HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form S-3
August 11, 2006
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As filed with the Securities and Exchange Commission on August 11, 2006

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

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.)**

4435 Eastgate Mall, Suite 400, San Diego, California 92121, (858) 587-9333

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Richard B. Hollis

Chairman of the Board, President and Chief Executive Officer

HOLLIS-EDEN PHARMACEUTICALS, INC.

4435 EASTGATE MALL, SUITE 400, San Diego, California 92121, (858) 587-9333

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Eric J. Loumeau, Esq.

HOLLIS-EDEN PHARMACEUTICALS, INC.

4435 Eastgate Mall, Suite 400, San Diego, California 92121, (858) 587-9333

Approximate date of commencement of proposed sale to the public:

As soon as practicable after the effective date of this Registration Statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨ _____

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨ _____

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Share (2)	Proposed Maximum Aggregate Offering Price (2)	Amount of Registration Fee
Common Stock (3)	200,000	$ 6.04	$ 1,208,000	$ 129.26

(1) Pursuant to Rule 416(a) of the Securities Act of 1933, as amended, this registration statement also covers such additional shares as may hereafter be offered or issued as a result of stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) of the Securities Act of 1933, as amended. The price per share and aggregate offering price are based upon the average of the high and low sales prices of Hollis-Eden s common stock on August 8, 2006 as reported on The Nasdaq Global Market.

(3) Each share of the registrant s common stock being registered hereunder includes Series B junior participating preferred stock purchase rights. Prior to the occurrence of certain events, the Series B junior participating preferred stock purchase rights will not be exercisable or evidenced separately from the registrant s common stock, and they have no value except as reflected in the market price of the shares to which they are attached.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. The selling stockholder may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION

Preliminary Prospectus Dated August 11, 2006

PROSPECTUS

200,000 Shares

HOLLIS-EDEN PHARMACEUTICALS, INC.

Common Stock

This prospectus relates to the resale, from time to time, of up to 200,000 shares of common stock of Hollis-Eden Pharmaceuticals, Inc., par value $0.01 per share, by the selling stockholder named in this prospectus in the section SELLING STOCKHOLDER, including its pledgees, assignees and successors-in-interest, whom we refer to in this document as the Selling Stockholder. On June 7, 2006, we consummated the purchase of substantially all of the assets of Aeson Therapeutics, Inc. (Aeson) pursuant to which we agreed, as consideration for Aeson s assets to (i) issue to Aeson a total of 35,000 shares of our common stock, of which 8,400 shares will be held in escrow for six months following the close of the acquisition to secure the indemnification and other obligations of Aeson under the purchase agreement, and (ii) issue to Aeson (or to the Aeson stockholders on a pro rata basis based on such stockholders respective percentage ownership of Aeson as of the date of distribution if Aeson has distributed any of the shares to its stockholders as of the time of the issuance) up to a total of 165,000 additional shares of our common stock based on the achievement of certain development milestones. We will not receive any of the proceeds from the sale of any of the shares covered by this prospectus. References in this prospectus to our company, we, our, and us refer to Hollis-Eden Pharmaceuticals, Inc.

Hollis-Eden s common stock is listed on The Nasdaq Global Market under the symbol HEPH. The closing sale price of the common stock, as reported on The Nasdaq Global Market on August 8, 2006, was $6.06 per share.

Investing in our common stock involves a high degree of risk. ***See Risk Factors, beginning on page 2.***

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2006.

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This prospectus is part of a registration statement we filed with the Securities and Exchange Commission (the SEC). You should rely only on the information contained in or incorporated by reference in this prospectus. The SEC allows us to incorporate by reference information that we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information.

HOLLIS-EDEN PHARMACEUTICALS

Hollis-Eden Pharmaceuticals, Inc. is a development-stage pharmaceutical company engaged in the discovery, development and commercialization of a proprietary new class of small molecule compounds that act as cellular signalers that drive biological function. These compounds, which are derived from our Hormonal Signaling Technology Platform, are metabolites or synthetic analogs of adrenal steroid hormones. We are developing these compounds with the goal of restoring the biological activity of cellular signaling pathways disrupted by disease and aging. In investigational studies, these compounds have been demonstrated in humans to possess several properties with potential therapeutic benefit they regulate innate and adaptive immunity, reduce nonproductive inflammation, and stimulate cell proliferation.

Our lead product candidate, NEUMUNE (HE2100), is entering late-stage development for the treatment of Acute Radiation Syndrome, or ARS, a life-threatening condition resulting from exposure to high levels of radiation following a nuclear or radiological incident. In addition, we have filed an Investigational New Drug application with the U.S. Food and Drug Administration, or FDA, to begin clinical trials with NEUMUNE in patients at high risk of developing healthcare-associated infections.

We are also profiling optimized second-generation compounds for potential clinical development in a broad spectrum of therapeutic categories including hematology, metabolic disorders, autoimmune disorders, pulmonary diseases, oncology and infectious diseases.

Hollis-Eden Pharmaceuticals, HE2000, HE2100, HE2200, HE2300, HE2400, IMMUNITIN, NEUMUNE, PHOSPHONOL, REVERSIONEX and the Hollis-Eden Pharmaceuticals stylized logo are trademarks of Hollis-Eden Pharmaceuticals, Inc. This prospectus also includes trademarks owned by other parties. All other trademarks mentioned are the property of their respective owners.

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.

USE OF PROCEEDS

Hollis-Eden will not receive any proceeds from the sale of the shares of common stock offered by the Selling Stockholder.

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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 diseases and disorders in which the body is unable to mount an appropriate immune response. However, all drug candidates require approval by the FDA before they can be commercialized in the U.S. as well as approval by various foreign government agencies before they can commercialized in other countries. These regulations change from time to time and new regulations may be adopted. None of our drug candidates have been approved for commercial sale. We may incur significant additional operating losses for the foreseeable future as we fund development, preclinical and clinical testing and other expenses in support of regulatory approval of our drug candidates. While limited clinical trials of our drug candidates have been conducted to date, significant additional trials are required, and we may not be able to demonstrate that these drug candidates are safe or effective. If we are unable to demonstrate the safety and effectiveness of a particular drug candidate to the satisfaction of regulatory authorities, the drug candidate will not obtain required government approval. If we do not receive FDA or foreign approvals for our drug candidates, we will not be able to sell products and will not generate revenues. If we receive regulatory approval of one of our drug candidates, such approval may impose limitations on the indicated uses for which we may market the resulting product, which may limit our ability to generate significant revenues. Further, U.S. or foreign regulatory agencies could change existing, or promulgate new, regulations at any time which may affect our ability to obtain approval of our drug candidates or require significant additional costs to obtain such approvals. In addition, if regulatory authorities determine that we or a partner conducting research and development activities on our behalf have not complied with regulations in the research and development of one of our drug candidates, then they may not approve the drug candidate and we will not be able to market and sell it. If we were unable to market and sell our drug candidates, our business and results of operations would be materially and adversely affected.

If we do not successfully commercialize our products, we may never achieve profitability.

We have experienced significant operating losses to date because of the substantial expenses we have incurred to acquire and fund development of our drug candidates. We have never had operating revenues and have never commercially introduced a product. Our accumulated deficit was approximately $176.3 million as of June 30, 2006. Our net losses for fiscal years 2005, 2004 and 2003 were approximately $29.4 million, $24.8 million and $25.7 million, respectively. Many of our research and development programs are at an early stage. Potential drug candidates are subject to inherent risks of failure. These risks include the possibilities that no drug candidate will be found safe or effective, meet applicable regulatory standards or receive the necessary regulatory clearances. Even safe and effective drug candidates may never be developed into commercially successful drugs. If we are unable to develop safe, commercially viable drugs, we may never achieve profitability. If we become profitable, we may not remain profitable.

The market for treating Acute Radiation Syndrome is uncertain.

We do not believe any drug has ever been approved and commercialized for the treatment of acute radiation syndrome. In addition, the incidence of large-scale exposure to nuclear or radiological events has been low. Accordingly, even if NEUMUNE, our lead drug candidate to treat ARS, is approved by the FDA, we cannot

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predict with any certainty the size of this market. The initial potential market for NEUMUNE is largely dependent on the size of stockpiling orders, if any, procured by government agencies. While a number of governments have historically stockpiled drugs to treat indications such as smallpox, anthrax exposure, plague, tularemia and certain long-term effects of radiation exposure, we are unaware of any significant stockpiling orders for drugs to treat ARS. On December 9, 2005, the U.S. Department of Health and Human Services (DHHS) issued a Request for Proposal (RFP) which specified an initial potential stockpiling order of up to 100,000 treatment regimens, which is substantially lower than we had anticipated. While we have responded to the RFP, we cannot guarantee that we will be able to meet the requirements set forth in the RFP or that we will receive any resulting stockpiling orders. A decision by any department of the U.S. Government to enter into a commitment to purchase NEUMUNE, whether before or after FDA approval, is largely out of our control. Our development plans and timelines may vary substantially depending on whether we receive such a commitment and the size of such commitment, if any. In addition, even if NEUMUNE is approved by regulatory authorities, we cannot guarantee that we will receive any stockpiling orders for NEUMUNE, that any such order would be profitable to us or that NEUMUNE will achieve market acceptance by the general public.

As a result of our intensely competitive industry, we may not gain enough market share to be profitable.

The biotechnology and pharmaceutical industries are intensely competitive. We have numerous competitors in the U.S. and elsewhere. Because we are pursuing potentially large markets, our competitors include major multinational pharmaceutical companies, specialized biotechnology firms and universities and other research institutions. Several of these entities have already successfully marketed and commercialized products that will compete with our products, assuming that our products gain regulatory approval. Companies such as Amgen Inc. have developed or are developing products to boost neutrophils after chemotherapy. We are aware of one company, Novelos Therapeutics, Inc., that is still in competition with us for the RFP for ARS issued by DHHS. A large number of companies, including Merck & Company, Inc., Pfizer Inc., Johnson & Johnson Inc. and Amgen Inc. are also developing and marketing new drugs for the treatment of chronic inflammatory conditions. Companies such as GlaxoSmithKline, Merck & Company, Inc., Roche Pharmaceuticals, Pfizer Inc. and Abbott Laboratories have significant market share for the treatment of a number of infectious diseases such as HIV. In addition, biotechnology companies such as Gilead Sciences Inc., Chiron Corporation and Vertex Pharmaceuticals Inc., as well as many others, have marketed products or research and development programs in these fields.

Many of these competitors have greater financial and other resources, larger research and development staffs and more effective marketing and manufacturing organizations than we do. In addition, academic and government institutions have become increasingly aware of the commercial value of their research findings. These institutions are now more likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to develop and market commercial products.

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

We may need to raise additional money before we achieve profitability; if we fail to raise additional money, it could be difficult or impossible to continue our business.

As of June 30, 2006, our cash and cash equivalents totaled approximately $53.5 million. In February 2006, we completed an offering of common stock and warrants to purchase common stock, pursuant to which we received net proceeds of approximately $24.4 million. Based on our current plans, we believe these financial

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resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements for at least the next 12 months. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We may require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

- we may not obtain additional financial resources when necessary or on terms favorable to us, if at all; and
- any available additional financing may not be adequate.

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

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

We own or have obtained a license to numerous U.S. and foreign patents and foreign patent applications. Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to our ability to commercialize our drug candidates, if approved and our ability to operate our business without infringing the proprietary rights of third parties. We place considerable importance on obtaining patent protection for significant new technologies, products and processes. Legal standards relating to the validity of patents covering pharmaceutical and biotechnology inventions and the scope of claims made under such patents are still developing. In some of the countries in which we intend to market our drug candidates, if approved, pharmaceuticals are either not patentable or have only recently become patentable. Past enforcement of intellectual property rights in many of these countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries may be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions. Our domestic patent position is also highly uncertain and involves complex legal and factual questions. The applicant or inventors of subject matter covered by patent applications or patents owned by or licensed to us may not have been the first to invent or the first to file patent applications for such inventions. Due to uncertainties regarding patent law and the circumstances surrounding our patent applications, the pending or future patent applications we own or have licensed may not result in the issuance of any patents. Existing or future patents owned by or licensed to us may be challenged, infringed upon, invalidated, found to be unenforceable or circumvented by others. Further, any rights we may have under any issued patents may not provide us with sufficient protection against similar competitive products or technologies that do not infringe on patents or otherwise cover commercially valuable products or processes.

Litigation or other disputes regarding patents and other proprietary rights may be expensive, cause delays in bringing products to market and harm our ability to operate.

The manufacture, use or sale of our drug candidates may infringe on the patent rights of others. If we are unable to avoid infringement of the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming and can preclude, delay or suspend commercialization of products. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, or fail to successfully defend an infringement action or have the patents we are alleged to infringe declared invalid, we may

- incur substantial money damages;

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encounter significant delays in bringing our drug candidates to market;

be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment without first obtaining licenses to do so; and/or

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

In addition, if another party claims the same subject matter or subject matter overlapping with the subject matter that we have claimed in a U.S. patent application or patent, we may decide or be required to participate in interference proceedings in the U.S. Patent and Trademark Office in order to determine the priority of invention. Loss of such an interference proceeding would deprive us of patent protection sought or previously obtained and could prevent us from commercializing our products. Participation in such proceedings could result in substantial costs, whether or not the eventual outcome is favorable. These additional costs could adversely affect our financial results.

Litigation may be expensive and time consuming and may adversely affect our operations.

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. Participation in such proceedings is time consuming and could result in substantial costs, whether or not the eventual outcome is favorable. These additional costs could adversely affect our financial results.

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

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

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

The requirements governing product licensing, pricing and reimbursement vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after product-licensing approval is granted. As a result, we may obtain regulatory approval for a drug candidate in a particular country, but then be subject to price regulations that reduce our profits from the sale of the product. In some foreign markets pricing of prescription pharmaceuticals is subject to continuing government control even after initial marketing approval. In addition, certain governments may grant third parties a license to manufacture our product without our permission. Such compulsory licenses may be on terms that are less favorable to us and would likely have the effect of reducing our revenues.

Varying price regulation between countries can lead to inconsistent prices and some re-selling by third parties of products from markets where products are sold at lower prices to markets where those products are sold at higher prices. Any practice of exploiting price differences between countries could undermine our sales in markets with higher prices and reduce the sales of our future products, if any.

While we do not have any applications for regulatory approval of our drug candidates currently pending, any decline in the size of the markets in which we may in the future sell commercial products, assuming our receipt of the requisite regulatory approvals, could cause the perceived market value of our business and the price of our common stock to decline.

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Our ability to commercialize our drug candidates successfully also will depend in part on the extent to which reimbursement for the cost of our drug candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations. Third-party payors are increasingly challenging the prices charged for medical products and services. If we succeed in bringing any of our drug candidates to the market, such drug candidates may not be considered cost effective and reimbursement may not be available or sufficient to allow us to sell such drug candidates on a profitable or competitive basis.

Delays in the conduct or completion of our preclinical or clinical studies or the analysis of the data from our preclinical or clinical studies may result in delays in our planned filings for regulatory approvals, or adversely affect our ability to enter into collaborative arrangements.

The current status of our drug candidates is set forth below. We have either completed or are in the midst of:

- animal efficacy studies with NEUMUNE for the treatment of radiation exposure;
- Phase I clinical trials with NEUMUNE in the United States and the Netherlands;
- Phase II clinical trials with IMMUNITIN in South Africa and Phase I/II clinical trials with IMMUNITIN in the United States for the treatment of HIV/AIDS; and
- Phase II clinical trials with IMMUNITIN in Thailand for the treatment of malaria

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

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

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

- delays in enrolling volunteers;
- interruptions in the manufacturing of our drug candidates or other delays in the delivery of materials required for the conduct of our studies;
- lower than anticipated retention rate of volunteers in a trial;
- unfavorable efficacy results;

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

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

failure to raise additional funds.

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If the manufacturers of our drug candidates do not comply with current Good Manufacturing Practices regulations, or cannot produce sufficient quantities of our drug candidates to enable us to continue our development, we will fall behind on our business objectives.

Manufacturers producing our drug candidates must follow current Good Manufacturing Practices regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to current Good Manufacturing Practices regulations and cannot be brought up to such a standard, we will be required to find alternative manufacturers that do conform. This may be a long and difficult process, and may delay our ability to receive FDA or foreign regulatory approval of our drug candidates.

We also rely on our manufacturers to supply us with a sufficient quantity of our drug candidates to conduct clinical trials. If we have difficulty in the future obtaining our required quantity and quality of supply, we could experience significant delays in our development programs and regulatory process.

Our ability to achieve any significant revenue may depend on our ability to establish effective sales and marketing capabilities.

Our efforts to date have focused on the development and evaluation of our drug candidates. As we continue preclinical and clinical studies and seek to commercialize our drug candidates, we may need to build a sales and marketing infrastructure. As a company, we have no experience in the sales and marketing of pharmaceutical products. If we fail to establish a sufficient marketing and sales force or to make alternative arrangements to have our drug candidates marketed and sold by others on attractive terms, it will impair our ability to commercialize our drug candidates and to enter new or existing markets. Our inability to effectively enter these markets would materially and adversely affect our ability to generate significant revenues.

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

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

We may face product liability claims related to the use or misuse of our drug candidates, which may cause us to incur significant losses.

We are currently exposed to the risk of product liability claims due to administration of our drug candidates in clinical trials, since the use or misuse of our drug candidates during a clinical trial could potentially result in injury or death. If we are able to commercialize our products, we will also be subject to the risk of losses in the future due to product liability claims in the event that the use or misuse of our commercial products results in injury or death. We currently maintain liability insurance on a claims-made basis. Because we cannot predict the magnitude or the number of claims that may be brought against us in the future, we do not know whether the insurance policies coverage limits are adequate. The insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. Any claims against us, regardless of their merit, could substantially increase our costs and cause us to incur significant losses.

Our securities could be subject to extreme price fluctuations that could adversely affect your investment.

The market prices for securities of life sciences companies, particularly those that are not profitable, are highly volatile. Publicized events and announcements may have a significant impact on the market price of our common stock. For example:

- biological or medical discoveries by competitors;

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public concern about the safety of our drug candidates;

delays in the conduct or analysis of our preclinical or clinical studies;

unfavorable results from preclinical or clinical studies;

delays in obtaining or failure to obtain purchase orders of our drug candidates;

announcements in the scientific and research community;

changes in the potential commercial markets for our drug candidates;

unfavorable developments concerning patents or other proprietary rights;

unfavorable domestic or foreign regulatory or governmental developments or actions; or

broader economic, industry and market trends unrelated to our performance.

may have the effect of temporarily or permanently driving down the price of our common stock. In addition, the stock market from time to time experiences extreme price and volume fluctuations which particularly affect the market prices for emerging and life sciences companies, such as ours, and which are often unrelated to the operating performance of the affected companies. For example, our stock price has ranged from $4.09 to $16.50 between January 1, 2004 and August 1, 2006.

These broad market fluctuations may adversely affect the ability of a stockholder to dispose of his shares at a price equal to or above the price at which the shares were purchased. In addition, in the past, following periods of volatility in the market price of a company s securities, securities class-action litigation has often been instituted against that company. Any litigation against our company, including this type of litigation, could result in substantial costs and a diversion of management s attention and resources, which could materially adversely affect our business, financial condition and results of operations.

We may be delisted from The Nasdaq Global Market, which could materially limit the trading market for our common stock.

Our common stock is quoted on The Nasdaq Global Market. In order to continue to be included in The Nasdaq Global Market, a company must meet Nasdaq s maintenance criteria. We may not be able to continue to meet these listing criteria. Failure to meet Nasdaq s maintenance criteria may result in the delisting of our common stock from The Nasdaq Global Market. If our common stock is delisted, in order to have our common stock relisted on The Nasdaq Global Market we would be required to meet the criteria for initial listing, which are more stringent than the maintenance criteria. Accordingly, if we were delisted we may not be able to have our common stock relisted on The Nasdaq Global Market. If our common stock is removed from listing on The Nasdaq Global Market, it may become more difficult for us to raise funds.

Because stock ownership is concentrated, you and other investors will have minimal influence on stockholders decisions.

Assuming that outstanding warrants and options have not been exercised, Richard B. Hollis, our Chief Executive Officer, owns approximately 9% of our outstanding common stock as of June 30, 2006. Assuming that Mr. Hollis exercises all of his outstanding warrants and options that vest within 60 days of June 30, 2006, Mr. Hollis would beneficially own approximately 14% of our outstanding common stock. As a result, Mr. Hollis may be able to significantly influence our management and all matters requiring stockholder approval, including the election of directors. Such concentration of ownership may also have the effect of delaying or preventing a change in control of our company.

Substantial sales of our stock may impact the market price of our common stock.

Future sales of substantial amounts of our common stock, including shares that we may issue upon exercise of options and warrants, could adversely affect the market price of our common stock. Further, if we raise

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additional funds through the issuance of common stock or securities convertible into or exercisable for common stock, the percentage ownership of our stockholders will be reduced and the price of our common stock may fall.

Issuing preferred stock with rights senior to those of our common stock could adversely affect holders of common stock.

Our charter documents give our board of directors the authority to issue shares of preferred stock without a vote or action by our stockholders. The board also has the authority to determine the terms of preferred stock, including price, preferences and voting rights. The rights granted to holders of preferred stock may adversely affect the rights of holders of our common stock. For example, a series of preferred stock may be granted the right to receive a liquidation preference a pre-set distribution in the event of a liquidation that would reduce the amount available for distribution to holders of common stock. In addition, the issuance of preferred stock could make it more difficult for a third party to acquire a majority of our outstanding voting stock. As a result, common stockholders could be prevented from participating in transactions that would offer an optimal price for their shares.

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WHERE YOU CAN GET MORE INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the SEC s public reference rooms at 100 F Street, N.E., Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference rooms. Our SEC filings are also available at the SEC s Web site at http://www.sec.gov.

We incorporate by reference the documents listed below, except as modified by this registration statement, and any reports and other documents we subsequently file with the SEC under Section 13 (a), 13(c), 14 or 15 (d) of the Securities Exchange Act of 1934, as amended (the Exchange Act):

Annual Report on Form 10-K for the year ended December 31, 2005;

Quarterly Reports on Form 10-Q for the quarter ended March 31, 2006 and June 30, 2006;

Current Reports on Form 8-K filed on January 31, 2006, February 1, 2006, February 2, 2006 and June 26, 2006; and

The description of our common stock included in our registration statement on Form S-4, No. 333-18725, as amended.

You may request a copy of these filings at no cost, by writing or telephoning us at the following address or telephone number:

Hollis-Eden Pharmaceuticals, Inc.

4435 Eastgate Mall, Suite 400

San Diego, CA 92121

Attn: Chief Accounting Officer

(858) 587-9333

These filings are also available free of charge on our website, at www.holliseden.com, as soon as reasonably practicable after we have electronically filed them with, or forwarded them to, the SEC. Information contained on our website is not part of this prospectus. You should rely only on the information contained or incorporated by reference in this prospectus and any prospectus supplement. We have not authorized anyone to provide you with information different from that contained in this prospectus or any prospectus supplement. The information contained in this prospectus and any prospectus supplement is accurate only as of the date of this prospectus and any prospectus supplement and, with respect to material incorporated by reference herein or in any prospectus supplement, the dates of such referenced material.

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FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but not always, made through the use of words or phrases such as anticipate, estimate, plans, projects, continuing, ong expects, management believes, we believe, we intend and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus.

You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to a number of factors, including:

- failure to achieve positive results in clinical trials involving our drug candidates;
- failure to obtain government regulatory approvals for our drug candidates;
- competitive factors;
- our ability to raise additional capital;
- uncertainty regarding our patents and patent rights;
- relationships with our consultants, academic collaborators and other third-party service providers; and
- our ability to enter into future collaborative agreements.

Because the risk factors referred to above, as well as the risk factors beginning on page 4 of this prospectus, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to publicly release any revision to the forward-looking statements or reflect events or circumstances after the date of this prospectus. Moreover, new factors that may impact those forward-looking statements may emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of any single factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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SELLING STOCKHOLDER

Summary

On June 7, 2006, we acquired substantially all of the assets of Aeson Therapeutics, Inc. (Aeson). As consideration for Aeson s assets, we agreed to issue 35,000 shares of our common stock to Aeson, of which 8,400 shares will be held in escrow for six months following the closing of the acquisition to secure the indemnification and other obligations of Aeson under the purchase agreement and to issue Aeson (or Aeson s stockholders on a pro rata basis based on such stockholders respective percentage ownership of Aeson as of the date of distribution if Aeson has distributed any of the shares to its stockholders as of the time of the issuance) up to 165,000 additional shares of our common stock based on the achievement of certain development milestones.

These shares of common stock have been or will be issued pursuant to the Asset Purchase Agreement, dated as of June 7, 2006 between Aeson and us. Pursuant to the Asset Purchase Agreement, we agreed to file with the SEC a registration statement covering the resale of all of our common stock covered by this prospectus pursuant to Rule 415 of the Securities Act. Accordingly, we filed a Registration Statement on Form S-3, of which this prospectus forms a part, on August 11, 2006 with respect to the resale of these shares from time to time.

Selling Stockholder Table

The following table sets forth the names of the Selling Stockholder, and the number of shares of common stock owned beneficially by them as of August 2, 2006 that may be offered under the terms of this prospectus. This information is based upon information provided by the Selling Stockholder. The applicable percentages of ownership are based on an aggregate of 24,900,811 shares issued and outstanding on August 2, 2006. The number of shares beneficially owned by the Selling Stockholder is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act, and is not necessarily indicative of beneficial ownership for any other purpose. The term Selling Stockholder includes the stockholder listed below and its transferees, pledges, donees or other successors. Although we have assumed for purposes of the table below that the Selling Stockholder will sell all of the shares offered by this prospectus, because the Selling Stockholder may offer from time to time all or some of its shares covered under this prospectus, or in another permitted manner, no assurances can be given as to the actual number of shares that will be resold by the Selling Stockholder or that will be held by the Selling Stockholder after completion of the resales. Except as described above, the Selling Stockholder does not have and within the past three years has not had, any position, office or other material relationship with us or any of our predecessors or affiliates.

Name	Number of Shares Being Offered	Percent of Shares Beneficially Owned After Offering
Aeson Therapeutics, Inc. (1)	200,000	*

* Less than 1%

(1) Includes 165,000 shares of Common Stock issuable on the achievement of certain developmental milestones.

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PLAN OF DISTRIBUTION

The Selling Stockholder and any of its pledgees, assignees and successors-in-interest may, from time to time, sell any or all of its shares of Common Stock on any stock exchange, market or trading facility on which the Common Stock is traded or in private transactions. These sales may be at market prices prevailing at the time of sale, at prices related to such prevailing market prices, or at fixed or negotiated prices. The Selling Stockholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- broker-dealers may agree with the Selling Stockholder to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The Selling Stockholder may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus. Broker-dealers engaged by the Selling Stockholder may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholder (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The Selling Stockholder do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The Selling Stockholder may from time to time pledge or grant a security interest in some or all of the shares of Common Stock owned by it and, if it defaults in the performance of its secured obligations, the pledgees or secured parties may offer and sell the shares of Common Stock from time to time under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the selling stockholder list to include the pledgee, transferee or other successors in interest as a selling stockholder under this prospectus.

The Selling Stockholder also may transfer the shares of Common Stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The Selling Stockholder and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by it may be deemed to be underwriting commissions or discounts under the Securities Act. The

Selling Stockholder has informed us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the Common Stock.

We are required to pay all fees and expenses incurred by us incident to the registration of the shares. We estimate that our expenses in connection with this offering will be $8,129.26.

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LEGAL MATTERS

Cooley Godward LLP, San Diego, California will pass upon the validity of the issuance of the common stock offered by this prospectus.

EXPERTS

The financial statements and management s report on the effectiveness of internal control over financial reporting incorporated by reference in this prospectus have been audited by BDO Seidman, LLP, an independent registered public accounting firm, to the extent and for the periods set forth in their reports incorporated herein by reference, and are incorporated herein in reliance upon such reports given upon the authority of said firm as experts in auditing and accounting.

We have not authorized any dealer, salesperson or other person to give any information or to make any representations not contained in this prospectus or any prospectus supplement. You must not rely on any unauthorized information. This prospectus is not an offer of these securities in any state where an offer is not permitted. The information in this prospectus is current as of August 11, 2006. You should not assume that this prospectus is accurate as of any other date.

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The expenses in connection with the issuance and distribution of the securities being registered are set forth in the following table (all amounts except the registration fee are estimated):

SEC Registration Fee	$ 129.26
Legal fees and expenses	3,000*
Accounting fees and expenses	5,000*
Total	$ 8,129.26*

* Estimated

Item 15. Indemnification of Officers and Directors.

Under Section 145 of the Delaware General Corporation Law, the registrant has broad powers to indemnify its directors and officers against liabilities they may incur in such capacities, including liabilities under the Securities Act.

The registrant s bylaws provide that the registrant shall indemnify its directors and executive officers and may indemnify its other officers, employees and other agents to the fullest extent permitted by Delaware law. The registrant is also empowered under its bylaws to enter into indemnification contracts with its directors and officers and to purchase insurance on behalf of any person whom it is required or permitted to indemnify. In addition, the registrant is required, subject to certain exceptions, to advance all expenses incurred by any director or executive officer in connection with a completed, pending or threatened action, suit or proceeding upon receipt of an undertaking by such director or executive officer to repay all amounts advanced by the registrant on such person s behalf if it is ultimately determined that such person is not entitled to be indemnified under the bylaws or otherwise.

The registrant s Certificate of Incorporation provides that to the fullest extent permitted under Delaware law, the registrant s directors will not be personally liable to the registrant and its stockholders for monetary damages for any breach of a director s fiduciary duty. The Certificate of Incorporation does not, however, eliminate the duty of care, and in appropriate circumstances, equitable remedies such as an injunction or other forms of non-monetary relief would remain available under Delaware law. Each director is subject to liability for breach of the director s duty of loyalty to the registrant, for acts or omissions not in good faith or involving intentional misconduct or knowing violations of law, for any transaction from which the director derived an improper personal benefit and for improper distributions to stockholders and loans to directors and officers. This provision does not affect a director s responsibilities under any other laws, such as the federal securities laws or state or federal environmental laws.

The registrant maintains directors and officers liability insurance.

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Item 16. Exhibits.
(a) Exhibits.

Exhibit

No.	Description
3.1	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 Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.4 to Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2001).
4.1	Rights Agreement dated as of November 15, 1999 among Registrant and American Stock Transfer and Trust Company (incorporated by reference to Exhibit 99.2 to Registrant s Current Report on Form 8-K dated November 15, 1999).
4.2	Certificate of Designation of Series B Junior Participating Preferred Stock (incorporated by reference to Exhibit 4.1 to Registrant s Current Report on Form 8-K dated November 15, 1999).
5.1	Opinion of Cooley Godward LLP.
23.1	Consent of BDO Seidman, LLP.
23.2	Consent of Cooley Godward LLP. Reference is made to Exhibit 5.1.
24.1	Power of Attorney. Reference is made to page II-4.

Item 17. Undertakings.
The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the registration statement is on Form S-3 or Form F-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to section 13 or section 15(d) of the Exchange Act that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each post-effective amendment shall be deemed to be a new registration statement relating to the securities it offers, and the offering of the securities at that time shall be deemed to be the initial bona fide offering thereof.

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(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of this offering.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC this form of indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against these liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by a director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of this issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, County of San Diego, State of California, on the 11th day of August, 2006.

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

Chairman of the Board and

Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN 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, his true and lawful attorney-in-fact and agent, 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 (including post-effective amendments) to this registration statement, 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 all that said attorney-in-fact and agent, or any of them, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement 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, Chief Executive Officer and Director *(Principal Executive Officer)*	August 11, 2006
/s/ DANIEL D. BURGESS **Daniel D. Burgess**	Chief Operating Officer/ Chief Financial Officer *(Principal Financial Officer)*	August 11, 2006
/s/ ROBERT W. WEBER **Robert W. Weber**	Vice President-Controller/ Chief Accounting Officer *(Principal Accounting Officer)*	August 11, 2006
/s/ J. PAUL BAGLEY III **J. Paul Bagley III**	Director	August 11, 2006

/s/ JEROME M. HAUER **Jerome M. Hauer**	Director	August 11, 2006
/s/ BRENDAN R. MCDONNELL **Brendan R. McDonnell**	Director	August 11, 2006

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Signature	Title	Date
/s/ THOMAS CHARLES MERIGAN, JR. **Thomas Charles Merigan, Jr.**	Scientific Advisor and Director	August 11, 2006
/s/ MARC R. SARNI **Marc R. Sarni**	Director	August 11, 2006
/s/ SALVATORE J. ZIZZA **Salvatore J. Zizza**	Director	August 11, 2006

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EXHIBIT INDEX

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