

HOLLIS EDEN PHARMACEUTICALS INC /DE/  
Form 10-Q  
November 03, 2006  
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**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 September 30, 2006

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**  
(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 a large accelerated filer, an accelerated filer, or a non-accelerated filer See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

YES  NO

As of November 2, 2006 there were 24,909,473 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, 2006

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

	Sept. 30, 2006 (Unaudited)	Dec. 31, 2005
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 47,445	\$ 45,130
Prepaid expenses	272	204
Deposits	64	52
Receivable from related party	6	7
Other receivables	320	8
Total current assets	48,107	45,401
Property and equipment, net of accumulated depreciation of \$959 and \$740, respectively	1,084	1,116
Receivable from related party		4
Restricted Cash	34	
Deposits	61	61
Total assets	\$ 49,286	\$ 46,582
<b>LIABILITIES AND STOCKHOLDERS EQUITY:</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,290	\$ 7,515
Deferred revenue	239	193
Total current liabilities	4,529	7,708
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.01 par value, 10,000 shares authorized; no shares issued or outstanding		
Common stock, \$.01 par value, 50,000 shares authorized; 24,960 and 20,782 shares issued; 24,901 and 20,723 shares outstanding, respectively	249	208
Paid-in capital	228,800	200,301
Cost of treasury stock (59 shares)	(346)	(346)
Deferred compensation	(356)	
Deficit accumulated during development stage	(183,590)	(161,289)
Total stockholders' equity	44,757	38,874
Total liabilities and stockholders' equity	\$ 49,286	\$ 46,582

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**

	Three months ended Sept. 30,		Nine months ended Sept. 30 to		Period from Inception (Aug.15, 1994) Sept. 30,
	2006	2005	2006	2005	2006
<b>Revenue:</b>					
Contract R&D revenue	\$ 82	\$ 5	\$ 204	\$ 5	\$ 323
<b>Total revenue</b>	<b>82</b>	<b>5</b>	<b>204</b>	<b>5</b>	<b>323</b>
<b>Operating expenses:</b>					
<b>Research and development:</b>					
R&D operating expenses	5,609	4,152	16,060	13,669	115,508
R&D SFAS 123R compensation expense related to equity awards	441		1,277		1,277
R&D costs related to common stock, option & warrant grants for collaborations					5,667
<b>Total research and development</b>	<b>6,050</b>	<b>4,152</b>	<b>17,337</b>	<b>13,669</b>	<b>122,452</b>
<b>General and administrative:</b>					
G&A operating expenses	1,304	1,957	5,007	6,469	48,513
G&A SFAS 123R compensation expense related to equity awards	653		2,110		2,110
G&A costs related to common stock, option & warrant grants		6	13	24	12,383
<b>Total general and administrative</b>	<b>1,957</b>	<b>1,963</b>	<b>7,130</b>	<b>6,493</b>	<b>63,006</b>
<b>Settlement of dispute</b>					<b>3,000</b>
<b>Total operating expenses</b>	<b>8,007</b>	<b>6,115</b>	<b>24,467</b>	<b>20,162</b>	<b>188,458</b>
<b>Other income (expense):</b>					
Loss on disposal of assets					(56)
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures					(7,627)
Interest income	660	449	1,961	1,146	12,616
Interest expense					(388)
<b>Total other income, net</b>	<b>660</b>	<b>449</b>	<b>1,961</b>	<b>1,146</b>	<b>4,545</b>
<b>Net loss</b>	<b>\$ (7,265)</b>	<b>\$ (5,661)</b>	<b>\$ (22,302)</b>	<b>\$ (19,011)</b>	<b>\$ (183,590)</b>
<b>Net loss per share-basic and diluted</b>	<b>\$ (0.29)</b>	<b>\$ (0.27)</b>	<b>\$ (0.91)</b>	<b>\$ (0.95)</b>	
	24,956	20,748	24,404	19,926	

Weighted average number of common shares outstanding-basic and diluted

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

	Nine months ended		Period from
	Sept. 30,		Inception
	2006	2005	(Aug. 15, 1994) to
			Sept. 30,
			2006
Cash flows from operating activities:			
Net loss	\$ (22,302)	\$ (19,011)	\$ (183,590)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	219	227	1,316
SFAS 123R compensation expense related to equity awards	3,387		3,387
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	142	112	959
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	2,859
Common stock issued as consideration for In Process R&D	180		2,809
Expense related to warrants issued as consideration to consultants	13		4,126
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	(68)	(92)	(272)
Deposits	(12)	(7)	(125)
Receivable from related party	5	(12)	(6)
Other Receivable	(312)	(306)	(320)
Accounts payable, accrued expenses and deferred revenue	(3,177)	(916)	5,173
Net cash used in operating activities	(21,925)	(19,981)	(146,581)
Cash flows provided by (used in) investing activities:			
Purchase of property and equipment	(187)	(445)	(2,463)
Net cash used in investing activities	(187)	(445)	(2,463)
Cash flows from financing activities:			
Contributions from stockholder			104
Restricted cash	(34)		(34)
Net proceeds from sale of preferred stock			4,000
Net proceeds from sale of common stock	24,375	9,515	159,132
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	86	371	17,777
Net cash from financing activities	24,427	9,886	196,489



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Net increase (decrease) in cash	2,315	(10,540)	47,445
Cash and equivalents at beginning of period	45,130	61,991	
Cash and equivalents at end of period	\$ 47,445	\$ 51,451	\$ 47,445

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		Period from
	Sept. 30,		Inception
	2006	2005	(Aug. 15, 1994) to
			Sept. 30,
			2006
<b>Supplemental Disclosure of Cash Flow Information:</b>			
Interest Paid	\$	\$	\$ 388
<b>Supplemental Disclosure of Non-Cash Financing Activities:</b>			
Conversion of debt to equity			10,371
Warrants issued to consultants in lieu of cash, no vesting	13		572
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, 2006, and for the three- and nine-month periods ended September 30, 2006 and 2005, and inception to date 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, 2005, which was filed with the United States Securities and Exchange Commission on March 16, 2006.

***New Accounting Pronouncement***

On July 13, 2006, the Financial Accounting Standards Board issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* , which is effective for fiscal years beginning after December 15, 2006, which establishes recognition and measurement thresholds that must be met before a tax benefit can be recognized in the financial statements. The Company is currently analyzing the effects of the new standard and its potential impact on its financial statements.

***Accounting for Stock-Based Compensation***

The Company has an equity-based incentive compensation plan known as The 2005 Equity Incentive Plan (the Plan ). The Plan allows us to grant stock options and other stock or stock-based awards, including stock appreciation rights, stock purchase awards, restricted stock awards and restricted

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stock units awards. The Plan also allows us to provide equity compensation to nonemployee directors and consultants. The exercise price for an option granted under the Plan is typically not less than the fair market value of the common stock subject to such option. The term of any options granted under the Plan may not exceed 10 years from the date of the grant. Options issued to employees generally vest over a four-year period, with 25% vesting on the first anniversary date and the balance vesting monthly during years two, three and four.

Prior to January 1, 2006, we applied Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for options. All stock options for employees (with the exception of three grants) have been granted at or above the market price where the exercise price of the option equaled or exceeded the market price of the stock on the date of the grant. As a result, under APB No. 25 there was no stock-based compensation expense for those grants. Compensation expense was taken for the three options granted at below market value (see 2005 Annual Report on Form 10-K, Notes to Financial Statements *No. 9 Stock Options* for more detail). As of September 30, 2006 the Plan has 5,922,013 shares of common stock reserved for issuance.

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards ( SFAS ) No. 123 (Revised 2004), Share-Based Payment (123R), requiring us to recognize expense related to the fair value of our stock-based compensation awards. We elected the modified prospective transition method as permitted by SFAS 123R; accordingly, results from prior periods have not been restated. Under this transition method, stock-based compensation expense for the nine months ended September 30, 2006 includes:

- a) compensation expense for all stock-based compensation awards granted prior to January 1, 2006 but not yet vested, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, *Accounting for Stock-Based Compensation*, and
- b) compensation expense for all stock-based compensation awards granted subsequent to December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R.

We adopted SFAS 123R in the first quarter of the 2006 fiscal year and therefore, the 2005 Form 10-K does not contain the incremental SFAS 123R disclosures. Therefore, we will include incremental SFAS 123R disclosures in each Form 10-Q during the first year of adoption.

The fair value of each stock option granted is estimated on the date of grant using the Black-Scholes option-pricing model. The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect the Company's experience. Compensation expense is recognized using the straight-line method for all stock-based awards issued after January 1, 2006. Compensation expense is recognized only for those options expected to vest, with forfeitures estimated at the date of grant based on the Company's historical experience and future expectations. Prior to the adoption of SFAS 123R, the effect of forfeitures on the pro forma expense amounts was not recognized. SFAS 123R requires forfeitures to be estimated at the time of the grant and revised as necessary in subsequent periods if actual forfeitures differ from those estimates.

Black-Scholes Option Valuation Assumptions (1)

	Nine Months Ended	
	September 30, 2006	September 30, 2005
Risk-free interest rate	4.75%	3.75%
Expected dividend yield	0%	0%
Expected life (2)	6.25 years	5 years
Expected volatility (3)	91%	136%

(1) Forfeitures are estimated based on historical experience.

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(2) The 2006 expected life is based on the safe-harbor method as described in SEC Staff Accounting Bulletin No. 107. The 2005 expected life was estimated at the time.

(3) The expected stock price volatility is estimated based on historical experience.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of the Company's options.

The weighted average, estimated fair values of employee stock options granted during the nine-month periods ended September 30, 2006 and September 30, 2005 were \$4.59 and \$6.65 per share, respectively.

The total stock-based compensation expense included in our statement of operations for the nine-month periods ended September 30, 2006 and September 30, 2005 was \$3,388,000 and \$-0-, respectively. Of the \$3,388,000 stock-based compensation expense, \$2,753,000 relates to awards granted prior to January 1, 2006.

As of September 30, 2006, the unrecognized stock-based compensation expense related to non-vested options and restricted shares was approximately \$7.3 million which is expected to be recognized over a weighted average period of approximately 1.2 years. During the nine-month period ended September 30, 2006 the total intrinsic value of the stock options exercised was \$145,000. The total fair value of options vested during the nine-month periods ended September 30, 2006 and September 30, 2005 were \$3.6 million and \$4.4 million, respectively. The Company issues new shares of common stock upon the exercise of stock options.

The following tables summarize the stock option activity for the nine months ended September 30, 2006:

## 2005 Equity Incentive Plan

(In thousands, except per share data and years)	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2005	4,646	\$ 9.57		
Granted	399	5.96		
Exercised	(6)	3.86		
Forfeited/Canceled	(49)	7.22		
Outstanding, September 30, 2006	4,990	\$ 9.31	5.2	\$ 525
Exercisable on September 30, 2006	4,085	\$ 9.43	4.4	\$ 513

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## 2005 Non-Employee Directors Equity Incentive Plan

(In thousands, except per share data and years)	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2005	30	\$ 10.75		
Granted	150	9.00		
Exercised				
Forfeited/Canceled				
Outstanding, September 30, 2006	180	\$ 9.29	8.6	-0-
Exercisable on September 30, 2006	73	\$ 11.58	7.9	-0-
Non-Plan Options				

(In thousands, except per share data and years)	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2005	1,846	\$ 6.89		
Granted				
Exercised	(28)	2.25		
Forfeited/Canceled	(200)	2.25		
Outstanding, September 30, 2006	1,618	\$ 7.54	2.5	\$ 348
Exercisable on September 30, 2006	1,552	\$ 7.45	2.3	\$ 348

Cash proceeds and the intrinsic value related to stock options exercised during the nine-month periods ended September 30, 2006 and September 30, 2005 to date, are provided in the following table (in thousands):

	Nine Months Ended September 30,	
	2006	2005
Proceeds from stock options exercised	\$ 86	\$ 110
Tax benefit related to stock options exercised (1)	NA	NA
Intrinsic value of stock options exercised (2)	\$ 145	\$ 164

- (1) SFAS 123R requires that the excess tax benefits received related to stock option exercises be presented as financing cash inflows. We currently do not receive a tax benefit related to the exercise of stock options due to the Company's net operating losses.

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- (2) The intrinsic value of stock options exercised is the amount by which the market price of the stock on the date of exercise exceeded the market price of the stock on the date of grant.

**Restricted Stock**

The fair value of restricted stock is based on the trading price of Hollis-Eden's common stock on the date of grant. We issued restricted stock for the first time during 2006 to certain employees. Restricted stock activity is as follows:

(Shares in thousands)	Shares	Weighted-Average Grant Date Fair Value
Outstanding at beginning of year		
Granted	68	\$ 6.20
Vested		
Forfeited		
Outstanding September 30, 2006, nonvested	68	\$ 6.20

The market price of the common stock on the date of the grant was initially recorded as deferred compensation within the stockholders' equity section of the Company's balance sheet and subsequently is being amortized over the 4-year vesting period. During the nine months ended September 30, 2006, \$67,000 of compensation expense was amortized and is included in general and administrative and research and development expense in the statement of operations.

In November 2005, the Financial Accounting Standards Board issued SFAS 123R-3, *Transition Election to Accounting for the Tax Effects of Share-Based Payment Awards*. This requires an entity to follow either the transition guidance (long method) for the additional-paid-in-capital pool, or the alternative transition (simplified method) as described in the pronouncement. We have until December 2006 to evaluate our available transition alternatives and make our one-time election.

**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 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. The Company has invoiced AFRRI for payments made to the subcontractors. Due to timing differences, as of September 30, 2006, a balance of \$70,000 is recorded as a receivable.

*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.

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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 \$239,227 recorded as deferred revenue and a receivable of \$250,000 as of September 30, 2006.

### **3. Equity Transactions**

On February 6, 2006 the Company raised approximately \$26.0 million in gross proceeds from the sale of 4,000,000 shares of the Company's common stock at a price of \$6.50 per share. The direct costs related to this financing were \$1.6 million, resulting in net proceeds of \$24.4 million. Additionally, the Company issued four-year warrants to purchase up to an additional 800,000 shares of common stock at an exercise price of \$8.75 per share. The warrants are not exercisable until six months following issuance.

On June 7, 2006 the Company issued 35,000 shares of the Company's common stock to Aeson Therapeutics, Inc. (Aeson) in connection with the purchase of substantially all of Aeson's assets, resulting in an expense of \$180,000. Upon certain events, the Company may be obligated to issue an additional 165,000 shares.

### **4. Litigation Matters**

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.

On January 9, 2006, the Company entered into a Settlement Agreement and General Release of Claims with certain former warrant holders of the Company who had made various allegations against the Company in connection with the expiration of their warrants in January 2002. Although the Company denied all such allegations, the Company agreed to settle all disputes between the parties. As part of the Settlement Agreement, the former warrant holders received compensation from the Company and the Company's insurance carrier. The Company's portion of such settlement is \$540,000, which was paid by the Company during the first quarter of 2006.

## **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*



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*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, 2005.*

### **Overview**

We are a development-stage pharmaceutical company engaged in developing a proprietary new class of small molecule compounds based on our Hormonal Signaling Technology Platform. These compounds, metabolites or synthetic analogs of adrenal steroid hormones, are designed to restore the biological activity of cellular signaling pathways disrupted by disease and aging. In investigational studies, they have been demonstrated in humans to possess several properties with potential therapeutic benefit—they regulate innate and adaptive immunity, reduce nonproductive inflammation, and stimulate cell proliferation. Our lead product candidate, NEUMUNE® (HE2100), is entering late-stage development for the treatment of Acute Radiation Syndrome (ARS), a life-threatening condition resulting from exposure to high levels of radiation following a nuclear or radiological incident, and is being explored for use in combating healthcare-associated infections. We also are profiling optimized second-generation compounds for potential clinical development in a broad spectrum of therapeutic categories including hematology, metabolic disorders, autoimmune disorders, pulmonary diseases, oncology and infectious diseases.

We have been unprofitable since our inception. As of September 30, 2006, we had an accumulated deficit of approximately \$183.6 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, 2006, we have generated approximately \$323,600 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 \$4.5 million in net other income consisting of \$12.6 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 \$122.4 million in research and development expenses, \$63.0 million in general and administrative expenses and \$3.0 million in the settlement of a dispute. The combination of these resulted in an aggregate net loss of approximately \$183.6 million for the period from our inception through September 30, 2006.

Research and development and general and administrative expenses include the expense for stock-based compensation in the three-month and nine-month periods ended September 30, 2006, while stock-based compensation expense was not included in our financial results for the same periods in 2005 (See [Stock-Based Compensation](#) below).

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Research and development expenses were approximately \$6.0 million and \$17.3 million for the three-month and nine-month periods ended September 30, 2006, respectively compared to \$4.2 million and \$13.7 million for the same periods in 2005. 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 primarily to the growth in our laboratory operations, as well as preclinical and clinical activities and personnel associated with advancing our lead compound, NEUMUNE, through development.

General and administrative expenses were \$1.9 million and \$7.1 million for the three-month and nine-month periods ended September 30, 2006, respectively, compared to \$1.9 million and \$6.5 million for the same periods in 2005. The general and administrative expenses relate primarily to salaries and benefits, facilities, legal, accounting/auditing, public and investor relations, consultants, insurance and travel. The changes in general and administrative expenses were driven by the impact of stock-based compensation expense related to the adoption of SFAS No. 123R in 2006, offset by a decrease in legal costs.

Other income (expense) was \$0.6 million and \$1.9 million for the three-month and nine-month periods ended September 30, 2006, respectively, compared to \$0.4 million and \$1.1 million for the same periods in 2005, composed entirely of interest income. The increase in interest income was due mainly to generally higher interest rates in 2006 than in 2005.

## **Stock-Based Compensation**

We have two equity-based incentive compensation plans, our 2005 Equity Incentive Plan and our 2005 Non-Employee Directors' Equity Incentive Plan. These Plans allow us to grant stock options and other stock or stock-based awards, including stock appreciation rights, stock purchase awards, restricted stock awards and restricted stock units awards. These Plans also allow us to provide equity compensation to non-employee directors and consultants. The exercise price of an option granted under these Plans is typically not less than the fair market value of the common stock subject to such option, and such option typically vest over four years.

Prior to January 1, 2006, we applied APB No. 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for options. As a result, generally there was no stock-based compensation expense for those grants in prior years.

Effective January 1, 2006, we adopted SFAS No. 123R, requiring us to recognize expense related to the fair value of our stock-based compensation awards. We elected the modified prospective transition method as permitted and accordingly, results from prior periods have not been restated. Under this transition method, stock-based compensation expense for the three- and nine month periods ended September 30, 2006 includes:

1. compensation expense for all stock-based compensation awards granted prior to January 1, 2006 but not yet vested, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, and
2. compensation expense for all stock-based compensation awards granted subsequent to December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R.

The fair value of each stock option granted is estimated on the date of grant using the Black-Scholes option-pricing model. The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect our experience. Compensation expense is recognized using the straight-line method for all stock-based awards issued after January 1, 2006. Compensation expense is recognized only for those options expected to vest, with forfeitures estimated at the date of grant based on our historical

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experience and future expectations. Prior to the adoption of SFAS 123R, the effect of forfeitures on the pro forma expense amounts was not recognized. SFAS 123R requires forfeitures to be estimated at the time of the grant and revised as necessary in subsequent periods if actual forfeitures differ from those estimates.

The total stock-based compensation expense included in our statement of operations for the nine-month periods ended September 30, 2006 and 2005 was \$3.4 million and \$-0-, respectively. Of the \$3.4 million stock-based compensation expense, \$2.8 million relates to awards granted prior to January 1, 2006.

As of September 30, 2006, the unrecognized stock-based compensation expense related to non-vested options and restricted shares was approximately \$7.3 million which is expected to be recognized over a weighted average period of approximately 1.2 years.

We did not modify terms of existing stock-based compensation awards prior to the adoption of SFAS 123R nor have we modified our compensation strategy as a result of SFAS 123R. (See note 1 of the Unaudited Notes to Financial Statements for the period ended September 30, 2006 for additional information).

**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 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 February 2006, we completed a sale of shares of our common stock and warrants from which we received gross proceeds of \$26.0 million. In addition, we have received a total of \$17.8 million from the exercise of warrants and stock options since our 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	Total	Payments Due by Period			More than five years
		Less than one year	One to three years	Three to five years	
Operating Leases	\$ 2,220	\$ 1,064	\$ 1,070	\$ 86	

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

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Our operations to date have consumed substantial capital without generating any revenues other than the small amount received under the CFFT collaboration, 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 a government order for NEUMUNE<sup>®</sup>, 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, 2006, our cash and cash equivalents totaled approximately \$47.4 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<sup>®</sup>, our lead drug candidate for Acute Radiation Syndrome, and if we do receive such an advance purchase contract, the amount of such contract, 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.

### **Cautionary Statement Regarding 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, 2005. 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.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

There have been no material changes to our investment portfolio from December 31, 2005 to the present. At September 30, 2006, our investment portfolio included only cash, money market accounts and a

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time deposit 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, 2006, 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. 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.

## **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.

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**Item 1A. 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. The risks described below include certain revisions to the risks set forth in our annual report on Form 10-K for the fiscal year ended December 31, 2005. 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 a proprietary class of small compounds 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 be 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 for the foreseeable future as we fund development, preclinical and clinical testing and other expenses in support of regulatory approval of our drug candidates. 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 drug candidates, we will not be able to sell products and will not generate revenues. If we receive regulatory approval of one of our drug candidates, such approval may impose limitations on the indicated uses for which we may market the resulting product, which may limit our ability to generate significant revenues. Further, U.S. or foreign regulatory agencies could change existing, or promulgate new, regulations at any time which may affect our ability to obtain approval of our drug candidates or require significant additional costs to obtain such approvals. In addition, if regulatory authorities determine that we or a partner conducting research and development activities on our behalf have not complied with regulations in the research and development of one of our drug candidates, then they may not approve the drug candidate and we will not be able to market and sell it. If we were unable to market and sell our drug candidates, our business and results of operations would be materially and adversely affected.

***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 \$183.6 million as of September 30, 2006. Our net losses for fiscal years 2005, 2004 and 2003 were approximately \$29.4 million, \$24.8 million and \$25.7 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 acute radiation syndrome. 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 ARS, is approved by the FDA,

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we cannot predict with any certainty the size of this market. The initial potential market for NEUMUNE is largely dependent on the size of stockpiling orders, if any, procured by government agencies. 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 December 9, 2005, the U.S. Department of Health and Human Services (DHHS) issued a Request for Proposal (RFP) which specified an initial potential stockpiling order of up to 100,000 treatment regimens, which is substantially lower than we had anticipated. While we have responded to the RFP, we cannot guarantee that we will be able to meet the requirements set forth in the RFP or that we will receive any resulting stockpiling orders. 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 or platelets after chemotherapy. A large number of companies, including Merck & Company, Inc., 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, Inc., Roche Pharmaceuticals, Pfizer Inc. and Abbott Laboratories have significant market share for the treatment of a number of infectious diseases such as HIV. In addition, biotechnology companies such as Gilead Sciences Inc., Chiron Corporation and Vertex Pharmaceuticals 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 or impossible to continue our business.*

As of September 30, 2006, our cash and cash equivalents totaled approximately \$47.4 million. In February 2006, we completed an offering of common stock and warrants to purchase common stock, pursuant to which we received net proceeds of approximately \$24.4 million. Based on our current plans, we believe these financial resources, and interest earned thereon, will be sufficient to meet our operating

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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.

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 numerous U.S. and foreign patents and foreign patent applications. Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to our ability to commercialize our drug candidates, if approved and our ability to operate our business 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 drug candidates, if approved, 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 similar competitive products or technologies that do not infringe on patents 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 and can preclude, delay or suspend commercialization of products. 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



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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.

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,

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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 payers are increasingly challenging the prices charged for medical products and services. If we succeed in 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;

Phase I 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; and

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

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

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

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

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***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 current 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.

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 preclinical and 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.

***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, are highly volatile. 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;

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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;

announcements in the scientific and research community;

changes in the potential commercial markets for our drug candidates;

unfavorable developments concerning patents or other proprietary rights;

unfavorable domestic or foreign regulatory or governmental developments or actions; or

broader economic, industry and market trends unrelated to our performance.

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 \$4.09 to \$16.50 between January 1, 2004 and November 1, 2006.

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 Global Market, which could materially limit the trading market for our common stock.***

Our common stock is quoted on The Nasdaq Global Market. In order to continue to be included in The Nasdaq Global 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 Global Market. If our common stock is delisted, in order to have our common stock relisted on The Nasdaq Global 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 Global Market. If our common stock is removed from listing on The Nasdaq Global Market, it may become more difficult for us to raise funds.

***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 9% of our outstanding common stock as of September 30, 2006. Assuming that Mr. Hollis exercises all of his outstanding warrants and options that vest within 60 days of September 30, 2006, Mr. Hollis would beneficially own approximately 14% 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.***

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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

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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 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 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, 2006.

**Item 3. Defaults Upon Senior Securities**

None

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

None

**Item 5. Other Information**

None

**Item 6. Exhibits**

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

<b>Exhibit Number</b>	<b>Description of Document</b>
*3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 4.1 to Registrant's Registration Statement on Form S-4 (No. 333-18725), as amended (the "Form S-4")).
*3.2	Bylaws of Registrant (incorporated by reference to Exhibit 4.2 to the Form S-4).
*3.3	Certificate of Designation of Series B Junior Participating Preferred Stock (incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K dated November 15, 1999).

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- \*3.4 Certificates of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.4 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001).
- \*4.1 Rights Agreement dated as of November 15, 1999 among Registrant and American Stock Transfer and Trust Company (incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K dated November 15, 1999).
- 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.

\* Previously filed.



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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 2, 2006

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

Dated: November 2, 2006

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