HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 8-K
March 31, 2009

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 27, 2009

HOLLIS-EDEN PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

000-24672	**13-3697002**
(Commission File No.)	**(IRS Employer Identification No.)**

4435 Eastgate Mall, Suite 400

San Diego, California 92121

(Address of principal executive offices and zip code)

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

Not Applicable.

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 2.02. RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On March 31, 2009, Hollis-Eden Pharmaceuticals, Inc. (the Company) issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2008 and certain other information. A copy of this press release is attached as Exhibit 99.1 to this report and incorporation by reference herein.

The information contained in this report, including the exhibit hereto, is being furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act whether made before or after the date hereof, regardless of any general incorporation language in such filing.

ITEM 5.02. DEPARTURE OF DIRECTORS OR PRINCIPAL OFFICERS; ELECTION OF DIRECTORS; APPOINTMENT OF CERTAIN OFFICERS; COMPENSATORY ARRANGEMENTS OF CERTAIN OFFICERS.

(b) On March 29, 2009, the Company received notice from Thomas C. Merigan, Jr., M.D. that he had resigned from the Company s board of directors effective March 29, 2009 for personal reasons.

ITEM 7.01. REGULATION FD DISCLOSURE.

On March 27, 2009, the Special Committee (consisting entirely of non-employee directors and constituting a majority of directors) (the Special Committee) of the Board of Directors (the Board) of the Company removed Richard Hollis, the Company s former Chief Executive Officer, as Chairman of the Board and appointed Salvatore J. Zizza, a current director, as the non-executive Chairman of the Board.

On March 31, 2009, the Company included the following disclosure on p. 7 of its Annual Report on Form 10-K filed with the Securities and Exchange Commission on the same date:

During 2008, Hollis-Eden initiated a Phase II clinical trial with TRIOLEX in type 2 diabetes patients. This Phase II, double-blinded placebo controlled 12-week dosing trial has enrolled over 90 patients with a hemoglobin A1c (HbA1c) level in excess of 7.5 percent who are on a stable dose of metformin only, the current first-line therapy for type 2 diabetes. The primary objectives of this trial are to evaluate the change in HbA1c from baseline to week 12 in the HE3286 treated group when compared to the placebo group and to evaluate the safety and tolerance of HE3286 10 mg per day (5 mg BID) compared to placebo from baseline to week 12.

We have completed three interim analyses of data from this on-going Phase II clinical trial with TRIOLEX in type 2 diabetes patients. The first interim analysis, which we planned pursuant to the study protocol when 25 percent of the subjects reached study-day 57, was completed in December 2008. The second interim analysis was completed in January 2009 and then expanded

in January 2009. The third interim analysis was completed in February 2009. Each interim analysis determined that, as of the date of such analysis, TRIOLEX was failing to meet its primary endpoint of lowering HbA1c in subjects treated with TRIOLEX compared to subjects treated with placebo. Each of these three interim analyses showed a statistically significant reversal in favor of placebo over TRIOLEX at day 57. The second interim analysis also showed a statistically significant reversal in favor of placebo over TRIOLEX at day 84 while the third interim analysis showed a trend in favor of placebo over TRIOLEX at day 84. Beginning with the first interim analysis, each of these interim analyses indicate that this trial will not achieve its primary endpoint of a statistically significant reduction in HbA1c at the conclusion of the trial for the total patient population. There were no safety related concerns identified in the interim analyses.

Enrollment in the trial is complete with 95 subjects. All subjects have completed dosing and we expect that the trial should be completed in the second quarter of 2009. We are evaluating all available data and will analyze the results from this study prior to determining the future development strategy for TRIOLEX in type 2 diabetes.

The information contained in this report, including the exhibit hereto, is being furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act whether made before or after the date hereof, regardless of any general incorporation language in such filing.

By filing this Current Report on Form 8-K and furnishing this information, the Company makes no admission as to the materiality of any information in this Item 7.01 of Current Report on Form 8-K.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.
(d) Exhibits.

99.1 Press release dated March 31, 2009.

SIGNATURE

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

HOLLIS-EDEN PHARMACEUTICALS, INC.

Dated: March 31, 2009

By: /s/ James M. Frincke
James M. Frincke
Interim Chief Executive Officer

EXHIBIT INDEX

99.1	Press release dated March 31, 2009.