

HOLLIS EDEN PHARMACEUTICALS INC /DE/

Form S-3

May 19, 2003

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As filed with the Securities and Exchange Commission on May 19, 2003

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
(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)

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)

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

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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 | Proposed | Proposed | Amount of Registration |
|--|-------------------------|----------------------------------|----------------------------------|------------------------|
| | | Maximum Offering Price Per Share | Maximum Aggregate Offering Price | |
| Common Stock | 50,000 | (1) \$6.84 | (1) \$342,000 | \$28 |

- (1) 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 price of Hollis-Eden's common stock on May 14, 2003 as reported on The Nasdaq National Market. It is not known how many shares will be purchased under this registration statement or at what price such shares will be purchased.

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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SUBJECT TO COMPLETION

Preliminary Prospectus Dated May 19, 2003

PROSPECTUS

50,000 Shares

HOLLIS-EDEN PHARMACEUTICALS, INC.

Common Stock

The selling stockholder identified in this prospectus is selling 50,000 shares of Hollis-Eden Pharmaceuticals, Inc. common stock. Hollis-Eden will not receive any of the proceeds from the sale of shares by the selling stockholder. 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 May 14, 2003, was \$6.84 per share.

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

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 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 we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

The date of this prospectus is _____, 2003.

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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 immune system disorders and hormonal imbalances.

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 stockholder.

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 prospectus and in our most recent annual report on Form 10-K as well as our other public filings with the Securities and Exchange Commission. 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.

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 expect to incur significant additional operating losses over the next several years as we fund development, clinical testing and other expenses while seeking regulatory approval. While limited clinical trials of our drug candidates have 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.

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 \$86.6 million as of March 31, 2003. Our net losses for fiscal years 2002, 2001 and 2000 were \$17.5 million, \$15.8 million and \$19.5 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

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effective drug candidates may never be developed into commercially successful drugs. If we are unable to develop safe, commercially viable drugs, we may never achieve profitability. If we become profitable, we may not remain profitable.

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

The biotechnology and pharmaceutical industries are intensely competitive. We have numerous competitors in the United States and elsewhere. Because we are pursuing potentially large markets, our competitors include major, multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions. Several of these entities have already successfully marketed and commercialized products that will compete with our products, assuming that our products gain regulatory approval. Companies such as 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 cardiovascular disease and 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 sufficient price that would permit us to generate profits.

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

As of March 31, 2003 our cash and cash equivalents totaled approximately \$19.4 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 into the second half of 2004.

We have recently streamlined our operations and focused our research and development expenditures, and we are developing further contingency plans that we believe will allow our existing resources to meet our needs into 2005 in the event we are unable to raise additional funds before that time.

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However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We will require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We intend to seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

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

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any available additional financing may not be adequate.

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

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

As of the date of this prospectus, we own or have obtained a license to over 80 issued U.S. and foreign patents and over 130 pending U.S. and foreign patent applications. Our success will depend in part on our ability to obtain additional United States and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate without infringing the proprietary rights of third parties. We place considerable importance on obtaining patent protection for significant new technologies, products and processes. Legal standards relating to the validity of patents covering pharmaceutical and biotechnology inventions and the scope of claims made under such patents are still developing. In some of the countries in which we intend to market our products, pharmaceuticals are either not patentable or have only recently become patentable. Past enforcement of intellectual property rights in many of these countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries may be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions. Our domestic patent position is also highly uncertain and involves complex legal and factual questions. The applicant or inventors of subject matter covered by patent applications or patents owned by or licensed to us may not have been the first to invent or the first to file patent applications for such inventions. Due to uncertainties regarding patent law and the circumstances surrounding our patent applications, the pending or future patent applications we own or have licensed may not result in the issuance of any patents. Existing or future patents owned by or licensed to us may be challenged, infringed upon, invalidated, found to be unenforceable or circumvented by others. Further, any rights we may have under any issued patents may not provide us with sufficient protection against competitive products or otherwise cover commercially valuable products or processes.

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

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

incur substantial money damages;

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

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

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

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

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

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

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

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

Varying price regulation between countries can lead to inconsistent prices and some re-selling by third parties of products from markets where products are sold at lower prices to markets where those products are sold at higher prices. This practice of exploiting price differences between countries could undermine our sales in markets with higher prices and reduce the sales of our future products, if any. While we do not have any applications for regulatory approval of our products currently pending, the decline in the size of the markets in which we may in the future sell commercial products could cause the perceived market value of our business and the price of our common stock to decline.

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

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

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

animal efficacy studies with HE2100 in the United States for the treatment of radiation exposure;

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

Phase II clinical trials with HE2000 in Thailand for the treatment of malaria;

Phase I/II clinical trial with HE2200 in the United States to determine whether the compound can improve an elderly person's immune response to a hepatitis B vaccine; and

Phase II clinical trial with HE2200 in the United States for cholesterol lowering.

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We may encounter problems with some or all of our completed or ongoing studies that may cause us or regulatory authorities to delay or suspend our ongoing studies or delay the analysis of data from our completed or ongoing studies. We rely, in part, on third parties to assist us in managing and monitoring clinical trials. 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 failing 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 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; or

failure to raise additional funds.

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

An outside manufacturer, Hovione-Soc. Química, S.A., is currently the primary producer of the active pharmaceutical ingredient for our drug candidate, HE2000, 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.

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

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

Our efforts to date have focused on the development and evaluation of our drug candidates. As we continue clinical studies and prepare for commercialization of our drug candidates, we may need to build a sales and marketing infrastructure. As a company, we have no experience in the sales and marketing of our drug candidates. If we fail to establish a sufficient marketing and sales force or to make alternative arrangements to have our products marketed and sold by others on attractive terms, it will impair our ability to commercialize our drug candidates and

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to enter new or existing markets. Our inability to effectively enter these markets would materially and adversely affect our ability to generate significant revenues.

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

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

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

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

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

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

biological or medical discoveries by competitors;

public concern about the safety of our drug candidates;

delays in the conduct or analysis of our clinical trials;

unfavorable results from clinical trials;

unfavorable developments concerning patents or other proprietary rights; or

unfavorable domestic or foreign regulatory developments;

may have the effect of temporarily or permanently driving down the price of our common stock. In addition, the stock market from time to time experiences extreme price and volume fluctuations which particularly affect the market prices for emerging and life sciences companies, such as ours, and which are often unrelated to the operating performance of the affected companies. For example, our stock price has ranged from \$3.30 to \$12.24 between January 1, 2002 and May 11, 2003.

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

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management's attention and resources, which could materially adversely affect our business, financial condition and results of operations.

The terms of our convertible debentures may limit our operational flexibility.

The existence of debt service obligations and the anti-dilution provisions of our debentures may limit our ability to obtain additional financing on terms favorable to us. In addition, if we do not obtain stockholder approval to make interest payments on our debentures in the form of stock, our required quarterly interest payments will deplete our cash reserves. If we do not raise additional funds, we may not be able to pay the principal or interest on the debentures when due. Payments on the debentures will reduce the funds that would otherwise be available for our operations and future business opportunities. Further, unless we obtain the consent of the holders of the debentures, if we enter into a transaction that would result in a change of control, we may be required to redeem the debentures to the extent that they have not already been converted to common stock. This requirement may deter a third party from entering into a change of control transaction with us.

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. In addition, if our common stock is not listed on any of The Nasdaq National Market, The Nasdaq SmallCap Market, the American Stock Exchange or the New York Stock Exchange, for more than 30 days, our debentures will be in default and we will be required to redeem the debentures at a 20% premium to their face value, to the extent that they have not already been converted into 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 20% of our outstanding common stock as of May 11, 2003. Assuming that Mr. Hollis exercises all of his outstanding warrants and options that vest within 60 days of May 11, 2003, Mr. Hollis would beneficially own approximately 28% of our outstanding common stock as of May 11, 2003. As a result, Mr. Hollis may be able to significantly influence the management of Hollis-Eden and all matters requiring stockholder approval, including the election of directors. Such concentration of ownership may also have the effect of delaying or preventing a change in control of Hollis-Eden.

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

Future sales of substantial amounts of our common stock, including shares that we may issue upon exercise of options and warrants, or upon conversion of debentures, could adversely affect the market price of our common stock. In addition, if we complete a future financing at a price

that is less than the conversion price of the debentures, the conversion price of the debentures may be adjusted downward, which would result in additional shares of our common stock being issuable upon conversion of the debentures. 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.

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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 will 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, 2002;

Quarterly Report on Form 10-Q for the quarter ended March 31, 2003;

Current Report on Form 8-K filed with the SEC on February 26, 2003;

Notice of Annual Meeting and Proxy Statement for the 2003 Annual Meeting of Stockholders held on June 20, 2003; and

Our registration statement on Form S-4, No. 333-18725, as amended, which includes a description of our common stock.

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

FORWARD-LOOKING STATEMENTS

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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 clinical trials;

failure to obtain government regulatory approvals;

competitive factors;

our ability to raise additional capital;

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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 STOCKHOLDER**

The following table sets forth the name of the selling stockholder, and the number of shares of common stock that it beneficially owns as of May 11, 2003 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 13,110,280 shares issued and outstanding on May 11, 2003. The number of shares beneficially owned by the 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 stockholder includes the stockholder listed below and its transferees, pledges, donees or other successors. The selling stockholder is offering all of the shares that it beneficially owns, and assuming it sells every share, will not beneficially own any shares of Hollis-Eden after the offering. The selling stockholder does not have, and within the past three years has not had, any position, office or other material relationship with Hollis-Eden or any of its predecessors or affiliates.

| <u>Selling Stockholder</u> | <u>Shares Being Offered</u> | <u>Percent of Shares Beneficially Owned Prior to the Offering</u> |
|----------------------------|-----------------------------|---|
| Humanetics Corporation | 50,000 | * |

* less than 1%

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PLAN OF DISTRIBUTION

The shares of common stock may be sold from time to time by the selling stockholders in one or more transactions at fixed prices, at market prices at the time of sale, at varying prices determined at the time of sale or at negotiated prices. The selling stockholders may offer their shares of common stock in one or more of the following transactions:

on any national securities exchange or quotation service at which the common stock may be listed or quoted at the time of sale, including The Nasdaq National Market;

in the over-the-counter market;

in private transactions;

through options; and

by pledge to secure debts and other obligations, or a combination of any of the above transactions.

If required, we will distribute a supplement to this prospectus to describe material changes in the terms of the offering.

The shares of common stock described in this prospectus may be sold from time to time directly by the selling stockholders. Alternatively, the selling stockholders may from time to time offer shares of common stock to or through underwriters, broker/dealers or agents. The selling stockholders and any underwriters, broker/dealers or agents that participate in the distribution of the shares of common stock may be deemed to be underwriters within the meaning of the Securities Act of 1933. Any profits on the resale of shares of common stock and any compensation received by any underwriter, broker/dealer or agent may be deemed to be underwriting discounts and commissions under the Securities Act of 1933.

Any shares covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act of 1933 may be sold under rule 144 rather than under the terms of this prospectus. The selling stockholders may transfer, will or gift such shares by other means not described in this prospectus.

To comply with the securities laws of certain jurisdictions, the common stock must be offered or sold only through registered or licensed brokers or dealers. In addition, in certain jurisdictions, the common stock may not be offered or sold unless they have been registered or qualified for sale or an exemption is available and complied with.

Under the Securities Exchange Act of 1934, any person engaged in a distribution of the common stock may not simultaneously engage in market-making activities with respect to the common stock for nine business days prior to the start of the distribution. In addition, each selling

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stockholder and any other person participating in a distribution will be subject to the Securities Exchange Act of 1934 which may limit the timing of purchases and sales of common stock by the selling stockholders or any such other person. These factors may affect the marketability of the common stock and the ability of brokers or dealers to engage in market-making activities.

We will pay all expenses of this registration. These expenses include the SEC s filing fees and fees under state securities or blue sky laws. We estimate that our expenses in connection with this offering will be \$4,028.00.

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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 of Hollis-Eden Pharmaceuticals, Inc. as of December 31, 2002 and 2001, and for each of the years ended December 31, 2002, 2001 and 2000, and for the period from August 15, 1994, the day we started doing business, to December 31, 2002, have been audited by BDO Seidman, LLP, as set forth in their report included in our Annual Report on Form 10-K for the year ended December 31, 2002. We incorporate these financial statements by reference into this prospectus in reliance upon such report given upon the authority of BDO Seidman, LLP as experts in accounting and auditing.

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 May 11, 2003. 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 | \$ 28 |
| Legal fees and expenses | 2,000 |
| Accounting fees and expenses | 2,000 |
| | <hr/> |
| Total | \$ 4,028 |

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;

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(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

(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.

Table of Contents**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, 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 16th day of May, 2003.

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.

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|---|--------------|
| /s/ RICHARD B. HOLLIS <hr/> Richard B. Hollis | Chairman of the Board, Chief Executive Officer and Director (Principal Executive Officer) | May 16, 2003 |
| /s/ DANIEL D. BURGESS <hr/> Daniel D. Burgess | Chief Operating Officer/Chief Financial Officer (Principal Financial Officer) | May 16, 2003 |
| /s/ ROBERT W. WEBER | Vice President–Controller/Chief Accounting Officer (Principal Accounting Officer) | May 16, 2003 |

| | | |
|------------------------------------|---------------------------------|--------------|
| <hr/> | | |
| Robert W. Weber | | |
| /s/ J. PAUL BAGLEY III | Director | May 16, 2003 |
| <hr/> | | |
| J. Paul Bagley III | | |
| <hr/> | | |
| Leonard Makowka | Director | |
| <hr/> | | |
| /s/ BRENDAN R. McDONNELL | Director | May 16, 2003 |
| <hr/> | | |
| Brendan R. McDonnell | | |
| /s/ THOMAS CHARLES MERIGAN, JR. | Scientific Advisor and Director | May 16, 2003 |
| <hr/> | | |
| Thomas Charles Merigan, Jr. | | |

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/s/ WILLIAM H. TILLEY

Director

May 16, 2003

William H. Tilley

/s/ SALVATORE J. ZIZZA

Director

May 16, 2003

Salvatore J. Zizza

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EXHIBIT INDEX

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