HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 10-Q
August 04, 2006
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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 June 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	**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 a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Exchange Act Rule 12b-2).

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨

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 August 1, 2006 there were 24,968,773 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 JUNE 30, 2006

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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)

	June 30, 2006 (Unaudited)	Dec. 31, 2005
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 53,446	$ 45,130
Prepaid expenses	360	204
Deposits	58	52
Receivable from related party	7	7
Other receivable	43	8
Total current assets	53,914	45,401
Property and equipment, net of accumulated depreciation of $885 and $740, respectively	1,121	1,116
Receivable from related party	1	4
Deposits	61	61
Total assets	$ 55,097	$ 46,582
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,154	$ 7,515
Deferred revenue	72	193
Total current liabilities	4,226	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; 24,946 and 20,782 shares issued; 24,887 and 20,723 shares outstanding, respectively	249	208
Paid-in capital	227,676	200,301
Cost of treasury stock (59 shares)	(346)	(346)
Deferred compensation	(383)	
Deficit accumulated during development stage	(176,325)	(161,289)
Total stockholders equity	50,871	38,874
Total liabilities and stockholders equity	$ 55,097	$ 46,582

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 June 30,		Six months ended June 30,		Period from Inception (Aug.15, 1994) to June 30,
	2006	**2005**	**2006**	**2005**	**2006**
Revenue:					
Contract R&D revenue	$ 67	$	$ 122	$	$ 241
Total revenue	67		122		241
Operating expenses:					
Research and development:					
R&D operating expenses	6,206	4,173	10,451	9,517	109,899
R&D SFAS 123R compensation expense related to equity awards	410		836		836
R&D costs related to common stock, option, & warrant grants for collaborations					5,667
Total research and development	6,616	4,173	11,287	9,517	116,402
General and administrative:					
G&A operating expenses	1,657	2,736	3,703	4,512	47,209
G&A SFAS 123R compensation expense related to equity awards	596		1,458		1,458
G&A costs related to common stock, option, & warrant grants	6	6	12	18	12,383
Total general and administrative	2,259	2,742	5,173	4,530	61,050
Settlement of dispute					3,000
Total operating expenses	8,875	6,915	16,460	14,047	180,452
Other income (expense):					
Loss on disposal of assets					(56)
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures					(7,627)
Interest income	691	377	1,302	697	11,957
Interest expense					(388)
Total other income (expense), net	691	377	1,302	697	3,886
Net loss	$ (8,117)	$ (6,538)	$ (15,036)	$ (13,350)	$ (176,325)
Net loss per share-basic and diluted	$ (0.33)	$ (0.33)	$ (0.62)	$ (0.68)	

Weighted average number of common shares outstanding-basic and diluted	24,919	19,742	24,127	19,515

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

	Six months ended June 30,		Period from Inception (Aug. 15, 1994) to June 30,
	2006	**2005**	**2006**
Cash flows from operating activities:			
Net loss	$ (15,036)	$ (13,350)	$ (176,324)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	145	144	1,242
SFAS 123R compensation expense related to equity awards	2,294		2,294
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	86	63	902
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	12	18	2,871
Common stock issued as consideration for In Process R&D	180		2,809
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	(156)	(197)	(360)
Deposits	(6)	(12)	(119)
Receivable from related party	3	(20)	(8)
Other Receivable	(35)	(1,149)	(43)
Accounts payable, accrued expenses and deferred revenue	(3,482)	(727)	4,871
Net cash used in operating activities	(15,995)	(15,230)	(140,649)
Cash flows provided by (used in) investing activities:			
Purchase of property and equipment	(150)	(375)	(2,426)
Net cash used in investing activities	(150)	(375)	(2,426)
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	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	7	17,775
Net cash from financing activities	24,461	9,522	196,521
Net increase (decrease) in cash	8,316	(6,083)	53,446
Cash and equivalents at beginning of period	45,130	61,991	
Cash and equivalents at end of period	$ 53,446	$ 55,908	$ 53,446

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

	Six months ended June 30,		Period from Inception (Aug. 15, 1994) to June 30,
	2006	**2005**	**2006**
Supplemental Disclosure of Cash Flow Information:			
Interest Paid	$	$	$ 388
Supplemental Disclosure of Non-Cash Financing Activities:			
Conversion of debt to equity			10,371
Warrants issued to consultants in lieu of cash, no vesting			559
Warrants issued in lieu of cash, commissions on private placement			733
Warrants issued in connection with convertible debentures			371

Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Notes to Financial Statements

(Unaudited)

1. Basis of Presentation

The information at June 30, 2006, and for the three and six-month periods ended June 30, 2006 and 2005, 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 stock units awards. The Plan also allows us to provide equity compensation to nonemployee directors and

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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 June 30, 2006 the Plan has 5,922,663 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 six months ended June 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)

	Six Months Ended	
	June 30, 2006	**June 30, 2005**
Risk-free interest rate	4.75%	3.72%
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 six-month periods ended June 30, 2006 and 2005 were $4.60 and $6.65 per share, respectively.

The total stock-based compensation expense included in our statement of operations for the six-month periods ended June 30, 2006 and 2005 was $2.3 million and $-0-, respectively. Of the $2.3 million stock-based compensation expense, $1.9 million relates to awards granted prior to January 1, 2006.

As of June 30, 2006, the unrecognized stock-based compensation expense related to non-vested options and restricted shares was approximately $8.4 million which is expected to be recognized over a weighted average period of approximately 1.3 years. During the six-month periods ended June 30, 2006 the total intrinsic value of the stock options exercised was $142,000. The total fair value of options vested during the six-month periods ended June 30, 2006 and 2005 were $2.7 million and $3.5 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 six months ended June 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	377	5.98		
Exercised	(5)	4.06		
Forfeited/Canceled	(49)	7.22		
Outstanding, June 30, 2006	4,969	$ 9.32	5.4	$ 423
Exercisable on June 30, 2006	3,983	$ 9.41	4.6	$ 423

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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, June 30, 2006	180	$ 9.29	8.8	-0-
Exercisable on June 30, 2006	63	$ 11.59	8.1	-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	1,926	$ 7.09		
Granted				
Exercised	(28)	2.25		
Forfeited/Canceled	(280)	4.96		
Outstanding, June 30, 2006	1,618	$ 7.54	2.8	-0-
Exercisable on June 30, 2006	1,543	$ 7.44	2.5	-0-

Cash proceeds and the intrinsic value related to stock options exercised during the fiscal years 2006 and 2005 to date, are provided in the following table (in thousands):

	Six Months Ended June 30, 2006	2005
Proceeds from stock options exercised	$ 86	$ 7
Tax benefit related to stock options exercised (1)	NA	NA
Intrinsic value of stock options exercised (2)	$ 142	$ 9

(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.

(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.

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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 June 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 six months ended June 30, 2006, $40,000 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 June 30, 2006, a balance of $43,200 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.

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 $71,727 recorded as deferred revenue as of June 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 resulting in an expense of $180,000 for the intellectual property rights of Aeson Therapeutics, Inc. Upon certain events, an additional 165,000 shares could be contingently issued.

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 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

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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 June 30, 2006, we had an accumulated deficit of approximately $176.3 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 June 30, 2006, we have generated approximately $241,000 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 $3.9 million in net other income consisting of $11.9 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 $116.4 million in research and development expenses, $61.0 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 $176.3 million for the period from our inception through June 30, 2006.

Research and development and general and administrative expenses include the expense for stock-based compensation in the three-month and six-month periods ended June 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).

Research and development expenses were approximately $6.6 million and $11.3 million for the three-month and six-month periods ended June 30, 2006, respectively compared to $4.2 million and $9.5 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 $2.3 million and $5.2 million for the three-month and six-month periods ended June 30, 2006, respectively, compared to $2.7 million and $4.5 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 a decrease in legal costs and the impact of stock-based compensations expense related to the adoption of SFAS No. 123R in 2006.

Other income (expense) was $0.7 million and $1.3 million for the three-month and six-month periods ended June 30, 2006, respectively, compared to $0.4 million and $0.7 million for the same periods in

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2005, comprised entirely of interest income. The increase in interest income was due mainly to generally higher interest rates in 2006 compared with the same period 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 six month periods ended June 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 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 six-month periods ended June 30, 2006 and 2005 was $2.3 million and $-0-, respectively. Of the $2.3 million stock-based compensation expense, $1.9 million relates to awards granted prior to January 1, 2006.

As of June 30, 2006, the unrecognized stock-based compensation expense related to non-vested options and restricted shares was approximately $8.4 million which is expected to be recognized over a weighted average period of approximately 1.3 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 June 30, 2006 for additional information).

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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 from inception.

On June 20, 2003, convertible debentures with a face value of $0.5 million were converted into 87,720 shares of our common stock, leaving a $9.5 million aggregate principal amount of convertible debentures outstanding. We became entitled to convert the outstanding debentures into common stock in August 2003, and the remaining aggregate principal amount of convertible debentures with a face value of $9.5 million were converted into 1,666,680 shares of our common stock with a value of $5.70 per share.

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

		Payments Due by Period			
	Total	Less than one year	One to three years	Three to five years	More than five years
Contractual Obligations					
Operating Leases	$ 1,193	$ 792	$ 382	$ 19	

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, 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, 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 June 30, 2006, our cash and cash equivalents totaled approximately $53.5 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 , 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 June 30, 2006, 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 June 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.

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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.

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.

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 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 $176.3 million as of June 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, 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.

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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. We are aware of one company, Novelos Therapeutics, Inc., that is still in competition with us for the RFP issued by DHHS. 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 June 30, 2006, our cash and cash equivalents totaled approximately $53.5 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 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.

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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