NOVARTIS AG
Form 6-K
October 08, 2009

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 or 15d-16 OF

THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated October 8, 2009

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F: x Form 40-F: o

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):

Yes: o **No**: x

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Yes: o **No**: x

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: o **No**: x

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- Investor Relations Release -

Novartis gains exclusive worldwide rights to PTK 0796, in Phase III study as potential first-in-class IV and oral broad-spectrum antibiotic

- *PTK 0796 potentially the first broad-spectrum antibiotic given by once-daily infusion or tablet to treat infections caused by drug-resistant bacteria such as MRSA*

- *Oral form of PTK 0796 could offer a convenient way for patients to continue outpatient antibiotic treatment after leaving hospital*

- *New antibiotics needed in fight against bacterial resistance, with an estimated 150,000 deaths a year from hospital-acquired infections across US(1) and EU(2)*

- *Novartis to make upfront payment to Paratek Pharmaceuticals; Paratek eligible for milestones and royalties on future sales*

Basel, October 8, 2009 Novartis has gained exclusive worldwide rights to market PTK 0796, potentially the first once-daily broad-spectrum antibiotic that can be given by intravenous (IV) infusion or oral tablet to treat a wide variety of life-threatening infections, including those caused by highly resistant bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA) and multi-drug resistant *Streptococcus pneumoniae* (MDRSP).

Under the agreement with Paratek Pharmaceuticals, a privately held company based in Boston, Massachusetts, the companies will share responsibility for developing PTK 0796. A Phase III study is already under way in complicated skin and skin structure infections (cSSSI), and clinical trials are planned in a number of other potential indications.

Because PTK 0796 may be given as a once-daily 30-minute IV infusion or daily oral tablet, it could offer patients a convenient way to continue antibiotic treatment after they have been discharged from hospital. Its broad spectrum of activity means it could be used as a single agent against

a range of bacteria, unlike other antibiotics which may have to be used in combination.

As the first in a new class of antibiotics, PTK 0796 is being developed to address the growing problem of bacterial resistance to currently available antibiotics, said Joe Jimenez, CEO of the Novartis Pharmaceuticals Division. It will potentially benefit patients by offering a flexible and highly effective approach to the treatment of a number of critical infections, and should form an important addition to our growing portfolio of antibiotic medicines.

The in-licensing of PTK 0796 represents a further expansion of the Novartis infectious diseases portfolio following the acquisition of Protez Pharmaceuticals in June 2008. The Protez transaction covered the North American and European rights to PTZ601 (razupenem), currently in Phase II development as the first injectable broad-spectrum antibiotic in the carbapenem class to cover MRSA.

PTK 0796, a first-in-class aminomethylcycline, has shown broad-spectrum activity against a wide range of bacteria, including both Gram-positive and Gram-negative strains a basic classification derived from the staining process used to analyze the cell wall as well as atypical and anaerobic bacteria, which grow with little or no oxygen.

In addition, PTK 0796 has shown activity against multi-drug resistant bacteria such as MRSA, vancomycin-resistant *enterococci* (VRE) and Gram-negatives producing ESBL (extended-spectrum beta-lactamase). These bacteria have developed resistance during decades of antibiotic use, so many of the standard therapies are no longer effective. Studies have estimated there were nearly 100,000 deaths from hospital-acquired infections in the US in 2002(1), and around 50,000 deaths a year in the EU(2).

Clinical studies involving a total of more than 500 patients have shown that PTK 0796 has a favorable safety and tolerability profile. A Phase II study in cSSSI found that clinical success rates among evaluable patients (n=188) were 98% for PTK 0796 and 93% for linezolid (Zyvox®*)(3). In this study PTK 0796 was used as a single agent, whereas Zyvox was used for Gram-positive infections only and an additional antibiotic had to be given for Gram-negative cases. The study met its primary safety and tolerability endpoints by showing no relevant difference between PTK 0796 and linezolid in terms of adverse events(3). In this study, approximately 50% of the infecting bacteria were MRSA(3).

The Novartis portfolio of medicines for hospital-based infections includes Cubicin® (daptomycin), marketed by Novartis in the EU and other countries for treating complicated skin and soft tissue infections (cSSTI), right-sided infective endocarditis (RIE) due to *Staphylococcus aureus* (*S. aureus*), and *S. aureus* bacteremia (SAB) when associated with RIE or cSSTI. Cubicin is the first of a new class of antibiotics called cyclic lipopeptides.

Terms of the agreement

The agreement states that Novartis will make an upfront payment to Paratek in return for the exclusive rights to commercialize PTK 0796 worldwide. Both companies will share responsibility and costs for developing PTK 0796. Paratek will be eligible to receive future milestone payments, and will also receive a royalty on net sales of PTK 0796 around the world.

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* Zyvox is a registered trademark of Pfizer Inc.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, potentially, could, eligible, future, can, will, planned, may, should, or similar expressions, or by express or implied discussions regarding potential future regulatory f or marketing approvals for PTK 0796, or the timing of any such potential filings or approvals, or regarding potential future revenues from PTK 0796, PTZ601 or Cubicin. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that PTK 0796 will be submitted or approved for sale in any market, or that any such approvals will occur at any particular time. Nor can there be any guarantee that PTK 0796, PTZ601 or Cubicin will achieve any particular levels of revenue in the future. In particular, management s expectations regarding these drugs could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical

data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the Group s assets and liabilities as recorded in the Group s consolidated balance sheet, and other

risks and factors referred to in Novartis AG s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in each of these areas. In 2008, the Group s continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Klevens RM, et al. Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. Public Health Reports Mar-Apr 2007 Vol. 122 p.160-166.

(2) Surveillance of Nosocomial Infections in Europe Analysis Results HELICS European Database, including 2005 data.

(3) Paratek Pharmaceuticals. Data on file.

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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.

Novartis AG

Date: October 8, 2009	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting