HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 10-Q
November 03, 2005
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark one)

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

For the Quarterly Period Ended September 30, 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)

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

4435 Eastgate Mall, Suite 400

SAN DIEGO, CALIFORNIA 92121

(Address of principal executive offices and zip code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ¨ NO x

As of November 4, 2005 there were 20,714,717 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, 2005

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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)

	Sept. 30, 2005 (Unaudited)	Dec. 31, 2004
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 51,451	$ 61,991
Prepaid expenses	268	176
Deposits	51	44
Receivable from related party	6	
Due from AFFRI and others	315	9
Total current assets	52,091	62,220
Property and equipment, net of accumulated depreciation of $689 and $462, respectively	1,179	961
Receivable from related party	6	
Deposits	61	61
Total assets	$ 53,337	$ 63,242
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,847	$ 5,008
Deferred revenue	245	
Total current liabilities	4,092	5,008
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $.01 par value, 10,000 shares authorized; no shares issued and outstanding		

Common stock, $.01 par value, 50,000 shares authorized; 20,771 and 19,347 shares issued; 20,712 and 19,288 shares outstanding, respectively	208	193
Paid-in capital	200,242	190,235
Cost of treasury stock (59 shares)	(346)	(346)
Deficit accumulated during development stage	(150,859)	(131,848)
Total stockholders equity	49,245	58,234
Total liabilities and stockholders equity	$ 53,337	$ 63,242

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

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Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Operations

(Unaudited)

All numbers in thousands, except per share amounts

	Three months ended Sept. 30,		Nine months ended Sept. 30,		Period from Inception (Aug. 15, 1994) to Sept. 30,
	2005	2004	2005	2004	2005
Revenue:					
Contract R&D revenue	$ 5	$	$ 5	$ 63	$ 68
Total revenue	5		5	63	68
Operating expenses:					
Research and development:					
R&D operating expenses	4,152	4,259	13,669	12,348	94,407
R&D costs related to common stock, option, & warrant grants for collaborations				3	5,667
General and administrative:					
G&A operating expenses	1,957	1,483	6,469	4,605	40,597
G&A costs related to common stock, option, & warrant grants	6	71	24	95	12,364
Total operating expenses	6,115	5,813	20,162	17,051	153,035
Other income (expense):					
Loss on disposal of assets		(9)		(9)	(56)
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures					(7,627)
Interest income	449	236	1,146	632	10,179
Interest expense					(388)
Total other income (expense), net	449	227	1,146	623	2,108
Net loss	$ (5,661)	$ (5,586)	$ (19,011)	$ (16,365)	$ (150,859)
Net loss per share-basic and diluted	$ (0.27)	$ (0.29)	$ (0.95)	$ (0.85)	
Weighted average number of common shares outstanding-basic and diluted	20,748	19,283	19,926	19,261	

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

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

Statements of Cash Flows (Unaudited)

All numbers in thousands

	Nine months ended Sept. 30,		Period from Inception (Aug. 15, 1994 to Sept. 30,)
	2005	2004	2005
Cash flows from operating activities:			
Net loss	$ (19,011)	$ (16,365)	$ (150,859)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	227	150	1,020
Disposal of assets		9	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	112	88	778
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	24	158	2,853
Common stock issued as consideration for In Process R&D		568	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	(92)	(356)	(268)
Deposits	(7)	(12)	(112)
Receivable from related party	(12)	18	(12)
Due from AFFRI and others	(306)		(315)
Estimated revenue in excess of billings		(12)	
Deferred revenue	245		245
Accounts payable and accrued expenses	(1,161)	(146)	4,491
Net cash used in operating activities	(19,981)	(15,900)	(118,334)
Cash flows provided by (used in) investing activities:			
Purchase of property and equipment	(445)	(803)	(2,261)
Net cash used in investing activities	(445)	(803)	(2,261)
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	9,515		134,757
Net proceeds from issuance of convertible debentures and warrants			9,214

Purchase of treasury stock			(346)
Proceeds from issuance of debt			371
Net proceeds from recapitalization			6,271
Net proceeds from warrants and options exercised	371	28	17,675
Net cash from financing activities	9,886	28	172,046
Net increase (decrease) in cash	(10,540)	(16,675)	51,451
Cash and equivalents at beginning of period	61,991	84,852	
Cash and equivalents at end of period	$ 51,451	$ 68,177	$ 51,451

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

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Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Cash Flows (Cont.)

(Unaudited)

All numbers in thousands

	Nine months ended Sept. 30,		Period from Inception (Aug. 15, 1994) to Sept. 30,
	2005	2004	2005
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

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Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Financial Statements

(Unaudited)

1. Basis of Presentation

The information at September 30, 2005, and for the three-month and nine-month periods ended September 30, 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

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.

As required by SFAS No. 148 and SFAS No. 123, the Company provides pro forma net income (loss) and pro forma net income (loss) 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 September 30,		Nine Months ended September 30,	
	2005	2004	2005	2004
Net loss - As reported	$ (5,661)	$ (5,586)	$ (19,011)	$ (16,365)

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	(1,251)	(1,300)	(3,661)	(3,809)
Net loss - Pro forma	$ (6,912)	$ (6,886)	$ (22,672)	$ (20,174)
Basic and diluted net loss per share - As reported	$ (0.27)	$ (0.29)	$ (0.95)	$ (0.85)
Basic and diluted net loss per share - Pro forma	$ (0.33)	$ (0.36)	$ (1.14)	$ (1.05)

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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 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 Company has not elected to early implement SFAS 123(R) for the year ended December 31, 2005.

2. Other Agreements and Commitments

AFRRI Collaboration

The Company is performing work on two task orders that were issued under a collaboration with the Armed Forces Radiobiology Research Institute (AFRRI). Under these task orders, the Company is conducting two radiation studies with a subcontractor. The task orders commit AFRRI to reimburse the Company for $2.0 million in subcontractor fees. The reimbursement amounts from AFRRI will be recorded in the same timeline as the subcontractor fees, resulting in no impact on the statement of operations. However, due to timing differences between payments made by the Company to the subcontractors and related reimbursements received from AFRRI, the Company has a receivable of $315,000 outstanding at September 30, 2005.

Study Funding Agreement

The Company has a Study Funding Agreement with Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT). The agreement commits CFFT to provide a total of $1.7 million to be paid in seven tranches 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 for each distinct agreed-upon event, and the Company has a liability of $245,031 recorded as deferred revenue as of September 30, 2005.

3. Equity Financing

On June 1, 2005 the Company raised approximately $10.0 million in gross proceeds from the sale of 1,333,333 shares of the Company s common stock. Additionally, the Company issued a four-year warrant to purchase up to an additional 266,667 shares of common stock at an exercise price of $10.00 per share. In connection with this transaction, the Company incurred approximately $0.5 million in direct costs and recorded net

proceeds of approximately $9.5 million.

4. Litigation Matters: Colthurst, Edenland and Mr. Prendergast

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. While it is impossible to predict accurately or to determine the eventual outcome of these matters, as of the date of this report, we do not believe that we are 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.

In January 2000, we entered into a Technology Assignment Agreement with Patrick T. Prendergast and Colthurst Ltd (Colthurst). The Technology Assignment Agreement replaced the Colthurst License Agreement dated May 18, 1994 among Hollis-Eden, Mr. Prendergast and Colthurst. This agreement

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assigned to us ownership of all patents, patent applications and current or future improvements of the technology under the Colthurst License Agreement, including IMMUNITIN . Upon signing the agreement, we issued to Colthurst 132,000 shares of our common stock, with an additional 528,000 shares of our common stock and warrants to purchase up to 400,000 shares of the Company s common stock to be issued over time upon the satisfaction of certain conditions. Because all of these conditions were not satisfied, we did not issue any additional shares or warrants to Colthurst, and we believe that we have no obligation to issue any additional shares or warrants.

On May 17, 2004, we received a copy of a Demand for Arbitration from Mr. Prendergast and his companies, claiming, among other things, that we breached the agreement with them when we did not issue to Colthurst the remaining 528,000 shares of our common stock and declared that the warrant to purchase up to 400,000 shares of our common stock would not vest as to any shares. We are contesting these claims vigorously, and we have filed counterclaims in arbitration seeking damages from Colthurst, Edenland and Mr. Prendergast for numerous breaches of these agreements by them. This arbitration is ongoing as of the date of this report.

While we believe that Colthurst did not satisfy the conditions required to receive the additional shares of our common stock and the shares underlying the warrant and that the claims underlying the demand for arbitration are without merit, we cannot guarantee that, as a result of this dispute, additional equity will not be issued, cash compensation will not be awarded, additional significant legal expenses will not be incurred, or that additional accounting charges will not be made.

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

The following discussion and analysis should be read in conjunction with the financial statements and notes included elsewhere in this report. The following discussion and analysis contains forward-looking statements that involve risks and uncertainties. This discussion represents our current judgment on the future direction of our business and our actual results may differ materially from those discussed here due to risks and factors including 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 as well as the risks and factors set forth below under the caption Risk Factors. Additional factors that could cause or contribute to such differences can be found in the financial statements and the related Management s Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2004.

Overview

We are a development-stage pharmaceutical company 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 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. As of September 30, 2005, we had an accumulated deficit of approximately $150.9 million. We expect to incur substantial additional operating losses and capital expenditures for the foreseeable future as we increase expenditures on research and development and begin to allocate significant and increasing resources to clinical testing and other activities in support of the development of our drug candidates. In addition, during the next few years, we may have to meet the substantial new challenge of developing the capability to market products if we are successful in obtaining regulatory approval for any of our current or future drug candidates. Accordingly, our activities to date are not as broad in depth or scope as the activities we may 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.

Our company was created on March 26, 1997, as a result of the merger of Hollis-Eden, Inc., a Delaware corporation, with and into our predecessor company, known as Initial Acquisition Corp., a Delaware corporation (IAC). Upon consummation of the merger of Hollis-Eden, Inc. with IAC, Hollis-Eden, Inc. ceased to exist, and IAC changed its name to Hollis-Eden Pharmaceuticals, Inc.

Results of Operations

We have devoted substantially all of our resources to the payment of research and development expenses and general and administrative expenses. From inception through September 30, 2005, we have generated approximately $68,000 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 $2.1 million in net other income consisting of $10.1 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 approximately $100.1 million in research and development expenses and $52.9 million in general and administrative expenses. The combination of these resulted in an aggregate net loss of approximately $150.9 million for the period from our inception through September 30, 2005.

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Research and development expenses were approximately $4.2 million and $13.7 million for the three-month and nine-month periods ended September 30, 2005, respectively, compared to $4.3 million and $12.4 million for the three-month and nine-month periods ended September 30, 2004, respectively. The research and development expenses relate primarily to the ongoing development, preclinical testing, and clinical trials for our drug candidates. The increase in research and development expenses was due mainly to the growth in our laboratory operations, as well as preclinical and clinical activities and personnel associated with the ongoing development of our lead drug candidate, NEUMUNE (HE2100).

General and administrative expenses were $1.9 million and $6.5 million for the three-month and nine-month periods ended September 30, 2005, respectively, compared to $1.6 million and $4.7 million for the three-month and nine-month periods ended September 30, 2004, respectively. The general and administrative expenses relate primarily to salaries and benefits, facilities, legal, accounting/auditing, public and investor relations, consultants, insurance and travel. The increase in general and administrative expenses for these periods was primarily attributable to increased legal fees associated with our ongoing legal proceedings. For additional information concerning these legal proceedings please see Part II, Item 1, Legal Proceedings below. We believe that our general and administrative expenses may continue to increase in 2005 as a result of increased legal fees and costs associated with compliance with new audit regulations, including Section 404 of the Sarbanes-Oxley Act of 2002.

Other income (expense) was $0.4 million and $1.1 million for the three-month and nine-month periods ended September 30, 2005, respectively, compared to $0.2 million and $0.6 million for the three-month and nine-month periods ended September 30, 2004, respectively, comprised entirely of interest income. The increase in interest income during these periods was due to generally higher interest rates for these periods compared with the same periods in 2004.

Liquidity and Capital Resources

Since our inception we have financed our operations primarily through the sale of shares of our 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 our 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 shares of our common stock and warrants, from which we received gross proceeds of $20.0 million. During January 1999, we completed two private placements of shares of our common stock raising approximately $25.0 million. In December 2001, we completed a private placement of shares of our 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 shares of our common stock and warrants, from which we received gross proceeds of $14.7 million. In October 2003 we completed a public offering of shares of our common stock from which we received $62.5 million in gross proceeds. In June 2005, we completed a sale of shares of our common stock and warrants from which we received $10.0 million in gross proceeds. In addition, since our inception we have received a total of $17.7 million from the exercise of warrants and stock options.

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.

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A summary of our current contractual obligations is as follows (in thousands):

	Payments Due by Period				
Contractual Obligations	**Total**	**Less than one year**	**One to three years**	**Three to five years**	**More than five years**
Operating Leases	$ 1,701	$ 676	$ 1,010	$ 15	

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. 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. As of September 30, 2005, our cash and cash equivalents totaled approximately $51.5 million.

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.

Caution on Forward-Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements that are based on our management s beliefs and assumptions and on information currently available to our management. Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities, the effects of future regulation and the effects of competition. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as anticipates, believes, could, estimates, expects, intends, may, plans, potential, predicts, projects, or similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in the Risk Factors section below and in our other filings with the Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2004. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Also, forward-looking statements represent our management s beliefs and assumptions only as of the date of this quarterly report on Form 10-Q. Our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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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 approval by the FDA before they can be commercialized in the U.S. as well as approval by various foreign government agencies before they can commercialized in other countries. 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 $150.9 million as of September 30, 2005. Our net losses for fiscal years 2004, 2003 and 2002 were approximately $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 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. On September 30, 2005, the U.S. Department of Health and Human Services (DHHS) issued a draft Request for Proposal (RFP) and sought comments to the draft from interested parties regarding the scope, design and requirements of the potential procurement. The draft RFP specified an initial potential stockpiling order of up to 100,000 treatment regimens, which is substantially lower than we had anticipated. While we have

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submitted our comments to DHHS regarding what we believe to be significant deficiencies contained in the draft RFP, including the insufficient number of treatment regimens, we cannot guarantee that DHHS will be responsive to any of our comments or that DHHS will increase the size of the potential procurement order in the final RFP. We also cannot guarantee that we will be able to meet the requirements set forth in the final RFP or that we will receive any resulting stockpiling orders. We have also submitted an unsolicited proposal to the U.S. Department of Defense for the potential procurement of NEUMUNE for use by the military. A decision by any department of the U.S. Government to enter into a commitment to purchase NEUMUNE, whether before or after 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 U.S. 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 of September 30, 2005, our cash and cash equivalents totaled approximately $51.5 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

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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; 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 U.S. 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;

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.

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In addition, if another party claims the same subject matter or subject matter overlapping with the subject matter that we have claimed in a U.S. patent application or patent, we may decide or be required to participate in interference proceedings in the U.S. 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.

Litigation may be expensive and time consuming and may adversely affect our operations.

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. Participation in such proceedings is time consuming and 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 drug candidates currently pending, any decline in the size of the markets in which we may in the future sell commercial products, assuming our receipt of the requisite regulatory approvals, could cause the perceived market value of our business and the price of our common stock to decline.

Our ability to commercialize our drug candidates successfully also will depend in part on the extent to which reimbursement for the cost of our drug candidates 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

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bringing any of our drug candidates to the market, such drug candidates may not be considered cost effective and reimbursement may not be available or sufficient to allow us to sell such drug candidates 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 for the treatment of radiation exposure and chemotherapy protection;
- Phase I safety and pharmacokinetic clinical trials with NEUMUNE in the United States and the Netherlands;
- 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 drug candidates do not comply with current Good Manufacturing Practices regulations, or cannot produce sufficient quantities of our drug candidates to enable us 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 drug candidates.

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

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

Our efforts to date have focused on the development and evaluation of our drug candidates. As we continue clinical studies and seek to commercialize 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 drug candidates 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 drug candidates, 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. 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;

delays in obtaining or failure to obtain purchase orders of our drug candidates;

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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 $4.53 to $16.50 between January 1, 2004 and October 31, 2005.

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 11% of our outstanding common stock as of September 30, 2005. Assuming that Mr. Hollis exercises all of his outstanding warrants and options that vest within 60 days of September 30, 2005, Mr. Hollis would beneficially own approximately 18% of our outstanding common stock. As a result, Mr. Hollis may be able to significantly influence our management 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 our company.

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 shares of preferred stock without a vote or action by our stockholders. The board also has the authority to determine the terms of

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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.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

At September 30, 2005, our investment portfolio included only cash and money market accounts and did 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

Based on the evaluation of 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 (the Exchange Act)) required by Rules 13a-15(b) or 15d-15(b) of the Exchange Act, our chief financial officer and chief executive officer have concluded that, as of September 30, 2005, our disclosure controls and procedures were sufficiently effective to ensure that the information required by the Company in the reports that it files under the Exchange Act is gathered, analyzed and disclosed with adequate timeliness, accuracy and completeness.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal controls over financial reporting during the period covered by this report, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met, and, as set forth above, our chief executive officer and chief financial officer have concluded, based on their evaluation, that our disclosure controls and procedures were sufficiently effective as of the end of the period covered by this report to provide reasonable assurance that the objectives of our disclosure control system were met.

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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. While it is impossible to predict accurately or to determine the eventual outcome of these matters, as of the date of this report, we do not believe that we are 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.

In January 2000, we entered into a Technology Assignment Agreement with Patrick T. Prendergast and Colthurst Ltd (Colthurst). The Technology Assignment Agreement replaced the Colthurst License Agreement dated May 18, 1994 among Hollis-Eden, Mr. Prendergast and Colthurst. This agreement assigned to us ownership of all patents, patent applications and current or future improvements of the technology under the Colthurst License Agreement, including IMMUNITIN . Upon signing the agreement, we issued to Colthurst 132,000 shares of our common stock, with an additional 528,000 shares of our common stock and warrants to purchase up to 400,000 shares of the Company s common stock to be issued over time upon the satisfaction of certain conditions. Because all of these conditions were not satisfied, we did not issue any additional shares or warrants to Colthurst, and we believe that we have no obligation to issue any additional shares or warrants.

On May 17, 2004, we received a copy of a Demand for Arbitration from Mr. Prendergast and his companies, claiming, among other things, that we breached the agreement with them when we did not issue to Colthurst the remaining 528,000 shares of our common stock and declared that the warrant to purchase up to 400,000 shares of our common stock would not vest as to any shares. We are contesting these claims vigorously, and we have filed counterclaims in arbitration seeking damages from Colthurst, Edenland and Mr. Prendergast for numerous breaches of these agreements by them. This arbitration is ongoing as of the date of this report.

While we believe that Colthurst did not satisfy the conditions required to receive the additional shares of our common stock and the shares underlying the warrant and that the claims underlying the demand for arbitration are without merit, we cannot guarantee that, as a result of this dispute, additional equity will not be issued, cash compensation will not be awarded, additional significant legal expenses will not be incurred, or that additional accounting charges will not be made.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

We made no unregistered sales of securities or repurchases of our securities during the quarter ended September 30, 2005.

Item 3. Defaults Upon Senior Securities

None

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

None

Item 5. Other Information

None

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Item 6. Exhibits

(a) The following exhibits are included as part of this report: [add forms of equity agreements?]

Exhibit Number	Description of Document
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 3, 2005

By: /s/ Daniel D. Burgess
Daniel D. Burgess

Chief Operating Officer/

Chief Financial Officer

(Principal Financial Officer)

Dated: November 3, 2005

By: /s/ Robert W. Weber
Robert W. Weber

Vice President-Controller/

Chief Accounting Officer

(Principal Accounting Officer)