## 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: April 14, 2003 (Date of earliest event reported)

# REGENERON PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

New York (State or Other Jurisdiction of Incorporation) 0-19034 (Commission File Number) 13-3444607 (IRS Employer Identification No.)

777 Old Saw Mill River Road Tarrytown, NY 10591-6707

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (914) 347-7000

## TABLE OF CONTENTS

ITEM 5. OTHER EVENTS
ITEM 7. FINANCIAL STATEMENTS, PRO FORMA FINANCIAL INFORMATION AND EXHIBITS
SIGNATURES
PRESS RELEASE

## **Table of Contents**

## ITEM 5. OTHER EVENTS

On April 14, 2003, the Company issued a press release announcing the results of its Phase II trial evaluating AXOKINE® for weight loss in overweight and obese people with type 2 diabetes.

## ITEM 7. FINANCIAL STATEMENTS, PRO FORMA FINANCIAL INFORMATION AND EXHIBITS

(c) Exhibits.

99a Press Release dated April 14, 2003

## **Table of Contents**

## **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.

REGENERON PHARMACEUTICALS, INC.

By: /s/ Stuart Kolinski

Name: Stuart Kolinski

Title: Vice President & General Counsel

Date: April 16, 2003

#### FOR IMMEDIATE RELEASE

## REGENERON'S AXOKINE® PROMOTES WEIGHT LOSS IN STUDY OF OVERWEIGHT AND OBESE PEOPLE WITH TYPE 2 DIABETES

Tarrytown, New York (April 14, 2003) — Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced initial results of its Phase II study evaluating AXOKINE<sup>®</sup> for weight loss in overweight and obese people with type 2 diabetes at doses of 1.0 microgram per kilogram (mcg/kg) and 0.5 mcg/kg per day. The study showed that 12 weeks of treatment with AXOKINE resulted in statistically significant and dose-dependent weight loss.

Subjects who were treated with AXOKINE (1.0 mcg/kg/day) and dietary counseling lost 6.5 pounds on average, while those treated with placebo and dietary counseling lost only 2.5 pounds (p<.01). Trends towards improvements in blood glucose and other metabolic parameters were also observed during this small, short-term study. AXOKINE was generally well-tolerated with no AXOKINE-related serious adverse events. The 1.0 mcg/kg dose is being studied in the ongoing Phase III AXOKINE program, which thus far has included over 2,500 overweight and obese non-diabetic subjects. Approximately 90 percent of study participants completed the 12-week study.

"Overweight and obesity are major contributing factors for 80% of the 16 million Americans with type 2 diabetes, and weight loss is a cornerstone of both preventing and treating this serious disease," said Hans-Peter Guler, M.D., Vice President of Clinical Sciences for Regeneron. "Moreover, several studies have shown that weight loss in people with diabetes is often more difficult to achieve than weight loss in non-diabetic individuals."

The preliminary data from the Phase II study are summarized below.

#### Comparison of Placebo versus AXOKINE-Treated Participants

• Average Weight Loss vs. Baseline:

		AXOKINE	
	Placebo	0.5 mcg/kg	1.0 mcg/kg
Intent-to-Treat Analysis **	2.5 lbs n=52	5.2 lbs n= 52 * p= .08	6.5 lbs n= 53 * p< 0.01
Completer Analysis ***	2.6 lbs n=48 (92%)	5.6 lbs n= 47 (90%) * p= .07	7.0 lbs n= 47 (89%) * p< 0.01

<sup>\*</sup> The p-value compared with Placebo

<sup>\*\*</sup> Includes all randomized subjects who have had at least one post-baseline observation

<sup>\*\*\*</sup> Includes only those subjects who completed the full 12 weeks of treatment.

Percentage of Patients Losing at Least 5% of Body Weight (i.e.,>12 lbs on average):

		AXUKINE		
	Placebo	0.5 mcg/kg	1.0 mcg/kg	
Intent-to-Treat Analysis*	5.8%	9.6%	18.9%	
	(3 out of 52)	(5 out of 52)	(10 out of 53)	
Completer Analysis**	6.2%	10.6%	21.3%	
	(3 out of 48)	(5 out of 47)	(10 out of 47)	

AVOLUME

Preliminary data at 12 weeks indicate that about a third of the 1.0 mcg/kg AXOKINE-treated participants developed antibodies to AXOKINE. In the recently reported Phase III study in non-diabetic subjects, about half of AXOKINE-treated participants developed antibodies at the 12-week time point. This lower incidence of antibodies observed in the Phase II study will need to be explored in a larger Phase III study in the diabetic population. In the Phase III one-year study, further weight loss appeared to be limited in those people who developed antibodies.

"Based on our clinical trials to date, it appears that AXOKINE can promote weight loss in both diabetic and non-diabetic individuals." said Leonard S Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "Regeneron is actively analyzing all of our new AXOKINE data, and, in the near future, we plan to meet with regulatory authorities to determine the appropriate path forward in the development of AXOKINE for the treatment of obesity."

#### Trial Design

The double-blind, randomized, placebo-controlled trial was designed to assess the short-term safety and efficacy of AXOKINE treatment compared with placebo with respect to weight loss in overweight and obese individuals diagnosed with type 2 diabetes mellitus and having a body mass index (BMI) of 27 to 50 kg/m2. BMI is a ratio of height to weight and is calculated as the weight of an individual in kilograms divided by the square of their height in meters. Normal weight is designated by BMIs of 18.5-24.9, overweight by BMIs of 25-29.9 and obesity by BMIs of 30 and above.

The trial enrolled 157 participants at 24 study sites in the United States. The average baseline weight for all participants was approximately 233 lbs.

After a 14-day run in period, participants were randomly assigned to receive daily subcutaneous injections of 0.5 mcg/kg of AXOKINE, 1.0 mcg/kg of AXOKINE or placebo for 12 weeks. All subjects received dietary counseling for a moderately reduced caloric intake. The initial 12-week phase of the trial is being followed by a 12-week, open-label extension phase, which is still ongoing.

#### **About AXOKINE**

AXOKINE is a modified form of ciliary neurotrophic factor (CNTF), which is in clinical development by Regeneron Pharmaceuticals for the treatment of obesity. This investigational compound has a novel mechanism of action – the inhibition of hunger signals that stimulate appetite. Ongoing Phase II and Phase III trials are studying the safety and efficacy of AXOKINE.

<sup>\*</sup> Includes all randomized subjects who have had at least one post-baseline observation

<sup>\*\*</sup> Completer analysis includes only those subjects who completed the full three months of treatment. Approximately 90% of study participants across all treatment groups completed the study.

#### **About Regeneron**

Regeneron is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic medicines for the treatment of serious medical conditions. Regeneron has therapeutic candidates for the potential treatment of obesity, rheumatoid arthritis, cancer, and asthma and has preclinical programs in other diseases and disorders.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of drugs and biologics, determinations by regulatory and administrative governmental authorities, competitive factors, technological developments, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement to be canceled or to terminate without any product success, and other material risks. A more complete description of these risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2002. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

########

Contact: Miriam Weber Biosector 2 mweber@biosector2.com (212) 414-5630

For non-media inquiry call (914) 509-7000.

Additional information about Regeneron and recent news releases are available on Regeneron's Worldwide Web Home Page at www.regn.com.