HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 10-Q
August 07, 2008
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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, 2008

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT 1934
For the transition period from _____ to _____.

Commission file number: 000-24672

HOLLIS-EDEN PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-3697002**
(State or other jurisdiction of incorporation)	**(I.R.S. Employer Identification No.)**
4435 Eastgate Mall, Suite 400, San Diego, California	**92121**
(Address of principal executive offices)	**(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, a non-accelerated filer, or a smaller reporting company. See definition of accelerated filer , large accelerated filer or smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨ Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company) Smaller reporting company x
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, 2008 there were 29,075,455 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, 2008

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Part I. Financial Information

Item 1. Financial Statements
Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Balance Sheets

All numbers in thousands (except par value)

	June 30, 2008 (Unaudited)	Dec. 31, 2007*
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 34,123	$ 43,215
Prepaid expenses	286	269
Deposits	2	7
Other receivables		645
Total current assets	34,411	44,136
Property and equipment, net of accumulated depreciation of $1,368 and $1,213, respectively	786	892
Restricted Cash	34	34
Deposits	61	61
Total assets	$ 35,292	$ 45,123
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable	1,344	455
Accrued expenses	2,300	2,563
Total current liabilities	$ 3,644	$ 3,018
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; 29,101 and 29,064 shares issued; 29,042 and 29,005 shares outstanding, respectively	291	291
Paid-in capital	258,079	256,801
Cost of treasury stock (59 shares)	(346)	(346)
Deficit accumulated during development stage	(226,376)	(214,641)
Total stockholders equity	31,648	42,105
Total liabilities and stockholders equity	$ 35,292	$ 45,123

* Derived from the audited financial statements as of December 31, 2007

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,
	2008	2007	2008	2007	2008
Revenue:					
Contract R&D revenue	$	$	$	$	$ 1,208
Total revenue					1,208
Operating expenses:					
Research and development:					
R&D operating expenses	4,173	4,324	8,299	8,611	144,429
R&D SFAS 123(R) compensation expense related to equity awards	261	260	480	601	3,097
R&D costs related to common stock, option & warrant grants for collaborations					5,882
Total research and development	4,434	4,584	8,779	9,212	153,408
General and administrative:					
G&A operating expenses	1,400	1,543	2,884	3,473	62,483
G&A SFAS 123(R) compensation expense related to equity awards	404	399	738	1,029	4,967
G&A costs related to common stock, option & warrant grants				17	12,412
Total general and administrative	1,804	1,942	3,622	4,519	79,862
Settlement of dispute					3,000
Total operating expenses	6,238	6,526	12,401	13,731	236,270
Other income (expense):					
Loss on disposal of assets				(71)	(142)
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures					(7,627)
Interest income	251	719	666	1,528	16,843
Interest expense					(388)
Total other income, net	251	719	666	1,457	8,686
Net loss	$ (5,987)	$ (5,807)	$ (11,735)	$ (12,274)	$ (226,376)
Net loss per share-basic and diluted	$ (0.21)	$ (0.20)	$ (0.40)	$ (0.42)	

Weighted average number of common shares outstanding-basic and diluted	29,040	28,949	29,023	28,934

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,
	2008	2007	2008
Cash flows from operating activities:			
Net loss	$ (11,735)	$ (12,274)	$ (226,376)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	154	156	1,853
SFAS 123(R) compensation expense related to equity awards	1,218	1,630	8,064
Disposal of assets		78	156
Amortization of deemed discount on convertible debentures			6,470
Amortization of deferred issuance cost			1,157
Common stock issued for the company 401k plan	60	74	1,294
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			2,859
Common stock issued as consideration for In Process R&D			2,809
Expense related to warrants issued as consideration to consultants		17	4,369
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	(17)	(281)	(286)
Deposits	5	34	(63)
Receivable from related party		4	
Other receivables	645		
Accounts payable	889	(584)	1,344
Accrued expenses	(263)	(3,628)	2,945
Net cash used in operating activities	(9,044)	(14,774)	(183,992)
Cash flows provided by (used in) investing activities:			
Purchase of property and equipment	(48)	(211)	(2,795)
Net cash used in investing activities	(48)	(211)	(2,795)
Cash flows from financing activities:			
Contributions from stockholder			104
Restricted cash			(34)
Net proceeds from sale of preferred stock			4,000
Net proceeds from sale of common stock			183,534
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		20	17,796
Net cash from financing activities		20	220,910
Net increase (decrease) in cash	(9,092)	(14,965)	34,123
Cash and equivalents at beginning of period	43,215	67,135	
Cash and equivalents at end of period	$ 34,123	$ 52,170	$ 34,123

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 (Continued)

(Unaudited)

All numbers in thousands

	Six Months ended June 30,		Period from Inception (Aug. 15, 1994) to June 30,
	2008	2007	2008
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, 2008, and for the three and six-month periods ended June 30, 2008 and 2007, 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 as amended for the year ended December 31, 2007, which was filed with the United States Securities and Exchange Commission on March 20, 2008.

New Accounting Pronouncements

At its December 2007 meeting, the Financial Accounting Standards Board, or the FASB, ratified the consensus reached by the Emerging Issues Task Force, or the EITF, Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property.* The EITF concluded that a collaborative arrangement is one in which the participants are actively involved and are exposed to significant risks and rewards that depend on the ultimate commercial success of the endeavor. Revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, and other accounting literature. Payments to or from collaborators would be evaluated and presented based on the nature of the arrangement and its terms, the nature of the entity s business and whether those payments are within the scope of other accounting literature. The nature and purpose of collaborative arrangements are to be disclosed along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other

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accounting literature; however, required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The Company is currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 141(R), *Business Combinations*, which replaces SFAS No. 141, *Business Combinations*, and requires an acquirer to recognize the assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions. This Statement also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the non-controlling interest in the acquiree, at the full amounts of their fair values. SFAS No. 141(R) makes various other amendments to authoritative literature intended to provide additional guidance or to confirm the guidance in that literature to that provided in this Statement. This Statement applies to business combinations for which the acquisition date is in fiscal years beginning after December 15, 2008. The Company is currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51*. SFAS No. 160 establishes accounting and reporting standards that require the ownership interests in subsidiaries held by parties other than the parent to be clearly identified, labeled and presented in the consolidated statement of financial position within equity, but separate from the parent s equity. This Statement also requires the amount of consolidated net income attributable to the parent and to the noncontrolling interest to be clearly identified and presented on the face of the consolidated statement of income. Changes in a parent s ownership interest while the parent retains its controlling financial interest in its subsidiary must be accounted for consistently, and when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary must be initially measured at fair value. The gain or loss on the deconsolidation of the subsidiary is measured using the fair value of any noncontrolling equity investment. The Statement also requires entities to provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. This Statement is effective for fiscal years beginning after December 15, 2008. The Company is currently in the process of evaluating the impact of adopting this pronouncement.

In June 2007, the EITF reached a consensus on Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received to Be Used in Future Research and Development Activities*. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided. This Issue is effective for fiscal years beginning after December 15, 2007, and earlier application is not permitted. The pronouncement has had no material effect on the Company s financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements.* SFAS No. 157 establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new circumstances. In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Liabilities.* SFAS No. 157 and 159 are effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, the FASB deferred the effective date of SFAS No. 157 for one year for non-financial assets and non-financial liabilities that are recognized or disclosed at fair value in the financial statements on a non recurring basis. In addition, the FASB issued a staff position that SFAS No. 157 does not apply under SFAS No. 13 Accounting for Leases and other accounting pronouncements that address fair value measurements for purposes of lease classifications under SFAS No. 13. The Company has adopted the pronouncements and it has had no material effect on the Company s financial statements.

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Accrued Expenses

Accrued expenses as of June 30, 2008 include approximately $0.5 million in accrued vacation expense, $138,000 in accrued salary/ bonus expense and $1.7 million in other research and development / general and administrative expenses.

Accrued expenses as of December 31, 2007 include approximately $0.5 million in accrued vacation expense, $0.7 million in accrued salary/ bonus expense and $1.3 million in other research and development / general and administrative expenses.

2. Other Agreements and Commitments

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. There were no revenues recorded during the three and six-months ended June 30, 2008 under the CFFT agreement. To date, $1.2 million has been paid upon completing agreed upon events.

3. Equity Transactions

Options to purchase 10,000 and 1,081,800 shares of common stock were granted in the three and six-month periods ended June 30, 2008, respectively. There were no options to purchase shares of common stock exercised in the three and six-month periods ended June 30, 2008. The Company accounts for stock option grants in accordance with FASB Statement 123(R), *Share-Based Payment*. Compensation costs related to share-based payments recognized in the Statements of Income were approximately $0.7 million and $1.2 million for the three-month and six-month periods ended June 30, 2008, respectively, and $0.6 million and $1.6 million for the same periods in 2007.

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 not possible 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 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 as amended for the year ended December 31, 2007.

Overview

We are a development-stage pharmaceutical company engaged in the discovery, development and commercialization of products for the treatment of diseases and disorders in which the body is unable to mount an appropriate immune or metabolic response due to disease or the process of aging. Our initial technology development efforts are primarily focused on a series of adrenal steroid hormones and hormone analogs that are derived from our Hormonal Signaling Technology Platform. We believe these compounds are key components of the body s natural regulatory system that potentially can be useful in treating a wide variety of medical conditions.

We have been unprofitable since our inception. As of June 30, 2008, we had an accumulated deficit of approximately $226.4 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.

On March 26, 1997, Hollis-Eden, Inc., a Delaware corporation, was merged with and into us, then known as Initial Acquisition Corp. (IAC), a Delaware corporation. Upon consummation of the merger of Hollis-Eden, Inc. with IAC, 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, 2008, we have incurred approximately $153.4 million in research and development expenses, $79.9 million in general and administrative expenses, and $3.0 million in the settlement of a dispute. From inception through June 30, 2008 we have generated approximately $1.2 million in revenues (which resulted from providing research and development services under our Study Funding Agreement with CFFT). We have earned $8.7 million in other income. The other income and expense is comprised of $7.6 million in deemed discount expense, $0.4 million in interest expense and $0.1 million loss on disposal of assets. These expenses have been offset by $16.8 million in interest income. The combination of these resulted in a net loss of $226.4 million for the period from inception until June 30, 2008.

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Research and development expenses were $4.4 million and $8.8 million for the three-month and six-month periods ended June 30, 2008, respectively, compared to $4.6 million and $9.2 million for the same periods in 2007. The research and development expenses relate primarily to the ongoing development, preclinical testing and clinical trials for our drug candidates. Research and development expenses decreased in 2008 compared to 2007 mainly due to the discontinuation of our NEUMUNE (HE2100) research and development program and a decrease in stock option compensation expenses.

General and administrative expenses were $1.8 million and $3.6 million for the three-month and six-month periods ended June 30, 2008, respectively, compared to $1.9 million and $4.5 million for the same periods in 2007. General and administrative expenses relate primarily to salaries and benefits, facilities, legal, accounting/auditing, investor relations, consultants, insurance and travel. General and administrative expenses decreased primarily as a result of reduced costs related to salaries, consulting, audit fees and stock option compensation expense.

Other income and expenses were $0.3 million and $0.7 million for the three-month and six-month periods ended June 30, 2008, respectively, compared to $0.7 million and $1.5 million for the same periods in 2007. The decrease in interest income was due to lower cash balances.

Liquidity and Capital Resources

We have financed our operations since inception primarily through the sale of shares of common stock. During the year ended December 31, 1995, we received cash proceeds of $250,000 from the sale of securities. In May 1996, we completed a private placement of shares of common stock, from which we received aggregate gross proceeds of $1.3 million. In March 1997, the Merger of IAC and Hollis-Eden, Inc. provided us with $6.5 million in cash and other receivables. In May 1998, we completed a private placement of common stock and warrants, from which we received gross proceeds of $20.0 million. During January 1999, we completed two private placements of common stock raising approximately $25.0 million. In December 2001, we completed a private placement of common stock and warrants, from which we received gross proceeds of $11.5 million. In February 2003, we completed a private placement of convertible debentures and warrants, from which we received gross proceeds of $10.0 million. In June 2003, we completed a private placement of common stock and warrants, from which we received gross proceeds of $14.7 million. In October 2003, we completed a public offering of our common stock from which we received $62.5 million in gross proceeds. In June 2005, we completed a sale of shares of our common stock and warrants from which we received $10.0 million in gross proceeds. During 2006 (in February and in November), we completed two sales of shares of our common stock and warrants from which we received, in the aggregate gross proceeds of approximately $52.0 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.

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

		Payments Due by Period			
Contractual Lease Obligations	**Total**	**Less than one year**	**One to three years**	**Three to five years**	**More than Five years**
Operating Leases	$ 1,757	$ 1,187	$ 570	$	$

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. We will continue to require substantial and increasing amounts of funds to conduct necessary research and development and preclinical and clinical testing of our drug candidates, and to market any drug candidates that receive regulatory approval. We do not expect to generate revenue from operations for the foreseeable future, and our ability to meet our cash obligations as they become due and payable may depend for at least the next several years on our ability to sell securities, borrow funds or some combination thereof. Based upon our current plans, we believe that our existing capital resources, together with interest thereon, will be sufficient to meet our operating expenses and capital requirements for at least the next 12 months. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We may not be successful in raising necessary funds. As of June 30, 2008, our cash and cash equivalents totaled approximately $34.1 million.

Our future capital requirements will depend upon many factors, including progress with preclinical testing and clinical trials, the number and breadth of our programs, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, the time and costs involved in obtaining regulatory approvals, competing technological and market developments, and our ability to establish collaborative arrangements, effective commercialization, marketing activities and other arrangements. We may incur increasing negative cash flows and net losses for the foreseeable future. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

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 as amended for the year ended December 31, 2007. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

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

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Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have been no material changes to our investment portfolio from December 31, 2007 to the present. At June 30, 2008, our investment portfolio included only cash, money market accounts and a 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 executive officer and interim chief financial officer have concluded that, as of June 30, 2008, 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 interim 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 interim chief financial officer have concluded, based on their evaluation, that our disclosure controls and procedures were sufficiently effective as of the end of the period covered by this report to provide reasonable assurance that the objectives of our disclosure control system were met.

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PART II Other Information

Item 1. Legal Proceedings

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. While it is impossible to predict accurately or to determine the eventual outcome of these matters, as of the date of this report, we do not believe that we are engaged in any legal proceedings that are expected, individually or in the aggregate, to have a material adverse effect on our business, financial condition or operating results.

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 description of risks below includes certain revisions to, and supersedes in its entirety, the description of the risk factors associated with our business previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K as amended for the fiscal year ended December 31, 2007. 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 several diseases and disorders. However, all drug candidates require approval by the U.S. Food and Drug Administration, or 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 and we do not expect that any of our present or future drug candidates will be commercially available for a number of years, if at all. We have incurred losses since our inception and we expect to continue to 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 our drug candidates are safe or effective. In addition, success in early development does not mean that later development will be successful because, for example, drug candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical testing. Our clinical experience with our drug candidates is limited, and to date our drug candidates have been tested in less than the number of patients that will likely need to be studied to gain regulatory approval. The data collected from clinical trials with larger patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of these drug candidates. In addition, we do not know whether early results from any of our ongoing clinical trials, including early results from our Phase I/II clinical trial of TRIOLEX in obese insulin resistant subjects, will be predictive of final results of any such trial. 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 and we will experience potentially significant delays in, or be required to abandon, development of the drug candidate. 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.

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

We have experienced significant operating losses to date because of the substantial expenses we have incurred to acquire and fund development of our drug candidates. We have never had significant operating revenues and have never commercially introduced a product. Our accumulated deficit was approximately $226.4 million as of June 30, 2008. Our net losses for fiscal years 2007, 2006 and 2005 were approximately $23.1 million, $30.2 million and $29.4 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 if we were ultimately to receive regulatory approval for one or more of our drug candidates, we may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost effectiveness, the cost of manufacturing the product on a commercial scale, the effect of competition with other drugs, or because we may have inadequate financial or other resources to pursue one or more of our drug candidates through commercialization. If we are unable to develop safe, commercially viable drugs, we may never achieve profitability. If we become profitable, we may not remain profitable.

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 candidates, assuming that our drug candidates gain regulatory approval. A large number of companies including Merck & Company, Inc., GlaxoSmithKline, Takeda Pharmaceuticals, Amylin Pharmaceuticals, Inc., AstraZeneca, Novartis, Novo Nordisk, Pfizer, Sanofi-Aventis and Eli Lilly and Co. are developing and marketing new drugs for the treatment of type 2 diabetes. Similarly, a large number of companies, including Merck & Company, Inc., Pfizer Inc., Johnson & Johnson Inc. and Amgen Inc., are developing and marketing new drugs for the treatment of chronic inflammatory conditions. In addition, there are also a number of other companies with drug candidates in development targeting late stage prostate cancer, including compounds already in Phase 3 clinical trials. One or more such compounds may be approved before any of our drug candidates could potentially be approved. Many, if not all, of these competing drug development programs are being conducted by pharmaceutical and biotechnology companies with considerably greater financial resources, human resources and experience than ours.

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.

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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, 2008, our cash and cash equivalents totaled approximately $34.1 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 will 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 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 our 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.

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

Our ability to commercialize our drug candidates successfully also will depend in part on the extent to which reimbursement for the cost of our drug candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations. Third-party 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:

- Phase I clinical trial with TRIOLEX (HE3286) in the United States under an Investigational New Drug Application, or an IND, for the treatment of metabolic diseases;
- Phase I/II clinical trial with TRIOLEX (HE3286) in the United States under an IND for the treatment of metabolic diseases;
- Phase II clinical trial with TRIOLEX (HE3286) in the United States in type 2 diabetes patients under an IND for the treatment of metabolic diseases;
- Phase I/II clinical trial with TRIOLEX (HE3286) in the United States under an IND for ulcerative colitis;
- Phase I/II clinical trial with TRIOLEX (HE3286) in the United States in rheumatoid arthritis patients under an IND for the treatment of diseases of inflammation; and
- Phase I/II clinical trial with APOPTONE (HE3235) in the United States in late-stage prostate cancer patients who have failed hormone therapy and at least one round of chemotherapy treatment under an IND for the treatment of hormone-sensitive cancers including prostate cancer.

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 studies of our drug candidates:

- we may not have the financial resources to continue research and development of any of our drug candidates;
- we may not be able to enter into collaborative arrangements relating to any drug candidate subject to delay in regulatory filing;

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we may lose any competitive advantage associated with early market entry; and

our ability to generate revenues may be delayed.

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 clinical trial;

unfavorable efficacy results;

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

reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;

failure to conduct a clinical trial in accordance with regulatory requirements or clinical protocols;

inspection of a clinical trial operations or clinical trial site by regulatory authorities resulting in the imposition of a clinical hold;

new communications from regulatory agencies about how to conduct these studies; or

failure to raise additional funds resulting in lack of adequate funding to continue a clinical trial or study.

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.

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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, most of which we cannot control, may have a significant impact on the market price of our common stock, which has been and is likely to continue to be volatile. For example:

- biological or medical discoveries by competitors;
- public concern about the safety of our drug candidates;
- delays in the conduct or analysis of our preclinical or clinical studies;
- unfavorable results from preclinical or clinical studies;
- delays in obtaining or failure to obtain purchase orders of our drug candidates;
- 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;

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

issuances of new equity securities by us, pursuant to our effective shelf registration statement or otherwise;

discussion of us or our stock price by the financial and scientific press and in online investor communities; or

additions or departures of key personnel

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 $1.40 to $10.25 between September 30, 2005 and August 1, 2008.

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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 and may materially limit the trading market of our common stock.

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

Assuming that outstanding warrants and options have not been exercised, Richard B. Hollis, our Chief Executive Officer, owns approximately 7.9% of our outstanding common stock as of June 30, 2008. Assuming that Mr. Hollis exercises all of his outstanding warrants and options that vest within 60 days of June 30, 2008, Mr. Hollis would beneficially own approximately 12.4% of our outstanding common stock. As a result, Mr. Hollis may be able to significantly influence our management and all matters requiring stockholder approval, including the election of directors. Such concentration of ownership may also have the effect of delaying or preventing a change in control of our company.

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

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

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

Our charter documents give our board of directors the authority to issue shares of preferred stock without a vote or action by our stockholders. The board also has the authority to determine the terms of 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.

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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 June 30, 2008.

Item 3. Defaults Upon Senior Securities

None

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

At our annual meeting of stockholders held on June 9, 2008, the following matters were submitted to a vote of security holders:

1. To elect one Class II director to hold office until the 2011 Annual Meeting of Stockholders. Elected to serve as a Class II director was Thomas C. Merigan, Jr., M.D. For Thomas C. Merigan, Jr., M.D. the results of voting were: 21,810,688 for, 2,882,765 withheld. The continuing directors are Richard B. Hollis, Salvatore J. Zizza, Jerome M. Hauer and Marc R. Sarni.

2. To approve an amendment to the Company s 2005 Equity Incentive Plan, as amended, to increase the aggregate number of shares of Common Stock authorized for issuance under the Plan by 800,000 shares. The 2005 Equity Incentive Plan, as amended, was approved with the following votes: 8,437,786 for, 1,624,350 against, 64,335 abstained, and 18,857,134 non-voted.

3. To approve an amendment to the Company's 2005 Non-Employee Directors' Equity Incentive Plan, as amended, to increase the aggregate number of shares of Common Stock authorized for issuance under the Plan by 150,000 shares. The 2005 Non-Employee Director s Equity Incentive Plan, as amended, was approved with the following votes: 8,595,591 for, 1,444,784 against, 86,096 abstained, and 18,857,134 non-voted.

4. To ratify the selection by the Audit Committee of the Board of Directors of BDO Seidman, LLP as the independent registered public accounting firm of the Company for its fiscal year ending December 31, 2008. The selection of BDO Seidman, LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2008 was ratified with the following votes: 24,047,759 for, 460,904 against, 184,786 abstained, and 4,290,156 non-voted.

Item 5. Other Information

None

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Item 6. Exhibits

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

Exhibit Number	Description of Document
*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.
*3.2	Bylaws of Registrant (incorporated by reference to Exhibit 3.2 to Registrant s Current Report on Form 8-K dated December 10, 2007).
*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).
*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).
#10.61	Letter Agreement between Cystic Fibrosis Foundation Therapeutics, Inc. and the Registrant dated June 12, 2008.
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 Robert W. Weber.
32.1	Section 1350 Certifications of Richard B. Hollis and Robert W. Weber.

* Previously filed.

\# Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

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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: August 5, 2008

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

Interim Chief Financial Officer/

Chief Accounting Officer/

Vice President-Operations

(Principal Financial and Accounting Officer)