NOVARTIS AG
Form 6-K
October 18, 2018
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 18, 2018

(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**:

Novartis announces planned acquisition of Endocyte to expand expertise in radiopharmaceuticals and build on commitment to transformational therapeutic platforms

· *Novartis to acquire Endocyte to accelerate development of innovative radioligand technology for treating cancer*

· *Acquisition would add ^{177}Lu-PSMA-617, a potential first-in-class radioligand therapy in Phase III development for metastatic castration-resistant prostate cancer (mCRPC)*

· *Endocyte offers radiopharmaceutical programs with significant sales potential*

Basel, October 18, 2018 - Novartis today announced that it has entered into an agreement and plan of merger with Endocyte, a US-based biopharmaceutical company focused on developing targeted therapeutics for cancer treatment. Under the terms of the agreement, Novartis would acquire all outstanding shares of Endocyte common stock for USD 24 per share. This offer values Endocyte's equity at USD 2.1 billion.

Endocyte uses drug conjugation technology to develop targeted therapies with companion imaging agents, including ^{177}Lu-PSMA-617, a potential first-in-class investigational radioligand therapy (RLT) for the treatment of metastatic castration-resistant prostate cancer (mCRPC). ^{177}Lu-PSMA-617 targets the prostate-specific membrane antigen (PSMA), present in the majority of patients with mCRPC, and has shown promising Phase II data. ^{177}Lu-PSMA-617 is currently being investigated in the Phase III global VISION clinical trial in men with mCRPC, a disease with limited treatment options and significant unmet medical need.

If completed, the Endocyte acquisition would expand the Novartis RLT platform with both a potential near-term product launch and early- stage clinical development programs. The deal would also enable Novartis to harness its research and development expertise to investigate the potential development of ^{177}Lu-PSMA-617 for use in earlier lines of prostate cancer therapy.

Liz Barrett, CEO, Novartis Oncology, said, "Novartis has a strong legacy of addressing unmet needs with transformative therapies and is building a leadership capability in new, technology-driven platforms that address some of the world's most complex health challenges, including cancer. Today's announcement about the proposed acquisition of Endocyte builds on our growing capability in radiopharmaceuticals, which is expected to be an increasingly important treatment option for patients and a key growth driver for our business. We are also excited about the opportunity to break into the prostate cancer arena with a near-term product that has the potential to make a meaningful impact for patients in great need of more options."

In a Phase II study, 50 patients with PSMA-positive mCRPC treated with ^{177}Lu-PSMA-617 showed a median prostate specific antigen (PSA) progression free survival (PFS) of 7.6 months ($p<0.0001$).[1] Median overall survival for the

first cohort of 30 patients enrolled was 13.5 months (p=0.0201).[1]

VISION is a global, prospective, open-label, multi-center, randomized Phase III trial of ^{177}Lu-PSMA-617 in combination with best supportive care versus best supportive care alone. The trial is currently enrolling patients with mCRPC. In September, the US Food and Drug Administration (FDA) agreed to radiographic progression-free survival (rPFS) as an alternative primary endpoint to OS in the trial.

The Endocyte pipeline includes additional investigational RLTs, including 225Ac-PSMA-617 in preclinical studies for the treatment of mCRPC.

Radiopharmaceuticals such as ^{177}Lu-PSMA-617 are innovative medicinal formulations containing radioisotopes that are used clinically for both diagnosis and therapy.

Through the acquisition of Advanced Accelerator Applications (AAA), Novartis acquired Lutathera® (lutetium Lu 177 dotatate / INN: lutetium (177Lu) oxodotreotide) - the first ever approved Peptide Receptor Radionuclide Therapy - for the treatment of somatostatin-receptor positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), an orphan disease.

Transaction Details

The transaction would be in the form of a merger of Endocyte and a newly formed Novartis subsidiary. Under the terms of the agreement and plan of merger, upon closing, holders of Endocyte common stock would receive USD 24 in cash per share. This offer values Endocyte's equity at USD 2.1 billion.

Closing of the transaction is subject to customary closing conditions, including the approval of Endocyte's stockholders and receipt of regulatory approvals. Until closing, Endocyte will continue to operate as a separate and independent company.

The acquisition of Endocyte is planned to be funded through available cash.

Disclaimer

This communication 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 expand," "commitment," "to acquire," "to accelerate," "would," "potential," "development," "plan," "promising," "being investigated," "If completed," "is building," "proposed," "expected," "excited," "opportunity," "enrolling," "pipeline," "investigational," "subject to," or similar expressions, or by express or implied discussions regarding the proposed acquisition of Endocyte by Novartis including the potential outcome and expected timing for completion of the proposed acquisition, 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 and investigational products described in this communication and the potential timing of any such approvals, or regarding potential future revenues from any such products. You should not place undue reliance on these statements. There can be no guarantee that the acquisition described in this communication will be completed, or that it will be completed as currently proposed, or at any particular time. There can be no guarantee that Novartis or any potential products that would be obtained with Endocyte will achieve any particular future financial results, or that Novartis will be able to realize any potential strategic benefits or opportunities as a result of the proposed acquisition. There can be no guarantee that the potential and investigational products described in this communication will be submitted or approved for sale in any market or at any particular time. There can be no 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 ability to obtain Endocyte stockholder approval and the satisfaction of the other conditions to the consummation of the proposed acquisition; the potential that the strategic benefits or opportunities expected to result from the proposed acquisition may not be realized or may take longer to realize than expected; the potential that the integration of Endocyte into Novartis subsequent to the closing of the proposed acquisition may not be successful, or may take longer to succeed than expected; potential adverse reactions to the proposed acquisition by customers, suppliers or strategic partners; dependence on key Endocyte personnel, customers and suppliers; 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 filings with the U.S. Securities and Exchange Commission, including the "Forward-Looking Statements" and "Risk Factors" sections of Novartis AG's current Form 20-F for the fiscal year ended December 31, 2017. Forward-looking statements are based on information, plans, estimates, beliefs and expectations regarding future events as of the date they are made and are subject to significant known and unknown risks and uncertainties, and there may be other factors that may cause actual results to differ materially from these forward-looking statements. Novartis undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, subsequent events or otherwise, except as required by applicable law.

Additional Information and Where to Find It

This communication may be deemed to be solicitation material in respect of the proposed acquisition of Endocyte by Novartis AG. In connection with the proposed acquisition, Endocyte intends to file relevant materials with the SEC,

including a proxy statement in preliminary and definitive form. **Stockholders of Endocyte are urged to read these materials (including any amendments or supplements thereto) and all other relevant documents filed with the SEC when such documents become available, including Endocyte's definitive proxy statement, because they will contain important information about the proposed acquisition**. Investors and security holders are able to obtain the documents (once available) free of charge at the SEC's web site, http://www.sec.gov, or from Endocyte by going to its investor relations web site at http://investor.endocyte.com/investor-relations

Participants in Solicitation

Novartis AG and its directors and executive officers, and Endocyte and its directors and executive officers, may be deemed to be participants in the solicitation of proxies from the holders of Endocyte shares of common stock in respect of the proposed acquisition. Information about the directors and executive officers of Novartis AG is set forth in the excerpts of Novartis AG's Annual Report for 2017, which was furnished to the SEC on Form 6-K on January 24, 2018 and incorporated by reference into Novartis AG's Annual Report on Form 20-F for the fiscal year ended December 31, 2017. Information about the directors and executive officers of Endocyte is set forth in the proxy statement for Endocyte's 2018 Annual Meeting of Stockholders, which was filed with the SEC on March 23, 2018. Information regarding interests of Novartis AG's and Endocyte's respective participants in the solicitation, will be set forth in the proxy statement relating to the proposed acquisition and other materials to be filed with the SEC in connection with the proposed acquisition.

About Novartis

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 1 billion people globally and we are finding innovative ways to expand access to our latest treatments. About 125 000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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References

[1] Hofman, M. [^{177}Lu]-PSMA-617 radionuclide treatment in patients with metastatic castration-resistant prostate cancer (LuPSMA trial): a single-centre, single-arm, phase 2 study. The Lancet Oncology. 2018 Jun;19(6):825-833

[2] Endocyte Investor Presentation October 2018

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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 18, 2018 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Title: Head Group Financial Reporting and Accounting