HALOZYME THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Industry	Biotechnology & Drugs
Sector	Healthcare
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 10, 2006

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 2.02 Results of Operations and Financial Condition.

On August 10, 2006, Halozyme Therapeutics, Inc. issued a press release to report its financial results for the three and six months ended June 30, 2006. The press release is attached as Exhibit 99.1, which is furnished under Item 2.02 of this report and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated August 10, 2006

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SIGNATURES

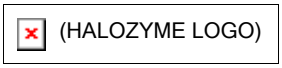
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Halozyme Therapeutics, Inc.

August 10, 2006

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

Exhibit 99.1



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HALOZYME THERAPEUTICS REPORTS
SECOND QUARTER 2006 FINANCIAL RESULTS
— Conference Call and Webcast Today at 8:00 a.m. PDT —

SAN DIEGO, August 10, 2006 – Halozyme Therapeutics, Inc. (AMEX: HTI), a biopharmaceutical company developing and commercializing recombinant human enzymes, today reported financial results for the three and six months ended June 30, 2006.

"This has been a productive quarter for our team, as we continue to make solid progress on multiple fronts," stated Jonathan Lim, MD, Halozyme's President and CEO. "Hylenex was made available to hospices and palliative care centers at the end of June, and Chemophase ®, our lead oncology product candidate, continues to advance in the clinic in a Phase I/IIa trial. We are also very excited about the two recent additions to our team, Bob Little as Vice President, Chief Commercial Officer and Connie Matsui as a Board Director."

Second Quarter 2006 and Subsequent Weeks' Highlights:

- Initiation of patient enrollment for the Chemophase Phase I/IIa clinical trial. This second clinical protocol for Chemophase is designed to evaluate multiple intravesical (in the bladder) administrations of Chemophase along with the widely-used anticancer drug mitomycin, or MMC, in patients with superficial bladder cancer, and follows the completion of the initial Phase I trial of single-administration Chemophase and mitomycin. This dose-finding Phase I/IIa study will enroll up to 36 evaluable patients with superficial bladder cancer. The objectives of the study include determining the maximum tolerated dose and dose-limiting toxicities, if any, of escalating doses of Chemophase in combination with mitomycin administered as weekly intravesical instillations for five weeks according to the usual standard of care; establishing the optimal dose of Chemophase with MMC to be recommended for future studies; and, observing patients for any preliminary evidence of anti-tumor activity of this combination therapy. The study is being conducted at several centers in the United States.

- Presentation of new preclinical data and pharmacokinetic data from a Phase I clinical trial of Chemophase combined with chemotherapy at the American Association for Cancer Research Annual Meeting in Washington, D.C. The results support the safety profile for Chemophase, a high dose formulation of the recombinant human hyaluronidase enzyme, rHuPH20, under investigation for its potential ability to increase the effectiveness of chemotherapy in the treatment of superficial bladder cancer. Pharmacokinetic data were obtained from the plasma of five bladder cancer patients dosed intravesically with 20,000 units of rHuPH20 along with 40 mg of MMC. The observed plasma levels of MMC were less than 1/40 th of the levels reported to be predictive of suppression of white blood cell production. The study was conducted at BCG Oncology in Phoenix, Arizona, under the supervision of Principal Investigator, Donald L. Lamm, MD.
- Availability of Hylenex, a liquid injectable formulation of recombinant human hyaluronidase, in the United States. Halozyme Therapeutics and Baxter Healthcare will focus predominantly on making the product available to hospices and palliative care centers, where additional clinical trials are planned with morphine and other injectable medications. In a Phase III-B clinical trial, Halozyme and Baxter studied the use of Hylenex with subcutaneous infusions of Lactated Ringer's solution using gravity flow without an infusion pump to achieve substantial flow rates with acceptable tolerability. Hylenex was approved by the U.S. Food and Drug Administration (FDA) on December 2, 2005, for use as a spreading agent to increase the absorption and dispersion of other injected drugs and for subcutaneous hydration.
- Presentation of new findings for HTI-101, the Company's second hyaluronidase enzyme candidate, at the 2006 Gordon Research Conference on Proteoglycans. The new study examined mice bearing a targeted genetic deletion or "knockout" of the mouse equivalent to the human gene encoding HTI-101. Knockout mice with one or both normal copies of the gene inactivated showed either significantly reduced or absent levels of enzyme in the blood, respectively. A commonly utilized pre-clinical cancer protocol of restoring blood levels of the enzyme by using an adenovirus encoding the mouse form of the enzyme was then performed. The results showed that increased blood levels of the HTI-101 enzyme were able to rescue animals with lung cancer and prolong their survival compared to those given the control virus.
- 510(k) clearance of MediCult A/S from the FDA for SynVitro $^{®}$ Cumulase for the treatment of oocytes to facilitate certain in vitro fertilization (IVF) procedures. The media-formulated SynVitro Cumulase product contains the active pharmaceutical ingredient found in Cumulase-10X, the first and only recombinant human hyaluronidase approved in the United States for cumulus removal in the IVF process.
- Addition of Robert Little as Vice President, Chief Commercial Officer to the management team. Mr. Little will help drive all of the Company's commercial activities for the FDA-approved Cumulase and Hylenex products, as well as prepare the markets for Enhanze $^{®}$ Technology. He will build upon and manage Halozyme's capabilities in areas such as sales and marketing, business development, alliance management and portfolio management, and reports directly to Jonathan Lim, MD. Previously, Mr. Little was Senior Vice President, Commercial Operations at Neurocrine Biosciences, where he

was responsible for building and managing the Company's commercial organization. During his tenure, Mr. Little implemented a 200-person CNS sales force that successfully co-detailed Zoloft ® with Pfizer, as well as a marketing team that provided commercial direction to the companies' new products in both research and development. From 1985 to 2003, Mr. Little was at Pharmacia, Inc. where his most recent position was Group Vice President, Diversified Products.

- Addition of Connie Matsui to the Board of Directors. Ms. Matsui has been Executive Vice President, Corporate Strategy and Communications of Biogen Idec since the merger between IDEC Pharmaceuticals and Biogen in November 2003. She joined IDEC Pharmaceuticals in November 1992 as Senior Director, Planning and Resource Development with primary responsibilities in strategic planning and human resources.

Second Quarter 2006 Financial Results

- Net loss for the second quarter of 2006 was $3.2 million, or $0.05 per share, compared with a net loss for the second quarter of 2005 of $2.9 million, or $0.06 per share. Net loss for the six months ended June 30, 2006 was $6.7 million, or $0.11 per share, compared to $6.1 million, or $0.12 per share, for the comparable period in 2005.
- Research and development expenses for the second quarter of 2006 were $1.9 million, compared with $2.1 million for the second quarter of 2005, reflecting a decrease in contract manufacturing and analytical costs related to the development and production of the Company's rHuPH20 enzyme.
- Selling, general and administrative expenses for the second quarter of 2006 were $1.6 million, compared with $0.9 million for the second quarter of 2005, reflecting an increase in compensation and legal expenses over the prior-year quarter.
- Cash and cash equivalents as of June 30, 2006 were $15.1 million, compared with $17.6 million as of March 31, 2006 and $19.1 million as of December 31, 2005.

Conference Call

Halozyme management will host an investment community conference call today to discuss these topics beginning at 8:00 a.m. PT (11:00 a.m. ET). To participate via telephone, please call 888-463-4487 for domestic callers, or 706-679-5355 for international callers. A telephone replay will be available for 48 hours by dialing 800-642-1687 from the U.S., or 706-645-9291 for international callers, and entering reservation number 4049929. The conference call will be broadcast live over the Internet at www.halozyme.com and will be available for 30 days.

About Hylenex

Hylenex recombinant (hyaluronidase human injection) is indicated for use as an adjuvant to increase the absorption and dispersion of other injected drugs, for hypodermoclysis, and as an adjunct in subcutaneous urography for improving resorption of radiopaque agents. Hylenex recombinant is contraindicated in patients with hypersensitivity to hyaluronidase enzyme or any other ingredient in the formulation. Warnings for the use of Hylenex consist of discontinuing

Hylenex if sensitization occurs, and not using Hylenex to enhance the absorption and dispersion of dopamine and/or alpha agonist drugs, for injection into or around an infected or acutely inflamed area because of the danger of spreading localized infection, to reduce the swelling of bites or stings, for application directly to the cornea, or for IV injections because the enzyme is rapidly inactivated. Precautions for the use of Hylenex consist of incompatibility with furosemide, benzodiazepines and phenytoin, and recommendation for consulting appropriate references to determine the usual precautions when considering administration of Hylenex with any drug (e.g., when epinephrine is injected along with hyaluronidase, the precautions for the use of epinephrine in cardiovascular disease, thyroid disease, diabetes, digital nerve block, ischemia of the fingers and toes, etc., should be observed). A preliminary skin test for hypersensitivity to Hylenex can be performed. The most frequently reported adverse experiences have been local injection site reactions. Hyaluronidase has been reported to enhance the adverse events associated with co-administered drug products. Edema has been reported most frequently in association with hypodermoclysis. Allergic reactions (uticaria or angioedema) have been reported in less than 0.1% of patients receiving hyaluronidase. Anaphylactic-like reactions following retrobulbar block or intravenous injections have occurred, rarely. The full prescribing information for Hylenex should be consulted prior to prescription or administration.

About Halozyme Therapeutics, Inc.

Halozyme is a biopharmaceutical company developing and commercializing recombinant human enzymes for the drug delivery, palliative care, oncology, and infertility markets. The Company's portfolio of products 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 extracts that carry potential risks of animal pathogen transmission and immunogenicity. The company has received FDA approval for two products: Cumulase, the first and only recombinant human hyaluronidase for cumulus removal in the IVF process; and Hylenex, for use as an adjuvant to increase the absorption and dispersion of other injected drugs. The versatility of the first enzyme, rHuPH20, enables Halozyme to develop the product as a medical device, drug enhancement agent, and therapeutic drug.

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 under development, product development plans, milestones, and clinical studies) 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-Q and other filings with the SEC.

HALOZYME THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS — UNAUDITED
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2006 AND 2005

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Revenues:				
Product sales	$ 119,662	$ 45,703	$ 192,943	$ 45,703
Expenses:				
Cost of sales	16,538	21,024	39,498	21,024
Research and development	1,914,925	2,055,036	4,106,994	4,472,328
Selling, general and administrative	1,603,172	915,301	3,134,464	1,768,920
Total expenses	3,534,635	2,991,361	7,280,956	6,262,272
Loss from operations	(3,414,973)	(2,945,658)	(7,088,013)	(6,216,569)
Other income, net	182,182	77,324	365,028	155,159
Net loss	$ (3,232,791)	$ (2,868,334)	$ 6,722,985)	$ (6,061,410)
Net loss per share, basic and diluted	$ (0.05)	$ (0.06)	$ (0.11)	$ (0.12)
Shares used in computing net loss per share, basic and diluted	61,841,867	49,945,467	61,152,991	49,761,501

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