# 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 UNDER THE SECURITIES EXCHANGE ACT OF 1934

#### For the month of September 2018

Commission File Number: 001-37384

GALAPAGOS NV (Translation of registrant's name into English)

#### Generaal De Wittelaan L11 A3 2800 Mechelen, Belgium

(Address of principal executive office)

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 [ ]

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):

**Note:** Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

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):

**Note:** Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

The information contained in this report on Form 6-K, including the Exhibit 99.1 is hereby incorporated by reference into the Company's Registration Statements on Forms F-3 (File No. 333-211765) and S-8 (File Nos. 333- 204567, 333-208697, 333-211834, 333-215783, 333-218160 and 333-225263).

On September 24, 2018, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

(c) <u>Exhibit 99.1</u>. Press release dated September 24, 2018

#### **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.

# GALAPAGOS NV (Registrant)

Date: September 24, 2018

/s/ Xavier Maes Xavier Maes Company Secretary

#### Galapagos reports initiation of global ROCCELLA Phase 2 clinical trial with GLPG1972/S201086 in osteoarthritis patients

# Mechelen, Belgium, September 24 2018, 07.30 CET - Galapagos NV (Euronext & NASDAQ: GLPG) reports first dosing in the global ROCCELLA Phase 2 trial with GLPG1972/S201086 in knee osteoarthritis patients. Galapagos receives a €9 million milestone payment from its collaboration partner Servier for this achievement.

ROCCELLA is a multiregional, randomized, double-blind, placebo-controlled, dose ranging trial evaluating the efficacy and safety of three different once-daily doses of GLPG1972/S201086 in patients with knee osteoarthritis (OA). ROCCELLA is planned to recruit approximately 850 patients in countries in Europe, Asia, North America and South America. Galapagos is responsible for ROCCELLA in the United States, where 300 patients are targeted to be recruited. Servier will run the trial in all other countries.

The primary objective of ROCCELLA is to demonstrate the efficacy of at least one dose of GLPG1972/S201086 compared to placebo in reducing cartilage loss after 52 weeks of treatment. This cartilage loss will be measured precisely by magnetic resonance imaging (MRI). Secondary objectives include safety and tolerability, several additional measures of structural progression, improvement in pain, function, stiffness, and patient global assessment.

GLPG1972/S201086 is a disease-modifying osteoarthritis drug (DMOAD) candidate that, in two animal models, has been shown to efficiently target a cartilage degrading enzyme called ADAMTS-5. A Phase 1 trial in healthy volunteers met all of its safety and pharmacokinetic targets and also demonstrated that GLPG1972/S201086 reduced the blood level of the ARGS neoepitope by approximately 50% within two weeks. ARGS neoepitope is a biomarker for ADAMTS-5 activity and, as such, serves as a reflection of cartilage breakdown. In a more recent Phase 1b trial in OA patients in the United States, similar findings were seen over a four-week period. Specifically, GLPG1972/S201086 was well tolerated and reduced ARGS neoepitope blood levels by up to 50%.

OA is a highly prevalent and disabling pathology. There are no treatments available today that counteract disease progression. Patients are left with only symptomatic treatments. As a result, OA represents an important unmet medical need. Galapagos developed investigational molecule GLPG1972/S201086 with the potential of becoming a first-in-class DMOAD as part of a collaboration with Servier that began in 2010. Galapagos has full U.S. commercial rights to GLPG1972/S201086 and is eligible to receive development, regulatory and other milestone payments plus royalties from Servier upon commercialization outside the United States.

GLPG1972/S201086 is an investigational drug candidate and its safety and efficacy have not yet been established. More information on the clinical study can be found at www.clinicaltrials.gov (NCT03595618).

#### **About Galapagos**

Galapagos (Euronext & NASDAQ: GLPG) is a clinical-stage biotechnology company specialized in the discovery and development of small molecule medicines with novel modes of action. Galapagos' pipeline comprises Phase 3 through to discovery programs in cystic fibrosis, inflammation, fibrosis, osteoarthritis and other indications. Our target discovery platform has delivered three novel mechanisms showing promising patient results in, respectively, inflammatory diseases, idiopathic pulmonary fibrosis and atopic dermatitis. Galapagos is focused on the development and commercialization of novel medicines that will improve people's lives. The Galapagos group, including fee-for-service subsidiary Fidelta, has approximately 675 employees, operating from its Mechelen, Belgium headquarters and facilities in the Netherlands, France, Switzerland, the US and Croatia. More information at www.glpg.com.

#### Contacts

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#### **Galapagos forward-looking statements**

This release may contain forward-looking statements, including, among other things, statements regarding the mechanism of action and profile of, timing and results of clinical trials with, and potential commercialization of, GLPG1972. Galapagos cautions the reader that forward-looking statements are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition and liquidity, performance or achievements of Galapagos, or industry results, to be materially different from any historic or future results, financial conditions and liquidity, performance or achievements expressed or implied by such forward-looking statements. In addition, even if Galapagos' results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are that Galapagos' expectations regarding its GLPG1972 development program may be incorrect, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing clinical research programs may not support registration or further development of GLPG1972 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner for OA Servier), and estimating the commercial potential of Galapagos' product candidates. A further list and description of these risks, uncertainties and other risks can be found in Galapagos' Securities and Exchange Commission (SEC) filings and reports, including in Galapagos' most recent annual report on Form 20-F filed with the SEC and other filings and reports filed by Galapagos with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. Galapagos expressly disclaims any obligation to update any such forward-looking statements in this document to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.