HALOZYME THERAPEUTICS INC

FORM 8-K
(Unscheduled Material Events)

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CIK	0001159036
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

April 19, 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 April 19, 2005, Halozyme Therapeutics, Inc. (the "Company") announced receipt of 510(k) clearance from the U.S. Food and Drug Administration (FDA) for Cumulase ™ for the treatment of oocytes to facilitate certain in vitro fertilization (IVF) procedures. The press release announcing the Company's 510(k) clearance is filed as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits.

Exhibit No.	Description
99.1	Press Release dated April 19, 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.

April 19, 2005

By: /s/ Jonathan E. Lim, MD
Jonathan E. Lim, MD
President and CEO

Exhibit 99.1

(HALOZYME THERAPEUTICS LOGO)

HALOZYME CONTACT INVESTOR RELATIONS CONTACTS

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HALOZYME THERAPEUTICS RECEIVES FDA 510(K) CLEARANCE FOR CUMULASE

SAN DIEGO, APRIL 19, 2005 - Halozyme Therapeutics, Inc. (AMEX: HTI), a development stage biopharmaceutical company focused on the development and commercialization of recombinant human enzymes, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for Cumulase(TM) for the treatment of oocytes to facilitate certain in vitro fertilization (IVF) procedures. The active pharmaceutical ingredient in Cumulase is the first and only recombinant human hyaluronidase approved in the United States for cumulus removal in the IVF process.

"We are thrilled to receive FDA 510(k) clearance to market our first product in the U.S.," said Jonathan Lim, MD, Halozyme's Chairman and CEO. "This achievement is a key milestone for our company and provides validation of our technology and our team's ability to develop and commercialize products based on recombinant human hyaluronidase."

Cumulase is an ex vivo formulation of rHuPH20 (recombinant human PH20 hyaluronidase) to replace bovine and ovine extracts currently used for the preparation of oocytes prior to IVF during the process of intracytoplasmic sperm injection (ICSI), in which the enzyme is an essential component. The enzyme strips away the hyaluronic acid that surrounds the oocyte, allowing the clinician to then perform ICSI, injecting the sperm into the oocyte. Cumulase provides the IVF specialist with a safer, purer and more reliable alternative to slaughterhouse-derived extracts.

The total Cumulase market consists of an estimated 500,000 ICSI cycles worldwide in 2005, with nearly 90,000 of those performed in the U.S. Halozyme received CE Mark approval of

Cumulase in late 2004 to market the product throughout the EU. The company has signed agreements with Cook Ob/Gyn Incorporated, MediCult A/S, and MidAtlantic Diagnostics, Inc., to distribute Cumulase worldwide. In February, Halozyme signed a commercial manufacturing supply agreement with Avid Bioservices to manufacture the recombinant human enzyme under current good manufacturing practices (cGMPs).

ABOUT HALOZYME THERAPEUTICS, INC.

Halozyme is a development stage 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 the Company's products and the market sizes for these products) 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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