HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 10-K
March 10, 2005

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, 2004

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

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

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

None

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

Common stock, $.01 par value per share

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

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

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

The aggregate market value of the voting stock held by nonaffiliates of the Registrant as of June 30, 2004, the end of Hollis-Eden Pharmaceuticals most recently completed second fiscal quarter, was approximately $197,084,992 based on the closing stock price of $12.05 for the Registrant s Common Stock as reported by the Nasdaq National Market.

As of March 1, 2005, there were outstanding 19,288,072 shares of the Registrant s Common Stock, $.01 par value per share.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of Registrant s definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the solicitation of proxies for our 2005 Annual Meeting of Stockholders to be held on June 17, 2005, are incorporated by reference into Part III of this Report.

Hollis-Eden Pharmaceuticals, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2004

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. In particular, statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are contained or incorporated by reference in this report. We have based these forward-looking statements on our current expectations about future events. While we believe these expectations are reasonable, such forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. The actual future results for Hollis-Eden Pharmaceuticals, Inc. may differ materially from those discussed here for various reasons, including those discussed in this report under the heading Risk Factors, Part II, Item 7 entitled Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere throughout this Annual Report. Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. We do not undertake and specifically decline any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments. When used in the report, unless otherwise indicated, we, our and us refers to Hollis-Eden Pharmaceuticals, Inc. and its subsidiaries.

PART I

Item 1. Business

GENERAL

OVERVIEW

Hollis-Eden Pharmaceuticals, Inc., a development-stage pharmaceutical company, is engaged in the discovery, development and commercialization of products for the treatment of diseases and disorders in which the body is unable to mount an appropriate immune response. Our initial technology development efforts are primarily focused on a series of hormones and hormone analogs that we have labeled immune regulating hormones (IRHs). We believe these compounds are key components of the body s natural regulatory system that potentially can be useful in treating a wide variety of medical conditions.

Preclinical and early clinical studies with these compounds indicate that they have the ability to significantly reduce a number of well known inflammatory mediators, while also stimulating 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.

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

Specifically, unlike traditional medical indications, NEUMUNE may be reviewed for approval on the basis of efficacy in animals and safety in humans. This potentially avoids the need to conduct large and expensive studies in humans to establish efficacy. Further, in addition to the potential to supply the military with NEUMUNE, we are pursuing an advance purchase contract under Project BioShield to provide NEUMUNE to the Strategic National Stockpile for use by first responders and civilians who may be at risk of radiation injury. Project BioShield is a recently

adopted piece of legislation that allocates $6 billion towards advance purchase contracts for development stage compounds that may be useful as medical countermeasures to weapons of mass destruction such as radiological or nuclear weapons. We believe that supplying NEUMUNE to the U.S. government under this program would also require us to have significantly less commercial infrastructure than would be necessary to launch a new drug for a traditional indication.

We have generated a substantial amount of data regarding the safety and activity of NEUMUNE in the setting of radiation injury in non-human primates. In 2005 we expect to initiate human clinical trials with NEUMUNE to establish safety and also anticipate producing significant additional data on the efficacy of the compound in non-human primates. We have also commenced work on scaling-up the manufacturing of this compound for potential commercial use.

Because of the attractive aspects of this market opportunity, we acquired an additional non-IRH development-stage compound for radiation protection with our acquisition of Congressional Pharmaceutical Corporation (CPC) and its lead product candidate, PHOSPHONOL (a phosphothioate). PHOSPHONOL is being developed to protect against the long-term complications of radiation exposure such as genetic mutations that can lead to cancer. We believe its development and commercialization path may have similar attributes to that of NEUMUNE.

Like radiation, many current cancer therapies can also cause damage to the bone marrow and lead to an increased number of genetic mutations. As a result, we believe there may be a significant opportunity for compounds similar to NEUMUNE and PHOSPHONOL in the area of protecting against the damaging effects of cancer chemotherapy. While these applications would require traditional clinical trial programs, we believe the market opportunity in these areas is significant. We are currently conducting preclinical studies with second-generation compounds that we believe may be well suited for development in this indication.

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

Another IRH, HE2000, is a Phase II clinical stage compound that has shown clinical activity in infectious diseases, including HIV and malaria, and may be a candidate for further development as a compound to be used in treating global infectious disease epidemics, as well as in combating bioterrorism.

We are pursuing a partially integrated approach to building our business. As such, we are utilizing third parties for many of our activities. We believe by being involved in the design and supervision of these activities, but not the day-to-day execution, we can preserve our flexibility and limit our expenditures during the development phase. If we are able to successfully develop our investigational drug candidates, we anticipate marketing them directly in the U.S. and potentially elsewhere. For certain therapeutic indications or geographic regions, we anticipate establishing strategic collaborations to commercialize these opportunities.

Our principal executive offices are located at 4435 Eastgate Mall, Suite 400, San Diego, CA 92121, and our telephone number is (858) 587-9333. We are incorporated in Delaware. We maintain a website at www.holliseden.com. The reference to our worldwide web address does not constitute incorporation by reference of the information contained on our website.

Our periodic and current reports that we file with the Securities and Exchange Commission, or SEC, are available free of charge, on our website, as soon as reasonably practicable after we have electronically filed them with, or furnished them to, the SEC.

TECHNOLOGY DESCRIPTION

Immune Regulating Hormones

Our primary technology development efforts are focused on a class of hormones and analogs of hormones found in the body that we believe are important components of the body s regulatory system. These compounds have demonstrated significant preclinical activity in protecting the bone marrow from the damaging effects of radiation and chemotherapy. In addition, IRHs appear to reduce inflammation in a broad-spectrum fashion while

also improving a number of components of the immune system in conditions of immune suppression. These hormones are known to be depleted as we age, and this process can be accelerated as a result of infectious diseases and other chronic immune system disorders.

Hematopoiesis. One of our key focus areas for immune regulating hormones revolves around their role in the hematopoietic system. Hematopoiesis is the process by which the body produces a number of key blood cell types, including neutrophils and platelets. Neutrophils are white blood cells that are critical early responders involved in combating foreign pathogens. When they are depleted, the host becomes highly susceptible to life-threatening infections. Similarly, a significant loss of platelets, which are key clotting elements in the blood, can lead to life-threatening bleeding episodes.

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

A number of preclinical studies with our immune regulating hormones indicate that these compounds can increase both neutrophils and platelets, as well as other important immune cells following radiation injury or chemotherapy. In addition, those cells that are produced following treatment with IRHs appear to be more effective at killing pathogens than untreated cells.

Mechanistically, IRHs appear both to increase the proliferative potential of residual bone marrow cells after injury and accelerate the rate at which new cells are generated. In addition, the ability of IRHs to regulate reactive oxygen species and reduce systemic inflammation may also contribute to preventing death of remaining bone marrow cells.

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

Role of Inflammation. The role of inflammation in disease pathogenesis has become increasingly recognized by the medical community. Chronic inflammation is generally believed to be caused by an over-stimulation of certain components of the immune system, such as reactive oxygen species and pro-inflamatory cytokines, due to persistent low-grade infections or the body s inability to differentiate between certain cells or tissues in the body and foreign pathogens. Published studies have now implicated chronic inflammation in a host of diseases ranging from autoimmune conditions such as arthritis and psoriasis, to infectious diseases, including HIV, malaria, and tuberculosis, and more recently to cardiovascular disease and a number of different cancer types.

One of the most widely used classes of agent for treating inflammation is the corticosteroid class. Industry market research indicates that there are more than 60 million new prescriptions for corticosteroids issued by physicians in the U.S. each year for a wide range of conditions. While these drugs are very potent anti-inflammatory agents, their chronic use can lead to immune suppression and other side effects including bone loss.

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

Our immune regulating hormones have been shown to regulate a broad array of reactive oxygen species and pro-inflammatory cytokines involved in inflammation and produce anti-inflammatory activities comparable to that historically seen with corticosteroids. In addition, certain members of our class of compounds has been

shown in early clinical trials to produce long-lasting reductions in a number of key inflammatory mediators, including TNF-alpha, IL-1 beta and IL-6. 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 body and recognize and destroy foreign cells they encounter. This response serves to fight the infection after initial exposure, pending development of adaptive immunity.

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

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

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

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

Our therapeutic strategy is based on the observation that this complicated balance of cytokines is regulated by competing levels of certain adrenal hormones. In young, healthy adults, the balance between corticosteroids such as cortisol, which have immunosuppressive properties, and the immune regulating hormones we are developing is a key determinant in whether appropriate levels of cytokines are produced to properly regulate

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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 relative to Th1 cytokines. As this situation continues, the immune system is dominated by Th2 cells unable to fight viral and other infections rather than the necessary cell-mediated Th1 cells. In this state of immune system dysregulation, the patient becomes highly susceptible to infection.

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

Hollis-Eden s Approach. With the advent of the technology revolution of the last several decades, scientists have been presented with a whole new series of tools that allow them to study very specific aspects of biological function. This led to a scientific approach that largely centered on how a certain drug might interact with a specific signaling function or target for a specific disease. While this approach has resulted in a number of successful drugs, frequently these compounds are not as effective in clinical practice as anticipated and produce a number of unintended side effects due to the complexity of interactions amongst different systems in human biology.

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

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

As factors such as chronic inflammation, innate and adaptive immunity and metabolic function are implicated in a host of diseases including virtually all diseases of aging, successfully applying this approach has potential utility for a number of important pharmaceutical markets. The hormone series that we are focused on is known to be involved in cell signaling at an upstream level, and these hormones are known to be depleted as we

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age. This depletion can be accelerated as a result of a number of the conditions we are pursuing. We believe that by starting with the lessons that evolutionary biology has taught us, the time to develop new therapeutics that target these systemic abnormalities will be shortened relative to the *ground up* approach being pursued by others.

Phosphothioate Technology

In February 2004, we acquired Congressional Pharmaceutical Corporation (CPC). CPC is a company that was formed to commercialize a series of compounds that have the potential to protect against DNA mutations that can occur as a result of radiation injury or chemotherapy. This DNA damage (mutagenesis) has been associated with an increased risk of a variety of different cancers and is believed to be a primary cause of the harmful long-term effects of radiation injury. CPC s lead compound, PHOSPHONOL, is part of a series of compounds from the phosphothioate class that has been licensed from the University of Chicago. These compounds appear to provide a molecular scaffolding around DNA that helps protect the genomic stability of DNA, reducing the chance for mutation. By improving the genomic stability, phosphothioates such as PHOSPHONOL may thus reduce the likelihood that genetic mutation will subsequently lead to cancers.

PRODUCTS IN DEVELOPMENT

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

NEUMUNE

NEUMUNE is being developed as a treatment for Acute Radiation Syndrome (ARS). ARS, also referred to as radiation sickness, is an acute illness caused by high doses of radiation exposure over a significant portion of the body in a relatively short time period. This exposure results in the depletion of hematopoietic stem cells and progenitors in the bone marrow, resulting in severe neutropenia (loss of white blood cells known as neutrophils) and thrombocytopenia (loss of key clotting elements known as platelets). Severe neutropenia can significantly increase an individual s susceptibility to life threatening infections, while thrombocytopenia increases the risk of bleeding. Either of these conditions can lead to mortality, which usually occurs in the first thirty to sixty days following exposure. If an individual can survive this initial period of insult, the bone marrow will generally return to normal production of these critical blood cell components.

To date, there are no therapeutics approved to mitigate ARS. Current treatment recommendations call for hospitalization of the exposed individual during this period of vulnerability so that these critical blood elements can be monitored aggressively and supportive care can be given where necessary. Unfortunately, in the type of mass casualty scenario that could occur following a nuclear or radiological event, local hospitals and treatment facilities are likely to be completely overwhelmed and such a treatment strategy is unlikely to be available for the vast majority of victims. What is needed is an agent that could potentially be useful on an outpatient basis, without the need for hospitalization, that

could protect those exposed from these life-threatening complications.

NEUMUNE is being developed by Hollis-Eden and the Armed Forces Radiobiology Research Institute (AFRRI) in the U.S. military to potentially fulfill this need. Published studies by AFRRI with our immune regulating hormone NEUMUNE have shown dramatic survival improvements in NEUMUNE-treated animals versus controls in models of radiation-induced immune suppression. The ability of NEUMUNE to stimulate both neutrophils and platelets as well as other components of innate immunity is believed to be the mechanism by which NEUMUNE exerted its protective effects in these studies.

AFRRI is a leader in studying the short-term and long-term effects of radiation injury. A principal AFRRI mission is the development of pharmaceutical agents that can be used to prevent injury from radiation caused by a nuclear accident or event. Over the years, AFRRI, in concert with another Department of Defense project, has screened thousands of compounds in an effort to find an acute radioprotectant suitable for widespread use. Out of this screening and profiling effort, NEUMUNE has emerged as a leading candidate based on its significant efficacy in preclinical models to date, its safety profile, and the comparatively low-cost nature of its manufacturing process.

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

Given the accelerated potential development path for NEUMUNE and the significant and largely untapped market opportunity for compounds that can treat acute radiation injury, this program has become a top priority for us. We have demonstrated that NEUMUNE has significant activity over a range of doses in maintaining neutrophils and platelets in studies involving more than 200 non-human primates. These studies also suggest NEUMUNE can provide a survival benefit versus placebo-treated animals. We anticipate initiating clinical trials in humans with NEUMUNE in the first half of 2005. The initial studies are expected to help us establish the safety of NEUMUNE in humans and to help us determine the concentration of the compound that can be achieved in human plasma. This information can then be used in selecting the final dose for the pivotal efficacy study in non-human primates and the larger human safety study that would be required. If results from these studies are successful, we anticipate being able to file a New Drug Application (NDA) with the FDA in 2006.

We believe the market opportunity for a drug that could be used to ameliorate the effects of acute radiation injury would be significant. Because the window of opportunity to treat radiation injury is short, we believe any drug to treat this condition will need to be stockpiled on a local level to be appropriately available for high risk populations. In light of the current risk of terrorism, high-risk areas may include any military installation or theater of operations, any urban or metropolitan area that is at risk of a radiological attack, and a 10 to 50 mile radius around any nuclear power plant or spent fuel facility. Such a definition would encompass a large portion of the highly populated areas in the U.S. In addition, we believe similar market opportunities exist in Europe and Asia. The only drug that has been widely stockpiled for radiation injury is potassium iodide. Potassium iodide is only effective against the long-term risk of thyroid cancer, and does not protect the body from the acute effects on the bone marrow, which can lead to rapid fatalities. Despite this limitation, potassium iodide has been stockpiled broadly for years in Europe and Japan for civilians living within close proximity of nuclear power plants, and the U.S. has recently begun purchasing millions of doses of the drug for similar uses in this country. Given that NEUMUNE may be useful in protecting against the immediate life-threatening effects of radiation, we believe there may be strong interest by government agencies to adopt a similar stockpiling strategy if NEUMUNE is successfully developed.

As a result of the increased threat, the U.S. government is allocating significant funding for the stockpiling of drugs that act as medical countermeasures to weapons of mass destruction. As an incentive to industry to develop these countermeasures, the U.S. government recently enacted Project BioShield, legislation that provides

a mechanism for placing large advance orders for investigational products in this area, even before they are approved. A total of $6 billion has been allocated to purchase the initial round of medical countermeasures under this legislation. In late 2004, the Department of Health and Human Services (HHS) issued a Request for Information (RFI) for therapeutics to treat ARS. The request was specifically targeted at therapies that could protect neutrophils and platelets from the damaging effects of radiation injury when given shortly after exposure to total body irradiation. We filed a formal response to this request detailing the potential for NEUMUNE in this indication. We believe the next step in the procurement process for countermeasures to ARS will likely be a formal Request for Proposal (RFP) process which would detail the specific requirements of any such order. There can be no assurance when or if HHS will move to the next stage of this procurement process and whether we will be able to participate.

Project BioShield also contains provisions enabling HHS to begin purchasing new medical countermeasures for the Strategic National Stockpile in advance of formal FDA approval. This provision, known as an Emergency Use Authorization, has already been implemented for other development stage medical countermeasures to weapons of mass destruction. In preparation for a similar potential order for NEUMUNE, Hollis-Eden has begun manufacturing scale-up activities. A decision by the U.S. Government to enter into a commitment to purchase NEUMUNE prior to FDA approval is largely out of our control. Our development plans and timelines may vary substantially depending on whether we receive such a commitment and the size of such commitment, if any.

IRHs in Chemotherapy Protection

As a result of our increasing knowledge of structure-activity relationships with this class of compounds, we are now profiling second-generation IRHs which we believe may be well suited for use in chemotherapy protection in cancer patients. As with radiation injury, chemotherapy can damage the bone marrow, causing depletion of neutrophils and platelets, which can be life-threatening. Preclinical data in non-human primates with several of our immune regulating hormones in models of chemotherapy-induced immune suppression indicate that these compounds could significantly protect both neutrophils and platelets. Assuming our profiling efforts are successful, we plan to select one of these compounds for clinical development in chemotherapy protection. Drugs that only stimulate neutrophils in this setting currently generate sales in excess of $2.5 billion annually, although we can not guarantee that our compounds, if approved, will generate significant sales.

PHOSPHONOL

We acquired exclusive commercialization rights to PHOSPHONOL in our recent acquisition of CPC. Like NEUMUNE, PHOSPHONOL is being developed to protect against the effects of radiation injury. However, whereas NEUMUNE addresses the short-term effects of radiation injury, PHOSPHONOL is designed to treat the long-term effects of radiation exposure. PHOSPHONOL appears to have the potential to stabilize the genome after radiation injury, thus reducing genetic mutations. By reducing genetic mutations, PHOSPHONOL may also reduce a variety of cancers that can occur a number of years after radiation injury.

We believe it may be possible to develop PHOSPHONOL pursuant to the same animal efficacy rule we are following with NEUMUNE. We have begun profiling PHOSPHONOL and other compounds in this series in a number of preclinical models designed to assess safety, efficacy and oral bioavailability. We are also preparing to open discussions with government authorities about specific objectives that would be required for a compound for this indication.

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

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inadvertent environmental radiation as well as for use in response to acts of terrorism and nuclear accidents. As with our immune regulating hormones, we also believe PHOSPHONOL and related compounds may potentially play an important role in protecting against damage from chemotherapy.

IMMUNITIN and Other IRHs in Infectious Disease

IMMUNITIN is a clinical-stage IRH that we have tested in clinical trials in infectious disease. While the primary market opportunities for pharmaceuticals have traditionally been in the U.S., Europe and Japan, our immune regulating hormones have a number of attributes that make them potentially useful globally. Included in these attributes are the potential broad-spectrum activity in multiple infectious diseases, the attractive safety profile to date, the low likelihood of resistance and the relative ease of manufacture. Increasing focus on the crisis that infectious diseases such as HIV, malaria and tuberculosis have created in the developing world has led to a number of recent third party initiatives designed to provide funding for effective approaches to these diseases. If we are able to receive support from these initiatives for both development and commercialization, subject to obtaining regulatory approvals, marketing IMMUNITIN and our other compounds in developing countries could become commercially attractive. In addition, as described above, similar funding initiatives and incentives have now been adopted by the U.S. government under Project BioShield to encourage the development of new drugs to serve as countermeasures against weapons of mass destruction. While NEUMUNE is being developed to protect against radiological and nuclear weapons, we believe IMMUNITIN and other IRHs may be useful against biological or chemical weapons. We are continuing to pursue opportunities in these areas under Project BioShield as well.

IMMUNITIN has been tested in a series of Phase I/II and Phase II clinical trials in HIV/AIDS patients in the U.S. and South Africa. In all of these studies, IMMUNITIN treatment appeared to be generally well tolerated with mild to moderate pain at the injection site being the most common adverse event. In addition to assessing the safety profile of IMMUNITIN in the trials, we have also assessed the effect of IMMUNITIN on a wide variety of immune and inflammatory markers that are associated with disease progression.

Results from a study employing intermittent subcutaneous dosing of IMMUNITIN in South African HIV patients receiving no other therapy demonstrated long-lasting, statistically significant declines in a number of key inflammatory mediators, including TNF-alpha, IL-1 and IL-6 compared to placebo-treated patients.

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

We have also tested IMMUNITIN as a monotherapy in late-stage AIDS patients. During this study, IMMUNITIN-treated patients experienced a statistically significant reduction in the number of opportunistic infections compared to those treated with placebo.

The ability of IMMUNITIN to reduce inflammation while stimulating innate and cell-mediated immunity seen in our HIV clinical trials also has possible implications for a number of other infectious diseases, including parasitic infections such as malaria. As a result, we entered into a collaboration with the U.S. Navy on a preclinical program in malaria with IMMUNITIN. Based on favorable results in multiple preclinical studies with the compound, we then proceeded with two Phase II clinical studies in malaria patients in Thailand. Results from these studies indicated that IMMUNITIN was very effective at reducing parasite count and cleared malarial parasites in most patients within seven days when the compound was delivered either by injection or as a buccal tablet.

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We have also shown in a series of preclinical studies in models of tuberculosis that IMMUNITIN is effective when given as a monotherapy in either the acute or chronic phase of this bacterial infection. In addition, IMMUNITIN appears to have an additive effect when combined with the current three-drug regimen standard of care of antibiotic treatment for TB in this model system.

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

We are profiling IMMUNITIN as well as second-generation analogs of IMMUNITIN in additional preclinical models and believe one or more of these compounds may be useful against biowarfare agents.

IRHs in Autoimmune Disease

Given the anti-inflammatory and immune stimulating effects seen with IMMUNITIN and other IRHs in preclinical and early clinical trials, we are also interested in exploring the potential for IRHs in autoimmune diseases. First-generation immune regulating hormones such as IMMUNITIN have been shown in preclinical and early clinical studies to provide broad-spectrum anti-inflammatory activity. These small molecule drug candidates are structurally similar to widely used corticosteroids, but unlike corticosteroids they do not appear to cause immune suppression or bone loss two common side effects of corticosteroids. Recently, striking anti-inflammatory effects were seen with IRHs in *in vivo* models of pleurisy (a model of lung inflammation), EAE (experimental autoimmune encephalomyelitis, a model of multiple sclerosis) and LPS challenge (lipopolysaccharide, a lethal model of endotoxic shock). In addition to these anti-inflammatory properties, IRHs were shown to improve immune function (rather than suppress it as would be expected with corticosteroids) in a popliteal lymph node assay and were also shown to counteract cortocisteroid-induced changes responsible for bone loss in *in vitro* studies. Compounds profiled in one or more of these studies included first-generation IRHs as well as a series of more than 10 new second-generation IRHs that were able to demonstrate more potent activity than the first-generation IRHs.

Hollis-Eden is continuing to profile these and other new IRHs in a number of preclinical models of autoimmunity and, if these results are successful, plans to enter one or more of these compounds into development for additional autoimmune indications. We are also collaborating with Cystic Fibrosis Foundation Therapeutics, the non-profit drug discovery and development arm of the Cystic Fibrosis Foundation, to develop a new anti-inflammatory agent for use in Cystic Fibrosis.

Competition

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

In the area of immune modulators for correcting immune dysregulation, a number of companies are targeting inhibition or enhancement of a single cytokine or other mediator. For example, Amgen s Enbrel targets TNF-alpha, as does Johnson & Johnson s Remicade. Drugs such as

Celebrex from Pfizer target COX-2. While these targeted approaches have shown clinical benefit and have generated significant sales volumes, redundant mechanisms in the immune system limit their effectiveness. In addition, side effects and cost issues may limit

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

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

Government Regulation

General

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

Approval Process

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

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

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

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

In Phase I clinical trials, studies usually are conducted on healthy volunteers or, in the case of certain terminal illnesses such as AIDS, patients with disease that has failed to respond to other treatment, to determine the maximum tolerated dose, side effects and pharmacokinetics of a product. Phase II studies are conducted on a small number of patients having a specific disease to determine initial efficacy in humans for that specific disease, the most effective doses and schedules of administration, and possible adverse effects and safety risks. Phase II/III differs from Phase II in that the trials involved may include more patients and, at the sole discretion

of the FDA, be considered the pivotal trials, or trials that will form the basis for FDA approval. Phase III normally involves the pivotal trials of a drug, consisting of wide-scale studies on patients with the same disease, in order to evaluate the overall benefits and risks of the drug for the treated disease compared with other available therapies. The FDA continually reviews the clinical trial plans and results and may suggest design changes or may discontinue the trials at any time if significant safety or other issues arise.

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

New Drug Application (NDA). Upon successful completion of Phase III clinical trials, the drug sponsor files an NDA for approval containing all information that has been gathered. The NDA must include the chemical composition of the drug, scientific rationale, purpose, animal and laboratory studies, results of human tests, formation and production details, and proposed labeling.

Post Approval. If an NDA is approved, the drug sponsor is required to submit reports periodically to the FDA containing adverse reactions, production, quality control and distribution records. The FDA may also require post-marketing testing to support the conclusion of efficacy and safety of the product, which can involve significant expense. After FDA approval is obtained for initial indications, further clinical trials may be necessary to gain approval for the use of the product for additional indications.

The testing and approval process is likely to require substantial time and effort, and there can be no assurance that any FDA approval will be granted on a timely basis, if at all. The approval process is affected by a number of factors, primarily the side effects of the drug (safety) and its therapeutic benefits (efficacy). Additional preclinical or clinical trials may be required during the FDA review period and may delay marketing approval. The FDA may also deny an NDA if applicable regulatory criteria are not met.

Outside the United States, we will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for our products. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursements vary widely from country to country.

Manufacturing

We do not have, and do not intend to establish, manufacturing facilities to produce our product candidates or any future products. We plan to control our capital expenditures by using contract manufacturers to make our products. We believe that there are a sufficient number of high quality FDA approved contract manufacturers available, and we have had discussions and in some cases established relationships to fulfill our near-term production needs for both clinical and commercial use.

The manufacture of our product candidates or any future products, whether done by outside contractors as planned or internally, will be subject to rigorous regulations, including the need to comply with the FDA s current Good Manufacturing Practice standards. As part of obtaining FDA approval for each product, each of the manufacturing facilities must be inspected, approved by and registered with the FDA. In addition to obtaining FDA approval of the prospective manufacturer s quality control and manufacturing procedures, domestic and foreign manufacturing facilities are subject to periodic inspection by the FDA and/or foreign regulatory authorities.

Patents

We currently own or have obtained a license to over 100 issued U.S. and foreign patents and over 100 pending U.S. and foreign patent applications.

We consider the protection of our technology, whether owned or licensed, to the exclusion of use by others, to be vital to our business. While we intend to focus primarily on patented or patentable technology, we may also rely on trade secrets, unpatented property, know-how, regulatory exclusivity, patent extensions and continuing technological innovation to develop our competitive position. In the United States and certain foreign countries, the exclusivity period provided by patents covering pharmaceutical products may be extended by a portion of the time required to obtain regulatory approval for a product.

In certain countries, pharmaceuticals are not patentable or only recently have become patentable, and enforcement of intellectual property rights in many countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many countries can be expected to be problematic or unpredictable. We cannot guarantee that any patents issued or licensed to us will provide us with competitive advantages or will not be challenged by others. Furthermore, we cannot be certain that others will not independently develop similar products or will not design around patents issued or licensed to us.

In most cases, patent applications in the United States are maintained in secrecy until 18 months after the earliest filing or priority date. Publication of discoveries in the scientific or patent literature, if made, tends to lag behind actual discoveries by at least several months. U.S. patent applicants can elect to prevent publication until the application issues by agreeing not to file the application outside the U.S. This option is rarely used for pharmaceutical patent applications. Consequently, we cannot be certain that a licensor of its intellectual property was the first to invent certain technology or compounds covered by pending patent applications or issued patents or that it was the first to file patent applications for such inventions. In addition, the patent positions of biotechnology companies, including our own, are generally uncertain, partly because they involve complex legal and factual questions.

In addition to the considerations discussed above, companies that obtain patents claiming products, uses or processes that are necessary for, or useful to, the development of our product candidates or future products could bring legal actions against us claiming infringement. Patent litigation is typically costly and time consuming, and if such an action were brought against us, it could result in significant cost and diversion of our 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.

Technology Agreements

In December 1999, we entered into a license agreement with Dr. Roger M. Loria. Dr. Loria exclusively licensed to us all rights to NEUMUNE and HE2200, together with all related patents and patent applications. This agreement was amended on April 9, 2002. Dr. Loria is a Professor of Microbiology and Immunology at Virginia Commonwealth University. He is a leading expert in the field of immune regulating hormones and is a scientific consultant to Hollis-Eden.

Also during January 2000, we entered into two new technology agreements with Patrick T. Prendergast, Colthurst Ltd. and Edenland, Inc. The first agreement, the Technology Assignment Agreement, replaced the Colthurst License Agreement dated May 18, 1994 among Hollis-Eden,

Mr. Prendergast and Colthurst. This agreement assigned to us ownership of all patents, patent applications and current or future improvements of the

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

On May 17, 2004, we received a copy of a Demand for Arbitration from Colthurst, Edenland and Mr. Prendergast, claiming, among other things, that we breached the agreements with them when we did not issue to Colthurst the remaining 528,000 shares of our common stock and declared that the warrant to purchase up to 400,000 shares of our common stock would not vest as to any shares, as described above.

While we cannot guarantee that, as a result of this dispute, additional equity will not be issued or that an additional accounting charge will not be made, we are confident in our analysis that Colthurst did not satisfy the conditions required to receive the additional shares of our common stock and the shares underlying the warrant, and we believe that the claims underlying the demand for arbitration are without merit. We intend to contest these claims vigorously, and we have filed a counterclaim in arbitration seeking damages from Colthurst, Edenland and Mr. Prendergast for numerous breaches of these agreements by them. We do not believe that this litigation will have a material adverse effect on our company or our financial condition.

In August 2002, we entered into a Sublicense Agreement with Pharmadigm, Inc. Under the agreement, we obtained exclusive worldwide rights to certain intellectual property of Pharmadigm and the University of Utah and we agreed to make aggregate payments of $0.9 million in cash or in shares of our common stock, at our option, over the next year. We elected to make such payments in equity and have issued a total of 168,921 shares of our common stock in complete satisfaction of this requirement. We will also make additional milestone and royalty payments to Pharmadigm if we meet specified development and commercialization milestones for products covered by the patents. No such mentioned milestones have been met to date. The principal patents licensed under the agreement, originally licensed to Pharmadigm from the University of Utah, relate to inventions by Dr. Raymond Daynes and Dr. Barbara A. Areneo. Dr. Daynes served as a scientific consultant to Hollis-Eden from 1999 to mid-2003.

In February 2004, we acquired CPC and replaced CPC as the exclusive licensee to certain intellectual property rights held by the University of Chicago. These intellectual property rights consist of a series of patents and patent applications that relate to discoveries made by David J. Grdina, Ph.D., Professor of Radiation and Cellular Oncology at the University of Chicago. The patented technology covers a series of compounds, which are currently in the preclinical stages of development that have the potential to protect against DNA mutations that can occur as a result of radiation injury or chemotherapy. In the acquisition we issued approximately 50,000 shares of our common stock to the former stockholders of CPC. In addition, if we achieve certain development milestones, we will be required to issue additional shares of our common stock to the former stockholders of CPC. In the event all of the milestones are achieved, the total number of additional shares that we would be required to issue to the former stockholders of CPC is 275,000, more than half of which would be issued only upon FDA approval of CPC s product. Furthermore, upon regulatory approval and commercialization of products covered by the licensed intellectual property, we may be required to pay royalties to the former stockholders of CPC and the University of Chicago. Following the acquisition, Dr. Grdina agreed to an exclusive consulting arrangement with us in the fields of hematopoiesis and radiation and chemotherapy exposure.

Employees

As of March 1, 2005, we had 62 full-time, non-union employees. We believe that our relations with our employees are good.

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Executive Officers and Senior Management

Our executive officers and senior management and their ages as of March 1, 2005 are as follows:

Name	Age	Position
Richard B. Hollis	52	Chairman of the Board, President and Chief Executive Officer
Daniel D. Burgess	43	Chief Operating Officer and Chief Financial Officer
James M. Frincke, Ph.D.	54	Chief Scientific Officer
Steven A. Gordziel, Ph.D.	58	Vice President, Product Development
Jessie R. Groothuis	58	Vice President, Clinical Affairs
Eric J. Loumeau	42	Vice President, Corporate General Counsel
Robert L. Marsella	52	Sr.Vice President, Business Development and Marketing
Christopher L. Reading, Ph.D.	57	Executive Vice President, Scientific Development
Dwight R. Stickney, M.D.	62	Vice President, Medical Affairs
Robert W. Weber	54	Chief Accounting Officer and Vice President Controller

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

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

James M. Frincke, Ph.D. joined Hollis-Eden as Vice President, Research and Development in November 1997, was promoted to Executive Vice President in March 1999, and to Chief Scientific Officer in December 2001. Dr. Frincke joined Hollis-Eden from Prolinx, Inc., where he served as Vice President, Therapeutics Research and Development from 1995 to 1997. During his 20 years in the biotechnology industry, Dr. Frincke has managed major development programs including drugs, biologicals, and cellular and gene therapy products aimed at the treatment of cancer, infectious diseases and organ transplantation. Since joining the biotechnology industry, Dr. Frincke has held vice president, research and development positions in top tier biotechnology companies including Hybritech/Eli Lilly and SyStemix Inc. (acquired by Novartis). In various capacities, he has been responsible for all aspects of pharmaceutical development including early stage research programs, product evaluation, pharmacology, manufacturing, and the management of regulatory and clinical matters for lead product opportunities. Dr. Frincke has authored or co-authored more than 100 scientific articles, abstracts and regulatory filings. Dr. Frincke received his B.S. in Chemistry and his Ph.D. in Chemistry from the University of California, Davis. Dr. Frincke completed his postdoctoral work at the University of California, San Diego.

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

Jessie R. Groothuis M.D., joined Hollis-Eden in 2004 as Vice President, Clinical Affairs. Before joining Hollis-Eden, Dr. Groothuis was Global Medical Director, Immunoscience Development at Abbott Laboratories, where she managed the global clinical trials and strategy for her division. Most recently at Abbott, Dr. Groothuis managed a 20-member team, oversaw large multi-site global clinical trials, and was responsible for the registration and launch of Synagis, a monoclonal antibody, in a number of international markets. Throughout her seven-year tenure with Abbott, she managed all phases of development for multiple drug candidates, and was lead investigator for four separate drugs in Abbott s pipeline. Prior to Abbott, Dr. Groothuis was Director of the *Neonatal High Risk Follow Up Clinic* and Professor of Pediatrics at the University of Colorado School of Medicine and The Children s Hospital, Department of Pediatrics. In this position she was lead clinical investigator on a number of large clinical trials in the area of immunology. Dr. Groothuis is board certified by the American Board of Pediatrics and the National Board of Medical Examiners. She received her B.S. from Stanford University, her M.D. from the University of Chicago and post-doctoral training at Vanderbilt University.

Eric J. Loumeau became Vice President, Corporate General Counsel in September 1999. Mr. Loumeau joined Hollis-Eden from the law firm of Cooley Godward LLP, where he had primary responsibility for Hollis-Eden s account for the previous four years. As a partner at Cooley Godward, Mr. Loumeau represented a number of private and public companies in corporate and securities law matters. He joined the firm in 1995 from Skadden, Arps, Slate, Meagher and Flom, where he was an associate for four years. Mr. Loumeau