HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 10-Q
November 06, 2009
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2009

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ 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 and 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 November 5, 2009 there were 29,417,589 shares of registrant s Common Stock, $.01 par value, outstanding.

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HOLLIS-EDEN PHARMACEUTICALS, INC.

Form 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2009

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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)

	Sept. 30, 2009 (Unaudited)	Dec. 31, 2008*
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 12,099	$ 24,152
Restricted cash	34	
Prepaid expenses	397	262
Other receivable	19	
Deposits	61	7
Total current assets	12,610	24,421
Property and equipment, net of accumulated depreciation of $1,493 and $1,496, respectively	421	641
Restricted Cash		34
Deposits		61
Total assets	$ 13,031	$ 25,157
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable	305	323
Accrued expenses	1,328	1,629
Total current liabilities	$ 1,633	$ 1,952
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; 29,452 and 29,228 shares issued; 29,393 and 29,169 shares outstanding, respectively	294	292
Paid-in capital	260,614	259,465
Cost of treasury stock (59 shares)	(346)	(346)
Deficit accumulated during development stage	(249,164)	(236,206)
Total stockholders equity	11,398	23,205
Total liabilities and stockholders equity	$ 13,031	$ 25,157

* Derived from the audited financial statements as of December 31, 2008

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

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Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Operations

(Unaudited)

All numbers in thousands, except per share amounts

	Three Months ended Sept. 30,		Nine Months ended Sept. 30,		Period from Inception (Aug. 15, 1994) to Sept. 30,
	2009	2008	2009	2008	2009
Revenue:					
Contract R&D revenue	$	$	$	$	$ 1,208
Total revenue					1,208
Operating expenses:					
Research and development:					
R&D operating expenses	2,411	3,339	8,260	11,638	159,482
R&D costs related to common stock, stock option grants including collaborations and technology purchases	167	221	469	701	9,946
Total research and development	2,578	3,560	8,729	12,339	169,428
General and administrative:					
G&A operating expenses	738	1,128	3,734	4,012	68,359
G&A costs related to common stock, option & warrant grants	103	377	605	1,115	18,758
Total general and administrative	847	1,505	4,345	5,127	87,123
Settlement of dispute					3,000
Total operating expenses	3,425	5,065	13,074	17,466	259,551
Other income (expense):					
Loss on disposal of assets	(12)		(19)		(166)
Non-cash amortization of deemed discount and deferred issuance costs on convertible debentures					(7,627)
Interest income	18	210	129	876	17,354
Interest expense					(388)
Total other income, net	12	210	116	876	9,179
Net loss	$ (3,413)	$ (4,855)	$ (12,958)	$ (16,590)	$ (249,164)
Net loss per share-basic and diluted	$ (0.12)	$ (0.17)	$ (0.44)	$ (0.57)	
Weighted average number of common shares outstanding-basic and diluted	29,389	29,073	29,288	29,040	

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

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Hollis-Eden Pharmaceuticals, Inc.

(A Development Stage Company)

Statements of Cash Flows

(Unaudited)

All numbers in thousands

	Nine Months ended Sept. 30, 2009	2008	Period from Inception (Aug. 15, 1994) to Sept. 30, 2009
Cash flows from operating activities:			
Net loss	$ (12,958)	$ (16,590)	$ (249,164)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	186	235	2,200
Loss on disposal of assets	39		201
Compensation expense related to equity awards	1,074	1,816	10,409
Amortization of deemed discount on convertible debentures			6,470
Amortization of deferred issuance cost			1,157
Common stock issued for the company 401k plan	78	105	1,488
Common stock issued as consideration for amendments to the license / finance agreements			67
Common stock and options issued as consideration for license fees, milestone payments, interest, note repayment and services			2,859
Expense related to warrants issued as consideration to consultants			4,369
Expense related to warrants issued to a director for successful closure of merger			570
Expense related to stock options issued			5,718
Expense related to common stock issued for the purchase of technology			1,848
Common stock issued as consideration for In Process R&D			2,809
Deferred compensation expense related to options issued			1,210
Changes in assets and liabilities:			
Prepaid expenses	(135)	20	(397)
Deposits	7	(2)	(61)
Other receivables	(19)	645	(19)
Accounts payable	(18)	307	996
Accrued expenses	(302)	(619)	1,280
Net cash used in operating activities	(12,048)	(14,083)	(205,990)
Cash flows provided by (used in) investing activities:			
Purchase of property and equipment	(5)	(70)	(2,821)
Net cash used in investing activities	(5)	(70)	(2,821)
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			17,796

Net cash from financing activities			220,910
Net increase (decrease) in cash	(12,053)	(14,153)	12,099
Cash and equivalents at beginning of period	24,152	43,215	
Cash and equivalents at end of period	$ 12,099	$ 29,062	$ 12,099

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

	Nine Months ended Sept. 30, 2009	2008	Period from Inception (Aug. 15, 1994) to Sept. 30, 2009
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 September 30, 2009, and for the three-month and nine-month periods ended September 30, 2009 and 2008, 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 , we or the Company) Annual Report on Form 10-K, for the year ended December 31, 2008, which was filed with the United States Securities and Exchange Commission on March 31, 2009 and amended on April 28, 2009.

New Accounting Pronouncements

Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property, ASC 808-10, 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 ASC 605-45, 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 accounting literature; however, required disclosure under ASC 808-10 applies to the entire collaborative agreement. ASC 808-10 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 adoption of this standard did not have a material impact on our financial statements.

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Effective July 1, 2009, the Company adopted a replacement of FASB Statement No. 162 The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles (ASC 105). This standard establishes only two levels of U.S. generally accepted accounting principles (GAAP), authoritative and nonauthoritative. The FASB Accounting Standards Codification (the Codification) became the source of authoritative, nongovernmental GAAP, except for rules and interpretive releases of the SEC, which are sources of authoritative GAAP for SEC registrants. All other non-grandfathered, non-SEC accounting literature not included in the Codification became nonauthoritative. The Company began using the new guidelines and numbering system prescribed by the Codification when referring to GAAP in the third quarter of fiscal 2009. As the Codification was not intended to change or alter existing GAAP, it did not have any impact on our financial statements.

Effective April 1, 2009, the Company adopted three accounting standard updates which were intended to provide additional application guidance and enhanced disclosures regarding fair value measurements and impairments of securities. They also provide additional guidelines for estimating fair value in accordance with fair value accounting. The first update, as codified in ASC 820-10-65, provides additional guidelines for estimating fair value in accordance with fair value accounting. The second accounting update, as codified in ASC 320-10-65, changes accounting requirements for other-than-temporary-impairment (OTTI) for debt securities by replacing the current requirement that a holder have the positive intent and ability to hold an impaired security to recovery in order to conclude an impairment was temporary with a requirement that an entity conclude it does not intend to sell an impaired security and it will not be required to sell the security before the recovery of its amortized cost basis. The third accounting update, as codified in ASC 825-10-65, increases the frequency of fair value disclosures. These updates were effective for fiscal years and interim periods ended after June 15, 2009. The adoption of these accounting updates did not have any impact on our financial statements.

Effective April 1, 2009, the Company adopted a new accounting standard for subsequent events, as codified in ASC 855-10. The update modifies the names of the two types of subsequent events either as recognized subsequent events (previously referred to in practice as Type I subsequent events) or non-recognized subsequent events (previously referred to in practice as Type II subsequent events). In addition, the standard modifies the definition of subsequent events to refer to events or transactions that occur after the balance sheet date, but before the financial statements are issued (for public entities) or available to be issued (for nonpublic entities). It also requires the disclosure of the date through which subsequent events have been evaluated. The update did not result in significant changes in the practice of subsequent event disclosures, and therefore the adoption did not have any impact on our financial statements.

Accrued Expenses

Accrued expenses as of September 30, 2009 include approximately $0.3 million in accrued vacation expense, $.03 million in 401K payables and $1.0 million in other research and development and general and administrative expenses.

Accrued expenses as of December 31, 2008 include approximately $0.5 million in accrued vacation expense and $1.1 million in other research and development and 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 on sales of a specified compound over a specified period following regulatory approval in the United States. Additional compensation is due to CFFT if net sales of this compound exceed a specified amount over a period of time.

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Revenue is recognized under this agreement on a milestone completion basis for each distinct agreed-upon event. There were no revenues recorded during the three-month or nine-month periods ended September 30, 2009 under the CFFT agreement. To date, $1.2 million has been paid upon completing agreed upon events.

3. Equity Transactions

Options to purchase 0 and 8,600 shares of common stock were granted in the three-month and nine-month periods ended September 30, 2009. There were no options to purchase shares of common stock exercised in the three-month or nine-month periods ended September 30, 2009. The Company accounts for stock option grants in accordance with ASC 718, Share-Based Payment. Compensation costs related to share-based payments recognized in the Statements of Income were approximately $0.3 million and $1.1 million for the three-month and nine-month periods ended September 30, 2009, respectively and $0.6 million and $1.8 million for the same periods in 2008. The Company may from time to time extend previous option grants.

In February 1997, as part of an employment agreement, the Company granted a non-statutory stock option to an executive to purchase 2,400,000 shares of the Company s common stock at a price of $5.00 per share, which vested ratably over a six-year period. The intrinsic value of the options was $1,848,000. As a result, the Company recorded as deferred compensation a non-cash charge of $1,848,000, which was being amortized ratably over the six-year vesting period. Through February 1999, the Company had amortized a total of $641,333. In March 1999, the Company announced the resignation of this executive, at which time the Company and the executive agreed that the option would remain outstanding for a total of 1,200,000 shares, including the acceleration of vesting of 400,000 shares. This acceleration is considered to be a new grant of options and, as such, the Company took a one-time non-cash charge of $4.9 million during the first quarter of 1999. No change was made to the terms of the option for the remaining 800,000 shares. In February 2008, 400,000 of the options were forfeited. The remaining 800,000 shares expired unexercised during February 2009.

4. Fair Value Measurement

We adopted ASC 820-10 as of January 1, 2008, for financial instruments measured at fair value on a recurring basis. ASC 820-10 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States and expands disclosures about fair value measurements.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820-10 establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). These tiers include:

Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets;

Level 2, defined as inputs other than quoted prices in active markets that are directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and

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Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant value drivers are observable.

We measure certain financial instruments at fair value on a recurring basis. Financial assets measured at fair value on a recurring basis are as follows at September 30, 2009:

	Level 1	Level 2	Level 3	Total
		In Thousands		
Money Market funds included in cash and cash equivalents	$ 11,454	$ 0	$ 0	$ 11,454
Total	$ 11,454	$ 0	$ 0	$ 11,454

5. 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.

The Company has evaluated all subsequent events through November 6, 2009, which represents the filing date of this Form 10Q with the Securities and Exchange Commission, to ensure that this Form 10-Q includes appropriate disclosure of events both recognized in the financial statements as of September 30, 2009 and events which occurred subsequent to September 30, 2009 but were not recognized in the financial statements. As of November 6, 2009, there were no subsequent events that required recognition or disclosure.

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, 2008.

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 current 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.

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We have been unprofitable since our inception in August 1994. As of September 30, 2009, we had an accumulated deficit of approximately $249.2 million. We expect to incur substantial additional operating losses and capital expenditures for the foreseeable future on clinical testing and other activities in support of the development of our drug candidates. In addition, in the future, 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.

Results of Operations

We have devoted substantially all of our resources to the payment of research and development expenses and general and administrative expenses. From inception through September 30, 2009, we have incurred approximately $169.4 million in research and development expenses, $87.1 million in general and administrative expenses, and $3.0 million in the settlement of a dispute. From inception through September 30, 2009, 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 $9.2 million in net, other income, as our $17.4 million of interest income has been partly offset by $7.6 million in deemed discount expense, $0.4 million in interest expense and $0.2 million loss on disposal of assets. The combination of these resulted in a net loss of $249.2 million for the period from inception until September 30, 2009.

Research and development expenses were $2.6 million and $8.7 million for the three-month and nine-month periods ended September 30, 2009, respectively, compared to $3.6 million and $12.3 million for the same periods in 2008. 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 by $1.0 million and $3.6 million for the three-month and nine-month periods ended September 30, 2009, respectively, compared to the same periods in 2008, primarily due to a decrease in general and preclinical research and development projects resulting from reduced personnel; stock option compensation expense also declined. These decreases were partly offset by an increase in clinical trial expenditures, including expenditures for a follow-on study of TRIOLEX (HE3286) in drug-naive inflamed, obese insulin resistant type 2 diabetic patients.

General and administrative expenses were $0.8 million and $4.3 million for the three-month and nine-month periods ended September 30, 2009, respectively, and $1.5 million and $5.1 million for the same periods in 2008. 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 by $0.7 million and $0.8 million for the three-month and nine-month periods ended September 30, 2009, respectively, compared to the same period in 2008. The decrease was due mainly to a decrease in salaries expense resulting from reduced personnel, investor communications and stock option compensation expense, offset by an increase in legal fees related primarily to the termination of our former chief executive officer Richard Hollis.

Other income, net was $0.01 million and $0.12 million for the three-month and nine-month periods ended September 30, 2009, respectively, compared to $0.2 million and $0.9 million for the same periods in 2008. The decrease in interest income was due to lower interest rates and cash balances.

Please refer to critical accounting policies included in the Form 10K filed on March 31, 2009, and amended on April 28, 2009.

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Liquidity and Capital Resources

A summary of our current contractual obligations as of September 30, 2009 is as follows (in thousands):

		Payments Due by Period			
Contractual Obligations	**Total**	**Less than one year**	**One to three years**	**Three to five years**	**More than five years**
Operating Leases	$ 272	$ 267	$ 5	$	$

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 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. The first nine months cash usage of approximately $12 million is not representative going forward due to staff reductions, winding down laboratory operations and the completion of some clinical trial activities. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of our capital resources before the time frames specified here. We may not be successful in raising necessary funds. As of September 30, 2009, our cash and cash equivalents totaled approximately $12.1 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.

Staffing and Strategy

During February 2009, we announced an aggressive cost-cutting plan to preserve capital and to focus on the advancement of our clinical development programs of TRIOLEX (HE3286) and APOPTONE (HE3235). As a result, we reduced our workforce by 20 employees (approximately 33%) and had 42 FTEs (full-time equivalents) at the end of the first quarter, March 2009. We continue to focus the company s efforts on the clinical programs and reassess the staffing requirements on a regular basis. During the second quarter, there was some attrition and several employees switched from full-time to a part time basis, bringing our FTEs to 36.5 at the end of the June. At the end of September, we had 27.5 FTEs and currently forecast the workforce to be approximately 20 FTE s at the end of 2009.

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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, 2008. 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, 2008 to the present. At September 30, 2009, 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

Evaluation of Disclosure Controls and Procedures

Based on the evaluation of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)) required by Rule 13a-15(b) of the Exchange Act, James M. Frincke, our chief executive officer, and Robert W. Weber, our chief financial officer, have concluded that, as of September 30, 2009, our disclosure controls and procedures were effective to ensure that the information required in the reports we file under the Exchange Act is gathered, reported-up, 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.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports we file with or submit to the SEC under the Securities and Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our

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management, including our chief executive officer and chief financial officer as appropriate, to allow for timely decisions regarding required disclosure. 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 errors 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 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, 2008 and our subsequent filings with the Securities and Exchange Commission*. Any of the following risks could materially adversely affect our business, financial condition, results of operations and prospects and, as a result, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.

We are still a development stage company.

We have never had any revenues from sales of products. None of our drug candidates has 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 clinical testing and other expenses in support of regulatory approval of our drug candidates.

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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 (FDA) before they can be commercialized in the United States 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. 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 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.

Recent publicity concerning the safety of certain drug products has resulted in heightened scrutiny by the FDA in the process of approving new drugs, which could delay or limit any regulatory approvals we may obtain for our drug candidates.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products after approval. In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government s clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from

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our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials by drug development companies. As a result, the FDA may require us to conduct additional preclinical studies or clinical trials during the clinical development of one or more of our drug candidates as a condition precedent to approval which could potentially delay our development plans, limit the indications for which our drug candidates are ultimately approved, and otherwise adversely impact us.

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 $249.2 million as of September 30, 2009. Our net losses for fiscal years 2008, 2007 and 2006 were approximately $21.6 million, $23.1 million and $30.2 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 as well as academic institutions, government agencies and private and public research institutions. Several of these entities have already successfully marketed and commercialized products that will compete with our drug 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 Inc., 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 or better-marketed than our drug candidates, our drug candidates,

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even if approved for sale, may not be able to compete successfully with our competitors existing products or new products under development. Similarly, we cannot predict whether any of our drug candidates, if approved, will have sufficient advantages to cause healthcare professionals to adopt our products over competing products. 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 need to raise additional money before we achieve profitability; if we fail to raise additional money, it could be difficult or impossible to continue our business.

As of September 30, 2009, our cash and cash equivalents totaled approximately $12.1 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.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline.

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

We own or have obtained a license to a number of 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

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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 our drug candidates. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, or fail to successfully defend an infringement action or have the patents we are alleged to infringe declared invalid, we may:

- incur substantial money damages;
- encounter significant delays in bringing our drug candidates to market;
- be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment without first obtaining licenses to do so; and/or
- not be able to obtain any required license on favorable terms, if at all.

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

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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 and/or future pricing regulations and reimbursement limitations may limit our potential profits from the sale of our products.

The requirements governing product licensing, pricing and reimbursement vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after product-licensing approval is granted. As a result, we may obtain regulatory approval for a drug candidate in a particular country, but then be subject to price regulations that reduce our profits from the sale of the product. In some foreign markets pricing of prescription pharmaceuticals is subject to continuing government control even after initial marketing approval. In addition, certain governments may grant third parties a license to manufacture our product without our permission. Such compulsory licenses may be on terms that are less favorable to us and would likely have the effect of reducing our revenues.

Varying price regulation between countries can lead to inconsistent prices and some re-selling by third parties of products from markets where products are sold at lower prices to markets where those products are sold at higher prices. Any practice of exploiting price differences between countries could undermine our sales in markets with higher prices and reduce the sales of our future products, if any.

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

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

The United States Congress is considering various proposals for fundamental reform of the health care and health insurance systems, including proposals championed by President Obama. Although it is premature to assess the exact effect on us of whatever proposals are to be adopted, it is likely that the overall effect of such legislation on us would be negative.

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 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;

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- 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 II clinical trial with TRIOLEX (HE3286) in the United States under an IND for the treatment of ulcerative colitis;

- Phase I 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;

- 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.

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If the manufacturers of our drug candidates do not comply with current Good Manufacturing Practices regulations, or cannot produce sufficient quantities of our drug candidates to enable us to continue our development, we will fall behind on our business objectives.

Manufacturers producing our drug candidates must follow current Good Manufacturing Practices regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to current Good Manufacturing Practices regulations and cannot be brought up to such a standard, we will be required to find alternative manufacturers that do conform. This may be a long and difficult process, and may delay our ability to receive FDA or foreign regulatory approval of our drug candidates.

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

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

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

Our founder, Richard Hollis, is no longer a Company officer or director.

Our founder and former chief executive officer Richard B. Hollis was terminated during March 2009. The departure of a founder, who has helped to shape our culture and vision, is always a special challenge for an emerging company.

If we were to lose the services of members of our management team, 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 upon the continued services of our management team. If we lose the services of one or more of these individuals, replacement could be difficult and may take an extended period of time and could impede significantly the achievement of our business objectives.

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.

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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 $0.27 to $10.25 between September 30, 2005 and November 5, 2009.

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.

We received a letter from The NASDAQ Stock Market on September 15, 2009. The letter states that Hollis-Eden is not in compliance with Nasdaq Marketplace Rule 4450(a)(5) (the Minimum Bid Price Rule) because its common stock had closed below $1.00 per share for 30 consecutive business days. The letter also states that in accordance with Nasdaq Marketplace Rules, we have 180 days, or until March 15, 2010, to regain compliance with the Minimum Bid Price Rule. This letter has no immediate effect on the NASDAQ listing or trading of Hollis-Eden s common stock.

We will regain compliance with the Minimum Bid Price Rule if the bid price of our common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days before March 15, 2010. However, if we do not regain compliance with the Minimum Bid Price Rule by March 15, 2010, the Nasdaq staff will provide us with a written notification that our common stock is subject to delisting.

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

Richard B. Hollis, our former Chief Executive Officer and a former member of our board of directors, owned approximately 7.8% of our outstanding common stock as of November 5, 2009. As a result, Mr. Hollis may be able to significantly influence 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 or conversion of convertible securities, 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.

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

We made no unregistered sales of securities or repurchases of our securities during the quarter ended September 30, 2009.

Item 3. Defaults Upon Senior Securities

None

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

None

Item 5. Other Information

None

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Item 6. Exhibits

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

Exhibit Number	Description of Document
*4.2	Amended and Restated Rights Agreement entered into on October 19, 2009 between Hollis-Eden Pharmaceuticals, Inc.and American Stock Transfer and Trust Company, LLC (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K dated October 22, 2009).
*4.3	Amendment and Restated Certificate of Designation of Series B Junior Preferred Stock (incorporated by reference to Exhibit 4.2 to our Current Report on Form 8-K dated October 22, 2009).
31.1	Rule 13a-14(a)/15d-14(a) Certification of James M. Frincke.
31.2	Rule 13a-14(a)/15d-14(a) Certification of Robert W. Weber.
32.1	Section 1350 Certifications of James M. Frincke and Robert W. Weber.

* Previously filed.

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Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

HOLLIS-EDEN PHARMACEUTICALS, INC.

Dated: November 6, 2009

/s/ Robert W. Weber
Robert W. Weber
Chief Financial Officer and
Vice President-Operations
(Principal Financial and Accounting Officer)