# 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 March 2022**

**Commission File Number: 001-40010**

# Pharvaris N.V.

(Translation of registrant's name into English)

**J.H. Oortweg 21**
**2333 CH Leiden**
**The Netherlands**
(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 ☒ 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.

**PHARVARIS N.V.**

On March 29, 2022, Pharvaris N.V. issued a press release. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release, dated March 29, 2022. |

**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.

**PHARVARIS N.V.**

Date: March 29, 2022

By: /s/ Berndt Modig
Name: Berndt Modig
Title: Chief Executive Officer

Exhibit 99.1

# Pharvaris Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Highlights

- **Phase 1 pharmacokinetics study demonstrates PHVS719 well tolerated with extended-release profile supporting once-daily dosing**
- **Orphan Drug Designation for PHA121 granted by FDA**
- **RAPIDe-1, Phase 2 on-demand study of PHVS416 for the treatment of HAE attacks ongoing; top-line data anticipated in 4Q22**
- **CHAPTER-1, Phase 2 prophylactic study of PHVS416 for the prevention of HAE attacks trial enrolling patients; top-line data anticipated in 4Q22**
- **Executing from a strong financial position with cash and cash equivalents balance of €209.4 million as of December 31, 2021; runway expected into 1Q24**

**Zug, Switzerland, March 29, 2022** – Pharvaris (Nasdaq: PHVS), a clinical-stage company developing novel, oral bradykinin-B2-receptor antagonists to treat and prevent HAE attacks, building on its deep-seated roots in hereditary angioedema (HAE), today reported financial results for the fourth quarter and year ended December 31, 2021 and provided recent business highlights.

"The time since our initial public offering in February 2021 has been transformational for Pharvaris, enabling us to reach clinical development milestones, including initiation and continued progress of our Phase 2 RAPIDe-1 on-demand study of PHVS416, the initiation and enrollment of our Phase 2 CHAPTER-1 prophylactic study of PHVS416, and the completion of our Phase 1 pharmacokinetics study for PHVS719," said Berndt Modig, chief executive officer of Pharvaris. "We look forward to our next milestones, including announcing top-line data from our Phase 2 trials, RAPIDe-1 and CHAPTER-1. We will continue to execute our strategy efficiently in 2022 supporting our mission to provide individual choice for managing HAE through potent and convenient oral on-demand and prophylactic therapies."

**Recent Business Highlights and Updates**

*Pipeline*

- **Top-line Phase 1 data demonstrate extended-release PHVS719 suitable for once-daily dosing.** The Phase 1 pharmacokinetics (PK) study of PHVS719 included 8 healthy volunteers dosed in an open-label

randomized five-period crossover single-dose study to assess bioavailability of two different extended-release formulations with and without food, in comparison to a single dose of PHVS416 without food. The pharmacokinetics of a single dose of PHVS719 (40 mg) under fasted conditions yielded exposure above 13.8 ng/mL (the $EC_{85}$ determined in a Phase 1 bradykinin challenge in healthy volunteers) by the two-hour timepoint and maintained this exposure for at least an additional 28 hours. The overall exposure was not affected by food. The 24-hour area-under-the-curve ($AUC_{24h}$) exposure of PHA121 using PHVS719 (40 mg) is similar to that observed in Phase 1 studies with PHVS416 softgel capsules dosed 20 mg twice a day with food (one of the doses used in the CHAPTER-1 prophylactic proof-of-concept study). The study showed that PHVS416 and PHVS719 were well tolerated. During the study, there were no severe adverse events (SAEs) or severe treatment-emergent adverse events (TEAEs) reported.

"We are thrilled to have achieved with the PHVS719 extended-release formulation for the first time the possibility of a once-daily oral bradykinin receptor antagonist for prevention of hereditary angioedema attacks," said Jochen Knolle, CSO of Pharvaris. "The versatile properties of PHA121, in this case the ability to be absorbed through the colon, combined with the appropriate slow-release technologies, has enabled a release profile well-suited to all-day exposure of compound. This single-dose study showed that PHVS719 (40 mg) maintained PHA121 exposure for a full day above the levels that prevented the effects of a surge of bradykinin as shown in our mechanistic study in healthy volunteers. We look forward to confirming these results in an upcoming multi-dose PK study, to support use of PHVS719 in a future pivotal clinical study when combined with the anticipated results of our CHAPTER-1 proof-of-concept study."

- **Orphan Drug Designation granted by FDA.** On March 18, 2022, the FDA granted orphan drug designation to PHA121, the active ingredient in our PHVS416 and PHVS719 product candidates, for treatment of bradykinin-mediated angioedema.
- **Phase 2 on-demand study (RAPIDe-1) of PHVS416 ongoing.** RAPIDe-1, a Phase 2 clinical study of PHVS416 for the on-demand treatment of HAE attacks, continues enrollment and attack surveillance across 33 clinical sites in Canada, Europe, Israel, the UK and the U.S. Top-line data from the study is anticipated to be available in the fourth quarter of 2022.
- **Phase 2 prophylactic study (HAE CHAPTER-1) of PHVS416 enrollment ongoing.** CHAPTER-1, a Phase 2 clinical trial of PHVS416 for the prophylactic treatment of HAE attacks, is enrolling patients across clinical sites in Canada, Europe, Israel, the UK and the U.S. Top-line data from the study is anticipated to be available in the fourth quarter of 2022.
- **RAPIDe-2 expected to initiate in 2022.** RAPIDe-2, an open-label extension study evaluating PHVS416 for the on-demand treatment of people with HAE, is expected to initiate in the second half of 2022.

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- **Preclinical data of PHA121 published in *International Immunopharmacology.*** In March 2022, Pharvaris announced the publication of preclinical data in *International Immunopharmacology* demonstrating the specificity and potency of PHA121, the active ingredient in our PHVS416 and PHVS719 product candidates.

*Corporate*

- **Board of Directors.** In December 2021, Pharvaris announced the appointments of Elisabeth Björk, M.D., and Anne Marie de Jonge Schuermans, Ph.D., to the board of directors with expected confirmation at the company's upcoming 2022 annual general meeting of shareholders. Dr. Björk and Dr. de Jonge Schuermans have replaced Martijn Kleijwegt and Rémi Droller, both of whom stepped down from the board in December 2021 to focus on new investments.

**Year End 2021 Financial Results**

- **Liquidity Position.** Cash and cash equivalents were €209.4 million as of December 31, 2021, compared to €98.6 million for December 31, 2020.
- **Research and Development (R&D) Expenses.** R&D expenses were €10.7 million for the fourth quarter and €35.8 million for the full year of 2021, compared to €7.7 million for the fourth quarter and €19.5 million for the full year of 2020.
- **General and Administrative (G&A) Expenses**. G&A expenses were €5.5 million for the fourth quarter and €18.3 million for the full year of 2021, compared to €2.1 million for the fourth quarter and €5.5 million for the full year of 2020.
- **Loss for the year.** Loss for the fourth quarter was €12.3 million, resulting in basic and diluted loss per share of €0.41. For the full year, loss was €42.7 million, resulting in basic and diluted loss per share of €1.40 per share. This compares to €10.6 million, or basic and diluted loss per share of €2.18, for the fourth quarter and €26.0 million, or basic and diluted loss per share of €5.36, for the full year of 2020.

**Note on International Financial Reporting Standards (IFRS)**

Pharvaris is a Foreign Private Issuer and prepares and reports consolidated financial statements and financial information in accordance with IFRS as issued by the International Accounting Standards Board. Pharvaris maintains its books and records in the Euro currency.

**About RAPIDe-1**

The RAPIDe-1 study is a clinical research study for people who have been diagnosed with HAE. The main purpose of the study is to find out how effective three different doses of the study drug, PHVS416, are in relieving

symptoms associated with HAE attacks. Researchers developed the study drug in the form of softgel capsules which are taken orally and could be a more convenient alternative to an injection into a vein or under the skin for resolving HAE attacks. For more information, visit https://hae-rapide.com/, https://hae-rapide.us/, or https://clinicaltrials.gov/ct2/show/NCT04618211.

**About HAE CHAPTER-1**
The HAE CHAPTER-1 study is a clinical research study for people who have been diagnosed with HAE. The main purpose of the study is to evaluate two different doses of the study drug, PHVS416, in preventing HAE attacks. Researchers developed the study drug in the form of softgel capsules which are taken orally and could be a more convenient alternative to an injection into a vein or under the skin for preventing HAE attacks. For more information, visit https://haechapter-1.com or https://clinicaltrials.gov/show/NCT05047185.

**About PHVS416**
PHVS416 is a softgel capsule formulation containing PHA121, a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor. Pharvaris is developing this formulation to provide fast and reliable symptom relief when patients want, through rapid exposure of attack-mitigating medicine in a convenient, small oral dosage form. PHVS416 is currently in Phase 2 clinical development for the on-demand treatment of HAE.

**About PHVS719**
PHVS719 is an extended-release tablet formulation containing PHA121, a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor. Pharvaris is developing this formulation to provide an easy way to prevent attacks with sustained exposure of attack-preventing medicine in a convenient, small oral dosage form. PHVS719 is currently in Phase 1 clinical development for the prophylactic treatment of HAE.

**About PHA121**
PHA121 (PHA-022121) is a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor that has completed Phase 1 clinical development for the treatment of HAE. PHA121 utilizes the same mechanism as icatibant, the leading therapy for on-demand treatment of HAE. Pharvaris is developing this novel small molecule for on-demand and prophylactic treatment of HAE and other bradykinin-mediated diseases through formulations optimized for each setting. Data from single- and multiple-ascending-dose Phase 1 studies in healthy volunteers demonstrate rapid exposure and linear pharmacokinetics at doses up to 50 mg. In a bradykinin-challenge study in healthy volunteers, PHA121 showed significant inhibition of

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bradykinin-induced hemodynamic changes with an average composite $EC_{50}$ of 2.4 ng/mL and $EC_{85}$ of 13.8 ng/mL, approximately four-fold more potent than historical data for icatibant. Quantitative modeling indicates that single oral doses of PHA121 will maintain pharmacological effectiveness for a substantially longer time than 30 mg of subcutaneous icatibant. PHA121 has been observed to be well-tolerated at all doses studied to date.

**About Pharvaris**

Pharvaris is a clinical-stage company developing novel, oral bradykinin-B2-receptor antagonists to treat and prevent HAE attacks, building on its deep-seated roots in HAE. By directly targeting this clinically proven therapeutic target with novel small molecules, the Pharvaris team aspires to offer people with all sub-types of HAE more effective and convenient alternatives to treat attacks, both on-demand and prophylactically. The company brings together the best talent in the industry with deep expertise in rare diseases and HAE. For more information, visit https://pharvaris.com/.

**Forward-Looking Statements**

This press release contains certain forward-looking statements that involve substantial risks and uncertainties. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements containing the words “believe,” “anticipate,” “expect,” “estimate,” “may,” “could,” “should,” “would,” “will,” “intend” and similar expressions. These forward-looking statements are based on management’s current expectations, are neither promises nor guarantees, and involve known and unknown risks, uncertainties and other important factors that may cause Pharvaris’ actual results, performance or achievements to be materially different from its expectations expressed or implied by the forward-looking statements. Such risks include but are not limited to the following: the expected timing, progress, or success of our clinical development programs, especially for PHVS416 and PHVS719, which are in early-stage clinical trials; risks associated with the COVID-19 pandemic, which may adversely impact our business, preclinical studies, and clinical trials; the timing of regulatory approvals; the value of our ordinary shares; the timing, costs and other limitations involved in obtaining regulatory approval for our product candidates PHVS416 and PHVS719, or any other product candidate that we may develop in the future; our ability to establish commercial capabilities or enter into agreements with third parties to market, sell, and distribute our product candidates; our ability to compete in the pharmaceutical industry and with competitive generic products; our ability to market, commercialize and achieve market acceptance for our product candidates; our ability to raise capital when needed and on acceptable terms; regulatory developments in the United States, the European Union and other jurisdictions; our ability to protect our intellectual property and know-how and operate our business without infringing the intellectual property rights or regulatory exclusivity of others; our ability to manage negative consequences from changes in applicable laws and regulations, including tax laws, our ability to

successfully remediate the material weakness in our internal control over financial reporting and to maintain an effective system of internal control over financial reporting; changes in general market, political and economic conditions, including as a result of the current conflict between Russia and Ukraine; and the other factors described under the headings "Cautionary Statement Regarding Forward-Looking Statements" and "Item 3. Key Information—D. Risk Factors" in our Annual Report on Form 20-F and other periodic filings with the Securities and Exchange Commission.

These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. While Pharvaris may elect to update such forward-looking statements at some point in the future, Pharvaris disclaims any obligation to do so, even if subsequent events cause its views to change. These forward-looking statements should not be relied upon as representing Pharvaris' views as of any date subsequent to the date of this press release.

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