HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 10-Q
May 13, 2003
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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 March 31, 2003

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	No
x	o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12-b-2 of the Exchange Act).

Yes	No
o	x

As of May 11, 2003 there were 13,110,280 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 MARCH 31, 2003

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Part I. Financial Information

Item 1. Financial Statements

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

All numbers in thousands (except par value)

	March 31, 2003	Dec. 31, 2002
	(Unaudited)	
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 19,424	$ 13,087
Prepaid expenses	372	123
Deposits	87	87
Total current assets	19,883	13,297
Property and equipment, net of accumulated depreciation of $355 and $327	367	398
Deferred issuance cost, net of accumulated amortization of $36 and $0	1,120	
Receivable from related party	23	274
Other receivable		13
Total assets	$ 21,393	$ 13,982
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,025	$ 2,950
Total current liabilities	3,025	2,950
Convertible debentures (face amount of 10,000), net of deemed discount of $6,266	3,734	
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; 13,142 and 12,972 shares issued, respectively	131	130
Paid-in capital	101,466	92,322
Cost of treasury stock (59 shares)	(346)	
Deficit accumulated during development stage	(86,617)	(81,420)
Total stockholders equity	14,634	11,032
Total liabilities and stockholders equity	$ 21,393	$ 13,982

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 March 31,		Period from Inception (Aug.15, 1994) to March 31,
	2003	2002	2003
Operating expenses:			
Research and development:			
R&D operating expenses	$ 2,305	$ 2,916	$ 53,686
R&D costs related to common stock, option, & warrant grants for collaborations	291	24	5,633
General and administrative:			
G&A operating expenses	973	1,180	23,287
G&A costs related to common stock, option, & warrant grants	1,365	214	11,406
Total operating expenses	4,934	4,334	94,012
Other income (expense):			
Gain / (Loss) on disposal of asset		(21)	(21)
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures	(240)		(240)
Interest income	48	137	7,777
Interest expense	(71)		(121)
Total other income (expense)	(263)	116	7,395
Net loss	$ (5,197)	$ (4,218)	$ (86,617)
Net loss per share-basic and diluted	(0.40)	(0.33)	
Weighted average number of common shares outstanding-basic and diluted	13,050	12,918	

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

	3 months ended March 31,		Period from Inception (Aug. 15, 1994) to Mar. 31,
	2003	2002	2003
Cash flows from operating activities:			
Net loss	$ (5,197)	$ (4,218)	$ (86,617)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	31	32	489
Disposal of assets		21	27
Amortization of deemed discount on convertible debentures	204		204
Amortization of deferred issuance cost	36		36
Common stock issued for the company 401k/401m plan		137	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, milestone payments and services	291	24	2,431
Common stock issued as consideration for In Process R&D			2,000
Expense related to warrants issued as consideration to consultants	803	214	3,397
Expense related to warrants issued to a director for successful closure of merger			570
Expense related to stock options issued	562		5,719
Deferred compensation expense related to options issued			1,210
Changes in assets and liabilities:			
Prepaid expenses	(249)	(146)	(372)
Deposits		(82)	(87)
Other receivables	13		
Loan receivable from related party	(3)	(3)	(23)
Accounts payable and accrued expenses	941	(514)	3,671
Wages payable	(220)	(500)	
Net cash used in operating activities	(2,788)	(5,035)	(65,134)
Cash flows provided by investing activities:			
Purchase of property and equipment		(9)	(883)
Payback of loan by a company officer	253		
Net cash used in investing activities	253	(9)	(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

Net proceeds from issuance of convertible debentures and warrants	9,214		9,214
Treasury stock	(346)		(346)
Proceeds from issuance of debt			371
Net proceeds from recapitalization			6,271
Net proceeds from warrants and options exercised	4		12,998
Net cash from financing activities	8,872		85,441
Net increase (decrease) in cash	6,337	(5,044)	19,424
Cash and equivalents at beginning of period	13,087	30,567	
Cash and equivalents at end of period	$ 19,424	$ 25,523	$ 19,424

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 (Cont.)
(Unaudited)

All numbers in thousands

	3 months ended March 31,		Period from Inception (Aug. 15, 1994) to Mar. 31, 2003
	2003	2002	
Supplemental Disclosure of Cash Flow Information:			
Interest Paid	$	$	$ 50
Supplemental Disclosure of Non-Cash Financing Activities:			
Conversion of debt to equity			371
Warrants issued to consultants in lieu of cash, no vesting			559
Warrants issued in lieu of cash, commissions on private placement			733
Warrants issued in connection with convertible debentures	371		371

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

NOTES TO FINANCIAL STATEMENTS

(UNAUDITED)

1. Basis of Presentation

The information at March 31, 2003, and for the three-month periods ended March 31, 2003 and 2002, 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, 2002, which was filed with the United States Securities and Exchange Commission on March 14, 2003.

Accounting for Stock-Based Compensation

During 1995, the Financial Accounting Standards Board issued SFAS 123, Accounting for Stock-Based Compensation, which defines a fair-value-based method of accounting for stock compensation plans. However, it also allows an entity to continue to measure compensation cost related to stock compensation plans using the method of accounting prescribed by the Accounting Principles Board Opinion No. 25 (APB 25), Accounting for Stock Issued to Employees. Entities electing to follow APB 25 must make pro forma disclosures of net income, as if the fair-value-based method of accounting defined in SFAS had been applied.

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If the Company had accounted for stock options issued to employees and directors in accordance with SFAS 123, the Company s net loss would have been reported as follows (in thousands, except per share amounts):

	Three Months ended March 31,	
	2003	2002
Net loss - As reported	$ (5,197)	$ (4,218)
Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards	(2,316)	(5,237)
Net loss - Pro forma	$ (7,513)	$ (9,455)
Basic and diluted net loss per share As reported	$ (0.40)	$ (0.33)
Basic and diluted net loss per share Pro forma	$ (0.58)	$ (0.73)

2. Other Agreements and Commitments

Convertible Debentures

On February 25, 2003, we completed a private placement in which we issued $10.0 million aggregate principal amount of three-year convertible debentures (debentures), bearing interest at 7.5% per year, and warrants to purchase 701,760 shares of common stock. The debentures are convertible into common stock at a price of $5.70 per share, which represented a premium to the average price of our common stock over several days prior to the closing. The conversion price of the debentures is subject to limited anti-dilution adjustments under certain circumstances. Warrants to purchase up to 350,880 shares of common stock are exercisable at a price per share of $6.17, subject to adjustment, and warrants to purchase up to 350,880 shares of common stock are exercisable at a price per share of $6.71, subject to adjustment. The warrants are exercisable until February 25, 2007.

In connection with the issuance of the debentures and warrants, the Company recorded approximately $3.5 million related to the beneficial conversion feature and approximately $3.0 million for the detachable warrants on the debentures. The total amount of the deemed discount on the debentures as a result of the warrant issuance and the beneficial conversion feature amounts to $6.5 million. The beneficial conversion feature and warrant value (deemed discount) will be amortized over the term of the debentures such that, by the time of expiration, total debt outstanding will be $10.0 million.

The Company incurred issuance costs of approximately $1.2 million, representing cash obligations of $0.8 million and the Black-Scholes value of approximately $0.4 million of a warrant issued to the placement agent to acquire an aggregate of 73,684 shares of common stock at an exercise price of $5.99. This warrant is exercisable from August 25, 2003 through February 25, 2008. The issuance costs were deferred and will be amortized as interest expense over the term of the debentures.

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The total amortization costs for the deemed discount and issuance costs were $0.2 million for the period ending March 31, 2003.

The debentures mature on February 25, 2006. We are required to make quarterly interest payments on the debentures while they remain outstanding. We are entitled to issue common stock, in lieu of cash, as payment of interest on the debentures, subject to certain limitations. If our stock is trading below certain price levels when interest payments on the debentures are due, we will not be permitted to issue shares of common stock in lieu of interest on the debentures unless we have first obtained stockholder approval. We are entitled to force conversion of the debentures into common stock in the event our common stock price exceeds $14.25 per share for 15 consecutive trading days or in the event we complete a public offering of our common stock of at least $20.0 million at a price equal to at least $11.40 per share.

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. This cost was expensed in the third quarter of 2002. We elected to make such payments in equity and have issued a total of 168,921 shares of our common stock in complete satisfaction of this requirement (of which 118,921 were issued in the quarter ended March 31, 2003). We may also make additional milestone and royalty payments to Pharmadigm if we meet specified development and commercialization milestones for products covered by the patents. The principal patents licensed under the agreement, originally licensed to Pharmadigm from the University of Utah, relate to inventions by Dr. Raymond Daynes and Dr. Barbara A. Areneo. Dr. Daynes is currently a scientific consultant to Hollis-Eden.

3. Accounting Treatment for Other Transactions

On February 28, 2003, we issued 50,000 shares of unregistered common stock to Humanetics Corporation as a milestone payment pursuant to the license agreement entered into in January 2000 with Humanetics Corporation. This resulted in a non-cash charge of $281,000 to Research and Development.

In March 2003, upon the expiration of a warrant to a director to purchase up to 50,000 shares of common stock at an exercise price of $20.50 per share, we issued a three-year warrant to purchase up to 250,000 shares of common stock at an exercise price of $10.00 per share to a director. A non-cash charge of $802,500 was expensed to General and Administrative.

In February 2003, we issued stock options to an officer and a director that resulted in a non-cash charge of $501,600.

In March 2003, we issued 13,500 stock options to a director for consulting services in lieu of cash. This resulted in a non-cash charge of $60,000.

In March 2003, we repurchased 59,000 shares of our common stock at a cost of $5.87 per share from an officer. Most of the proceeds were used to repay an outstanding loan to that executive officer.

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

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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, 2002.

General

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 other conditions resulting from 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 as a hormone replacement therapy to reestablish balance to the immune system 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 we increase expenditures on research and development and begin to allocate significant and increasing resources to clinical testing and other activities. 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 (the Merger), 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 March 31, 2003. We have devoted substantially all of our resources to the payment of research and development expenses, licensing fees plus general and administrative expenses. From inception until March 31, 2003, we have incurred expenses of approximately $59.3 million in research and development and $34.7 million in general and administrative expenses, which have been partially offset by $7.4 million in net other income, resulting in a loss of $86.6 million for the period.

Research and development expenses were $2.6 million and $2.9 million for the three-month periods ended March 31, 2003 and 2002, respectively. The research and development expenses relate primarily to the ongoing development, preclinical testing, and clinical trials for our investigational drug candidates. The decrease in research and development expenses was due mainly to reduced preclinical and clinical trial activities after streamlining our operations and focusing our research and development expenditures during the second half of 2002.

General and administrative expenses were $2.3 million and $1.4 million for the three-month periods ended March 31, 2003 and 2002, respectively. The general and administrative expenses relate to salaries and benefits, facilities, legal, investor relations, insurance and travel. Included in the three-month period ended March 31, 2003 was $1.4 million in non-cash charges related to the issuance of a warrant to a director and issuance of stock options to an officer and a director. Included in the three-month period ended March 31, 2002 was $0.2 million in non-cash charges related to the issuance of a warrant to a consultant. The increase in general and administrative expenses was due to the non-cash expenses described above. Excluding non-cash charges, general and administrative expenses decreased by $0.3 million for the comparable three-month periods

Other income (expense) was ($263,000) and $116,000 for the three-month periods ended March 31, 2003 and 2002, respectively. Included in the three-month period ended March 31, 2003 was interest

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expense of $240,000 in the form of non-cash amortization of the deemed discount on the convertible debenture and the deferred issuance costs. Interest expense on the convertible debentures was $71,000 in the three-month period ended March 31, 2003. Interest income was $48,000 and $137,000 for the three-month periods ended March 31, 2003 and 2002, respectively. The decline in interest income is due to lower interest rates and 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 warrants, from which we received gross proceeds of $20 million. During January 1999, we completed two private placements of common stock raising 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.

On February 25, 2003, we completed a private placement in which we issued $10.0 million aggregate principal amount of three-year convertible debentures, bearing interest at 7.5% per year, and warrants to purchase 701,760 shares of common stock. The debentures are convertible into common stock at a price of $5.70 per share, which represented a premium to the average price of our common stock over several days prior to the closing. The conversion price of the debentures is subject to limited anti-dilution adjustments under certain circumstances. Warrants to purchase up to 350,880 shares of common stock are exercisable at a price per share of $6.17, subject to adjustment, and warrants to purchase up to 350,880 shares of common stock are exercisable at a price per share of $6.71, subject to adjustment. The warrants are exercisable until February 25, 2007.

The debentures mature on February 25, 2006. We are required to make quarterly interest payments on the debentures while they remain outstanding. We are entitled to issue common stock, in lieu of cash, as payment of interest on the debentures, subject to certain limitations. If our stock is trading below certain price levels when interest payments on the debentures are due, we will not be permitted to issue shares of common stock in lieu of interest on the debentures unless we have first obtained stockholder approval. We are entitled to force conversion of the debentures into common stock in the event our common stock price exceeds $14.25 per share for 15 consecutive trading days or in the event we complete a public offering of our common stock of at least $20.0 million at a price equal to at least $11.40 per share.

Our net proceeds from the sale of the debentures were approximately $9.2 million, after the payment of $800,000 as fees and expenses relating to the offering. In addition, in connection with the offering, we issued to our placement agent a warrant to purchase 73,684 shares of our common stock having an exercise price of $5.99 per share. This warrant is exercisable from August 25, 2003 through February 25, 2008.

A summary of our contractual obligations as of March 31, 2003 is as follows (in thousands):

	Payments Due by Period				
Contractual Obligations	**Total**	**1 Year or Less**	**2 to 3 Years**	**4 to 5 Years**	**After 5 Years**
Operating Leases	$ 1,259	$ 837	$ 422	$	$
Convertible Debentures	10,000		10,000		
Total	$ 11,259	$ 837	$ 10,422	$	$

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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. In addition, because of our recent debt financing, we will also require liquidity to service our debt obligations. 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. 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 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. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We may not be successful in raising necessary funds.

Our future capital requirements will 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, effective commercialization, marketing activities and other arrangements. Our future capital requirements will also depend on whether our debentures are converted into shares of common stock prior to their maturity and whether we are able to pay accrued interest under the debentures in shares of our common stock. We expect to continue to incur increasing negative cash flows and net losses for the foreseeable future. We intend to seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

At March 31, 2003, our investment portfolio included only cash and money market accounts and does not contain 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.

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Item 2. Changes in Securities

On February 15, 2003, we issued 118,921 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.

On February 25, 2003, we completed a private placement in which we issued $10.0 million aggregate principal amount of three-year convertible debentures, bearing interest at 7.5% per year, and warrants to purchase 701,760 shares of common stock. The debentures are convertible into common stock at a price of $5.70 per share, which represented a premium to the average price of our common stock over several days prior to the closing. The conversion price of the debentures is subject to limited anti-dilution adjustments under certain circumstances. Warrants to purchase up to 350,880 shares of common stock are exercisable at a price per share of $6.17, subject to adjustment, and warrants to purchase up to 350,880 shares of common stock are exercisable at a price per share of $6.71, subject to adjustment. The warrants are exercisable until February 25, 2007. In addition, in connection with the offering, we issued to our placement agent a warrant to purchase 73,684 shares of our common stock having an exercise price of $5.99 per share. This warrant is exercisable from August 25, 2003 through February 25, 2008.

On February 28, 2003, we issued 50,000 shares of unregistered common stock to Humanetics Corporation as a milestone payment pursuant to the license agreement entered into in January 2000 with Humanetics.

In March 2003, upon the expiration of a warrant to a director to purchase up to 500,000 shares of common stock at an exercise price of $20.50 per share, we issued a three-year warrant to purchase up to 250,000 shares of common stock at an exercise price $10.00 per share to a director.

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

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

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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 through 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 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 either commercialized products, or have large 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

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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.

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. 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.

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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 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

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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;
- 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.

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.

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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.

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 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.

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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 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

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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.

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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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:

On February 26, 2003, we filed a report on Form 8-K dated February 25, 2003 with the SEC announcing that we completed a private placement of convertible debentures and warrants to purchase shares of our common stock.

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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: May 11, 2003 By: /s/ DANIEL D. BURGESS

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

Dated: May 11, 2003 By: /s/ ROBERT W. WEBER

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

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Certification

I, Richard B. Hollis, certify that:

1. I have reviewed this report on Form 10-Q of Hollis-Eden Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this report (the Evaluation Date); and

c) presented in this report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: May 11, 2003

By: /s/ RICHARD B. HOLLIS

Richard B. Hollis
Chairman and Chief Executive Officer
(Principal Executive Officer)

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Certification

I, Daniel B. Burgess, certify that:

1. I have reviewed this report on Form 10-Q of Hollis-Eden Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this report (the Evaluation Date); and

c) presented in this report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: May 11, 2003

By: /s/ Daniel D. Burgess

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