NOVARTIS AG
Form 6-K
October 30, 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 October 30, 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 announces the planned acquisition of Advanced Accelerator Applications to strengthen oncology portfolio

- Novartis to acquire Advanced Accelerator Applications pending outcome of tender offer and works council consultation

- *Acquisition would add Lutathera®, a first-in-class RadioLigand Therapy (RLT) approved in Europe and under review in the US for neuroendocrine tumors (NETs)*

- *Integration of Advanced Accelerator Applications would build on Novartis' expertise in diseases associated with NETs and introduce a new technology platform to Novartis providing an innovative approach to treating cancer*

- *Advanced Accelerator Applications would bring to Novartis an expanded pipeline of RLT programs with significant sales potential, including 177Lu- PSMA-R2 entering Phase 1/2 for prostate cancer*

Basel, October 30, 2017 – Novartis announced today, that it has 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 subject to certain conditions. Advanced Accelerator Applications (NASDAQ:AAAP) is a radiopharmaceutical company that develops, produces and commercializes Molecular Nuclear Medicines including Lutathera® (177Lu-DOTATATE), a first-in-class RLT product for neuroendocrine tumors (NETs). Radiopharmaceuticals, such as Lutathera, are unique medicinal formulations containing radioisotopes which are used clinically for both diagnosis and therapy. The transaction would strengthen Novartis' oncology presence with both near-term product launches as well as a new technology platform with potential applications across a number of oncology early development programs.

“Novartis has a strong legacy in the development and commercialization of medicines for neuroendocrine tumors where significant unmet need remains for patients,” said Bruno Strigini, CEO, Novartis Oncology. “With Lutathera we can build on this legacy by expanding the global reach of this novel, differentiated treatment approach and work to maximize Advanced Accelerator Applications broader RLT pipeline and an exciting technology platform.”

Lutathera was approved in Europe in September 2017 for the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Lutathera is under review in the U.S. with a Prescription Drug User Fee Act (PDUFA) date of January 26, 2018.

The efficacy and safety of Lutathera were established in the pivotal Phase III trial known as NETTER-1. The primary endpoint of the study was progression free survival with secondary endpoints including objective response rates, overall survival, safety and tolerability. The study met its primary endpoint with Lutathera achieving statistically significant and clinically meaningful 79% reduction in risk of disease progression or death compared to the control therapy (hazard ratio 0.21, 95% confidence interval: 0.13 -0.33, $p<0.0001$). At the time of study publication in the *New England Journal of Medicine* (January 2017), median PFS in the control arm was 8.4 months and had not yet been reached in the Lutathera arm.

In addition to Lutathera, AAA brings a broad set of skills in developing, manufacturing and commercializing radiopharmaceuticals, including the companion diagnostics for Lutathera (NETSPOT® and SomaKit TOC™). AAA had sales of EUR 109 million in 2016.

Transaction Details

Under the terms of the memorandum of understanding, which has been approved by AAA's Board of Directors, Novartis will make a cash offer of USD 41 per ordinary share of AAA and USD 82 per American Depositary Share (each representing 2 ordinary shares of AAA) subject to certain conditions. This offer values AAA's equity at USD 3.9 billion.

The transaction to acquire AAA is planned to be fully funded through external short- and long- term debt.

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.

Transaction Terms

The tender offer will be implemented in accordance with the terms and conditions of the binding memorandum of understanding between Novartis and Advanced Accelerator Applications. In addition to the offer terms, the memorandum of understanding contains representations, warranties and undertakings by Novartis and Advanced Accelerator Applications typical in similar transactions. The memorandum of understanding may be terminated by Novartis or Advanced Accelerator Applications under certain circumstances prior to the commencement or completion of the tender offer, including, for example, a material breach by either party of the terms and conditions of the memorandum of understanding prior to the commencement of the tender offer, the Board of Directors of AAA not issuing their positive recommendation following successful completion of the works council consultation, or amending its recommendation in a manner adverse to Novartis, non-receipt of customary transactional regulatory approvals and certain other circumstances. The parties have further agreed on certain expense reimbursement and termination fees payable by AAA to Novartis under certain circumstances, including, if the Board of Directors of AAA determines not to issue a positive recommendation following completion of the works council consultation or subsequently changes or withdraws its recommendation.

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Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995, that can generally be identified by words such as “planned,” “to strengthen,” “to acquire,” “would,” “under review,” “potential,” “intends,” “pipeline,” “can,” “work to,” “will,” or similar expressions, or by express or i discussions regarding the potential outcome of the tender offer for Advanced Accelerator Applications to be commenced by Novartis, 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; and regarding potential marketing approvals, new indications or labeling for the potential, investigational or approved products described in this press release, or regarding potential future revenues from such products. 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 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 of potential strategic benefits, synergies or opportunities as a result of the proposed acquisition. Nor can there be any guarantee that the potential, investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations could be affected by, among other things: 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 release, as well as potential regulatory actions or delays with respect to the development of the products described in this 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; the uncertainties inherent in the research and development of new healthcare products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection; safety, quality or manufacturing issues; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; the particular prescribing preferences of physicians and patients; uncertainties regarding actual or potential legal proceedings, including, among others, potential legal proceedings with respect to the proposed acquisition; 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 as a result of new information, future events or otherwise.

Lutathera® and Netspot® are registered trademarks of Advanced Accelerator Applications.

Additional Information

This press release is neither an offer to purchase nor a solicitation of an offer to sell securities. The tender offer for the outstanding ordinary shares and American Depositary Shares of Advanced Accelerator Applications (the “*Company*”) described in this press release has not commenced. At the time the tender offer is commenced, Novartis and an indirect wholly owned subsidiary of Novartis (“*Purchaser*”) will file, or will cause to be filed, a Schedule TO Tender Offer Statement with the U.S. Securities and Exchange Commission (the “*SEC*”) and the Company will file a Schedule 14D-9 Solicitation/Recommendation Statement with the SEC, in each case with respect to the tender offer. The Schedule TO Tender Offer Statement (including an offer to purchase, a related letter of transmittal and other offer

documents) and the Schedule 14D-9 Solicitation/Recommendation Statement will contain important information that should be read carefully before any decision is made with respect to the tender offer. Those materials and all other documents filed by, or caused to be filed by, Novartis and Purchaser with the SEC will be available at no charge on the SEC's website at www.sec.gov. The Schedule TO Tender Offer Statement and related materials may be obtained for free under the "Investors – Financial Data" section of Novartis website at https://www.novartis.com/investors/financial-data/sec-filings. The Schedule 14D-9 Solicitation/Recommendation Statement and such other documents may be obtained for free from the Company under the "Investor Relations" section of the Company's website at http://investorrelations.adacap.com/.

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: October 30, 2017 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Title: Head Group Financial Reporting and Accounting