NOVARTIS AG
Form 6-K
November 14, 2017

UNITED STATES

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 November 13, 2017

(Commission File No. 1-15024)

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Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

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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: 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):

Yes: **No**:

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):

Yes: **No**:

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**:

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis highlights its differentiated late stage pipeline at the R&D update and investor event

- *RTH258 meets primary endpoint of non-inferiority and demonstrates superiority versus aflibercept in key secondary endpoint measures of disease activity in patients with nAMD*

- *AMG 334 has a robust data package, even in difficult to treat patients, and is on track to be the first CGRP to market for treatment of patients with chronic or episodic migraine*

- *Cosentyx has strong differentiation based on its unique biology, which has been proven to deliver a high level of enthesitis resolution and no radiographic progression in spondyloarthritis*

- *ACZ885 feedback from regulators supports moving forward with regulatory submissions for treatment of patients with inflammatory CV risk*

London, November 13, 2017 – Novartis has had a strong year in innovation with several key approvals and positive trial readouts. Today Novartis holds an R&D and investor update in London, which will provide deeper insights into key late-stage pipeline projects. In the Oncology business unit, Novartis is pursuing multiple indications for *Kymriah*, the first-in-class CAR-T therapy, and could further strengthen the oncology pipeline if the proposed acquisition of Advanced Accelerator Applications is closed. In the Pharmaceuticals business unit, Novartis continues to strengthen its position in Multiple Sclerosis through BAF312 (siponimod), OMB157 (ofatumumab) and the recent pediatric findings for *Gilenya.* During the investor event Novartis will provide a deep dive on the four selected programs below.

In Ophthalmology, RTH258 (brolucizumab) data presented at the American Academy of Ophthalmology showed superiority versus aflibercept in key secondary endpoints reflective of disease activity in patients with nAMD. Patients treated with RTH258 showed fewer signs of specific disease activity than patients treated with aflibercept. RTH258 patients showed less retinal fluids, less fluid in the deepest part of the retina and superior reductions in retinal thickness. Novartis expects to file for the nAMD indication by Q4 2018 and expects to start clinical trials in DME and RVO during 2018. Additionally, RTH258 creates the potential opportunity for Novartis to enter the attractive growing US retina market.

In Neuroscience, AMG 334 (erenumab) is being developed to deliver an effective and safe prophylactic treatment for patients suffering from chronic or episodic migraine. This debilitating disease affects more than 10% of adults, mainly in their prime working years. AMG 334 has shown encouraging results in reducing monthly migraine days, even in difficult to treat patients. AMG 334 is a fully human, potent, selective CGRP antagonist targeting the receptor and it was the first CGRP antagonist to be filed in the US and EU, on track for a potential first-in-class launch in 2018.

In Immunology, *Cosentyx* continues to build on its best-in-class profile, which has demonstrated sustained control of signs and symptoms in PSO, PsA and AS. *Cosentyx* has strong differentiation based on its unique biology which has shown a high level of enthesitis resolution and no radiographic progression in psoriatic arthritis and ankylosing spondylitis. By targeting the IL-17A pathway, the cornerstone cytokine of enthesitis, *Cosentyx* has the potential to change the course of disease in AS and PsA. *Cosentyx* is uniquely positioned to continue growth in all indications, particularly in spondyloarthritis, where the segment opportunity is larger than psoriasis.

In Cardiology, ACZ885 (canakinumab) data showed there was a significant reduction in major adverse cardiac events, in a subpopulation of patients who achieved hsCRP<2mg/L three months after the initial treatment. This well defined target population is critical to establishing the product’s value proposition and commercial uptake. Feedback from FDA and EU regulators supports moving forward with regulatory submissions for cardiovascular risk reduction, which are planned for Q4 and onwards.

The novelty of approach to reduce CV risk is recognized by the regulators and there is interest in understanding the relationship between hsCRP and patient response.

For background slides and webcast (audio only) please refer to the following link:
http://www.novartis.com/investors/event-calendar/index.shtml

The background slide decks will be available on Monday November 13th, 2017.

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “pipeline,” “on track,” “moving forward,” “will,” “pursuing,” “could,” “continues,” “expects,” “by Q4 2018,” “during 2018,” “potential,” “gro developed,” “encouraging,” “launch,” “to build,” “positioned,” “opportunity,” “planned,” “for Q4 and onwards,” “interest in,” terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational and approved products described in this press release, including RTH258, AMG 334, ACZ885, BAF312, OMB157, Cosentyx, Kymriah and Gilenya, or regarding potential future revenues from such investigational and approved products, or by express or implied discussions regarding the potential outcome of the tender offer for Advanced Accelerator Applications, and the potential impact on Novartis of the proposed acquisition, including express or implied discussions regarding potential future sales or earnings of Novartis, and any potential strategic benefits, synergies or opportunities expected as a result of the proposed acquisition. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward- looking statements. There can be no guarantee that any new products will be approved for sale in any market, or that any new indications will be approved for any existing products in any market, or that any approvals which are obtained will be obtained at any particular time, or that any such products will achieve any particular revenue levels. Neither can there be any guarantee that the investigational or approved products described in this press release will be commercially successful in the future. Nor can there be any guarantee that the proposed acquisition described in this press release will be completed, or that it will be completed as currently proposed, or at any particular time. Neither can there be any guarantee that Novartis will achieve any particular future financial results as a result of the proposed acquisition, or that Novartis will be able to realize any potential strategic benefits, synergies or opportunities as a result of the proposed acquisition. Nor can there be any guarantee that shareholders will achieve any particular level of shareholder returns. Neither can there be any guarantee that the Group, or any of its divisions, will be commercially successful in the future, or achieve any particular credit rating or financial results. In particular, our expectations could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally, including potential regulatory actions or delays relating to the completion of the potential acquisition described in this press release, as well as potential regulatory actions or delays with respect to the development of the products described in this press release; the potential that the strategic benefits, synergies or opportunities expected from the proposed acquisition may not be realized or may take longer to realize than expected; uncertainties regarding actual or potential legal proceedings, including, among others, potential legal proceedings with respect to the proposed acquisition; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products which commenced in prior years and will continue this year; the particular prescribing preferences of

physicians and patients; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures, such as from increased publicity on pharmaceuticals pricing, including in certain large markets; general economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; uncertainties regarding future demand for our products; safety, quality or manufacturing issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. 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.

Additional Information

Novartis announced October 30, 2017, that it had entered a memorandum of understanding with Advanced Accelerator Applications (AAA) under which Novartis intends to commence a tender offer for 100% of the share capital of AAA. The transaction is subject to certain closing conditions. Novartis will commence a tender offer upon completion of works council consultation and AAA's Board of Directors recommending the tender offer to AAA shareholders. The senior management and Directors of AAA have, in their capacity as shareholders of AAA, undertaken to tender their shares into the proposed tender offer. The transaction is additionally subject to (i) the valid tender pursuant to the tender offer of ordinary shares (including ordinary shares in the form of American Depositary Shares) of AAA representing at least 80% of the outstanding ordinary shares on a fully diluted basis and (ii) receipt of customary transactional regulatory approvals and other customary closing conditions. Until such time as the closing conditions are satisfied, Lutathera® remains under the custody and control of AAA. Novartis does not currently own or control these projects and will not have the ability to influence them until closing of the proposed acquisition of AAA which is subject to certain closing conditions and regulatory approvals.

Lutathera® is a registered trademark of Advanced Accelerator Applications.

About Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 121,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://www.novartis.com.

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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: November 13, 2017 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Head Group Financial
Title: Reporting and
Accounting