HALOZYME THERAPEUTICS INC

FORM 8-K
(Unscheduled Material Events)

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Fiscal Year	12/31

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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

August 12, 2005

HALOZYME THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	000-49616	88-0488686
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

11588 Sorrento Valley Road, Suite 17, San Diego, California	92121
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (858) 794-8889

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 (see General Instruction A.2. below):

☐ 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))

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Item 8.01 Other Events.

On August 11, 2005, Halozyme Therapeutics, Inc. announced the clearance of its investigational new drug application ("IND") for Chemophase ™ by the U.S. Food and Drug Administration. The press release announcing the clearance of the IND is attached hereto as Exhibit 99.1 and is incorporated by reference.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits.

Exhibit No.	Description
99.1	Press Release dated August 11, 2005.

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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 hereunto duly authorized.

Halozyme Therapeutics, Inc.

August 12, 2005

By: /s/ David A. Ramsay
David A. Ramsay
Secretary and Chief Financial Officer

Exhibit 99.1

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HALOZYME THERAPEUTICS RECEIVES FDA CLEARANCE TO INITIATE CHEMOPHASE CLINICAL TRIAL

SAN DIEGO, August 11, 2005 – Halozyme Therapeutics, Inc. (AMEX: HTI), a biopharmaceutical company focused on the development and commercialization of recombinant human enzymes, today announced it has received clearance from the U.S. Food and Drug Administration (FDA) for its Chemophase ™ Investigational New Drug (IND) application. The initial clinical protocol under this IND is a Phase I study designed to evaluate a single intravesical administration of Chemophase along with mitomycin in patients with superficial bladder cancer.

“We are thrilled to be able to begin our Chemophase study,” said Jonathan Lim, MD, Halozyme’s Chairman and CEO. “This novel therapeutic biologic is being developed to enhance the delivery of chemotherapy. Based on the promising pre-clinical data gathered to date, and the previous clinical work done with bovine hyaluronidase in bladder cancer, co-delivery of Chemophase may increase the penetration of mitomycin throughout the tumor and reach residual tumor cells that otherwise might develop into recurrent tumors. We are excited about potentially bringing this therapeutic into the clinic in the fourth quarter, which will represent another important milestone for Halozyme.”

According to data from the American Cancer Society, National Cancer Institute, American Urological Association, and Southwest Oncology Group Study, over 180,000 patients present with new or recurrent cases of superficial bladder cancer in the US every year, all of whom would be potential candidates for Chemophase in the event it is approved as first line treatment with mitomycin. The clinical protocol has received Institutional Review Board approval, and the Phase 1 study will enroll up to ten patients to obtain five evaluable patients with superficial

bladder cancer. The objectives of the Chemophase clinical trial are to determine the safety, tolerability and pharmacokinetics of Chemophase administered intravesically with mitomycin.

About Halozyme Therapeutics, Inc.

Halozyme is a biopharmaceutical company dedicated to developing and commercializing recombinant human enzymes for the infertility, ophthalmology, and oncology communities. The company's portfolio of products under development is based on intellectual property covering the family of human enzymes known as hyaluronidases. Halozyme's recombinant human enzymes may replace current animal slaughterhouse-derived enzymes that carry potential risks of animal pathogen transmission and immunogenicity. The versatility of the first enzyme, rHuPH20, enables Halozyme to develop the product as a medical device, drug enhancement agent, and therapeutic biologic.

Safe Harbor Statement

In addition to historical information, the statements set forth above include forward-looking statements (including, without limitation, statements concerning pre-clinical data, the potential effectiveness of products under development, the timing and nature of clinical trials for products under development, and the demand and potential market for these products, if approved by the FDA) that involve risk and uncertainties that could cause actual results to differ materially from those in the forward-looking statements. The forward-looking statements are also identified through use of the words "believe," "enable," "may," "will," "could," "intends," "estimate," "anticipate," "plan," "predict," "probable," "potential," "possible," "should," "continue," and other words of similar meaning. Actual results could differ materially from the expectations contained in forward-looking statements as a result of several factors, including regulatory approval requirements and competitive conditions. These and other factors that may result in differences are discussed in greater detail in the company's reports on Forms 10-KSB, 10-QSB and other filings with the Securities and Exchange Commission.

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