HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 10-Q
November 14, 2002
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark one)

x **Quarterly Report Under Section 13 or 15 (d) Of the Securities Exchange Act of 1934**
For Quarterly Period Ended September 30, 2002

o **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act 1934**
For the period from _____ to _____.

HOLLIS-EDEN PHARMACEUTICALS, INC

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of incorporation)

000-24672	**13-3697002**
(Commission File No.)	**(I.R.S. Employer Identification No.)**

4435 Eastgate Mall, Suite 400
SAN DIEGO, CALIFORNIA 92121
(Address of principal executive offices and zip code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

As of November 11, 2002 there were 12,972,443 shares of registrant s Common Stock, $.01 par value, outstanding.

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HOLLIS-EDEN PHARMACEUTICALS, INC.
Form 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2002

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Part I. Financial Information

Item I. Financial Statements

Hollis-Eden Pharmaceuticals, Inc.
(A Development Stage Company)
Balance Sheets

All numbers in thousands (except par value)	September 30, 2002 (Unaudited)	Dec. 31, 2001
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 16,441	$ 30,567
Prepaid expenses	146	169
Deposits	78	27
Total current assets	16,665	30,763
Property and equipment, net of accumulated depreciation of $296 and $335	429	422
Other receivable from related party	280	277
Total assets	$ 17,374	$ 31,462
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,438	$ 3,602
Total liabilities	3,438	3,602
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $.01 par value, 10,000 shares authorized; no shares outstanding		
Common stock, $.01 par value, 50,000 shares authorized; 12,922 and 12,896 shares issued and outstanding	129	129
Paid-in capital	92,074	91,649
Deficit accumulated during development stage	(78,267)	(63,918)
Total stockholders equity	13,936	27,860
Total liabilities and stockholders equity	$ 17,374	$ 31,462

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

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Hollis-Eden Pharmaceuticals, Inc.
(A Development Stage Company)
Statements of Operations
(Unaudited)

All numbers in thousands, except per share amounts	3 months ended Sept. 30, 2002	3 months ended Sept. 30, 2001	9 months ended Sept. 30, 2002	9 months ended Sept. 30, 2001	Period from Inception (Aug.15, 1994) to Sept. 30, 2002
Operating expenses:					
Research and development:					
R&D operating expenses	$ 3,572	$ 2,714	$ 10,949	$ 8,372	$ 49,313
R&D costs related to common stock, option, & warrant grants for collaborations	14	24	55	72	5,330
General and administrative:					
G&A operating expenses	995	991	3,421	3,498	21,211
G&A costs related to common stock, option, & warrant grants	17	208	231	208	10,009
Total operating expenses	4,598	3,937	14,656	12,150	85,863
Other income (expense):					
Gain / (Loss) on disposal of asset			(21)		(21)
Interest income	83	243	328	1,047	7,667
Interest expense					(50)
Total other income	83	243	307	1,047	7,596
Net loss	$ (4,515)	$ (3,694)	$ (14,349)	$ (11,103)	$ (78,267)
Net loss per share-basic and diluted	(0.35)	(0.32)	(1.11)	(0.96)	
Weighted average number of common shares outstanding-basic and diluted	12,922	11,616	12,921	11,609	

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

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Hollis-Eden Pharmaceuticals, Inc.
(A Development Stage Company)
Statements of Cash Flows
(Unaudited)

All numbers in thousands	9 months ended Sept. 30, 2002	9 months ended Sept. 30, 2001	Period from Inception (Aug. 15, 1994) to Sept. 30, 2002
Cash flows from operating activities:			
Net loss	$ (14,349)	$ (11,103)	$ (78,267)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	92	97	427
Disposal of assets	21		28
Common stock issued for the company 401k/401m plan	137	95	296
Common stock issued as consideration for amendments to the license agreements			33
Common stock issued as consideration for termination of a finance agreement			34
Expense related to common stock issued for the purchase of technology			1,848
Common stock and options issued as consideration for license fees and services	55	72	1,925
Common stock issued as consideration for In Process R&D			2,000
Expense related to warrants issued as consideration to consultants	214	208	2,562
Expense related to warrants issued to a director for successful closure of merger			570
Expense related to stock options issued	17		5,157
Deferred compensation expense related to options issued			1,210
Changes in assets and liabilities:			
Prepaid expenses	22	(18)	(147)
Deposits	(51)		(78)
Other receivables			
Loan receivable from related party	(3)	(37)	(280)
Accounts payable and accrued expenses	336	308	3,438
Wages payable	(500)	(581)	
Net cash used in operating activities	(14,009)	(10,959)	(59,244)
Cash flows provided by investing activities:			
Purchase of property and equipment	(119)	(118)	(883)
Net cash used in investing activities	(119)	(118)	(883)

Cash flows from financing activities:			
Contributions from stockholder			104
Net proceeds from sale of preferred stock			4,000
Net proceeds from sale of common stock			52,829
Proceeds from issuance of debt			371
Net proceeds from recapitalization			6,271
Net proceeds from warrants and options exercised	2	23	12,993
Net cash from financing activities	2	23	76,568
Net increase (decrease) in cash	(14,126)	(11,054)	16,441
Cash and equivalents at beginning of period	30,567	34,298	
Cash and equivalents at end of period	$ 16,441	$ 23,244	$ 16,441

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

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

NOTES TO FINANCIAL STATEMENTS

(UNAUDITED)

1. Basis of Presentation

The information at September 30, 2002, and for the three-month and nine-month periods ended September 30, 2002 and 2001, is unaudited. In the opinion of management, these financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year. These financial statements should be read in conjunction with the Hollis-Eden Pharmaceuticals, Inc. (Hollis-Eden) Annual Report on Form 10-K for the year ended December 31, 2001, which was filed with the United States Securities and Exchange Commission on March 1, 2002.

While management believes that the discussion and analysis in this report is adequate for a fair presentation of the information, management recommends that this discussion and analysis be read in conjunction with Management s Discussion and Analysis of Results of Operations and Financial Condition included in the Company s Annual Report on Form 10-K for the year ended December 31, 2001.

2. Other Agreements and Commitments

Aeson Therapeutics

In March 2002, we amended certain of our agreements with Aeson Therapeutics, Inc. (Aeson). Under the amendments, we paid Aeson $1.0 million for further clinical development of HE2500. The payment extended the initial date by which we could exercise our option to acquire the remainder of Aeson to September 30, 2002. We also received additional equity securities as a result of our $1.0 million payment and now have approximately a 25% equity stake in Aeson. The $1.0 million payment was expensed as in-process R&D during the second quarter of 2002. The amendments also provided that if we did not exercise our initial option to acquire the remainder of Aeson then we, at our sole option, could make an additional payment of $1.0 million to allow us to extend the date by which we may exercise our option to acquire the remainder of Aeson through April 11, 2003.

We elected not to exercise our option to acquire the remainder of Aeson by September 30, 2002 or to make the additional payment required to extend our option until April 2003. Accordingly, our option to acquire Aeson has now expired. We continue to hold a 25% equity interest in Aeson.

Pharmadigm

In August 2002, we entered into a Sublicense Agreement with Pharmadigm, Inc. Under the agreement, we obtained exclusive worldwide rights to certain intellectual property of Pharmadigm and the University of Utah and we agreed to make aggregate payments of $0.9 million in cash or in shares of our common stock, at our option, over the next year. The $0.9 million payment to Pharmadigm is comprised of a $50,000 sublicense issue fee and the remainder as payments related to reimbursement of costs incurred and technology transfer, to be paid over the next year in cash or in shares of our common stock, at our option. The $0.9 million payment was expensed as in-process R&D during the third quarter 2002. We will also make additional milestone and royalty payments to Pharmadigm if we meet specified development and commercialization milestones for products covered by the patents that we licensed under the agreement. The principal patents licensed under the agreement, originally licensed to Pharmadigm from the University of Utah, relate to inventions by Dr. Raymond Daynes and Dr. Barbara A. Araneo. Dr. Daynes is currently a scientific consultant to Hollis-Eden.

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Item 2. Management s Discussion and Analysis of Results of Operations and Financial Condition

The forward-looking comments contained in the following discussion involve risks and uncertainties. Our actual results may differ materially from those discussed here due to factors such as the timing, success and cost of preclinical research and clinical studies, the timing, acceptability and review periods for regulatory filings, the ability to obtain regulatory approval of products, our ability to obtain additional funding and the development of competitive products by others. Additional factors that could cause or contribute to such differences can be found in the following discussion, as well as in the Company s Annual Report on Form 10-K for the year ended December 31, 2001.

General

Hollis-Eden Pharmaceuticals, Inc., a development-stage pharmaceutical company, is engaged in the discovery, development and commercialization of products for the treatment of infectious diseases and other conditions resulting from immune system disorders and hormonal imbalances. Our initial technology development efforts are focused on a series of potent hormones and hormone analogs that we believe are key components of the body s natural regulatory system. We believe these compounds can be used to reestablish balance to the immune and metabolic systems in situations of dysregulation.

We have been unprofitable since our inception and we expect to incur substantial additional operating losses for at least the next few years as a result of the continuing development activities necessary to bring our potential products to market. In addition, during the next few years, we may have to meet the substantial new challenge of developing the capability to market products. Accordingly, our activities to date are not as broad in depth or scope as the activities we must undertake in the future, and our historical operations and financial information are not indicative of the future operating results or financial condition or ability to operate profitably as a commercial enterprise when and if we succeed in bringing any drug candidates to market.

On March 26, 1997, Hollis-Eden, Inc., a Delaware corporation, was merged with and into us, then known as Initial Acquisition Corp. (IAC), a Delaware corporation. Upon consummation of the merger of Hollis-Eden, Inc. with IAC, Hollis-Eden, Inc. ceased to exist, and IAC changed its name to Hollis-Eden Pharmaceuticals, Inc.

Results of Operations

We have not generated any revenues for the period from August 15, 1994 (inception of Hollis-Eden) through September 30, 2002. We have devoted substantially all of our resources to the payment of licensing fees and research and development expenses plus expenses related to the startup of our business. From inception until September 30, 2002, we have incurred expenses of approximately $54.6 million in research and development, of which $5.3 million are non-cash expenses, and $31.2 million in general and administrative expenses, of which $10.0 million are non-cash expenses. Our expenses have been partially offset by $7.6 million in net interest income, resulting in a loss of $78.2 million for the period.

Research and development expenses were approximately $3.5 million and $11.0 million for the three- and nine-month periods ended September 30, 2002, compared to $2.7 million and $8.4 million for the same periods in 2001. Research and development expenses relate primarily to the ongoing development, preclinical testing, and clinical trials for our investigational drug candidates. The increase in research and development expenses for the three-month period ended September 30, 2002, compared to the same period in 2001, was due mainly to our obligation of $0.9 million for fees payable to Pharmadigm, Inc. under a license agreement that we entered into in August 2002. The $0.9 million payment to Pharmadigm is comprised of a $50,000 sublicense issue fee and the remainder as payments related to reimbursement of costs incurred and technology transfer, to be paid over the next year in cash or in shares of our common stock, at our option. If we choose to pay in common stock, the number of shares of common stock will be calculated using a formula set forth in the license agreement. The increase in research and development expenses in the nine-month period ended September 30, 2002, compared to the same period in 2001, was due mainly to the $0.9 million in fees payable

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to Pharmadigm, Inc. in September 2002, a $1.0 million investment in Aeson Therapeutics for in-process R&D in April 2002, a $1.0 million increase in salaries and benefits during the period in 2002, and a $1.1 million increase in clinical activities during the period in 2002. The increase in expenses during the first nine months of 2002 were offset by a $0.6 million decrease in preclinical expenses, $0.3 million decrease in patent fees and $0.2 million decrease in consulting expenses during the period in 2002.

General and administrative expenses were $1.0 million and $3.6 million for the three- and nine-month periods ended September 30, 2002, compared to $1.2 million and $3.7 million for the same periods in 2001. General and administrative expenses relate to salaries and benefits, facilities, legal, investor relations, insurance and travel.

Net interest income was $0.1 million and $0.3 million for the three- and nine-month periods ended September 30, 2002, compared to $0.2 million and $1.0 million for the same periods in 2001. The decline in interest income in both the three- and nine-month periods ended September 30, 2002, compared to the same periods in 2001, is due to lower interest rates and to lower average balances of cash and cash equivalents as a result of ongoing operating losses.

Liquidity and Capital Resources

We have financed our operations since inception primarily through the sale of shares of common stock. During the year ended December 31, 1995, we received cash proceeds of $250,000 from the sale of securities. In May 1996, we completed a private placement of shares of common stock, from which we received aggregate gross proceeds of $1.3 million. In March 1997, the merger of IAC and Hollis-Eden, Inc. provided us with $6.5 million in cash and other receivables. In May 1998, we completed a private placement of common stock and preferred stock and warrants to purchase common stock, from which we received gross proceeds of $20 million. During January 1999, we completed two private placements from which we received aggregate gross proceeds of approximately $25 million. In December 2001, we completed a private placement of common stock and warrants, from which we received gross proceeds of $11.5 million. In addition, we have received a total of $13 million from the exercise of warrants and stock options from inception.

As of September 30, 2002, our cash, cash equivalents and short-term investments were $16.4 million compared to $30.5 million at December 31, 2001. The decrease was primarily due to $14.1 million of cash used for operations. We expect to continue to use our cash, cash equivalents and short-term investments to fund our ongoing research and development programs.

Our operations to date have consumed substantial capital without generating any revenues, and we will continue to require substantial and increasing amounts of funds to conduct necessary research and development and preclinical and clinical testing of our drug candidates, and to market any drug candidates that receive regulatory approval. We do not expect to generate revenue from operations for the foreseeable future, and our ability to meet our cash obligations as they become due and payable is expected to depend for at least the next several years on our ability to sell securities, borrow funds or some combination thereof. We may not be successful in raising necessary additional capital resources to fund our ongoing operations. We may also seek additional funding through collaborative arrangements with strategic partners or with governmental entities. If adequate funds are not available we may be required to delay, scale back or eliminate one or more of our drug discovery or development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or product candidates that we would not otherwise relinquish.

Based upon our current plans, we believe that our existing capital resources, together with interest thereon, will be sufficient to meet our operating expenses and capital requirements at least into the second half of 2003. 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 2004 in the event we are unable to raise additional funds before that time. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of our available capital resources earlier than expected. Our future capital requirements will

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depend upon many factors, including progress with preclinical testing and clinical trials, the number and breadth of our programs, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, the time and costs involved in obtaining regulatory approvals, competing technological and market developments, and our ability to establish collaborative arrangements for the development of our drug candidates or for the effective commercialization and marketing of any drug candidate approved by regulatory authorities. We expect to continue to incur increasing negative cash flows and net losses for the foreseeable future.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

At September 30, 2002, our investment portfolio included only cash and money market accounts and had no fixed-income securities. There would be no material impact to our investment portfolio, in the short term, associated with any change in interest rates, and any decline in interest rates over time will reduce our interest income, while increases in interest rates over time will increase our interest income.

Item 4. Controls and Procedures

An evaluation was performed under the supervision and with the participation of the Company s management, including the Company s Chief Executive Officer and Chief Operating Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company s disclosure controls and procedures within 90 days before the filing date of this quarterly report. Based on that evaluation, the Company s management, including the Company s Chief Executive Officer and Chief Operating Officer and Chief Financial Officer, concluded that the Company s disclosure controls and procedures were effective. There have been no significant changes in the Company s internal controls or in other factors that could significantly affect internal controls subsequent to their evaluation.

PART II Other Information

Item 1. Legal Proceedings

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. As of the date of this quarterly report, we are not engaged in any legal proceedings that are expected, individually or in the aggregate, to have a material adverse effect on our business, financial condition or operating results.

Item 2. Changes in Securities

On October 15, 2002, we issued 50,000 shares of unregistered Common Stock to Pharmadigm, Inc. as a contractual obligation and as consideration, in part, for the sublicense granted to us pursuant to the sublicense agreement entered into in August 2002 with Pharmadigm.

The issuance of these securities was deemed to be exempt from registration under the Securities Act of 1933, as amended, by virtue of Section 4(2) and/or Regulation D promulgated under such Act. The recipients represented their intention to acquire the securities for investment only and not with a view to distribution thereof. Appropriate legends are affixed to the securities issued in such transaction.

Item 3. Defaults upon Senior Securities

None

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Item 4. Submission of Matters to a Vote of Securities Holders

None

Item 5. Other Information

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 report and in our most recent annual report on Form 10-K. 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 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 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 $78.3 million through September 30, 2002. Our net losses for fiscal years 2001, 2000 and 1999 were $15.8 million, $19.5 million and $15.3 million, respectively. Our net loss for the nine months ended September 30, 2002 was $14.3 million. Many of our research and development programs are at an early stage. Potential drug candidates are subject to inherent risks of failure. These risks include the possibilities that no drug candidate will be found safe or effective, meet applicable regulatory standards or receive the necessary regulatory clearances. Even safe and effective drug candidates may never be developed into commercially successful drugs. If we are unable to develop safe, commercially viable drugs, we may never achieve profitability. If we become profitable, we may not remain profitable.

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

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

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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 September 30, 2002 our cash and cash equivalents totaled approximately $16.4 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 2003. 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 2004 in the event we are unable to raise additional funds before that time. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We will require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We intend to seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

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

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

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

As of the date of this report, 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. Pharmaceuticals are either not patentable or have only recently become patentable in some of the countries in which we intend to market our products. 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

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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.

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

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regulatory approval for a drug candidate in a particular country, but then be subject to price regulations that reduce our profits from the sale of the product. In some foreign markets pricing of prescription pharmaceuticals is subject to continuing government control even after initial marketing approval. In addition, certain governments may grant third parties a license to manufacture our product without our permission. Such compulsory licenses typically would be on terms that are less favorable to us and would have the effect of reducing our profits.

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

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

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

The current status of our drug candidates is 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;
- 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;
- a Phase II clinical trial with HE2000 in Singapore for the treatment of Hepatitis B;
- a 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
- a Phase II clinical trial with HE2200 in the United States for cholesterol lowering.

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

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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 our lead 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.

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

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

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

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

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

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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 $2.12 to $19.25 between January 1, 2000 and September 30, 2002.

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

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

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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 21% of our outstanding common stock as of May 31, 2002. Assuming that Mr. Hollis exercises all of his outstanding warrants and options that vest within 60 days of May 31, 2002, Mr. Hollis would beneficially own approximately 28% of our outstanding common stock as of May 31, 2002. As a result, Mr. Hollis may be able to significantly influence the management of Hollis-Eden and all matters requiring stockholder approval, including the election of directors. Such concentration of ownership may also have the effect of delaying or preventing a change in control of Hollis-Eden.

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. Similarly, 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 of holders of our common stock may be adversely affected by the rights granted to holders of preferred 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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Item 6. Exhibits and Reports on Form 8-K

(a) The following exhibits are included as part of this report:

Exhibit Number	Description of Document
99.1	Certifications Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002

(b) Reports on Form 8-K:

None.

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Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HOLLIS-EDEN PHARMACEUTICALS, INC.

Dated: November 11, 2002 By: /s/ DANIEL D. BURGESS

Daniel D. Burgess
Chief Operating Officer/
Chief Financial Officer
(Principal Financial Officer)

Dated: November 11, 2002 By: /s/ ROBERT W. WEBER

Robert W. Weber
Vice President-Controller
Chief Accounting Officer
(Principal Accounting Officer)