

ALTANA AKTIENGESELLSCHAFT

Form 6-K

May 26, 2004

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**Form 6-K**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**Report of Foreign Private Issuer  
Pursuant to Rules 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934**

Dated: May 26<sup>th</sup>, 2004

**ALTANA Aktiengesellschaft**

(Translation of Registrant's name into English)

**Am Pilgerrain 15  
D-61352 Bad Homburg v. d. Höhe  
Federal Republic of Germany**  
(Address of principal executive offices)

Indicate by check mark whether the Registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F

Form 40-F

Indicate by check mark if the Registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the Registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether the Registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes

No

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b):  
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This Report on Form 6-K is hereby incorporated by reference into the Registrant's Registration Statements on Form S-8, dated September 13, 2002 (File No. 333-99485) and dated September 24, 2003 (File No. 333-109074)

This Report on Form 6-K contains:

Press Release of May 25<sup>th</sup>, 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, thereunto duly authorized.

ALTANA Aktiengesellschaft

Dated: May 26<sup>th</sup>, 2004

By: /s/ Hermann Küllmer  
Name: Dr. Hermann Küllmer  
Title: Chief Financial Officer and Member  
of the Management Board

By: /s/ Rudolf Pietzke  
Name: Dr. Rudolf Pietzke  
Title: General Counsel

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**Press release**

**ALTANA AG**  
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**New Roflumilast data presented at ATS**

**Roflumilast Shown to Improve Lung Function In Moderate to Severe COPD Patients, Data Shows**

**Orlando, Bad Homburg, May 25, 2004** ALTANA AG's investigational anti-inflammatory medicine roflumilast improved lung function in patients with Chronic Obstructive Pulmonary Disease (COPD) according to a placebo controlled study presented at the annual meeting of the American Thoracic Society (ATS).

An investigational oral phosphodiesterase type-4 inhibitor, roflumilast is being co-developed by ALTANA (NYSE: AAA; FSE: ALT) and Pfizer Inc (NYSE: PFE) as a treatment for COPD and asthma.

The results of this study provide an exciting indication that roflumilast may be an effective option in the management of those who suffer from COPD, said Klaus Rabe, MD, PhD, Professor of Medicine, Leiden University Medical Center, Leiden, The Netherlands.

**Results of the RECORD study**

COPD is a progressive disease of the airways characterized by a gradual loss of lung function and is most commonly caused by smoking. The RECORD study was a 24-week double blind, placebo-controlled trial involving more than 1,400 patients in 11 countries with moderate to severe COPD.

Lung function among patients who received roflumilast (250 mcg or 500 mcg) significantly improved over placebo ( $p = 0.0134$  and  $p < 0.0001$ , respectively) from baseline as measured by the amount of air exhaled in one second. Conversely, patients who received placebo showed a significant decline in lung function from baseline ( $p = 0.0041$ ). Similarly, the amount of air exhaled in six seconds (FEV6) significantly improved during the treatment period with roflumilast (500 mcg) while significant deterioration occurred among patients who received placebo.

In addition, patients treated with roflumilast (500 mcg) had 34 percent fewer exacerbations compared with placebo. The mean number of exacerbations in the roflumilast treatment group was 1.03 and 0.75 for the 250 mcg and 500 mcg, respectively, compared to 1.13 for the placebo group over the 24-week trial period ( $p = 0.029$ ). Exacerbations typically require increase use of bronchodilator or steroid therapy and/or physician and emergency room visits to control symptoms.

Roflumilast was generally well tolerated in the treatment of patients with COPD. Side effects due to study medication (250 mcg, 500 mcg) included diarrhea (2.3%, 6.1%), nausea (1.0%, 3.2%), headache (0.7%, 1.8%) and abdominal pain (0.2%, 1.6%). Most were mild or moderate in severity and only a small number of patients (< 3%) with these side effects discontinued the study.

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These results indicate we may have a new therapeutic modality to improve lung function in COPD patients with an anti-inflammatory, said Professor Rabe. The 34 percent reduction in exacerbations appears to be promising for roflumilast to impact this important indicator of morbidity.

**About Roflumilast**

Roflumilast was submitted to European regulatory authorities in February 2004 and is expected to be the first PDE 4 inhibitor approved to treat both COPD and asthma.

**About COPD**

COPD is the fourth leading cause of death in the United States, though estimates suggest the disease will become the third-leading cause of death by 2020. COPD is estimated to cost more than \$30 billion annually in the United States, with \$14.7 billion in direct health care costs and \$15.7 billion in indirect costs.

COPD patients suffer from impaired quality of life due to the progressive deterioration of respiratory symptoms. Symptoms range from chronic cough and sputum production to severely disabling shortness of breath. Frequent exacerbations are not uncommon and increase in frequency and severity as the disease progresses. The most important risk factor for COPD is smoking. Other causes of COPD include occupational dusts and chemicals. While air pollution adds to the total burden of inhaled particles in the lungs, its role in causing COPD is uncertain.

**About ALTANA**

ALTANA AG is an international pharmaceuticals and chemicals Group with sales of 2.7 billion in 2003 and currently about 10,600 employees all over the world. Its pharmaceutical business ALTANA Pharma concentrates on innovative prescription therapeutics. For more information please visit [www.altana.com](http://www.altana.com).

**About Pfizer**

Pfizer Inc. discovers, develops, manufactures and markets leading prescription medicines for humans and animals and many of the world's best-known consumer brands. For more information about Pfizer, please see [www.pfizer.com](http://www.pfizer.com).

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*This press release contains forward-looking statements, i.e., current estimates or expectations of future events or future results. The forward-looking statements appearing in this press release include the information that Roflumilast may be an effective option in the treatment of COPD. These statements are based on beliefs of ALTANA's management as well as assumptions made by and information currently available to ALTANA. Many factors that ALTANA is unable to predict with accuracy could cause ALTANA's actual results, performance or achievements to be materially different from those that may be expressed or implied by such forward-looking statements. These factors include new information or results regarding Roflumilast currently unknown to ALTANA.*

*Forward-looking statements speak only as of the date they are made. ALTANA does not intend, and does not assume any obligation, to update forward-looking statements to reflect facts, circumstances or events that have occurred or changed after such statements have been made.*

This press release is also available on the Internet at [www.altana.com](http://www.altana.com).

For inquiries please contact:

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