cost of raising capital and totaled approximately $133,000. These warrants have been exercised.

Upon the successful closure of the Merger and Redemption of the Class A Common Stock Purchase Warrants and Class B Unit Purchase Warrants, the Company issued additional placement agent warrants to purchase 452,830 shares of common stock at an exercise price of $2.475 per share. These warrants have been exercised.

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 May 15, 2002.

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 15, 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 Warrants

During February 1998, as part of payment for services relating to investor relations, the Company issued warrants to purchase 150,000 shares with an exercise price of $14.75 per share and an expiration date of February 4, 1999. The warrants were estimated to have a value of $408,000, which was expensed in 1998. These warrants have been exercised.

HOLLIS-EDEN PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENT (Continued)

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 6, 2001. Of the warrants issued, 157,000 were issued as finder 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 22, 2002.

1999 Consulting Warrants

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, warrants 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 warrants are not subject to any vesting provisions. The warrants were 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 these warrants was extended to March 2003. The warrant extension did not result in an additional non-cash charge.

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.

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.

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. These warrants expire December 11, 2003. As a finders fee, we issued two warrants to the placement agent 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.

HOLLIS-EDEN PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENT (Continued)

The following table summarizes stock warrant activity for 1999 through 2001 (in thousands, except per share amounts):

		Price Per Share	
	Shares	Range	Weight Average
Outstanding, December 31, 1998	3,562	$ 2.48 17.00	$ 12.33
1999			
Issued	590	18.25 20.50	20.16
Exercised	755	2.48 14.75	6.88
Canceled	7	11.02	11.02
Outstanding, December 31, 1999	3,390	$ 2.48 20.50	$ 14.91
2000			
Issued	400	25.00	25.00
Exercised	133	2.48 9.50	5.71
Canceled	123	6.03 15.90	11.51
Outstanding, December 31, 2000	3,534	$ 9.00 25.00	$ 16.52
2001			
Issued	308	3.09 12.00	9.48
Canceled	1,837	17.00 25.00	18.74
Outstanding, December 31, 2001	2,005	$ 3.09 20.50	$ 13.40

Subsequent to year-end, warrants for 704 shares have expired and the actual warrants outstanding as of January 24, 2002 are for a total of 1,301 shares.

For various price ranges, the following table summarizes the weighted average prices of outstanding warrants as of December 31, 2001 (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	33	$ 3.48	33	$ 3.48
$5.01 $10.00	234	8.84	234	8.84
$10.01 $15.00	1,148	11.14	1,148	11.14
$15.01 $20.00	90	18.25	90	18.25
$20.01 $25.00	500	20.50	500	20.50

HOLLIS-EDEN PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENT (Continued)

10. Common Stock

On January 21, 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, were converted into 164,962 shares of Common Stock at a price of $2.25 per share. During March and April of 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 d