

HOLLIS EDEN PHARMACEUTICALS INC /DE/

Form S-3

March 16, 2004

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As filed with the Securities and Exchange Commission on March 16, 2004

Registration No. 333-

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## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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### FORM S-3

### REGISTRATION STATEMENT

*UNDER*

*THE SECURITIES ACT OF 1933*

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## 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, California 92121, (858) 587-9333

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

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Richard B. Hollis

Chairman of the Board 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)

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**Copies to:**

**Eric J. Loumeau, Esq.**

**HOLLIS-EDEN PHARMACEUTICALS, INC.**

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

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**Approximate date of commencement of proposed sale to the public:**

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

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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.

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 delivery of the prospectus is expected to be made pursuant to Rule 434, please 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)	323,589	\$ 12.25	\$ 3,963,965	\$ 503

- (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. 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 March 10, 2004 as reported on The Nasdaq National Market.
- (3) Each share of the registrant's common stock being registered hereunder includes Series A junior participating preferred stock purchase rights. Prior to the occurrence of certain events, the Series A 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 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 stockholders 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 March 16, 2004**

**PROSPECTUS**

**323,589 Shares**

**HOLLIS-EDEN PHARMACEUTICALS, INC.**

**Common Stock**

This prospectus relates to the resale, from time to time, of up to 323,589 shares of common stock of Hollis-Eden Pharmaceuticals, Inc., par value \$0.01 per share, by the selling stockholders named in this prospectus in the section **SELLING STOCKHOLDERS**, including their pledgees, assignees and successors-in-interest, whom we collectively refer to in this document as the **Selling Stockholders**. On February 24, 2004, we consummated the acquisition of Congressional Pharmaceutical Corporation ( **CPC** ) pursuant to which we: (i) agreed to issue to the **Selling Stockholders** a total of 48,589 shares of our common stock, of which 4,362 shares will be issued in repayment of a loan, and (ii) agreed to issue to the **Selling Stockholders** up to a total of 275,000 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 National Market under the symbol HEPH. The closing sale price of the common stock, as reported on The Nasdaq National Market on March 10, 2004, was \$11.92 per share.

**Investing in our common stock involves a high degree of risk. See *Risk Factors*, beginning on page 3.**

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**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.**

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The date of this prospectus is \_\_\_\_\_, 2004.

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This prospectus is part of a registration statement we filed with the Securities and Exchange Commission. 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., a development-stage pharmaceutical company, is engaged in the discovery, development and commercialization of products for the treatment of diseases and disorders in which the body is unable to mount an appropriate immune response. Our initial development efforts target radiation and chemotherapy induced immune suppression and immune dysregulation caused by infectious diseases such as HIV, malaria and tuberculosis.

Hollis-Eden's executive offices are located at 4435 Eastgate Mall, Suite 400, San Diego, California 92121, telephone number (858) 587-9333.

## **USE OF PROCEEDS**

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

## **RISK FACTORS**

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

**If we do not obtain government regulatory approval for our products, we cannot sell our products and we will not generate revenues.**

Our principal development efforts are currently centered around immune regulating hormones, a class of drug candidates which we believe shows promise for the treatment of a variety of infectious diseases and immune system and metabolic disorders. However, all drug candidates require U.S. FDA and foreign government approvals before they can be commercialized. These regulations change from time to time and new regulations may be adopted. None of our drug candidates has been approved for commercial sale. We may incur significant additional operating losses over the next several years as we fund development, clinical testing and other expenses while seeking regulatory approval. While limited clinical trials of our drug candidates have been conducted to date, significant additional trials are required, and we may not be able to demonstrate that these drug candidates are safe or effective. If we are unable to demonstrate the safety and effectiveness of a particular drug candidate to the satisfaction of regulatory authorities, the drug candidate will not obtain required government approval. If we do not receive FDA or foreign approvals for our products, we will not be able to sell our products and will not generate revenues. If we receive regulatory

approval of a product, such approval may impose limitations on the indicated uses for which we may market the product, which may limit our ability to generate significant revenues.



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

We have experienced significant operating losses to date because of the substantial expenses we have incurred to acquire and fund development of our drug candidates. We have never had operating revenues and have never commercially introduced a product. Our accumulated deficit was approximately \$107.1 million as of December 31, 2003. Our net losses for fiscal years 2003, 2002 and 2001 were \$25.7 million, \$17.5 million and \$15.8 million, respectively. Many of our research and development programs are at an early stage. Potential drug candidates are subject to inherent risks of failure. These risks include the possibilities that no drug candidate will be found safe or effective, meet applicable regulatory standards or receive the necessary regulatory clearances. Even safe and effective drug candidates may never be developed into commercially successful drugs. If we are unable to develop safe, commercially viable drugs, we may never achieve profitability. If we become profitable, we may not remain profitable.

### **The market for treating severe acute radiation injury is uncertain.**

We do not believe any drug has ever been approved and commercialized for the treatment of severe acute radiation injury. In addition, the incidence of large-scale exposure to nuclear or radiological events has been low. Accordingly, even if NEUMUNE™ (HE2100), our lead drug candidate to treat acute radiation injury, is approved by the FDA, we cannot predict with any certainty the size of this market. The potential market for NEUMUNE is largely dependent on the size of stockpiling orders, if any, procured by the U.S. and foreign governments. While a number of governments have historically stockpiled drugs to treat indications such as smallpox, anthrax exposure, plague, tularemia and certain long-term effects of radiation exposure, we are unaware of any significant stockpiling orders for drugs to treat the acute effects of radiation injury. Due to these uncertainties, we cannot guarantee that we will receive any stockpiling orders for NEUMUNE or that NEUMUNE will achieve market acceptance by the general public.

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

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

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

Our competitors may succeed in developing or licensing technologies and drugs that are more effective or less costly than any we are developing. Our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates before we do. If competing drug

candidates prove to be more effective or less costly than our drug candidates, our drug candidates, even if approved for sale, may not be able to compete successfully with our competitors' existing products or new products under development. If we are unable to compete successfully, we may never be able to sell enough products at a price sufficient to permit us to generate profits.

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

As of December 31, 2003, our cash and cash equivalents totaled approximately \$84.9 million. Based on our current plans, we believe these financial resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements at least well into 2006. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We may require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

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

any available additional financing may not be adequate.

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

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

We own or have obtained a license to over 100 issued U.S. and foreign patents and over 100 pending U.S. and foreign patent applications. Our success will depend in part on our ability to obtain additional United States and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate without infringing the proprietary rights of third parties. We place considerable importance on obtaining patent protection for significant new technologies, products and processes. Legal standards relating to the validity of patents covering pharmaceutical and biotechnology inventions and the scope of claims made under such patents are still developing. In some of the countries in which we intend to market our products, pharmaceuticals are either not patentable or have only recently become patentable. Past enforcement of intellectual property rights in many of these countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries may be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions. Our domestic patent position is also highly uncertain and involves complex legal and factual questions. The applicant or inventors of subject matter covered by patent applications or patents owned by or licensed to us may not have been the first to invent or the first to file patent applications for such inventions. Due to uncertainties regarding patent law and the circumstances surrounding our patent applications, the pending or future patent applications we own or have licensed may not result in the issuance of any patents. Existing or future patents owned by or licensed to us may be challenged, infringed upon, invalidated, found to be unenforceable or circumvented by others. Further, any rights we may have under any issued patents may not provide us with sufficient protection against competitive products or otherwise cover commercially valuable products or processes.

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

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The manufacture, use or sale of our drug candidates may infringe on the patent rights of others. If we are unable to avoid infringement of the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if

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we do not obtain a license, develop or obtain non-infringing technology, or fail to successfully defend an infringement action or have the patents we are alleged to infringe declared invalid, we may

incur substantial money damages;

encounter significant delays in bringing our drug candidates to market;

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

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

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

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

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

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

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

Varying price regulation between countries can lead to inconsistent prices and some re-selling by third parties of products from markets where products are sold at lower prices to markets where those products are sold at higher prices. This practice of exploiting price differences between

countries could undermine our sales in markets with higher prices and reduce the sales of our future products, if any.

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

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

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

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

animal efficacy studies with NEUMUNE in the United States for the treatment of radiation exposure and chemotherapy protection;

Phase II clinical trials with IMMUNITIN™ (HE2000) in South Africa and Phase I/II clinical trials with IMMUNITIN in the United States for the treatment of HIV/AIDS;

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

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

we may not have the financial resources to continue research and development of any of our drug candidates; and

we may not be able to enter into collaborative arrangements relating to any drug candidate subject to delay in regulatory filing.

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

delays in enrolling volunteers;

interruptions in the manufacturing of our drug candidates or other delays in the delivery of materials required for the conduct of our studies;

lower than anticipated retention rate of volunteers in a trial;

unfavorable efficacy results;

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

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

failure to raise additional funds.



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

An outside manufacturer, Hovione Soc. Química, S.A., is currently the primary producer of the active pharmaceutical ingredient for our drug candidate IMMUNITIN, and may produce other compounds for us in the future. Manufacturers producing our drug candidates must follow current Good Manufacturing Practices regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to the Good Manufacturing Practices regulations and cannot be brought up to such a standard, we will be required to find alternative manufacturers that do conform. This may be a long and difficult process, and may delay our ability to receive FDA or foreign regulatory approval of our products.

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

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

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

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

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

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

We are currently exposed to the risk of product liability claims due to administration of our drug candidates in clinical trials, since the use or misuse of our drug candidates during a clinical trial could potentially result in injury or death. If we are able to commercialize our products, we will also be subject to the risk of losses in the future due to product liability claims in the event that the use or misuse of our commercial products results in injury or death. We currently maintain liability insurance on a claims-made basis in an aggregate amount of \$5 million. Because we cannot predict the magnitude or the number of claims that may be brought against us in the future, we do not know whether the insurance policies' coverage limits are adequate. The insurance is expensive, difficult to obtain and may not be available in the future on

acceptable terms, or at all. Any claims against us, regardless of their merit, could substantially increase our costs and cause us to incur significant losses.

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### **Trading in our securities could be subject to extreme price fluctuations that could adversely affect your investment.**

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

biological or medical discoveries by competitors;

public concern about the safety of our drug candidates;

delays in the conduct or analysis of our clinical trials;

unfavorable results from clinical trials;

unfavorable developments concerning patents or other proprietary rights; or

unfavorable domestic or foreign regulatory developments;

may have the effect of temporarily or permanently driving down the price of our common stock. In addition, the stock market from time to time experiences extreme price and volume fluctuations which particularly affect the market prices for emerging and life sciences companies, such as ours, and which are often unrelated to the operating performance of the affected companies. For example, our stock price has ranged from \$5.00 to \$36.25 between January 1, 2003 and March 5, 2004.

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

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

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

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

Assuming that outstanding warrants and options have not been exercised, Richard B. Hollis, our Chief Executive Officer, owns approximately 14% of our outstanding common stock as of March 5, 2004. Assuming that Mr. Hollis exercises all of his outstanding warrants and options that vest within 60 days of March 5, 2004, Mr. Hollis would beneficially own approximately 20% of our outstanding common stock. As a result, Mr. Hollis may be able to significantly influence the management of Hollis-Eden and all matters requiring stockholder approval, including the election of directors. Such concentration of ownership may also have the effect of delaying or preventing a change in control of Hollis-Eden.

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

Future sales of substantial amounts of our common stock, including shares that we may issue upon exercise of options and warrants, could adversely affect the market price of our common stock. Further, if we raise additional funds through the issuance of common stock or securities convertible into or exercisable for common stock, the percentage ownership of our stockholders will be reduced and the price of our common stock may fall.

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

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

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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 450 Fifth Street, N.W., 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 future filings we may make with the SEC under Section 13 (a), 13(c), 14 or 15 (d) of the Securities Exchange Act of 1934:

Annual Report on Form 10-K for the year ended December 31, 2003;

Current Report on Form 8-K filed with the SEC on February 26, 2004;

Notice of Annual Meeting and Proxy Statement for the 2003 Annual Meeting of Stockholders held on June 20, 2003; 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](http://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 contains forward-looking statements that involve risks and uncertainties. These include statements about our expectations, plans, objectives, assumptions or future events. In some cases, you can identify forward-looking statements by terminology such as anticipate, estimate, plans, potential, projects, continuing, ongoing, expects, management believes, we believe, we intend and similar expressions. Forward-looking statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed for the reasons described in this prospectus. You should not place undue reliance on these forward-looking statements.

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 preclinical or clinical studies;

failure to obtain government regulatory approvals;

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 arrangements.

You should also consider carefully the statements under **Risk Factors** and other sections of this prospectus, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements and could materially and adversely affect our business, operating results and financial condition. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the applicable cautionary statements.

The forward-looking statements speak only as of the date on which they are made, and, except to the extent required by federal securities laws, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each 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.

We use data and industry forecasts throughout this prospectus, which we have obtained from internal surveys, market research, publicly available information and industry publications. Industry publications generally state that the information they provide has been obtained from sources believed to be reliable but that the accuracy and completeness of such information is not guaranteed. Similarly, we believe that the

surveys and market research we or others have performed are reliable, but we have not independently verified this information. We do not represent that any such information is accurate.



**Table of Contents****SELLING STOCKHOLDERS****Summary**

On February 24, 2004, we acquired all of the capital stock of Congressional Pharmaceutical Corporation ( CPC ). In exchange for CPC 's capital stock, we agreed to issue 48,589 shares of our common stock to CPC stockholders, of which 4,362 shares will be issued in repayment of a loan to CPC, as well as the right to receive up to 275,000 additional shares of our common stock based on the achievement of certain development milestones. In addition to the capital stock, we received exclusive intellectual property rights licensed from the University of Chicago to develop a series of compounds that have the potential to protect against DNA mutations. We agreed to issue shares of our common stock to the following CPC stockholders: Daniel L. Smith, Gil Price, Dave Grdina, Jeff Murley, Yasushi Kataoka, The University of Chicago, Anthony J. Valdella and Sally J. Valdella, David Ryan, James E. Sellman and Barbara B. Sellman, N. Mathew Lisagor, Mark G. and Margarita S. Treuth, Gust Kouvaris, Gregg Allan Zeleniak, Gene Logic Inc., Richard B. Toren, Margaret L. and William R. Miller, Robert Bret Hart, Orrick Investments 2002 LLC and James Smith. Daniel L. Smith and Gil Price were directors and officers (President, CFO and Secretary and CEO, respectively) of CPC before the merger.

These shares of common stock have been or will be issued pursuant to the Agreement and Plan of Merger and Reorganization, dated as of February 24, 2004 between CPC and us. Pursuant to the Merger 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 March 16, 2004, with respect to the resale of these shares from time to time.

**Selling Stockholders Table**

The following table sets forth the names of the Selling Stockholders, and the number of shares of common stock owned beneficially by them as of March 10, 2004 that may be offered under the terms of this prospectus. This information is based upon information provided by each Selling Stockholder. The applicable percentages of ownership are based on an aggregate of 19,212,647 shares issued and outstanding on March 1, 2004. The number of shares beneficially owned by each Selling Stockholder is determined under rules promulgated by the SEC, and is not necessarily indicative of beneficial ownership for any other purpose. The term Selling Stockholders includes the stockholders listed below and their transferees, pledges, donees or other successors. Although we have assumed for purposes of the table below that the Selling Stockholders will sell all of the shares offered by this prospectus, because the Selling Stockholders may offer from time to time all or some of their 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 Stockholders or that will be held by the Selling Stockholders after completion of the resales. Except as described above, none of the Selling Stockholders has, or within the past three years has 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
Gil Price(1)	110,361	*
Daniel L. Smith(2)	107,953	*
Dave Grdina(3)	51,717	*
The University of Chicago(4)	14,022	*
Anthony J. Valdella & Sally J. Valdella(5)	10,774	*
James Smith(6)	6,464	*

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David Ryan(7)	3,231	*
James E. Sellman and Barbara B. Sellman(8)	3,231	*
N. Mathew Lisagor(9)	2,693	*

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Name	Number of Shares Being Offered	Percent of Shares Beneficially Owned After Offering
Mark G. and Margarita S. Treuth(10)	2,693	*
Jeff Murley(11)	1,723	*
Yasushi Kataoka(12)	1,723	*
Orrick Investments 2002 LLC(13)	1,615	*
Gust Kouvaris(14)	1,077	*
Gregg Allan Zeleniak(15)	1,077	*
Robert Bret Hart(16)	1,077	*
Richard B. Toren(17)	1,077	*
Margaret L. and William R. Miller(18)	538	*
Gene Logic Inc.(19)	538	*

\* Less than 1%

- (1) Includes 93,313 shares of Common Stock issuable on the achievement of certain developmental milestones and 2,038 shares of Common Stock in repayment of a loan.
- (2) Includes 90,992 shares of Common Stock issuable on the achievement of certain developmental milestones and 2,324 shares of Common Stock in repayment of a loan.
- (3) Includes 44,551 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (4) Includes 12,079 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (5) Includes 9,281 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (6) Includes 5,569 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (7) Includes 2,784 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (8) Includes 2,784 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (9) Includes 2,320 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (10) Includes 2,320 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (11) Includes 1,485 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (12) Includes 1,485 shares of Common Stock issuable on the achievement of certain developmental milestones.

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- (13) Includes 1,392 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (14) Includes 928 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (15) Includes 928 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (16) Includes 928 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (17) Includes 928 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (18) Includes 464 shares of Common Stock issuable on the achievement of certain developmental milestones.
- (19) Includes 464 shares of Common Stock issuable on the achievement of certain developmental milestones.

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**PLAN OF DISTRIBUTION**

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

The Selling Stockholders may from time to time pledge or grant a security interest in some or all of the shares of Common Stock owned by them and, if they default in the performance of their 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 of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

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The Selling Stockholders 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 Stockholders 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 them may be deemed to be underwriting commissions or discounts under the Securities Act. The Selling Stockholders have informed us that none of them 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 \$5,503.

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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 incorporated by reference in this Prospectus, have been audited by BDO Seidman, LLP, independent certified public accountants, to the extent and for the periods set forth in their report incorporated herein by reference, and are incorporated herein in reliance upon such report given upon the authority of said firm as experts in auditing and accounting.

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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 March 16, 2004. You should not assume that this prospectus is accurate as of any other date.

**Table of Contents****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	\$ 503
Legal fees and expenses	3,000
Accounting fees and expenses	2,000
	<hr/>
Total	\$ 5,503
	<hr/>

**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 of 1933, as amended (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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**Table of Contents****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).
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.**

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the registrant pursuant to the provisions described in Item 15, the registrant has been informed that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or person controlling the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or person controlling the registrant 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 of 1933 and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes:

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

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment 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; and

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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 the offering.

The undersigned registrant undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) 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.

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<hr/> <b>Robert W. Weber</b>	Chief Accounting Officer	
	<i>(Principal Accounting Officer)</i>	
/s/ J. PAUL BAGLEY III	Director	March 5, 2004
<hr/> <b>J. Paul Bagley III</b>		
/s/ BRENDAN R. McDONNELL	Director	March 8, 2004
<hr/> <b>Brendan R. McDonnell</b>		
/s/ THOMAS CHARLES MERIGAN, JR.	Scientific Advisor and Director	March 5, 2004
<hr/> <b>Thomas Charles Merigan, Jr.</b>		
/s/ WILLIAM H. TILLEY	Director	March 8, 2004
<hr/> <b>William H. Tilley</b>		
/s/ SALVATORE J. ZIZZA	Director	March 8, 2004
<hr/> <b>Salvatore J. Zizza</b>		

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**Table of Contents****EXHIBIT INDEX**

<b><u>Exhibit Number</u></b>	<b><u>Description of Document</u></b>
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