# 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): August 2, 2004

# RIGEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

#### Delaware

(State or other jurisdiction of incorporation)

**0-29889** (Commission File No.)

94-3248524

(IRS Employer Identification No.)

### 1180 Veterans Boulevard South San Francisco, CA 94080

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (650) 624-1100

#### ITEM 5. OTHER EVENTS.

On August 2, 2004, Rigel Pharmaceuticals, Inc. announced the successful results of a Phase II clinical study evaluating the use of R112, for the treatment of the symptoms of allergic rhinitis. The press release dated August 2, 2004, titled "Rigel's R112 Demonstrates Robust Effect in Reducing Symptoms of Allergic Rhinitis in Large Phase II Clinical Trial," is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Neither the filing of any press release as an exhibit to this Current Report on Form 8-K nor the inclusion in that press release of a reference to Rigel's internet address shall, under any circumstances, be deemed to incorporate the information available at that internet address into this Current Report on Form 8-K. The information available at the Rigel's internet address is not part of this Current Report on Form 8-K or any other report filed by Rigel with the Securities and Exchange Commission.

# ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS.

(c) Exhibits

Exhibit Number

Description

99.1 Press Release entitled "Rigel's R112 Demonstrates Robust Effect in Reducing Symptoms of Allergic Rhinitis in Large Phase II Clinical Trial," dated August 2, 2004.

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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.

RIGEL PHARMACEUTICALS, INC.

Dated: August 2, 2004

By: /s/ James H. Welch
James H. Welch
Vice President, Chief Financial Officer and Secretary

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EXHIBIT INDEX

Number Description

# Rigel's R112 Demonstrates Robust Effect in Reducing Symptoms of Allergic Rhinitis in Large Phase II Clinical Trial

R112 Shows Rapid Onset and Sustained Effect in Treatment of Allergic Rhinitis

Management Will Host Conference Call at 4:30 PM Eastern Today

South San Francisco, CA - August 02, 2004

Rigel Pharmaceuticals, Inc. (NASDAQ: RIGL) today announced the successful results of a Phase II clinical study evaluating the use of R112, for the treatment of the symptoms of allergic rhinitis. The day one data indicated that R112 reduced the Global Nasal Allergy Symptom Score by 7.0 points (38%) versus 5.4 points (29%) for placebo (p=0.0005), an absolute difference of 9%, and a relative improvement over placebo of 24%. Results on day two were of similar magnitude (p=0.0016).

The randomized, placebo-controlled "Park" study enrolled 319 patients who were verified to suffer from allergic rhinitis. The primary objective of the study was to measure safety and efficacy of R112 as an intranasal treatment for allergic rhinitis. The Global Nasal Allergy Symptom Score used in the study showed a greater than 20% relative improvement for R112 over placebo (an absolute difference of 9% over placebo) and up to 38% improvement for R112 from baseline measurements (prior to drug initiation). There were no significant drug-related adverse events reported in the trial, and adverse event frequencies were indistinguishable from placebo. As early as the 30-minute time interval after dosing, R112 showed a statistically significant improvement in symptom scores over placebo, demonstrating a rapid onset of action in symptom improvement. Furthermore, these beneficial effects lasted throughout the entire measurement period until the end of the park day. In particular, symptoms most closely associated with chronic nasal congestion (e.g. stuffy nose) were dramatically improved with R112 over placebo.

"These results support R112 as a potential new treatment option for the millions of sufferers with this chronic condition," said Eli Meltzer, M.D., Allergy & Asthma Medical Group and Research Center. "Many patients with allergic rhinitis have tried multiple medications with inadequate symptom relief. R112 represents an entirely different therapeutic modality and in this study demonstrated a broad and comprehensive biological effect, excellent safety and a rapid onset of action."

"R112 shows excellent promise in the treatment of allergic rhinitis, and we plan to continue our clinical evaluation of it in phase III trials," stated James M. Gower, chairman and CEO of Rigel. "Our approach of using primary human cells, in this case human mucosal mast cells, to identify and validate targets critical to human disease mechanisms has enabled us to discover and design a class of molecules which work via a novel mechanism, blocking syk kinase. We believe this is an important advance in treating allergic diseases of the respiratory pathway, including both allergic rhinitis and allergic asthma."

#### **Conference Call Details**

Rigel will host a conference call today at 4:30 p.m. Eastern/ 1:30 p.m. Pacific to discuss the results of this trial. To access the live call, please dial 1-800-851-3032 (U.S.) or 706-679-0704 (international) fifteen minutes before the conference begins. Live audio of the conference call will be simultaneously broadcast over the Internet and will be available to members of the news media, investors and the general public. Access to live and archived audio of the conference call will be available by following the appropriate links from Rigel's home page: www.rigel.com. Following the live broadcast, a replay of the call will also be available at 1-800-642-1687, or 706-645-9291 for international callers, until August 16. The replay passcode is 8392996.

#### **About Allergic Rhinitis**

Allergic rhinitis is a common condition that affects nearly 59 million people in the United States — nearly 20 percent of the population. Allergic rhinitis is characterized by inflammation of the nasal membranes accompanying symptoms that may include sneezing, nasal congestion, nasal itching and rhinorrhea. The eyes, ears, sinuses and throat can also be involved. The U.S. market for allergic rhinitis therapies approaches \$4 billion.\*

## The Role of Immune Mediators in Allergic Rhinitis

Allergic rhinitis involves inflammation of the mucous membranes of the nose, eyes, eustachian tubes, middle ear,

sinuses and pharynx. This inflammation is characterized by a complex interaction of inflammatory mediators but ultimately is triggered by an immunoglobulin E (IgE)-mediated response to a foreign allergen. When a specific allergen (e.g., pollen) is inhaled into the nose, it can bind to the IgE on mast cells present in the mucus membranes, leading to immediate and delayed release of a number of mediators, which can ultimately lead to common allergic symptoms such as nasal congestion, sneezing, itching and rhinorrhea. These mediators include histamine, tryptase, chymase, kinins, heparin, leukotrienes and PGD2.

#### R112 and its Mechanism of Action

R112 binds to an intracellular target (syk, a kinase that regulates IgE receptor signaling) in mast cells and interrupts the signal from the IgE receptor, thus preventing cellular activation and subsequent chemical mediator release. However, unlike common allergy drugs such as antihistamines or antileukotrienes that block only a single mediator, R112 is designed to block all of the major pathways that are triggered in an allergic attack, potentially making R112 a more effective and comprehensive drug. In the current Park study, R112 significantly diminished both the acute and chronic symptoms of allergic rhinitis such as sneezing, itchy nose, nasal congestion, cough and facial pain, underscoring the correlation of beneficial clinical outcomes and R112's broad mechanism of action. Currently, steroids are the only other non-injectable class of agents that are able to block multiple mediators in the allergic response, but these have a slow onset of action, sometimes requiring multiple days of treatment before a positive effect is seen. In the phase I/II trial completed earlier, R112 began to diminish chemical mediator release within minutes after allergen challenge. R112 is delivered intranasally, and no systemic exposure to R112 has been detected in any intranasal administration in any human trials completed to date.

# About Rigel (www.rigel.com)

Rigel's mission is to become a source of novel, small-molecule drugs to address large, unmet medical needs. We have initiated four development programs: asthma/allergy, hepatitis C, rheumatoid arthritis and oncology. Rigel has begun clinical testing of its first two product candidates, R112 for allergic rhinitis and R803 for hepatitis C, and expects to begin clinical trials of R406 for the treatment of rheumatoid arthritis by the end of 2004, to be followed by clinical trials for drug candidates in oncology and asthma.

This press release contains "forward-looking" statements, including statements related to Rigel's plans to pursue clinical development of product candidates and the timing thereof and the potential efficacy of product candidates. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "will," "plans," "intends," "expects" and similar expressions are intended to identify these forward-looking statements. There are a number of important factors that could cause Rigel's results to differ materially from those indicated by these forward-looking statements, including risks associated with the timing and success of clinical trials and the commercialization of product candidates, as well as other risks detailed from time to time in Rigel's SEC reports, including its Annual Report on Form 10-K for the year ended December 31, 2003 and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2004. Rigel does not undertake any obligation to update forward-looking statements.

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