

ALTANA AKTIENGESELLSCHAFT

Form 6-K

March 22, 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: March 22, 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): 82-\_\_\_\_\_

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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 March 22, 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: March 22, 2004

By: /s/ Hermann Küllmer

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

/s/ Rudolf Pietzke

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Name: Dr. Rudolf Pietzke  
Title: General Counsel

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**Press release**

**ALTANA AG**

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**New clinical data on Alvesco (ciclesonide) and its intranasal formulation**

**Bad Homburg, Germany, March 22, 2004** - ALTANA AG (NYSE: AAA, FSE: ALT) announced today that new clinical data on its inhaled asthma drug Alvesco® (ciclesonide), and on its intranasal formulation of ciclesonide were presented at the 2004 American Academy of Allergy, Asthma and Immunology (AAAAI) 60th Annual Meeting in San Francisco. Safety studies with Alvesco® showed that lower-leg growth in children was not affected. The data presented for the intranasal formulation of ciclesonide showed a dose response in patients with allergic rhinitis.

In safety studies with Alvesco® (inhaled ciclesonide) in pre-pubertal children with mild asthma, 40, 80 and 160 µg/day of Alvesco® did not affect short-term lower-leg growth (growth velocity of the right lower leg was about 0.4 mm/week in each treatment group) or HPA-axis function (mean values of urinary free cortisol: placebo -7.85±4.88; 40 µg/d ciclesonide -8.48±5.51; 80 µg/d ciclesonide -7.03±3.79; 160 µg/d ciclesonide -8.98±5.68; nmol/mmol creatinine). In children with asthma, treatment with daily doses of 40-160 µg Alvesco® was associated with a minimal potential for systemic side effects and a local adverse event profile similar to placebo.

**Intranasal formulation for allergic rhinitis**

The intranasal formulation of ciclesonide is in Phase II/III of clinical development for the treatment of allergic rhinitis. The data presented from a phase II study showed that ciclesonide 100 µg/day and 200 µg/day resulted in a significantly greater change from baseline compared with placebo reflected in total nasal symptom score (TNSS). TNSS changed from baseline: placebo -4.19, 25 µg/d ciclesonide -4.81, 50 µg/d -4.79, 100 µg/d -5.33, 200 µg/d -5.83. Intranasal ciclesonide was generally well tolerated, with a relatively low incidence of adverse events. The most common adverse events were headache and pharyngitis.

The product will primarily be developed in the U.S. where the allergic rhinitis market is valued at \$6 billion, with intranasalsteroids valued at approximately \$2 billion. The intranasal formulation of ciclesonide is one of the next exciting ciclesonide programs to follow Alvesco® in the development of this unique molecule.

**Alvesco®**

Alvesco® is an inhaled corticosteroid with novel release and distribution properties. Inhaled corticosteroids are considered to be the foundation of asthma treatment, and they work by reducing inflammation – the underlying disease process – in the lungs and airways. In clinical trials, Alvesco® was shown to improve lung function, asthma symptoms,

and reduce the need for medications necessary to treat acute asthma attacks. The most frequently reported adverse events seen in Alvesco® clinical trials were nasopharyngitis, headache and upper respiratory tract infection.

Alvesco® was approved in Australia in February and has been submitted for approval in the United Kingdom, Canada and other countries. Additionally, ALTANA's U.S. partner Aventis applied to the FDA for approval of the asthma drug Alvesco® at the end of 2003. Teijin, our partner in Japan, has submitted an application for approval for Alvesco® in January 2004.

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**Asthma**

Asthma is a chronic lung disease caused by airway inflammation and results in airway constriction in response to certain stimuli. It is characterized by a variety of symptoms including wheezing, coughing and a tightening of the airways, which causes shortness of breath and can be life-threatening. According to the Global Initiative for Asthma (GINA) more than 300 million people worldwide suffer from asthma. The prevalence of asthma is increasing by approximately 50 percent every decade and worldwide deaths from asthma total more than 180,000 annually.

*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 information on the presentation of study results. These statements are based on beliefs of ALTANA's management and information currently available to ALTANA. Many factors that ALTANA is unable to predict with accuracy could cause ALTANA's actual performance to be materially different from the one that may be expressed or implied by such forward-looking statements.*

*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)

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