

HOLLIS EDEN PHARMACEUTICALS INC /DE/

Form 10-Q

May 10, 2005

Table of Contents

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark one)

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

For the Quarterly Period Ended March 31, 2005

or

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

For the transition period from _____ to _____ .

HOLLIS-EDEN PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of incorporation)

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-Q

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

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 May 4, 2005 there were 19,297,713 shares of registrant's Common Stock, \$.01 par value, outstanding.

Table of Contents

HOLLIS-EDEN PHARMACEUTICALS, INC.

Form 10-Q

FOR THE QUARTER ENDED MARCH 31, 2005

INDEX

	Page
PART I <u>Financial Information</u>	
Item 1 <u>Financial Statements (Unaudited)</u>	3
<u>Balance Sheets - March 31, 2005 and December 31, 2004</u>	3
<u>Statements of Operations for the Three-Month Periods Ended March 31, 2005 and 2004 and Period from Inception (August 15, 1994) to March 31, 2005</u>	4
<u>Statements of Cash Flows for the Three-Month Periods Ended March 31, 2005 and 2004 and Period from Inception (August 15, 1994) to March 31, 2005</u>	5
<u>Notes to Financial Statements</u>	6
Item 2 <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	7
Item 3 <u>Quantitative and Qualitative Disclosures about Market Risk</u>	10
Item 4 <u>Controls and Procedures</u>	10
PART II <u>Other Information</u>	
Item 1 <u>Legal Proceedings</u>	10
Item 2 <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	10
Item 3 <u>Defaults Upon Senior Securities</u>	10
Item 4 <u>Submission of Matters to a Vote of Security Holders</u>	11
Item 5 <u>Other Information</u>	11
Item 6 <u>Exhibits</u>	18

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

	March 31, 2005	Dec. 31, 2004
	(Unaudited)	
ASSETS:		
Current assets:		
Cash and cash equivalents	\$ 54,198	\$ 61,991
Prepaid expenses	116	176
Deposits	82	44
Receivable from related party	7	
Receivable from other party		9
	<u>54,403</u>	<u>62,220</u>
Total current assets	54,403	62,220
Property and equipment, net of accumulated depreciation of \$526 and \$462, respectively	1,255	961
Receivable from related party	3	
Deposits	61	61
	<u>55,722</u>	<u>63,242</u>
Total assets	\$ 55,722	\$ 63,242
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,288	\$ 5,008
	<u>4,288</u>	<u>5,008</u>
Total current liabilities	4,288	5,008
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, no par value, 10,000 shares authorized; no shares issued and outstanding		
Common stock, \$.01 par value, 50,000 shares authorized; 19,347 issued and 19,288 shares outstanding	193	193
Paid-in capital	190,247	190,235
Cost of treasury stock (59 shares)	(346)	(346)
Deficit accumulated during development stage	(138,660)	(131,848)

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-Q

Total stockholders' equity	51,434	58,234
Total liabilities and stockholders' equity	\$ 55,722	\$ 63,242

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>Three months ended March 31,</u>		<u>Period from</u>
			<u>Inception</u>
			<u>(Aug.15, 1994)</u>
			<u>to March 31,</u>
	<u>2005</u>	<u>2004</u>	<u>2005</u>
Revenue:			
Contract R&D revenue	\$	\$	\$ 63
Total revenue			63
Operating expenses:			
Research and development:			
R&D operating expenses	5,344	4,665	86,082
R&D costs related to common stock, option, & warrant grants for collaborations		3	5,667
General and administrative:			
G&A operating expenses	1,776	1,429	35,904
G&A costs related to common stock, option, & warrant grants	12	9	12,352
Total operating expenses	7,132	6,106	140,005
Other income (expense):			
Loss on disposal of assets			(56)
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures			(7,627)
Interest income	320	205	9,353
Interest expense			(388)
Total other income (expense), net	320	205	1,282
Net loss	\$ (6,812)	\$ (5,901)	\$ (138,660)
Net loss per share-basic and diluted	\$ (0.35)	\$ (0.31)	
Weighted average number of common shares outstanding-basic and diluted	19,288	19,232	

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

	Three months ended March 31,		Period from
	2005	2004	Inception (Aug. 15, 1994) to March 31, 2005
Cash flows from operating activities:			
Net loss	\$ (6,812)	\$ (5,901)	\$ (138,660)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	63	32	856
Disposal of assets			63
Amortization of deemed discount on convertible debentures			6,470
Amortization of deferred issuance cost			1,157
Common stock issued for the company 401k plan			666
Common stock issued as consideration for amendments to the license / finance agreements			67
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, note repayment and services interest, note repayment and services	12	72	2,841
Common stock issued as consideration for In Process R&D		569	2,629
Expense related to warrants issued as consideration to consultants			4,113
Expense related to warrants issued to a director for successful closure of merger			570
Expense related to stock options issued			5,718
Deferred compensation expense related to options issued			1,210
Changes in assets and liabilities:			
Prepaid expenses	60	63	(116)
Deposits	(38)		(143)
Receivable from related party	(10)		(10)
Other receivable	9	(3)	
Accounts payable and accrued expenses	(720)	(260)	4,932
Net cash used in operating activities	(7,436)	(5,428)	(105,789)
Cash flows provided by (used in) investing activities:			
Purchase of property and equipment	(357)	(209)	(2,174)
Net cash provided by (used in) investing activities	(357)	(209)	(2,174)
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			125,242
Net proceeds from issuance of convertible debentures and warrants			9,214
Purchase of treasury stock			(346)

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-Q

Proceeds from issuance of debt			371
Net proceeds from recapitalization			6,271
Net proceeds from warrants and options exercised			17,305
Net cash from financing activities			162,161
Net increase (decrease) in cash	(7,793)	(5,637)	54,198
Cash and equivalents at beginning of period	61,991	84,852	
Cash and equivalents at end of period	\$ 54,198	\$ 79,215	\$ 54,198

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>Three months ended March 31,</u>		<u>Period from Inception (Aug. 15, 1994)</u>
	<u>2005</u>	<u>2004</u>	<u>to March 31, 2004</u>
Supplemental Disclosure of Cash Flow Information:			
Interest Paid	\$	\$	\$ 388
Supplemental Disclosure of Non-Cash Financing Activities:			
Conversion of debt to equity			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

Hollis-Eden Pharmaceuticals, Inc.**(A Development Stage Company)****Notes to Financial Statements****(Unaudited)****1. Basis of Presentation**

The information at March 31, 2005, and for the three-month periods ended March 31, 2005 and 2004, 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 or the Company) Annual Report on Form 10-K for the year ended December 31, 2004, which was filed with the United States Securities and Exchange Commission on March 10, 2005.

Accounting for Stock-Based Compensation

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-Q

The Company has elected to follow Accounting Principles Board Opinion No. 25 (APB 25), *Accounting for Stock Issued to Employees*, and related interpretations in accounting for its employee stock options rather than the alternative fair value accounting provided for under SFAS No. 123, *Accounting and Disclosure for Stock-Based Compensation*. The Company has also adopted the pro forma disclosure requirements of SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123*. In accordance with APB 25, compensation cost relating to stock options granted by the Company is measured as the excess, if any, of the market price of the Company's stock at the date of grant over the exercise price of the stock options. This expense is recognized over the vesting period of the stock options.

Table of Contents

As required by SFAS No. 148 and SFAS No. 123, the Company provides pro forma net income and pro forma net income per common share disclosures for stock-based awards made during the periods presented as if the fair-value-based method defined in SFAS No. 123 had been applied.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options vesting period. The Company's net loss would have been reported as follows (*in thousands, except per share amounts*):

	Three Months ended	
	March 31,	
	2005	2004
Net loss - As reported	\$ (6,812)	\$ (5,901)
Add: Stock-based employee compensation expense included in reported net loss, net of tax		
Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards	(1,207)	(1,167)
Net loss - Pro forma	\$ (8,019)	\$ (7,068)
Basic and diluted net loss per share - As reported	\$ (0.35)	\$ (0.31)
Basic and diluted net loss per share - Pro forma	\$ (0.42)	\$ (0.37)

In December 2004, SFAS No. 123(R), Share-Based Payment, which addresses the accounting for employee stock options, was issued. SFAS 123(R) revises the disclosure provisions of SFAS 123 and supercedes APB Opinion No. 25. SFAS 123(R) requires that the cost of all employee stock options, as well as other equity-based compensation arrangements, be reflected in the financial statements based on the estimated fair value of the awards. This statement is effective for all public entities that file as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. We are currently evaluating the provisions of FAS 123R and its effect on our financial statements. The effect of adopting this statement on the Company's historical statements of operations is reflected on a proforma basis above. The Company has not elected to early implement SFAS 123(R) for the year ended December 31, 2005.

2. Other Agreements and Commitments

None

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

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-Q

following discussion, as well as in the Company's Annual Report on Form 10-K for the year ended December 31, 2004. 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 myelosuppression and immune dysregulation caused by a variety of infections and autoimmune diseases. Our initial technology development efforts are primarily focused on a

Table of Contents

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.

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 devoted substantially all of our resources to the payment of research and development expenses and general and administrative expenses. From inception until March 31, 2005, we have generated approximately \$63,000 in revenues (which resulted from providing research and development services under our Study Funding Agreement with Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT)). We also generated \$1.3 million in net other income consisting of \$9.3 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 \$91.7 million in research and development and \$48.3 million in general and administrative expenses. The combination of these resulted in a net loss of \$138.7 million for the period from inception until March 31, 2005.

Research and development expenses were approximately \$5.3 million and \$4.7 million for the three-month periods ended March 31, 2005 and 2004, respectively. 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 and personnel associated with advancing our lead compound, NEUMUNE, through development. We expect research and development expenses to increase in 2005, compared to 2004, as our products move into the more expensive later stages of development.

General and administrative expenses were \$1.8 million and \$1.4 million for the three-month periods ended March 31, 2005 and 2004, respectively. The general and administrative expenses relate to salaries and benefits, facilities, legal, accounting/auditing, public and investor relations, consultants, insurance and travel. The increase in general and administrative expenses is due mainly to legal and accounting/audit fees, as well as increases in personnel and recruiting. We expect general and administrative expenses to increase in 2005 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 \$0.3 million and \$0.2 million for the three-month periods ended March 31, 2005 and 2004, respectively, comprised entirely of interest income. The increase in interest income is due to higher interest rates in the current period.

Table of Contents**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 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 from 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 in August 2003 and 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 is as follows (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	Less than one year	One to three years	Three to five years	More than five years
Operating Leases	\$ 2,164	\$ 819	\$ 1,319	\$ 26	

We may also be required to make substantial milestone or royalty payments in cash based on the terms of some of our agreements.

Our operations to date have consumed substantial capital without generating any revenues other than the small amount received under the CFFT collaboration in 2004, 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 NEUMUNE product for radiation treatment, 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 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 for at least the next 12 months. 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, whether we receive an advance purchase contract from the U.S. government for NEUMUNE, 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.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures about Market Risk

At March 31, 2005, 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

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Hollis-Eden's management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Exchange Act Rule 13a-15(e) 15d 15(e). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in enabling the Company to record, process, summarize and report information required to be included in the Company's periodic SEC filings within the required time period.

Changes in Internal Control over Financial Reporting

There was no change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

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

The Company made no unregistered sales of securities and repurchases of its securities during the quarter ended March 31, 2005.

Item 3. Defaults upon Senior Securities

None

Table of Contents

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 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 diseases and disorders in which the body is unable to mount an appropriate immune response. 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 have been approved for commercial sale. We may incur significant additional operating losses over the next several years as we fund development, clinical testing and other expenses while seeking regulatory approval. While limited clinical trials of our drug candidates have been conducted to date, significant additional trials are required, and we may not be able to demonstrate that these drug candidates are safe or effective. If we are unable to demonstrate the safety and effectiveness of a particular drug candidate to the satisfaction of regulatory authorities, the drug candidate will not obtain required government approval. If we do not receive FDA or foreign approvals for our products, we will not be able to sell our products and will not generate revenues. If we receive regulatory approval of a product, such approval may impose limitations on the indicated uses for which we may market the product, which may limit our ability to generate significant revenues.

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 \$138.7 million as of March 31, 2005. Our net losses for fiscal years 2004, 2003 and 2002 were \$24.8 million, \$25.7 million and \$17.5 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.

The market for treating Acute Radiation Syndrome is uncertain.

We do not believe any drug has ever been approved and commercialized for the treatment of severe acute radiation injury. In addition, the incidence of large-scale exposure to nuclear or radiological events has been low. Accordingly, even if NEUMUNE, our lead drug candidate to treat Acute Radiation Syndrome (ARS), is approved by the FDA, we cannot predict with any certainty the size of this market. The potential market for NEUMUNE is largely dependent on the size of stockpiling orders, if any, procured by the U.S. and foreign governments. While a number of governments have historically stockpiled drugs to treat

Table of Contents

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 ARS. While we have filed a formal response to the U.S. Department of Health and Human Services Request for Information (RFI) for therapeutics to treat ARS, at least one other company has responded to this RFI, and we cannot guarantee that our response to this RFI will result in a U.S. Department of Health and Human Services Request for Proposal (RFP) or any stockpiling orders. A decision by the U.S. Government to enter into a commitment to purchase NEUMUNE prior to FDA approval is largely out of our control. Our development plans and timelines may vary substantially depending on whether we receive such a commitment and the size of such commitment, if any. In addition, even if NEUMUNE is approved by regulatory authorities, we cannot guarantee that we will receive any stockpiling orders for NEUMUNE, that any such order would be profitable to us 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 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. A large number of companies, including Merck & Company, Pfizer Inc., Johnson & Johnson Inc. and Amgen Inc. are also developing and marketing new drugs for the treatment of chronic inflammatory conditions. Companies such as 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 marketed products or research and development programs in these fields.

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

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

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 March 31, 2005, our cash and cash equivalents totaled approximately \$54.2 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 for at least the next 12 months. 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.

Table of Contents

You should be aware that in the future:

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

any available additional financing may not be adequate.

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

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

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

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

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;

Edgar Filing: HOLLIS EDEN PHARMACEUTICALS INC /DE/ - Form 10-Q

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

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

Table of Contents

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 may be on terms that are less favorable to us and would likely have the effect of reducing our revenues.

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

Table of Contents

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

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

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

Phase I safety and pharmacokinetic clinical trials with NEUMUNE;

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;

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

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

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

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

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

delays in enrolling volunteers;

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

lower than anticipated retention rate of volunteers in a trial;

unfavorable efficacy results;

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

new communications from regulatory agencies about how to 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.

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.

Table of Contents

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

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

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

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

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

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

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 preclinical or clinical studies;

unfavorable results from preclinical or clinical studies;

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 \$6.50 to \$16.50 between January 1, 2004 and April 20, 2005.

Table of Contents

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. Any litigation against our company, including this type of litigation, could result in substantial costs and a diversion of management's attention and resources, which could materially adversely affect our business, financial condition and results of operations.

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

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

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

Assuming that outstanding warrants and options have not been exercised, Richard B. Hollis, our Chief Executive Officer, owns approximately 12% of our outstanding common stock as of March 31, 2005. Assuming that Mr. Hollis exercises all of his outstanding warrants and options that vest within 60 days of March 31, 2005, Mr. Hollis would beneficially own approximately 19% 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 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.

Table of Contents

Item 6. Exhibits

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

Exhibit

Number	Description of Document
10.39	Registrant's 2005 Equity Incentive Plan.
10.40	Registrant's 2005 Non-Employee Director's Equity Incentive Plan.
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.

Table of Contents

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: May 6, 2005

By: /s/ Daniel D. Burgess

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

Dated: May 6, 2005

By: /s/ Robert W. Weber

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