HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 8-K
June 11, 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): June 8, 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 7.01 REGULATION FD DISCLOSURE.
Clinical Trials Update

Type 2 Diabetes

During 2008, Hollis-Eden Pharmaceuticals (the Company) initiated a Phase II clinical trial with TRIOLEX in type 2 diabetes patients. This Phase II, double-blinded placebo controlled 12-week dosing trial enrolled 96 subjects with a hemoglobin A1c (HbA1c) level in excess of 7.5 percent who were on a stable dose of metformin, the current first-line therapy for type 2 diabetes. The primary objectives of this trial were to evaluate the safety and tolerance of HE3286, 10 mg per day (5 mg twice daily), compared to placebo from baseline to week 12 and to evaluate the change in HbA1c from baseline to week 12 in the HE3286 treated group when compared to the placebo group.

In the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2009 and on Form 10-Q filed on May 13, 2009 we reported the results of three interim analyses of unaudited data completed in December 2008, January 2009 and February 2009. Each interim analysis determined that, as of the date of each 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 and 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 indicated that this trial would not achieve its primary endpoint of a statistically significant reduction in HbA1c at the conclusion of the trial for the total patient population.

A final analysis of activity (HbA1c) in the clinical study of unaudited data was performed on all subjects that completed dosing on day 84 of the study (72 patients). Contrary to the interim analyses, there was no significance in favor of the placebo at the end of the study. The previously reported results were due to overrepresentation of non-obese patients enrolled prior to a protocol amendment on September 11, 2008. This amendment established an additional enrollment criterion of a body mass index (BMI) greater than or equal to 26 kg/m^2 . After the amendment was effective, only individuals with a BMI of 26 or greater were enrolled into the study, and thus reflected more heavily in the final data analysis when this stage of the study was completed. In the final analysis there was no statistical difference between treatment and placebo for HbA1c in the overall patient population.

A retrospective analysis of unaudited data was performed on the subpopulation of patients that represent the inflamed, obese, insulin-resistant, diabetic population. This group is reflective of the impaired glucose tolerance subjects that responded to treatment in the company s Phase I study. This analysis included patients who met the following criteria at baseline: BMI greater than or equal to 28; fasting plasma insulin levels greater than or equal to 4 μU/mL; fasting plasma C-peptide levels greater than or equal to 2 ng/mL; and

serum monocyte chemotactic protein-1 (MCP-1) levels greater than or equal to 400 pg/mL. This phenotype represented 35% of all subjects (89 patients) with values for these parameters at baseline. Twenty-two individuals with this phenotype completed the 84 days of dosing. Those treated with TRIOLEX (10 patients) were found to show improvements in clinical parameters compared to placebo patients (12 patients). These included statistical trends for a decrease in HbA1c (-0.53%, $p = 0.06$) and a decrease in fasting plasma glucose (-28.75 mg/dL, $p = 0.09$), as well as non-significant decreases in fasting plasma C-peptide (-0.43 ng/mL), fasting plasma insulin (0.48 µU/mL), fructosamine (25.75 µmol/L), HOMA2 insulin resistance (0.65 IR), and increases in HOMA2 insulin sensitivity (11.3%S) and HOMA2 beta cell function (17.95%B). The observed changes in these secondary indicators of activity are all consistent with the observed decreases in HbA1c and glucose in this diabetic subpopulation.

Sensitivity analysis using last observation carried forward indicated that individuals in this subpopulation who completed at least 29 days of dosing showed improvement. A biostatistician who is an expert in analyzing data from type 2 diabetes clinical trials independently confirmed these results.

The company has initiated a follow-on study in drug-naïve inflamed, obese insulin resistant type 2 diabetes patients

Inflammatory Diseases: Ulcerative Colitis and Rheumatoid Arthritis

In its autoimmunity and inflammatory diseases program, Hollis-Eden has recently completed a clinical trial with TRIOLEX in patients with ulcerative colitis (UC). This Phase I/II dose ranging study evaluated the safety, tolerance, pharmacokinetics and activity of TRIOLEX when administered orally for 28 days in patients with active mild-to-moderate UC. We anticipate analyzing all of the available data and reporting the results during the second half of this year.

The Company is also engaged in a Phase I rheumatoid arthritis (RA) clinical trial. It is a 28-day oral dose ranging study assessing safety, pharmacokinetics and the potential for a drug interaction between TRIOLEX and methotrexate in patients with stable RA on methotrexate treatment. The last patient was recently enrolled and we plan to release the results during the second half of this year.

Prostate Cancer

In the third quarter of 2008, Hollis-Eden commenced a Phase I/II clinical trial with its oral drug candidate APOPTONE in late-stage (advanced) prostate cancer patients who have failed hormone therapy and at least one course of taxane based chemotherapy

This Phase I/II open-label dose escalating study, conducted in association with the Prostate Cancer Clinical Trial Consortium (PCCTC), is evaluating the safety, tolerance, pharmacokinetics and potential activity of APOPTONE when administered twice daily in late-stage (advanced) prostate cancer patients. This is an ongoing study that will continue to enroll patients until a safe and

potentially active dose is identified. We are currently enrolling patients in the fourth cohort dose level. Based on safety findings and stable disease after an initial 28-day cycle of therapy, patients are eligible for additional cycles of treatment. Potential activity of the compound will be measured by effects on well-established markers of progression free survival, as determined by standard prostate-specific antigen (PSA) levels, CT, or bone scan, and an effect on circulating tumor cells.

To date, in an analysis of unaudited data, we have seen a good safety profile with stable disease in 5 of 13 evaluable patients. Evaluable patients are defined as having successfully completed two or more 28-day cycles. The 13 evaluable patients have completed between two and six 28-day cycles.

The information contained in this report 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.

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: June 11, 2009

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