

NOVARTIS AG
Form 6-K
April 09, 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 April 9, 2018

(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: 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 International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

<http://www.novartis.com>

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis enters agreement to acquire AveXis Inc. for USD 8.7 bn to transform care in SMA and expand position as a gene therapy and Neuroscience leader

AveXis lead product candidate, AVXS-101, has potential to be first-ever one-time gene replacement therapy for spinal muscular atrophy (SMA), a disease which results in early death or lifelong disability with considerable healthcare costs

AVXS-101 has Breakthrough therapy designation in the US, PRIME designation in the EU and Sakigake in Japan; expected US patient availability in 2019

Financially attractive acquisition with multi-billion dollar peak sales potential; strong Core Operating Income and EPS contribution as of 2020

AveXis offers a valuable gene therapy platform, with potential beyond SMA, and scalable manufacturing to accelerate potential future gene therapy programs and launches

Deal completion expected in mid 2018

Basel, April 9, 2018 — Novartis announced today that it has entered into an agreement and plan of merger with AveXis, Inc. to acquire the US-based Nasdaq-listed clinical stage gene therapy company for USD 218 per share or a total of USD 8.7 billion in cash. The transaction was unanimously approved by the Boards of both companies.

AveXis has several ongoing clinical studies for the treatment of SMA, an inherited neurodegenerative disease caused by a defect in a single gene, the survival motor neuron (SMN1). The lead AveXis gene therapy candidate, AVXS-101, has highly compelling clinical data in treating SMA Type 1, which is the number one genetic cause of death in infants, where 9 out of 10 infants do not live to their second birthday or are permanently ventilator dependent. It is estimated that one out of every 6,000-10,000 children born is affected by some form of SMA.

Vas Narasimhan, CEO of Novartis, said: “The proposed acquisition of AveXis offers an extraordinary opportunity to transform the care of SMA. We believe AVXS-101 could create a lifetime of possibilities for the children and families impacted by this devastating condition. The acquisition would also accelerate our strategy to pursue high-efficacy, first-in-class therapies and broaden our leadership in neuroscience. We would gain with the team at AveXis another gene therapy platform, in addition to our CAR-T platform for cancer, to advance a growing pipeline of gene therapies across therapeutic areas. We look forward on the closing of the deal to a smooth transition for AveXis employees and welcoming them to Novartis.”

The US Food and Drug Administration (FDA) has granted AVXS-101 Orphan Drug designation for the treatment of SMA as well as Breakthrough Therapy designation for SMA Type 1. A BLA filing with the FDA for AVXS-101 is expected in the second half of 2018 and approval and launch in the US is expected in 2019. PRIME and Sakigake designations have been secured in Europe and Japan, respectively.

If approved, AVXS-101 would be a first-in-class one-time therapy that addresses the root genetic cause of SMA by effectively replacing the defective SMN1 gene. In a clinical study, AVXS-101 showed life-saving efficacy, with all 15 infants treated event free at 20 months compared with an event-free survival rate of 8 percent in an historical cohort (*NEJM*, November 2017). AveXis will also present two-year data to the American Academy of Neurology on April 25, 2018.

Paul Hudson, CEO Novartis Pharmaceuticals, said: “Bringing AveXis on board would support both our ambition to be a leader in neurodegenerative diseases and our Neuroscience franchise priorities to strengthen our position in devastating pediatric neurological diseases such as SMA. We relish the opportunity to leverage our expertise, our 70-plus year heritage in neuroscience and our global footprint to help AVXS-101 benefit high-need SMA patients around the world.”

AveXis also offers state of the art AAV9 gene therapy manufacturing capabilities and valuable R&D capabilities, which in addition to AVXS-101, includes other pipeline products for Rett Syndrome (RTT) and a genetic form of amyotrophic lateral sclerosis (ALS) caused by mutations in the superoxide dismutase 1 (SOD1) gene. AAV9 is considered to be a clinically proven gene delivery platform for diseases of the central nervous system (CNS).

Assuming mid 2018 completion, the acquisition impact would be slightly negative to Core Operating Income in 2018 and 2019, mainly due to R&D investments. As of 2020, Novartis would expect the acquisition impact to strongly contribute to Core Operating Income and Core EPS accretion driven by a significant increase in sales.

The transaction is expected to close in mid 2018, pending the successful fulfilment of the tender offer and all other closing conditions. On completion, Novartis plans a smooth transition of operations and the integration of AveXis’ talented and dedicated employees to continue the mission of bringing AVXS-101 to patients worldwide.

Conference calls for Investors will take place on Monday April 9, 2018 at 08:00 CET and 18:00 CET. Details can be found at <https://www.novartis.com/investors/event-calendar>

Transaction Details

Under the terms of the agreement and plan of merger, Novartis has formed an acquisition subsidiary, Novartis AM Merger Corporation (“*Purchaser*”), that will commence a tender offer to purchase all outstanding shares of AveXis for USD 218 per share. Following the completion of the tender offer, Novartis expects to promptly consummate a merger of Purchaser and AveXis in which shares of AveXis that have not been purchased in the tender offer will be converted into the right to receive the same cash price per share as paid in the tender offer (other than shares held by stockholders who properly demand and perfect appraisal rights under Delaware law). The tender offer and the merger are subject to customary closing conditions, including the tender of at least a majority of outstanding AveXis shares

on fully diluted basis and the expiration or termination of the waiting period under the Hart Scott Rodino Antitrust Improvements Act.

The transaction to acquire AveXis is planned to be funded through available cash and short- term borrowing.

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 shares of common stock, par value USD 0.0001, of AveXis, Inc. (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

Page 3 of 4

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 and the Company 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 also 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 also may be obtained for free from the Company under the “Investor + Media” section of the Company’s website at <http://investors.avaxis.com/phoenix.zhtml?c=254285&p=irol-IRHome>.

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 “to acquire,” “to transform,” “candidate,” “potential,” “Breakthrough Therapy Designation,” “PRIME designation,” “Sakigake,” “expected,” “offers,” “to accelerate,” “to be,” “ongoing,” “would,” “potentially,” “believe,” “can,” “hopefully,” “excited,” “pipeline,” “Orphan Drug Designation,” “would,” “priorities,” “to strengthen,” “opportunity,” “pending,” “will,” “expects,” “subject to,” “planned,” or similar expressions, or by or implied discussions regarding the potential outcome of the tender offer for the shares of AveXis Inc. 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 tender offer or the 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 or any potential products which would be obtained with AveXis will achieve any particular future financial results, 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 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 successful integration of AveXis into the Novartis Group subsequent to the closing of the transaction and the timing of such integration; potential adverse reactions to the proposed transaction by customers, suppliers or strategic partners; dependence on key AveXis personnel and customers; 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

Page 4 of 4

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.

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 2017, the Group achieved net sales of USD 49.1 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 122,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit <http://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis>

For Novartis multimedia content, please visit www.novartis.com/news/media-library

For questions about the site or required registration, please contact media.relations@novartis.com

###

Novartis Media Relations

Central media line: +41 61 324 2200

E-mail: media.relations@novartis.com

Paul Barrett

Novartis Global External Communications

+41 61 324 52 24 (direct)

+41 79 797 8137 (mobile)

paul.barrett@novartis.com

Antonio Ligi

Novartis Global External
Communications

+41 61 324 13 74 (office)

+41 79 723 36 81 (mobile)

antonio.ligi@novartis.com

Eric Althoff
Novartis Global External Communications
+41 61 324 7999 (office)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Novartis Investor Relations

Central investor relations line: +41 61 324 7944

E-mail: investor.relations@novartis.com

Central	North America
Samir Shah	+41 61 324 7944 Richard Pulik +1 212 830 2448
Pierre-Michel Bringer	+41 61 324 1065 Cory Twining +1 212 830 2417
Thomas Hungerbuehler	+41 61 324 8425
Isabella Zinck	+41 61 324 7188

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: April 9, 2018 By: /s/ PAUL PENEPEPENT
Name: Paul Penepent
Head Group Financial
Title: Reporting and
Accounting