

HOLLIS EDEN PHARMACEUTICALS INC /DE/

Form 10-Q

November 08, 2004

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## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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### Form 10-Q

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(Mark one)

**Quarterly Report Pursuant to Section 13 or 15 (d) Of the Securities Exchange Act of 1934**

For the Quarterly Period Ended September 30, 2004

or

**Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_ .

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## HOLLIS-EDEN PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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DELAWARE

(State or other jurisdiction of incorporation)

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**000-24672**  
(Commission File No.)

**13-3697002**  
(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**

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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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES  NO

As of November 3, 2004 there were 19,285,095 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, 2004

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**Table of Contents****Part I. Financial Information****Item I. Financial Statements****Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Balance Sheets****(Unaudited)****All numbers in thousands (except par value)**

	<u>Sept. 30, 2004</u>	<u>Dec. 31, 2003</u>
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 68,177	\$ 84,852
Prepaid expenses	491	134
Deposits	19	27
Receivable from related party		18
Estimated revenue in excess of billings	12	
	<u>68,699</u>	<u>85,031</u>
Property and equipment, net of accumulated depreciation of \$566 and \$434, respectively	926	282
Deposits	87	68
	<u>69,712</u>	<u>85,381</u>
<b>Total assets</b>	<b>\$ 69,712</b>	<b>\$ 85,381</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY:</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,183	\$ 3,329
	<u>3,183</u>	<u>3,329</u>
<b>Total current liabilities</b>	<b>3,183</b>	<b>3,329</b>
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; 19,340 and 19,272 shares issued, respectively	193	193
Paid-in capital	190,138	189,296
Cost of treasury stock (59 shares)	(346)	(346)
Deficit accumulated during development stage	(123,456)	(107,091)
	<u>193</u>	<u>193</u>

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Total stockholders' equity	66,529	82,052
Total liabilities and stockholders' equity	\$ 69,712	\$ 85,381

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

**Table of Contents****Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Statements of Operations****(Unaudited)****All numbers in thousands, except per share amounts**

	<u>3 months ended Sept. 30,</u>		<u>9 months ended Sept. 30,</u>		<u>Period from</u> <u>Inception</u> <u>(Aug.15, 1994)</u>
	<u>2004</u>	<u>2003</u>	<u>2004</u>	<u>2003</u>	<u>to Sept. 30,</u> <u>2004</u>
<b>Revenue:</b>					
Contract R&D revenue	\$		\$ 63		\$ 63
<b>Total revenue</b>			<b>63</b>		<b>63</b>
<b>Operating expenses:</b>					
<b>Research and development:</b>					
R&D operating expenses	\$ 4,259	\$ 2,619	\$ 12,348	\$ 6,665	\$ 74,172
R&D costs related to common stock, option, & warrant grants for collaborations		10	3	312	5,667
<b>General and administrative:</b>					
G&A operating expenses	1,483	1,197	4,605	3,325	32,079
G&A costs related to common stock, option, & warrant grants	71	81	95	2,160	12,302
<b>Total operating expenses</b>	<b>5,813</b>	<b>3,907</b>	<b>17,051</b>	<b>12,462</b>	<b>124,220</b>
<b>Other income (expense):</b>					
Loss on disposal of assets	(9)		(9)	(2)	(32)
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures		(6,414)		(7,627)	(7,627)
Interest income	236	74	632	173	8,748
Interest expense		(81)		(338)	(388)
<b>Total other income (expense), net</b>	<b>227</b>	<b>(6,421)</b>	<b>623</b>	<b>(7,794)</b>	<b>701</b>
<b>Net loss</b>	<b>\$ (5,586)</b>	<b>\$ (10,328)</b>	<b>\$ (16,365)</b>	<b>\$ (20,256)</b>	<b>\$ (123,456)</b>
<b>Net loss per share-basic and diluted</b>	<b>\$ (0.29)</b>	<b>\$ (0.66)</b>	<b>\$ (0.85)</b>	<b>\$ (1.45)</b>	
Weighted average number of common shares outstanding-basic and diluted	19,283	15,642	19,261	14,002	

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

**Table of Contents****Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Statements of Cash Flows****(Unaudited)****All numbers in thousands**

	<u>9 months ended Sept. 30,</u>		<u>Period from</u> <u>Inception</u>
			<u>(Aug. 15, 1994)</u>
			<u>to Sept. 30,</u>
	<u>2004</u>	<u>2003</u>	<u>2004</u>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (16,365)	\$ (20,256)	\$ (123,456)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation	150	90	727
Disposal of assets	9	2	38
Amortization of deemed discount on convertible debentures		6,470	6,470
Amortization of deferred issuance cost		1,157	1,157
Common stock issued for the company 401k plan	88	204	607
Common stock issued as consideration for amendments to the license / finance agreements			67
Common stock issued in lieu of cash, note repayment	60		60
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, interest and services	98	535	2,790
Common stock issued as consideration for In Process R&D	568		2,569
Expense related to warrants issued as consideration to consultants		1,518	4,113
Expense related to warrants issued to a director for successful closure of merger			570
Expense related to stock options issued		561	5,718
Deferred compensation expense related to options issued			1,210
<b>Changes in assets and liabilities:</b>			
Prepaid expenses	(356)	(68)	(491)
Deposits	(12)		(106)
Receivable from related party	18		
Other receivable		10	
Estimated revenue in excess of billings	(12)		(12)
Accounts payable and accrued expenses	(146)	(99)	3,828
<b>Net cash used in operating activities</b>	<u>(15,900)</u>	<u>(9,876)</u>	<u>(92,293)</u>
<b>Cash flows provided by (used in) investing activities:</b>			
Purchase of property and equipment	(803)	(4)	(1,691)
Payback of loan by a company officer		253	
	<u></u>	<u></u>	<u></u>



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Net cash provided by (used in) investing activities	(803)	249	(1,691)
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		13,812	125,242
Net proceeds from issuance of convertible debentures and warrants		9,214	9,214
Purchase of treasury stock		(346)	(346)
Proceeds from issuance of debt			371
Net proceeds from recapitalization			6,271
Net proceeds from warrants and options exercised	28	3,580	17,305
Net cash from financing activities	28	26,260	162,161
Net increase (decrease) in cash	(16,675)	16,633	68,177
Cash and equivalents at beginning of period	84,852	13,087	
Cash and equivalents at end of period	\$ 68,177	\$ 29,720	\$ 68,177

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

**Table of Contents****Hollis-Eden Pharmaceuticals, Inc.****(A Development Stage Company)****Statements of Cash Flows (Cont.)****(Unaudited)****All numbers in thousands**

	<u>9 months ended Sept. 30,</u>		<u>Period from</u>
			<u>Inception</u>
			<u>(Aug. 15, 1994)</u>
			<u>to Sept. 30,</u>
	<u>2004</u>	<u>2003</u>	<u>2004</u>
<b>Supplemental Disclosure of Cash Flow Information:</b>			
Interest Paid	\$	\$ 338	\$ 388
<b>Supplemental Disclosure of Non-Cash Financing Activities:</b>			
Conversion of debt to equity		10,000	10,371
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 September 30, 2004, and for the three-month and nine-month periods ended September 30, 2004 and 2003, 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

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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, 2003, which was filed with the United States Securities and Exchange Commission on March 15, 2004.

### *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 (loss), as if the fair-value-based method of accounting defined in SFAS 123 had been applied.

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In December 2002, the FASB issued SFAS No. 148 Accounting for Stock-Based Compensation Transition and Disclosure, which amended SFAS No. 123, Accounting for Stock-Based Compensation. The new standard provides alternative methods of transition for a voluntary change to the fair-value-based method of accounting for stock-based employee compensation. Additionally, the standard amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. This standard is effective for financial statements for the year ended December 31, 2002. In compliance with SFAS No. 148, the Company has elected to continue to follow the intrinsic value method in accounting for its stock-based employee compensation plan as defined by Accounting Principles Board Opinion No. 25 and has made the applicable pro forma disclosures below.

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 September 30,		Nine Months ended September 30,	
	2004	2003	2004	2003
Net loss - As reported	\$ (5,586)	\$ (10,328)	\$ (16,365)	\$ (20,256)
Add: Stock-based employee compensation expense included in reported net loss, net of tax	-0-	-0-	-0-	122
Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards	(1,300)	(880)	(3,809)	(3,960)
Net loss - Pro forma	\$ (6,886)	\$ (11,208)	\$ (20,174)	\$ (24,094)
Basic and diluted net loss per share - As reported	\$ (0.29)	\$ (0.66)	\$ (0.85)	\$ (1.45)
Basic and diluted net loss per share - Pro forma	\$ (0.36)	\$ (0.72)	\$ (1.05)	\$ (1.72)

**2. Other Agreements and Commitments***Congressional Pharmaceutical Corporation*

In February 2004, the Company acquired Congressional Pharmaceutical Corporation (CPC) and replaced CPC as the exclusive licensee to certain intellectual property rights held by the University of Chicago. These intellectual property rights consist of a series of patents and patent applications that relate to discoveries made by David J. Grdina, Ph.D., Professor of Radiation and Cellular Oncology at the University of Chicago. The patented technology covers a series of compounds that have the potential to protect against DNA mutations that can occur as a result of radiation injury or chemotherapy. To acquire CPC, the Company issued 44,227 shares of common stock at a price of \$12.85 to the former stockholders of CPC valued at approximately \$568,500 in accordance with Emerging Issues Task Force No. 99-12. An additional 4,362 shares of common stock at a price of \$13.76 were issued to two shareholders of CPC in full payment of an existing CPC loan of approximately \$60,000. In addition, if the Company achieves certain development milestones, it will be required to issue additional shares of our common stock to the former stockholders of CPC. In the event all of the milestones are achieved, the total number of additional shares that the Company would be required to issue to the former stockholders of CPC is 275,000, more than half of which would be issued only upon FDA



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approval of CPC's product. Furthermore, upon regulatory approval and commercialization of products covered by the licensed intellectual property, the Company may be required to pay royalties to the former stockholders of CPC and the University of Chicago. From its inception, CPC has not developed commercial products or generated sales. The assets consist solely of intellectual property rights. FASB interpretation #4

Applicability of FASB Statement #2 to Business Combinations Accounted for by the Purchase Method states costs assigned to assets to be used in a particular research and development project and that have no alternative future use shall be charged to expense at the date of the consumption of this combination. Since CPC's technology is in the early stage of development, it has been expensed as in-process research and development. The pro-forma presentation of the CPC acquisition as if it had occurred at the beginning of both periods presented, would have had an immaterial impact to our statement of operations.

Following the acquisition, Dr. Grdina agreed to an exclusive one year consulting arrangement with the Company in the fields of hematopoiesis and radiation and chemotherapy exposure.

### *Study Funding Agreement*

During the second quarter of 2004, the Company began performing on a Study Funding Agreement entered into with Cystic Fibrosis Foundation Therapeutics, Inc. ( CFFT ). The agreement commits CFFT to provide funding towards a multi-center clinical trial of one of the Company's compounds in development. In accordance with the agreement, CFFT will provide a total of \$1.7 million to be paid based on the Company's completion of certain agreed upon events. The agreement also contains a provision indicating that upon termination of this agreement by either party, CFFT shall pay the Company for all work performed through the date of termination, plus reasonable costs of bringing the study to an orderly close.

In return for this funding, the Company has agreed to pay CFFT a minimum royalty over a specified period following regulatory approval in the United States of America. Additional compensation is due to CFFT if net sales of this compound exceed a specified amount over a period of time.

Revenue is recognized under this agreement on a percentage of completion method. During the nine months ended September 30, 2004, the Company recognized \$63,000 in revenues. Additionally, the Company completed the first agreed upon event, which triggered a payment of \$51,000. This results in revenue recognition of \$12,000 in excess of billings as of September 30, 2004.

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

*The following discussion contains forward-looking statements that 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, 2003. This discussion and analysis should be read in conjunction with the financial statements and notes included elsewhere in this report.*

### **General**

Hollis-Eden Pharmaceuticals, Inc., a development-stage pharmaceutical company, is engaged in the discovery, development and commercialization of products for the treatment of diseases and disorders in which the body is unable to mount an appropriate immune response. Our initial development efforts target radiation- and chemotherapy-induced immune suppression and immune dysregulation caused by infectious diseases such as HIV, malaria and tuberculosis. Our initial technology development efforts are primarily 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 immune regulating hormones (IRHs) can be used to reestablish host immunity in situations of dysregulation.

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We have been unprofitable since our inception, and we may continue 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 if and when 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**

In the second quarter of 2004, we generated, for the first time, a small amount of revenue. This revenue resulted from providing research and development services under our Study Funding Agreement with Cystic Fibrosis Foundation Therapeutics, Inc. We have devoted substantially all of our resources to the payment of research and development expenses and general and administrative expenses. From inception until September 30, 2004, we have generated approximately \$63,000 in revenues and \$0.7 million in net other income consisting of \$8.7 million in interest income, which was partially offset by \$7.6 million in deemed discount expense and \$0.4 million in interest expense. We have incurred expenses of approximately \$79.8 million in research and development and \$44.4 million in general and administrative expenses. The combination of these resulted in a net loss of \$123.5 million for the period from inception until September 30, 2004.

Contract revenues of \$63,000 were recorded in the second quarter of 2004. The contract revenues consist of reimbursable expenses related to our agreement with Cystic Fibrosis Foundation Therapeutics, Inc.

Research and development expenses were approximately \$4.3 million and \$12.4 million for the three-month and nine-month periods ended September 30, 2004, compared to \$2.6 million and \$7.0 million for the same periods in 2003. The 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 was due mainly to the growth in our laboratory operations, preclinical activities, consulting and personnel as well as our investment in CPC, which was expensed as in-process R&D in the first quarter of 2004. We expect research and development expenses to increase in 2004, compared to 2003, as our products move into the more expensive later stages of development.

General and administrative expenses were \$1.6 million and \$4.7 million for the three-month and nine-month periods ended September 30, 2004, compared to \$1.3 million and \$5.5 million for the same periods in 2003. The general and administrative expenses relate to salaries and benefits, facilities, legal, accounting/auditing, public and investor relations, consultants, insurance and travel. Included in the nine-month period ended September 30, 2003 was \$0.7 million in non-cash charges related to the issuance of a warrant and a change in the terms of a warrant issued to a placement agent. Additionally, included in the nine-month period ended September 30, 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. The decrease in general and administrative expenses was due mainly to the non-cash expenses in 2003 described above. Excluding non-cash charges, general and administrative expenses increased by \$0.3 million and \$1.3 million for the comparable three-month and nine-month periods. The increase is due mainly to consulting, travel and



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accounting/audit fees, as well as increases in personnel and recruiting. We expect general and administrative expenses to increase in 2004, compared to 2003, as a result of the increased costs of compliance with new audit regulations, including Section 404 of the Sarbanes-Oxley Act of 2002, and costs associated with preparing for the potential launch of our products.

Other income (expense) was \$0.2 million and \$0.6 million for the three-month and nine-month periods ended September 30, 2004, compared to (\$6.4) million and (\$7.8) million for the same periods in 2003. Included in the three-month and nine-month periods ended September 30, 2003 was interest expense of \$6.4 million and \$7.6 million, respectively, in the form of non-cash amortization of the deemed discount on the converted debentures and the related deferred issuance costs. Interest expense on the converted debentures was \$0.1 million and \$0.3 million in the three-month and nine-month periods ended September 30, 2003, respectively. Interest income was \$0.2 million and \$0.6 million for the three-month and nine-month periods ended September 30, 2004, compared to \$0.1 and \$0.2 million for the same periods in 2003. The increase in interest income is due to higher average balances of cash and cash equivalents.

**Liquidity and Capital Resources**

We have financed our operations since inception primarily through the sale of shares of common stock. In April 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 February 2003, we completed a private placement of convertible debentures and warrants, from which we received gross proceeds of \$10.0 million. In June 2003, we completed a private placement of common stock and warrants, from which we received gross proceeds of \$14.7 million. In October 2003, we completed a public offering of our common stock from which we received \$62.5 million in gross proceeds. In addition, we have received a total of \$17.3 million from the exercise of warrants and stock options since inception.

On June 20, 2003, convertible debentures with a face value of \$0.5 million were converted into 87,720 shares of our common stock, leaving a \$9.5 million aggregate principal amount of convertible debentures outstanding. We became entitled to convert the outstanding debentures into common stock as of the close of market on Friday, August 8, 2003, at which point the volume weighted average price of our common stock had exceeded \$14.25 for 15 consecutive trading days. On August 11, 2003, the remaining aggregate principal amount of convertible debentures with a face value of \$9.5 million were converted into 1,666,680 shares of our common stock with a value of \$5.70 per share.

A summary of our current contractual obligations as of September 30, 2004 is as follows (in thousands):

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less than one year</u>	<u>One to three years</u>	<u>Three to five years</u>	<u>More than five years</u>
Operating Leases	\$ 2,320	\$ 802	\$ 1,319	\$ 199	

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Our operations to date have consumed substantial capital without generating any product 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. With the possible exception of sales of our investigational product NEUMUNE, which is being developed as a treatment for radiation injury, we do not expect to generate revenue from our

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drug candidates for the foreseeable future, and our ability to meet our cash obligations as they become due and payable may 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 well into 2006. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We may 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. We may incur increasing negative cash flows and net losses for the foreseeable future. We may 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 September 30, 2004, 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**

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic reports filed with the Securities and Exchange Commission ( SEC ) is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and that such information is accumulated and communicated to our management as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Operating Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures during the quarter ended September 30, 2004. Based on that evaluation, our management, including our Chief Executive Officer and Chief Operating Officer and Chief Financial Officer, concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) were effective and that there has been no change in our internal control over financial reporting during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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### **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. Unregistered Sales of Equity Securities and Use of Proceeds**

On July 1, 2004, the Company entered into an agreement with a consulting firm for services. The Company agreed to issue a two-year warrant to this firm to purchase up to 8,000 shares of common stock at an exercise price of \$11.75 per share. The warrant vests 2,000 shares immediately, with the remaining shares vesting at a rate of 2,000 shares per month until such warrant is fully vested. If the agreement is terminated, vesting of the warrant will terminate immediately.

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 recipient represented its 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 transactions.

The Company made no repurchases of its securities during the quarter ended September 30, 2004.

#### **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**

*In evaluating our business, 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, as well as our other public filings with the Securities and Exchange Commission. Any of the following risks could materially adversely affect our business, financial condition, results of operations and prospects.*

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

Our principal development efforts are currently centered around immune regulating hormones, a class of drug candidates which we believe shows promise for the treatment of a variety of infectious diseases and immune system and metabolic disorders. However, all drug candidates require U.S. FDA and foreign government approvals before they can be commercialized. These regulations change from time to time and new regulations may be adopted. None of our drug candidates has been approved for commercial sale. We may incur significant additional operating losses over the next several years as we fund development, clinical testing and other expenses while seeking regulatory approval. While limited clinical trials of our drug candidates have been conducted to date, significant additional trials are required, and we may not be able to demonstrate that these drug candidates are safe or effective. If we are unable to demonstrate the safety and effectiveness of a particular drug candidate to the satisfaction of regulatory authorities, the drug candidate will not obtain required government approval. Some of the factors that may affect whether government approval is obtained include adverse results from toxicology studies, human safety studies, efficacy studies, stability studies or pharmacokinetic studies, as well as unanticipated manufacturing and formulation complications or delays. If we do not receive FDA or foreign approvals for our products, we will not be able to sell our products and will not generate revenues. If we receive regulatory approval of a product, such approval may impose limitations on the indicated uses for which we may market the product, which may limit our ability to generate significant revenues.

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

We have experienced significant operating losses to date because of the substantial expenses we have incurred to acquire and fund development of our drug candidates. We have generated a small amount of contract revenue but have never commercially introduced a product. Our accumulated deficit was approximately \$123.5 million as of September 30, 2004. Our net losses for fiscal years 2003, 2002 and 2001 were \$25.7 million, \$17.5 million and \$15.8 million, respectively. Many of our research and development programs are at an early stage. Potential drug candidates are subject to inherent risks of failure. These risks include the possibilities that no drug candidate will be found safe or effective, meet applicable regulatory standards or receive the necessary regulatory clearances. Even safe and effective drug candidates may never be developed into commercially successful drugs. If we are unable to develop safe, commercially viable drugs, we may never achieve profitability. If we become profitable, we may not remain profitable.

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

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

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

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

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.

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

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

As of September 30, 2004, our cash and cash equivalents totaled approximately \$68.2 million. Based on our current plans, we believe these financial resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements at least well into 2006. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We may require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

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

any available additional financing may not be adequate; and

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

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

We own or have obtained a license to over 100 issued U.S. and foreign patents and over 100 pending U.S. and foreign patent applications. Our success will depend in part on our ability to enforce our existing patents, 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, we may not be able to obtain any required license on favorable terms, if at all. 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.

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 than we

could obtain from arm s-length negotiation and would have the effect of reducing our revenues.

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

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

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

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

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

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

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

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

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

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

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

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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;

new communications from regulatory agencies about how to best conduct these studies; 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 IMMUNITIN, and may produce other compounds for us in the future. Manufacturers producing our drug candidates must follow current Good Manufacturing Practices regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to the Good Manufacturing Practices regulations and cannot be brought up to such a standard, we will be required to find alternative manufacturers that do conform. This may be a long, difficult and expensive process, and may delay our ability to receive FDA or foreign regulatory approval of our products.

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

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

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

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

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

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and retain the qualified personnel needed for our business. Loss of the services of or the failure to recruit key scientific and technical personnel could adversely affect our business, operating results and financial condition.

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

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

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

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

biological or medical discoveries by competitors;

public concern about the safety of our drug candidates;

delays in the conduct or analysis of our clinical trials;

unfavorable results from clinical trials;

unfavorable developments concerning patents or other proprietary rights; or

unfavorable domestic or foreign regulatory developments;

may have the effect of temporarily or permanently driving down the price of our common stock. In addition, the stock market from time to time experiences extreme price and volume fluctuations which particularly affect the market prices for emerging and life sciences companies, such as ours, and which are often unrelated to the operating performance of the affected companies. For example, our stock price has ranged from \$5.00 to \$36.25 between January 1, 2003 and October 19, 2004.

These broad market fluctuations may adversely affect the ability of a stockholder to dispose of his shares at a price equal to or above the price at which the shares were purchased. In addition, in the past, following periods of volatility in the market price of a company's securities, securities

class-action litigation has often been instituted against that company. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which could materially adversely affect our business, financial condition and results of operations.

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

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

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

Assuming that outstanding warrants and options have not been exercised, Richard B. Hollis, our Chief Executive Officer, owns approximately 14% of our outstanding common stock as of September 30, 2004. Assuming that Mr. Hollis exercises all of his outstanding warrants and options that vest within 60 days of September 30, 2004, Mr. Hollis would beneficially own approximately 20% of our outstanding common stock. As a result, Mr. Hollis may be able to significantly influence the management of Hollis-Eden and all matters requiring stockholder approval, including the election of directors. Such concentration of ownership may also have the effect of delaying or preventing a change in control of Hollis-Eden.

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

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

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

Our charter documents give our board of directors the authority to issue series of preferred stock without a vote or action by our stockholders. The board also has the authority to determine the terms of preferred stock, including price, preferences and voting rights. The rights granted to holders of preferred stock may adversely affect the rights of holders of our common stock. For example, a series of preferred stock may be granted the right to receive a liquidation preference—a pre-set distribution in the event of 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.

## **Item 6. Exhibits**



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

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
31.1	Rule 13a-14(a)/15d-14(a) Certification of Richard B. Hollis.
31.2	Rule 13a-14(a)/15d-14(a) Certification of Daniel D. Burgess.
32.1	Section 1350 Certifications of Richard B. Hollis and Daniel D. Burgess.

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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 thereunto duly authorized.

HOLLIS-EDEN PHARMACEUTICALS, INC.

Dated: November 4, 2004

By: /s/ Daniel D. Burgess

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

Dated: November 4, 2004

By: /s/ Robert W. Weber

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