# 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 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

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 September 12, 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 99.1 to this Report on Form 6-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended or the Exchange Act. Exhibits 99.2 and 99.3 to this Report on Form 6-K shall be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Number 333-263198) and Form S-8 (Registration Numbers 333-252897) of Pharvaris N.V. and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

# **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: September 12, 2022 By: /s/ Berndt Modig

Name: Berndt Modig

Title: Chief Executive Officer

# EXHIBIT INDEX

Exhibit No.	Description
No. 99.1	Press Release, dated September 12, 2022.
99.2	Management's Discussion and Analysis of Financial Condition and Results of Operations as of and for the Three and Six Months Ended June 30, 2022.
99.3	Unaudited Condensed Consolidated Interim Financial Statements as of and for the Three and Six Months Ended June 30, 2022.
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#### Pharvaris Reports Second Quarter 2022 Financial Results and Provides Business Update

- Formal letters received from FDA relating to the previously announced hold on clinical studies of PHA121 in the U.S.
- Top-line data anticipated in 4Q22 for RAPIDe-1, a global Phase 2 study of PHVS416 for the acute treatment of HAE attacks ongoing outside the U.S.
- Executing from a strong financial position with cash and cash equivalents of €201 million as of June 30, 2022

**Zug, Switzerland, September 12, 2022** – <u>Pharvaris</u> (Nasdaq: PHVS), a clinical-stage company developing novel, oral bradykinin-B2-receptor antagonists to treat and prevent hereditary angioedema (HAE) attacks, today reported financial results for the second quarter ended June 30, 2022, and provided a business update.

"Pharvaris is dedicated to bringing therapeutic alternatives to people living with HAE and we maintain our belief in the potential of PHA121. Our team is committed to working with the FDA to resolve the hold on clinical trials involving PHA121 in the U.S. and we deeply appreciate the patience of the HAE community during this time," said Berndt Modig, Chief Executive Officer of Pharvaris. "Having evaluated the impact of the clinical hold, we anticipate announcing top-line Phase 2 data for RAPIDe-1 in the fourth quarter of this year. As we work to address the FDA's concerns and continue interactions with other regulatory authorities, we maintain a disciplined operational approach with our strong cash position expected to provide runway through the first quarter of 2024."

# **Recent Business Updates**

• Pharvaris announced that it has received formal clinical hold letters from the U.S. Food and Drug Administration (FDA). This follows the <u>previously announced</u> verbal notification of a hold on the clinical trials of PHA121 in the U.S. under Investigational New Drug (IND) applications for the on-demand and prophylactic treatment of HAE attacks. The FDA requested that Pharvaris conduct an additional long-term rodent toxicology study and update the Investigator's Brochure. The letters stated that the nonclinical observations are unlikely due to B2 receptor antagonism. Pharvaris plans to request a Type A meeting to discuss on-demand and prophylactic proposals to address the clinical holds.

- RAPIDe-1, a global Phase 2 study of PHVS416 for the on-demand treatment of HAE, continues evaluating enrolled patients outside the U.S. with top-line data anticipated in 4Q22. The previously announced target enrollment of 72 people with HAE across 33 sites in Canada, Europe, Israel, the UK, and the U.S. was achieved. Subsequent to the clinical hold, the company continues to evaluate PHVS416 for HAE attacks in patients enrolled outside the U.S. The goal of RAPIDe-1 is to assess PHVS416 as an oral acute treatment of HAE attacks by comparing safety and symptom relief (skin pain, skin swelling, and abdominal pain) during HAE attacks across three doses and placebo. The primary endpoint of RAPIDe-1 is the change of the composite of the three measured symptoms (skin pain, skin swelling and abdominal pain) using a visual analogue scale (VAS-3) four hours after treatment. One of the measured symptoms must have a VAS score of 30 before treatment to be considered a qualified HAE attack. Other key secondary endpoints include the time to onset of symptom relief, as well as safety and tolerability. Given the current dataset of evaluable attacks, Pharvaris anticipates announcing top-line data in the fourth quarter of 2022.
- Working with country-specific regulatory authorities regarding ongoing CHAPTER-1 Phase 2 study of PHVS416 for the prophylactic treatment of HAE attacks. Pharvaris has notified country-specific regulatory authorities in Canada, Europe, Israel, and the UK of the clinical hold in the U.S. When the company has more clarity regarding the impact of the U.S. clinical hold and additional feedback from global regulatory authorities, Pharvaris will provide guidance on the timing of announcing top-line data for the CHAPTER-1 trial. The study is designed to enroll 30 patients globally in CHAPTER-1 with a goal of evaluating proof of concept of PHVS416 for oral prophylaxis against HAE attacks. The safety and efficacy of two doses and placebo will be evaluated by comparing the number of investigator-confirmed attacks during participants' 12-week treatment period. Data from this study is expected to inform design of an anticipated Phase 3 study utilizing PHVS719, an extended-release formulation of PHA121.
- Strengthened executive team. With the appointment of Joan Schmidt, J.D., as Chief Legal Officer, effective June 2022, the company further strengthened its capabilities in legal, compliance, and governance.
- Held Annual Meeting of Shareholders and appointed Elisabeth Björk, M.D., and Anne Marie de Jonge Schuermans, Ph.D., to the Board of Directors. On June 29, 2022, the company held an Annual Meeting of Shareholders at which all proposals were approved. Dr. Björk and Dr. de Jonge Schuermans were appointed as Non-Executive Directors.

#### **Upcoming Events**

 Pharvaris will attend the upcoming Morgan Stanley 20th Annual Global Healthcare Conference, which is being held in New York from September 12-14, 2022. Mr. Modig and Morgan Conn, Ph.D., Chief Business Officer, will participate in a fireside chat on Monday, September 12, at 4:15 p.m. ET. A live audio webcast will be available on the Investors section of the Pharvaris website at <a href="https://ir.pharvaris.com/news-events/events-presentations">https://ir.pharvaris.com/news-events/events-presentations</a>. A replay will be available on Pharvaris' website for 30 days following the fireside chat.

#### **Second Quarter 2022 Financial Results**

- **Liquidity Position.** Cash and cash equivalents were €201 million as of June 30, 2022, compared to €209 million as of December 31, 2021. The net cash position reflects increased operating expenses, offset by favorable foreign exchange effects.
- Research and Development (R&D) Expenses. R&D expenses were €13.7 million for the quarter ended June 30, 2022, compared to €8.1 million for the quarter ended June 30, 2021.
- General and Administrative (G&A) Expenses. G&A expenses were €7.7 million for the quarter ended June 30, 2022, compared to €4.7 million for the quarter ended June 30, 2021.
- Loss for the period. Loss for the quarter ended June 30, 2022 was &12.6 million, or basic and diluted loss per share of &0.38, compared to &15.2 million, or basic and diluted loss per share of &0.46, for the quarter ended June 30, 2021.

# 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 PHVS416**

PHVS416 is an investigational softgel capsule formulation containing PHA121, a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor. Pharvaris aims to develop this formulation to provide fast and reliable symptom relief, through rapid exposure of attack-mitigating therapy in a convenient, small oral dosage form. In healthy volunteers, a single dose of PHVS416 showed rapid exposure exceeding predicted therapeutically efficacious levels within 15 minutes. PHVS416 is currently in Phase 2 clinical development for the on-demand 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. 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 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. In clinical studies, 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 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 <a href="https://pharvaris.com/">https://pharvaris.com/</a>.

# 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: uncertainty in the outcome of our interactions with regulatory authorities, including the FDA with respect to the clinical hold on PHA121 clinical trials in the U.S.; the expected timing, progress, or success of our clinical development programs, especially for PHVS416 and PHVS719, which are in mid-stage global clinical trials and are currently on hold in the U.S. as a result of the clinical hold; risks associated with the COVID-19 pandemic, which may adversely impact our business, nonclinical 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.

#### **Contacts**

# **Pharvaris**

Maryann Cimino Director of Corporate Relations +1-617-710-7305 maryann.cimino@pharvaris.com

#### Management's Discussion and Analysis of Financial Condition and Results of Operations

This management's discussion and analysis is designed to provide you with a narrative explanation of our financial condition and results of operations. We recommend that you read this discussion together with our unaudited condensed consolidated interim financial statements, including the notes thereto, for the three and six months ended June 30, 2022 and 2021 included as Exhibit 99.3 to the Report on Form 6-K to which this discussion is attached as Exhibit 99.2. We also recommend that you read "Item 4. Information on the Company", "Item 5. Operating and Financial Review and Prospects" and our audited consolidated financial statements for fiscal year 2021, and the notes thereto, which appear in our Annual Report on Form 20-F for the year ended December 31, 2021 (the "Annual Report") filed with the U.S. Securities and Exchange Commission (the "SEC"). In addition, we recommend that you read any public announcements made from time to time by Pharvaris N.V.

The following discussion is based on our financial information prepared in accordance with the International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board (the "IASB"), which may differ in material respects from generally accepted accounting principles in the United States and other jurisdictions. We maintain our books and records in euros. Unless otherwise indicated, all references to currency amounts in this discussion are in euros.

The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described under "Item 3. Key Information—D Risk factors" in the Annual Report.

Unless otherwise indicated or the context otherwise requires, all references to "Pharvaris" or the "Company," "we," "our," "ours," "us", or similar terms refer to Pharvaris N.V. and its subsidiaries.

#### Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for rare diseases with significant unmet need, initially focused on angioedema and other bradykinin-mediated diseases. Our first molecule, PHA121, is a novel, small-molecule bradykinin B2-receptor antagonist for the treatment of hereditary angioedema, or HAE. Bradykinin-B2-receptor inhibition is a clinically validated mechanism for the treatment of HAE, as demonstrated by icatibant, which is a bradykinin B2-receptor antagonist approved in Europe in 2008 and in the United States in 2011 (as FIRAZYR®). We designed PHA121 to improve upon the therapeutic profile of existing therapies and, through oral delivery, to provide patients with quality of life and convenience that is superior to current standard-of-care HAE treatments, which are injectables. We believe PHA121 has the potential to provide a safe, effective and convenient option for both acute and prophylactic treatments of HAE, in the form of our PHVS416 on-demand rapid exposure product candidate, and for prophylaxis of HAE, in the form of our PHVS719 small daily dose extended-release product candidate. We believe that our product candidates may address a broader range of angioedema attacks than other available treatments since PHA121 blocks the actual signal that leads to angioedema (the interaction of bradykinin, or BK, with the bradykinin B2 receptor), rather than an upstream signal. By blocking the action of bradykinin, we can prevent its aberrant signaling regardless of the pathway that generates it.

In our completed Phase 1 trials to-date, we have observed that PHA121 was orally bioavailable and well tolerated at all doses studied, with approximately dose-proportional exposure. We also have demonstrated proof-of-mechanism through a clinical pharmacodynamics, or PD, assessment with the bradykinin challenge, which had been utilized as a validated surrogate assessment for dose selection in the icatibant development program. The data also allowed us to compare the projected therapeutic performance of PHA121 in comparison with that of icatibant, but we do not yet have data from a PHA121 Phase 2 study. We plan to progress PHA121 through clinical development for on-demand and prophylactic use with our on-demand product candidate, PHVS416, and extended-release product candidate, PHVS719, respectively.

We commenced our RAPIDe-1 Phase 2 clinical trial of PHVS416 in February 2021. We also commenced CHAPTER-1, a Phase 2 clinical trial for prophylaxis in 2021 using twice-daily dosing of the PHVS416 softgel capsules. Our primary objective with CHAPTER-1 is to assess the safety profile of PHVS416 dose regimens for prophylactic treatments in HAE patients. Please see "Recent Announcements" for an update regarding these clinical trials. We also initiated a Phase 1 clinical trial with PHVS719 in 2021 to assess pharmacokinetics of the extended-release formulation and reported results in the first quarter of 2022. In healthy volunteers, a single dose of PHVS719 was well tolerated with an extended-release profile supporting oncedaily dosing.

A wide variety of events beyond our control, including natural or man-made disasters, power shortages, fires, extreme weather conditions, pandemics, epidemics or outbreaks of infectious diseases, political instability or other events could disrupt our business or operations or those of our development partners, manufacturers, regulators or other third parties with whom we conduct business now or in the future. These events may cause businesses and government agencies to be shut down, supply chains to be interrupted, slowed, or rendered inoperable, and individuals to become ill, quarantined, or otherwise unable to work and/or travel due to health reasons or governmental restrictions.

In response to the COVID-19 outbreak, the governments of many countries, states, cities and other geographic regions have taken preventative or protective actions, such as imposing restrictions on travel and business operations and advising or requiring individuals to limit or forego their time outside of their homes. We have also taken steps to identify and mitigate the adverse effects and risks to the Company as a result of the pandemic. We have modified our business practices, including implementing work from home arrangements for employees able to perform their duties remotely and practicing safe social distancing in our operations. We expect to continue to take actions as may be required or recommended by government authorities or in the best interests of our employees and business partners. While the impact of COVID-19 on the Company's operations and financial performance has so far been limited, the extent to which COVID-19 may impact our financial condition or results of operations in the future is uncertain. For instance, the ongoing spread of variants of the COVID-19 virus may continue to interrupt, or delay, our clinical trial activities, regulatory reviews, manufacturing activities and supply chain. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are uncertain and cannot be predicted, including new information which may emerge concerning the severity of the COVID-19 pandemic and the actions to contain COVID-19 or treat its impact, including among other things, the effectiveness and outreach of COVID-19 vaccines.

In addition, the invasion of Ukraine and the retaliatory measures that have been taken, or could be taken in the future, by the United States, NATO, and other countries have created global security concerns that could result in a regional conflict and also adversely affect our ability to conduct ongoing and future clinical trials of our product candidates. For example, our RAPIDe-1 study includes a significant number of patients in Germany, Poland, and Bulgaria. A further escalation of the conflict in Ukraine may potentially impact our ability to complete our ongoing and planned clinical trials in these countries on a timely basis, or at all. Clinical trials in these countries could be suspended or terminated, and we may be prevented from obtaining data on patients already enrolled at affected sites. Any of the foregoing could impede the execution of our clinical development plans.

#### **Recent Announcements**

On May 11, 2022, we announced the appointment of Joan Schmidt, J.D., to the newly created position of Chief Legal Officer, effective June 1, 2022.

On August 22, 2022, we announced that the U.S. Food and Drug Administration (the "FDA") had verbally informed us that, based on its review of nonclinical data, it is placing a clinical hold on the clinical trials of PHA121 in the United States (the "clinical hold"). The FDA indicated it will provide a formal clinical hold letter to Pharvaris within approximately 30 days following the verbal notice.

On September 12, 2022, we announced that we have received formal clinical hold letters from the FDA. The FDA requested that we conduct an additional long-term rodent toxicology study and update the Investigator's Brochure. The letters stated that the nonclinical observations are unlikely due to B2 receptor antagonism, the primary mechanism of action of our compound. We plan to request a Type A meeting with the FDA to discuss ondemand and prophylactic proposals to address the clinical holds. In the RAPIDe-1 study, subsequent to the clinical hold in the U.S., we continue to evaluate PHVS416 for HAE attacks in patients enrolled outside the U.S. Given the current dataset of evaluable attacks, we anticipate announcing top-line data for the RAPIDe-1 study in the fourth quarter of 2022. We are working with country-specific regulatory authorities regarding the ongoing CHAPTER-1 Phase 2 study of PHVS416 for the prophylactic treatment of HAE attacks. We have notified country-specific regulatory authorities in Canada, Europe, Israel, and the UK of the U.S. clinical hold. When we have more clarity regarding the impact of the U.S. clinical hold and additional feedback from global regulatory authorities, we will provide guidance on the timing of announcing top-line data for the CHAPTER-1 trial.

#### **Financial Operations Overview**

#### Revenues

We did not record any revenues during the period covered by the historical financial information included in this Report. We do not expect to recognize any revenues before we are able to commercialize our first product.

#### Research and development expenses

We are focused on the clinical development of PHA121. Since our inception, we have devoted substantially all our resources to research and development efforts relating to the development of PHA121 and our product candidates PHVS416 and PHVS719. We expect that we will continue to incur significant research and development expenses as we seek to complete the clinical development of, and achieve regulatory approval for, our product candidates PHVS416 and PHVS719, and in connection with discovery and development of any additional product candidates.

Research and development expenses consist of the following:

- employee benefits expenses, which includes salaries, pensions, share-based compensation expenses, bonus plans and other related costs for research and development staff;
- nonclinical expenses, which include costs of our outsourced discovery and nonclinical development studies;
- clinical expenses, which includes costs of conducting and managing our sponsored clinical trials, including clinical investigator cost, costs
  of clinical sites, and costs for CRO's assisting with our clinical development programs;
- manufacturing expenses, which include costs related to manufacturing of active pharmaceutical ingredients and manufacturing of the
  products used in our clinical trials and research and development activities;
- costs related to regulatory activities, including collecting data, preparing and submitting filings, communicating with regulatory authorities
  and reviewing the design and conduct of clinical trials for compliance with applicable requirements;
- costs in connection with investigator-sponsored clinical trials and evaluations;
- · advisers' fees, including discovery, nonclinical, clinical, chemistry, manufacturing, and controls- related and other consulting services;
- · intellectual property costs, which includes costs associated with obtaining and maintaining patents and other intellectual property; and
- license costs.

We anticipate that our total research and development expenses will continue to increase as we continue to progress PHVS416 and PHVS719 through clinical development.

There is a risk that any clinical development or product discovery program may not result in commercial approval. To the extent that we fail to obtain approval to commercialize our product candidate in a timely manner, we would need to continue to conduct nonclinical studies or clinical trials over a longer period of time, and we anticipate that our research and development expenses may further increase.

Clinical development timelines and associated costs may vary significantly and the successful development of our product candidate is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts, including patient recruitment and selection that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, our product candidates

Moreover, we cannot assure that we will be able to successfully develop or commercialize our product candidates, if approved for marketing. This is due to numerous risks and uncertainties associated with developing drugs. See "Item 3. Key Information—D. Risk factors" in our Annual Report for a discussion of these risks and uncertainties.

#### Selling and distribution expenses

Historically, we have not incurred any selling and distribution expenses. If our product candidates are approved for registration and marketing, we anticipate incurring substantial selling and distribution expenses in future periods in order to establish an infrastructure for marketing and distribution, obtain supplies of active pharmaceutical ingredients, and manufacture commercial quantities of our product candidate.

#### General and administrative expenses

We anticipate that we will continue to incur significant general and administrative expenses as we advance our research and development portfolio. General and administrative expenses consist of the following:

- employee benefits, including salaries, pensions, share-based compensation expenses, bonus plans and other related costs for staff and independent contractors in executive and operational functions;
- independent auditors' and advisers' fees, including accounting, tax, legal, and other consulting services;
- rental expenses, facilities and IT expenses, and other general expenses relating to our operations; and
- expenses related to the build-out of our commercial organization, including assessments of the HAE market landscape, pricing research, and congress attendance.

We anticipate that the continuing development of our business and the expense of maintaining directors' and officers' liability insurance, will contribute to future increase in general and administrative expenses. We also expect that general and administrative expenses will increase in the future as we incur additional costs associated with being a public company in the United States.

#### Share-based compensation expenses

In 2016, we implemented an Equity Incentive Plan, or the Plan, in order to advance the interests of our shareholders by enhancing our ability to attract, retain and motivate persons who are expected to make important contributions to us and by providing such persons with performance-based incentives that are intended to better align the interests of such persons with those of our shareholders. In order to incentivize our directors and employees, our Board adopted the Pharvaris N.V. 2021 Equity Incentive Plan (the "2021 Plan") for employees, consultants and directors prior to the completion of our initial public offering ("IPO"). The 2021 Plan became effective upon our conversion from Pharvaris B.V. into Pharvaris N.V., which occurred prior to the consummation of our IPO. The 2021 Plan provides for the grant of options, stock appreciation rights, restricted stock, RSUs, performance stock awards, other stock-based awards, performance cash awards and substitute awards. The fair values of these instruments are recognized as personnel expenses in either research and development expenses or general and administrative expenses.

#### Result of operations

The financial information shown below was derived from our unaudited condensed consolidated interim financial statements for the three and six months ended June 30, 2022 and 2021 included as Exhibit 99.3 to this Report on Form 6-K. The discussion below should be read along with these condensed consolidated interim financial statements, and it is qualified in its entirety by reference to them.

Comparison of the three months ended June 30, 2022 and 2021

		For the three months ended June 30				
	2022	2022 2021 Change				
		(in €)				
Research and development expenses	(13,721,637)	(8,060,599)	(5,661,038)	70%		
General and administrative expenses	(7,660,133)	(4,664,726)	(2,995,407)	64%		
Total operating expenses	(21,381,770)	(12,725,325)	(8,656,445)	68%		
Operating loss	(21,381,770)	(12,725,325)	(8,656,445)	68%		
Finance income/(expense)	11,501,804	(2,474,483)	13,976,287	(565)%		
Loss before tax	(9,879,966)	(15,199,808)	5,319,842	(35)%		
Income taxes	(2,741,102)	(2,965)	(2,738,137)	92349%		
Loss for the period	(12,621,068)	(15,202,773)	2,581,705	(17)%		

#### Revenues

We did not generate any revenues for the three months ended June 30, 2022 and June 30, 2021.

Research and development expenses

	Fo	For the three months ended June 30			
	2022	2022 2021 Change (in €)			
Personnel expenses	(3,061,036)	(1,759,669)	(1,301,367)	74%	
Clinical expenses	(7,175,545)	(3,496,223)	(3,679,322)	105%	
Nonclinical expenses	(1,016,793)	(1,181,660)	164,867	(14)%	
Manufacturing costs	(2,419,143)	(1,601,980)	(817,163)	51%	
Intellectual Property costs	(49,120)	(21,067)	(28,053)	133%	
Total research and development expenses	(13,721,637)	(8,060,599)	(5,661,038)	<u>70</u> %	

Research and development expenses increased from &8,060,599 for the three months ended June 30, 2021 to &13,721,637 for the three months ended June 30, 2022. The increase in the research and development expenses is mainly driven by the progress made in the PHVS416 and PHVS719 development programs in the three months ended June 30, 2022. Clinical expenses increased by &3,679,322 for the three months ended June 30, 2022 compared to the three months ended June 30, 2021 due to the progress on and expansion of the on-demand and prophylactic programs. Nonclinical expenses decreased by &164,867 for the three months ended June 30, 2022 compared to the three months ended June 30, 2021 due to completion of certain nonclinical studies supporting the PHVS416 and PHVS719 clinical trial programs. Manufacturing costs relating to the API and pharmaceutical development of PHVS416 and PHVS719 increased by &817,163 for the three months ended June 30, 2022 compared to the three months ended June 30, 2021 due to supply costs associated with both clinical programs, the post-Phase 3 nonclinical study package and preparations for commercial supply. In the personnel expenses for the three months ended June 30, 2022 and 2021 an amount of &1,014,655 and &694,084, respectively, was included which related to share-based payments compensation arrangements. The increase in the share-based compensation is due to the new grants awarded in the three months ended June 30, 2022 and the cumulative charges of the awards granted up the three months ended March 31, 2022. The remaining increase in personnel expenses is driven by the growth of our organization resulting in additional employees hired, and yearly merit adjustments.

#### General and administrative expenses

	For the three months ended June 30			
	2022	2021	Change	%
		(in €)		
Personnel expenses	(3,825,151)	(1,795,721)	(2,029,430)	113%
Consulting fees	(254,899)	(161,559)	(93,340)	58%
Professional fees	(911,170)	(324,793)	(586,377)	181%
Accounting, tax and auditing fees	(290,159)	(648,626)	358,467	(55)%
Facilities, communication and office expenses	(1,618,732)	(1,510,566)	(108,166)	7%
Travel expenses	(260,446)	(2,563)	(257,883)	10062%
Other expenses	(499,576)	(220,898)	(278,678)	126%
Total general and administrative expenses	(7,660,133)	(4,664,726)	(2,995,407)	64%

General and administrative expenses increased from  $\[Engine{\epsilon}\]4,664,726$  for the three months ended June 30, 2021 to  $\[Engine{\epsilon}\]7,660,133$  for the three months ended June 30, 2022. The increase in general and administrative expenses was mainly driven by the growth of the Company following the completion of the IPO, which also led to additional expenses inherent to being a public company and increasing costs related to our commercial buildout. In the personnel expenses for the three months ended June 30, 2022 and 2021 an amount of  $\[Engine{\epsilon}\]2,128,184$  and  $\[Engine{\epsilon}\]1,078,654$  respectively, was included which related to share-based compensation arrangements. The increase in the share-based compensation expenses is due to the new grants (options and RSUs) made in three months ended June 30, 2022 and the cumulative charges of the awards already granted in the three months ended March 31, 2022. The remaining increase in personnel expenses is driven by the growth of our organization resulting in additional employees hired, and yearly merit adjustments.

# Finance income/(expense)

Finance income/(expense) for the three months ended June 30, 2022 and 2021 were €11,501,804 and (€2,474,483) respectively, a change of €13,976,287. The amount mainly relates to unrealized foreign exchange income, which is the result of translating the Company's bank balances held in USD to EUR. The foreign exchange rates changed in favor of the Company in the second quarter of 2022.

#### Income taxes

Income taxes are accounted for in line with IAS 34. The interim period is considered part of a larger financial year, where the income tax is recognized in each interim period based on the best estimate of the weighted average annual income tax rate expected for the full financial year. The estimated tax expenses are determined based on a full year basis and subsequently allocated using the expected full year effective tax rate. The one-off items are recognized in full in the interim period in which they emerge. In the total interim tax charge, no distinction is made between current and deferred tax expenses/income.

The total tax expense over the three months ended June 30, 2022 principally relates to the Dutch fiscal unity for the utilization of a deferred tax asset ("DTA") on carry forward losses which previously was not recognized, and a current tax expense which is calculated over the six months ended June 30, 2022, mainly driven by foreign exchange gains.

		For the six months ended June 30				
	2022	2022 2021 Change				
		(in €)				
Research and development expenses	(27,236,126)	(16,132,053)	(11,104,073)	69%		
General and administrative expenses	(13,525,138)	(8,436,415)	(5,088,724)	60%		
Total operating expenses	(40,761,264)	(24,568,468)	(16,192,796)	66%		
Operating loss	(40,761,264)	(24,568,468)	(16,192,796)	66%		
Finance income	14,892,983	3,344,373	11,548,610	345%		
Loss before tax	(25,868,281)	(21,224,095)	(4,644,186)	22%		
Income taxes	(2,779,817)	(21,554)	(2,758,263)	12797%		
Loss for the period	(28,648,098)	(21,245,649)	(7,402,449)	35%		

#### Revenues

We did not generate any revenues for the six months ended June 30, 2022 and June 30, 2021.

#### Research and development expenses

	For the six months ended June 30			
	2022	2021	Change	%
D 1	(5.500.207)	(in €)	(1,000,040)	4007
Personnel expenses	(5,590,207)	(3,768,165)	(1,822,042)	48%
Clinical expenses	(13,741,610)	(6,761,928)	(6,979,682)	103%
Nonclinical expenses	(1,832,918)	(2,143,713)	310,795	(14)%
Manufacturing costs	(5,883,668)	(2,920,172)	(2,963,496)	101%
License costs	_	(500,000)	500,000	(100)%
Intellectual Property costs	(187,723)	(38,075)	(149,648)	393%
Total research and development expenses	(27,236,126)	(16,132,053)	(11,104,073)	69%

Research and development expenses increased from  $\[ \in \] 16,132,053$  for the six months ended June 30, 2021 to  $\[ \in \] 27,236,126$  for the six months ended June 30, 2022. The increase in the research and development expenses is mainly driven by the progress made in the PHVS416 and PHVS719 development programs in the first six months of 2022. Clinical expenses increased by  $\[ \in \] 6,979,682$  for the six months ended June 30, 2022 compared to the six months ended June 30, 2021 due to the progress on and expansion of the on-demand and prophylactic programs. Nonclinical expenses decreased by  $\[ \in \] 310,795$  for the six months ended June 30, 2022 compared to the six months ended June 30, 2021 due to completion of certain nonclinical studies supporting the PHVS416 and PHVS719 clinical trial programs. Manufacturing costs relating to the API and pharmaceutical development of PHVS416 and PHVS719 increased by  $\[ \in \] 2,963,496$  for the six months ended June 30, 2022 compared to the six months ended June 30, 2021 due to supply costs for both clinical programs, the post-Phase 3 nonclinical study package and preparations for commercial supply. For the six months ended June 30, 2021 license costs reflected a milestone payment of  $\[ \in \] 500,000$  that was paid to Analyticon upon the start of the clinical Phase 2. In the personnel expenses for the six months ended June 30, 2022 and 2021 an amount of  $\[ \in \] 1,943,566$  and  $\[ \in \] 2,052,787$ , respectively, was included related to the share-based compensation arrangements. The decrease in the share-based compensation expenses is due to a remeasurement of the fair values of the stock options related to the performance periods 2021 and 2022 that occurred in the six months ended June 30, 2021 and the offset due to the new grants during the 6-month period, and the cumulative charges for the grants up to December 31, 2021. The remaining increase in personnel expenses was driven by the growth of our organization and yearly merit adjustments.

	For the six months ended June 30			
	2022	2021	Change	%
		(in €)		
Personnel expenses	(6,270,034)	(3,036,786)	(3,233,248)	106%
Consulting fees	(432,811)	(390,872)	(41,939)	11%
Professional fees	(1,795,170)	(1,132,706)	(662,464)	58%
Accounting, tax and auditing fees	(594,657)	(1,086,756)	492,099	(45)%
Facilities, communication and office expenses	(3,246,830)	(2,462,147)	(784,683)	32%
Travel expenses	(404,200)	(3,357)	(400,843)	11941%
Other expenses	(781,436)	(323,791)	(457,645)	141%
Total general and administrative expenses	(13,525,138)	(8,436,415)	(5,088,724)	60%

General and administrative expenses increased from &8,436,415 for the six months ended June 30, 2021 to &13,525,138 for the six months ended June 30, 2022. This is mainly driven by the growth of our organization following the completion of the IPO, which also led to additional expenses related to the operations of a public company and increasing costs related to our commercial buildout. In the personnel expenses for the six months ended June 30, 2022 and 2021 an amount of &3,146,211 and &1,816,561 respectively, was included which related to share-based compensation arrangements. The increase in the share-based compensation expenses is due to the grants made in the first six months of 2022. The remaining increase in personnel expenses is driven by the growth of our organization resulting in additional employees hired, and yearly merit adjustments.

#### Finance income/(expense)

Finance income for the six months ended June 30, 2022 and 2021 were €14,892,983 and €3,344,373 respectively, a change of €11,548,610. The amount mainly relates to unrealized foreign exchange income, which is the result of translating the group's bank balances held in USD to EUR. The EUR/USD exchange rate has changed to our favor for the six months ended June 30, 2022.

#### Income taxes

Income taxes are accounted for in line with IAS 34. The interim period is considered part of a larger financial year, where the income tax is recognized in each interim period based on the best estimate of the weighted average annual income tax rate expected for the full financial year. The estimated tax expenses are determined based on a full year basis and subsequently allocated using the expected full year effective tax rate. The one-off items are recognized in full in the interim period in which they emerge. In the total interim tax charge, no distinction is made between current and deferred tax expenses/income.

The total tax expense over the six months ended June 30, 2022 principally relates to the Dutch fiscal unity for the utilization of a DTA on carry forward losses which previously was not recognized, and a current tax expense which is calculated over the six months ended June 30, 2022, mainly driven by foreign exchange gains.

# **Liquidity and Capital Resources**

Since inception, we have incurred significant operating losses. For the six months ended June 30, 2022 and 2021 we incurred losses of €28,648,098 and €21,245,649 respectively. Since inception, we have not generated any revenues or net cash flows from sales. We will not receive any revenues or net cash flows from sales of our product candidate until it has been approved by regulatory authorities and we have commercialized it. There is no assurance that we will be able to do so.

To date, we have relied solely on the issuance of equity securities to finance our operations and internal growth. On March 1, 2022, we entered into a sales agreement with SVB Securities LLC, or SVB Securities, pursuant to which we may sell ordinary shares having an aggregate offering price of up to \$75 million from time to time through SVB Securities. During the six months ended June 30, 2022, we sold a total of 588,100 ordinary shares in two different transactions under the sales agreement generating total net proceeds of \$9,698,504, after deducting \$299,954 which was payable to SVB Securities as commission in respect of such sales. As of June 30, 2022 we had cash and cash equivalents of €201.4 million. Our cash and cash equivalents consist solely of cash at bank.

We do not expect positive operating cash flows in the foreseeable future and remain dependent on additional financing to fund our research and development expenses, general and administrative expenses and financing costs. We believe that the available cash balances are sufficient to execute our operating plan and strategies and to meet the anticipated working capital requirements and settle all expected liabilities for at least twelve months from the issuance date of our unaudited condensed consolidated interim financial statements for the three and six months ended June 30, 2022 and 2021. Accordingly, the unaudited condensed consolidated interim financial statements have been prepared on a going concern basis.

Our future viability is dependent on our ability to raise additional capital to finance operations. We will need to finance our operations through public or private securities offerings, debt financings or other sources, which may include licensing, collaborations or other strategic transactions or arrangements. Although we have been successful in raising capital in the past, there is no assurance that we will be successful in obtaining such additional financing on terms acceptable to us, if at all. If we are unable to obtain funding, we could be forced to delay, reduce, or eliminate some or all of our research and development programs for product candidates, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations.

Our contractual obligations and commitments as of June 30, 2022 amounted to €16 million, primarily related to research and development commitments.

#### **Cash Flows**

#### Comparison for the six months ended June 30, 2022 and June 30, 2021

The following table sets forth our primary sources and uses of our cash and cash equivalents for each of the periods set forth below:

	For the six months ended June 30				
	2022	2021	Change	%	
		(in <b>€</b> )			
Net cash flows used in operating activities	(31,568,574)	(22,058,913)	(9,509,661)	43%	
Net cash flows used in investing activities	(49,739)	(33,554)	(16,185)	48%	
Net cash flows provided by financing activities	8,823,313	144,306,260	(135,482,947)	(94)%	
Net increase (decrease) in cash and cash equivalents	(22,794,999)	122,213,793	(145,008,792)	(119)%	
Cash and cash equivalents at the beginning of the period	209,353,132	98,628,871	110,724,261	112%	
Effect of exchange rate changes	14,824,955	3,475,076	11,349,879	327%	
Cash and cash equivalents at the end of the period	201,383,087	224,317,740	(22,934,653)	(10)%	

# Operating activities

Net cash used in operating activities reflects our results for the period adjusted for, among other things, depreciation, unrealized foreign exchange results, share-based compensation, changes in working capital and interest accruals and payments.

Net cash used in operating activities was &31,568,574 for the six months ended June 30, 2022, an increase of &9,509,661, compared to &22,058,913 for the six months ended June 30, 2021, primarily reflecting the increase in research and development expenses and other operating expenses, due to progression made in the PHVS416 and PHVS719 development programs and the growth of our organization in 2021 and 2022.

# Investing activities

Net cash flows used in investing activities increased by  $\in$ 16,185 from  $\in$ 33,554 for the six months ended June 30, 2021 to  $\in$ 49,739 for the six months ended June 30, 2022, primarily as a result of capital expenditure related to office equipment in 2022.

# Financing activities

Net cash flows provided by financing activities decreased by  $\in$ 135,482,947 from  $\in$ 144,306,260 for the six months ended June 30, 2021 to  $\in$  8,823,313 for the six months ended June 30, 2022. The net cash inflow in 2021 was the result of the proceeds from the IPO net of underwriting discount and other transaction costs. The cash inflow in six months ended June 30, 2022 relates to the sale of the ordinary shares under the sales agreement with SVB Securities offset by cash flows related to financial lease and transaction costs.

#### **Off-Balance Sheet Arrangements**

As of June 30, 2022, we did not have any off-balance sheet arrangements other than the disclosed commitments.

#### **Quantitative and Qualitative Disclosures About Market Risk**

During the six months ended June 30, 2022, there were no significant changes to our quantitative and qualitative disclosures about market risk from those reported in "Item 11. Quantitative and Qualitative Disclosures About Market Risk" in the Annual Report.

#### **Critical Accounting Estimates and Judgments**

There have been no material changes to the significant accounting policies and estimates described in Note 2.19 to our consolidated financial statements in the Annual Report.

# **Cautionary Statement Regarding Forward-Looking Statements**

Certain statements in this management's discussion and analysis are or may be forward-looking statements with respect to us, our industry and our business that involve substantial risks and uncertainties. All statements other than statements of historical fact contained in this management's discussion and analysis, including statements regarding our future financial condition, results of operations and/or business achievements, including, without limitation, statements containing the words "believe," "anticipate," "expect," "estimate," "may," "could," "should," "would," "will," "intend" and similar expressions are forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Such forward-looking statements involve unknown risks, uncertainties and other factors which may cause our actual results, financial condition, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that might cause such a difference include, but are not limited to:

- uncertainty in the outcome of our interactions with regulatory authorities, including the FDA with respect to the clinical hold on PHA121 clinical trials in the U.S;
- the expected timing, progress, or success of our clinical development programs, especially for PHVS416 and PHVS719, which are in mid-stage global clinical trials and are currently on hold in the U.S. as a result of the clinical hold;
- risks associated with the COVID-19 pandemic, which may adversely impact our business, nonclinical studies and clinical trials, the timing
  of regulatory approvals and 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 market, commercialize and achieve market acceptance for our product candidates PHVS416 and PHVS719 or any of our other product candidates that we may develop in the future, if approved;
- our ability to establish commercial capabilities or enter into agreements with third parties to market, sell and distribute our product candidates;
- our dependence on third parties to perform critical activities related to the research, nonclinical safety and toxicology studies, development and manufacturing of our product candidates;
- disruptions at the FDA and other government agencies;
- the expense, time and uncertainty involved in the development and consistent manufacturing and supply of our product candidates, some or all of which may never reach the regulatory approval stage;

- our ability to raise capital when needed and on acceptable terms;
- our ability to enter into any new licensing agreements or to maintain any licensing agreements with respect to our product candidates;
- our reliance on collaboration partners and licensees, whose actions we cannot control;
- the willingness of private insurers and other payors to provide reimbursement for our products;
- regulatory developments in the United States, the European Union and other jurisdictions;
- the outcome and timing of price negotiations with governmental authorities;
- our ability to compete in the pharmaceutical industry and with competitive generic products;
- 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;
- side effects or adverse events associated with the use of our product candidates;
- our ability to defend against costly and damaging liability claims resulting from the testing of our product candidates in the clinic or, if, approved, any commercial sales;
- a loss of any of our key personnel;
- our estimates of market sizes and anticipated uses of our product candidates;
- our estimates of future performance;
- our estimates regarding anticipated operating losses, future revenues, expenses, capital requirements and our needs for additional financing;
- our ability to comply with existing or future laws and regulations in a cost-efficient manner;
- our ability to manage negative consequences from changes in applicable laws and regulations, including tax laws;
- our ability to successfully remediate the material weaknesses in our internal control over financial reporting and to maintain an effective system of internal control over financial reporting;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act
  or a foreign private issuer; and
- changes in general market, political and economic conditions, including as a result of inflation and the current conflict between Russia and Ukraine.

You should refer to "ITEM 3. Key information—D. Risk factors." section of our Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this management's discussion and analysis will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material.

In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all.

We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

In addition, statements that "we believe" and other similar statements reflect our belief and opinions on the relevant subject. These statements are based upon information available to us as of the date of this management's discussion and analysis, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

Pharvaris N.V.

**Unaudited Condensed Consolidated Interim Financial Statements** 

As of and for the three and six months ended June 30, 2022

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# Unaudited condensed consolidated statements of profit or loss and other comprehensive income or loss

		Three months ended June 30 2022 2021		Six months er 2022	ided June 30 2021
	Notes	€	€	€	€
Research and development expenses	3	(13,721,637)	(8,060,599)	(27,236,126)	(16,132,053)
General and administrative expenses	4	(7,660,133)	(4,664,726)	(13,525,138)	(8,436,415)
Total operating expenses		(21,381,770)	(12,725,325)	(40,761,264)	(24,568,468)
Finance income/(expense)	6	11,501,804	(2,474,483)	14,892,983	3,344,373
Loss before income tax		(9,879,966)	(15,199,808)	(25,868,281)	(21,224,095)
Income taxes	7	(2,741,102)	(2,965)	(2,779,817)	(21,554)
Loss for the period		(12,621,068)	(15,202,773)	(28,648,098)	(21,245,649)
Other comprehensive income/(Loss)					
Exchange gains arising on translation of foreign operations		(89,091)	426	(80,411)	1,675
Total comprehensive loss attributable to:					
Equity holders of the Company		(12,710,159)	(15,202,347)	(28,728,509)	(21,243,974)
Loss per share attributable to the equity holders of the Company during the periods					
Basic and diluted loss per share:	19	(0.38)	(0.46)	(0.86)	(0.77)

The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.

# Unaudited condensed consolidated statements of financial position

		June 30, 2022	December 31, 2021
Assets	Notes	$\epsilon$	$\epsilon$
Non-current assets			
Property, plant and equipment	8	141,846	108,099
Right of use assets	9	210,714	243,250
Current assets	,	210,711	213,230
Deferred tax assets	7	99,852	172,052
Receivables	10	331,928	700,079
Other current assets	11	4,575,567	1,513,452
Cash and cash equivalents	12	201,383,087	209,353,132
Total assets		206,742,994	212,090,064
Equity and liabilities			
Equity			
Share capital	13	4,051,916	3,978,226
Share premium		288,100,008	278,742,900
Other reserves		14,713,625	9,774,416
Currency translation reserve		(54,483)	25,928
Accumulated loss		(116,237,411)	(87,568,401)
Total equity		190,573,655	204,953,069
Long term liabilities			
Non-current lease liability	9	102,093	150,752
Current liabilities			
Trade and other payables	14	4,168,955	2,490,572
Accrued liabilities	15	8,981,038	4,270,082
Current lease liability	9	110,772	99,432
Current tax liability		2,806,481	126,157
Total liabilities		16,169,339	7,136,995
Total equity and liabilities		206,742,994	212,090,064

The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.

# Unaudited condensed consolidated statements of changes in equity

For the six months ended June 30, 2022 and June 30, 2021

		Share	Share	Other	Currency translation	Accumulated	Total
		capital	premium	reserves	reserve	losses	Equity
	Notes	$\epsilon$	€	€	€	€	€
Balance at January 1, 2021		235,693	138,034,580	1,979,875	(4,365)	(44,459,954)	95,785,829
Net loss				_	_	(21,245,649)	(21,245,649)
Increase in par value	13	2,592,621	(2,592,621)	_	_	_	_
Issue of share capital	13	1,141,329	156,014,570	_		_	157,155,899
Transaction costs on issue of shares		_	(13,154,360)	_	_	_	(13,154,360)
Currency translation reserve		_	_	_	1,675	_	1,675
Shares issued upon exercise of RSUs	18	1,709	_	(35,161)	_	(231,803)	(265,255)
Share-based payments	18	_	_	3,869,348	_	_	3,869,348
Shares issued upon exercise of options	18	4,080	133,360	(56,520)	_	_	80,920
Balance at June 30, 2021		3,975,432	278,435,529	5,757,542	(2,690)	(65,937,406)	222,228,407
Balance at January 1, 2022		3,978,226	278,742,900	9,774,416	25,928	(87,568,401)	204,953,069
Net loss		_	_	_	_	(28,648,098)	(28,648,098)
Issue of share capital	13	70,572	9,464,901	_	_	_	9,535,473
Transaction costs on issue of shares		_	(307,710)	_	_	_	(307,710)
Currency translation reserve		_	_	_	(80,411)	_	(80,411)
Share-based payments	18	_	_	5,089,777	_	_	5,089,777
Settlement of share-based payments		3,118	199,917	(150,568)		(20,912)	31,555
Balance at June 30, 2022		4,051,916	288,100,008	14,713,625	(54,483)	(116,237,411)	190,573,655

The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.

# Unaudited condensed consolidated statements of cash flows

For the six months ended June 30,

	Notes	2022 €	<u>2021</u> €
Operating activities	Notes	E	E
Loss before tax		(25,868,281)	(21,224,095)
Non-cash adjustments to reconcile loss before tax to net cash flows from operations:			
Share-based payment expense	18	5,089,777	3,869,348
Depreciation expense	4	68,195	15,048
Net foreign exchange (gain)/loss	6	(14,971,998)	(3,503,986)
Finance costs	6	79,016	159,613
Changes in working capital:			
Decrease/(Increase) in receivables		368,151	(143,187)
(Increase) in other current assets		(2,563,219)	(3,919,580)
Increase in trade and other payables		1,678,383	2,367,811
Increase in accrued liabilities		4,609,866	481,628
Paid interest		(58,463)	(134,418)
Income taxes paid			(27,095)
Net cash flows used in operating activities		(31,568,574)	(22,058,913)
Investing activities			
Purchase of property, plant and equipment	8	(49,739)	(33,554)
Net cash flows used in investing activities		(49,739)	(33,554)
Financing activities			
Proceeds from issue of shares	13	9,587,940	157,236,819
Transaction costs		(727,308)	(12,925,547)
Decrease in financial liability		(37,319)	(5,012)
Net cash flows provided by financing activities		8,823,313	144,306,260
Net increase (decrease) in cash and cash equivalents		(22,794,999)	122,213,793
Cash and cash equivalents at the beginning of the period		209,353,132	98,628,871
Effect of exchange rate changes		14,824,955	3,475,076
Cash and cash equivalents at the end of the period	12	201,383,087	224,317,740

The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements

#### Notes to the unaudited condensed consolidated interim financial statements

#### 1. Corporate and Group information

This section provides general corporate and group information about Pharvaris N.V. and its subsidiaries.

# 1.1 Corporate information

Pharvaris N.V. was incorporated on September 30, 2015 and is based in Leiden, the Netherlands.

The address of its registered office is J.H. Oortweg 21, Leiden. The Company's registered office is located at J.H. Oortweg 21, Leiden. It has been registered at the Chamber of Commerce under file number 64239411.

Pharvaris is a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for rare diseases with significant unmet need, initially focused on angioedema and other bradykinin-mediated diseases.

The unaudited condensed consolidated interim financial statements of Pharvaris N.V. (the "Company" or "Pharvaris") and its subsidiaries (collectively, "The Group") as of June 30, 2022 and December 31, 2021, and for the three and six months ended June 30, 2022 and 2021 were authorized for issue in accordance with a resolution of the directors on September 12, 2022.

#### 1.2 Group information

Subsidiaries

The unaudited condensed consolidated interim financial statements of the Group include:

			% of equity is	nterest as
		Country of	June 3	0,
Name	Legal seat	incorporation	2022	2021
Pharvaris Holdings B.V.	Leiden	The Netherlands	100%	100%
Pharvaris Netherlands B.V.	Leiden	The Netherlands	100%	100%
Pharvaris GmbH	Zug	Switzerland	100%	100%
Pharvaris, Inc.	Delaware	United States of America	100%	100%

The ultimate parent company

The ultimate parent company of the Group is Pharvaris N.V.

# 2. Summary of significant accounting policies

# 2.1 Basis of preparation

The unaudited condensed consolidated interim financial statements have been prepared in accordance with IAS 34 Interim Financial Reporting as issued by the International Accounting Standards Board and should be read in conjunction with the Group's annual consolidated financial statements for the year ended December 31, 2021 ("last annual financial statements"). These unaudited condensed consolidated interim financial statements do not include all the information required for a complete set of financial statements prepared in accordance with IFRS as issued by the IASB.

However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group's financial position and performance since the last annual financial statements.

The unaudited condensed consolidated interim financial statements have been prepared on a historical cost basis. Unless otherwise stated, the unaudited condensed consolidated interim financial statements are presented in euros and all values are rounded to the nearest EUR (€), except per share amounts.

# Revision of prior period loss per share

In the period ended June 30, 2022, the Company determined that it had incorrectly computed the weighted average number of ordinary shares outstanding used as denominator in calculating its basic and diluted loss per share in previously issued interim financial statements. This error had no impact to the Company's operating expenses, or loss for the period, and had no impact to the Company's consolidated statements of financial position, consolidated statements of changes in equity or consolidated statements of cash flows.

The Company assessed the materiality of these errors on the previously issued condensed consolidated interim financial statements and concluded that the errors were not material to any period presented. The impact of the revision of the previously issued interim financial statements is as follows:

# As reported vs revised 'weighted average number of shares':

	As reported weighted average number of shares (Quarterly)	As reported weighted average number of shares (YTD)	Revision of weighted average number of shares (Quarterly)	Revision of weighted average number of shares (YTD)
Q1 2021	9,104,630	9,104,630	22,104,888	22,104,888
Q2 2021	16,154,350	16,154,350	33,126,351	27,646,066
Q3 2021	23,282,105	23,282,105	33,128,593	29,493,657
O1 2022	33,135,821	33,135,821	33,151,892	33,151,892

#### As reported vs revised 'basic and diluted loss per share':

	As reported basic and diluted loss per share (Quarterly)	As reported basic and diluted loss per share (YTD)	Revision of basic and diluted loss per share (Quarterly)	Revision of basic and diluted loss per share (YTD)
Q1 2021	(0.66)	(0.66)	(0.27)	(0.27)
Q2 2021	(0.94)	(1.32)	(0.46)	(0.77)
Q3 2021	(0.39)	(1.31)	(0.28)	(1.03)
Q1 2022	(0.48)	(0.48)	(0.48)	(0.48)

# 2.2 Going concern

Pharvaris is a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for rare diseases with significant unmet need, initially focused on angioedema and other bradykinin-mediated diseases. These therapies will need to go through clinical development trials to achieve regulatory approval for commercialization. Therefore, Pharvaris is incurring annual research and development and other operating costs and has no revenues to date (as is typical in the biotech industry for development stage and early commercial stage companies). As such, Pharvaris anticipates on-going negative operating cash flows for several years before the company has a product candidate ready for commercialization, if at all. This makes the Group dependent on external capital sources, debt capital and equity capital. The Group is currently fully financed by equity capital.

As of June 30, 2022 and December 31, 2021 the Group had cash of  $\[ \in \]$  201.4 million and  $\[ \in \]$  209.4 million, respectively. The Group incurred net losses of  $\[ \in \]$  28.6 million in the six months ended June 30, 2022 and  $\[ \in \]$  21.2 million in the same period in 2021 and negative operating cash flows of  $\[ \in \]$  31.6 million and  $\[ \in \]$  22.1 million in the six months ended June 30, 2022 and the six months ended June 30, 2021 respectively.

The Group does not expect positive operating cash flows in the foreseeable future and remains dependent on additional financing to fund its research and development expenses, general and administrative expenses and financing costs. The Group believes that the available cash balances are sufficient to execute the Group's operating plan and strategies and to meet the anticipated working capital requirements and settle all expected liabilities for at least twelve months from the issuance date of these unaudited condensed consolidated interim financial statements. Accordingly, the unaudited condensed consolidated interim financial statements have been prepared on a going concern basis.

The future viability of the Group is dependent on its ability to raise additional capital to finance its operations. The Group will need to finance its operations through public or private securities offerings, debt financings or other sources, which may include licensing, collaborations or other strategic transactions or arrangements. Although the Group has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing on terms acceptable to the Group, if at all. If the Group is unable to obtain funding, the Group could be forced to delay, reduce, or eliminate some or all of its research and development programs for product candidates, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Group may be unable to continue operations.

# Impact of COVID-19

The Group has taken steps to identify and mitigate the adverse effects and risks to it as a result of the pandemic. The Group has modified its business practices, including implementing work from home arrangements for employees able to perform their duties remotely and practicing safe social distancing in our operations. The Group expects to continue to take actions as may be required or recommended by government authorities or in the best interests of its employees and business partners. While the impact of COVID-19 on the Group's operations and financial performance has so far been limited, the extent to which COVID-19 may impact its financial condition or results of operations in the future is uncertain. For instance, the ongoing spread of variants of the COVID-19 virus may continue to interrupt, or delay, the Group's clinical trial activities, regulatory reviews, manufacturing activities and supply chain.

The COVID-19 outbreak delayed, and may continue to delay, enrollment in the Group's clinical trials due to prioritization of hospital resources towards the outbreak or other factors, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results and could delay our ability to obtain regulatory approvals and commercialize our product candidates. In addition, even with the Group's distributed operations, employee vaccinations and its observation of social distancing measures, there remains the possibility that key personnel may become ill or are otherwise unable to work, which could affect the Group's operations.

Furthermore, the spread of the virus may affect the operations of key governmental agencies, such as the FDA, which may delay the development of the Company's product candidates. The spread of an infectious disease, including COVID-19 may also result in the inability of the Group's suppliers to deliver components or raw materials, and the inability of the Group's CDMOs to provide supplies of our product candidates for the Group's planned clinical trials, on a timely basis or at all. Further, an infectious disease. including COVID-19 may also impact the ability of the Group's CROs, including nonclinical CROs, to provide services to support the Group's clinical program. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in the Group's clinical trials, any of which could materially affect the Group's business, financial condition and results of operations.

The extent to which the COVID-19 pandemic impacts the Group's business will depend on future developments, which are uncertain and cannot be predicted, including amongst other things, new information which may emerge concerning the severity of the COVID-19 pandemic and the actions to contain COVID-19 or treat its impact, including among other things the effectiveness and outreach of COVID-19 vaccines. If the Group is unable to meet its milestones it might jeopardize our funding opportunities.

# 2.3 Use of judgements and estimates

In preparing these unaudited condensed consolidated interim financial statements, management has made judgements and estimates that affect the application of accounting policies and the reported amounts of assets and liabilities, income and expense. Actual results may differ from these estimates.

The significant judgements made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those described in the last annual financial statements.

# 2.4 Change in significant accounting policies

The accounting policies applied in these unaudited condensed consolidated interim financial statements are the same as those applied in the consolidated financial statements for the year ended December 31, 2021.

# 3. Research and development expenses

	For the three months ended June 30			onths ended June 30	
	2022	2021	2022	2021	
D (N. 4. 5)	€ (2.0(1.02()	€ (1.750.660)	€ (5.500.207)	€ (2.7(0.1(5))	
Personnel expenses (Note 5)	(3,061,036)	(1,759,669)	(5,590,207)	(3,768,165)	
Clinical expenses	(7,175,545)	(3,496,223)	(13,741,610)	(6,761,928)	
Nonclinical expenses	(1,016,793)	(1,181,660)	(1,832,918)	(2,143,713)	
Manufacturing costs	(2,419,143)	(1,601,980)	(5,883,668)	(2,920,172)	
License costs	_	_	_	(500,000)	
Intellectual Property costs	(49,120)	(21,067)	(187,723)	(38,075)	
	(13,721,637)	(8,060,599)	(27,236,126)	(16,132,053)	

Development expenses are currently not capitalized but are recorded in the unaudited condensed consolidated statements of profit or loss and other comprehensive income because the recognition criteria for capitalization are not met.

Clinical expenses include costs of conducting and managing our sponsored clinical trials, including clinical investigator cost, costs of clinical sites, and costs for CRO's assisting with our clinical development programs.

Nonclinical expenses include costs of our outsourced discovery, preclinical and nonclinical development studies.

Manufacturing expenses include costs related to manufacturing of active pharmaceutical ingredients and manufacturing of the products used in our clinical trials and research and development activities

License costs during the period ended June 30, 2021 consist of a milestone payment of €500,000 which was paid to AnalytiCon upon commencement of Phase 2 development.

# 4. General and administrative expenses

	For the three months ended June 30		For the six months	ended June 30
	2022	2021	2022	2021
	€	€	€	€
Personnel expenses (Note 5)	(3,825,151)	(1,795,721)	(6,270,034)	(3,036,786)
Consulting fees	(254,899)	(161,559)	(432,811)	(390,872)
Professional fees	(911,170)	(324,793)	(1,795,170)	(1,132,706)
Accounting, tax and auditing fees	(290,159)	(648,626)	(594,657)	(1,086,756)
Facilities, communication & office expenses	(1,618,732)	(1,510,566)	(3,246,830)	(2,462,147)
Travel expenses	(260,446)	(2,563)	(404,200)	(3,357)
Other expenses	(499,576)	(220,898)	(781,436)	(323,791)
	(7,660,133)	(4,664,726)	(13,525,138)	(8,436,415)

In 2021 the Group entered into a number of lease arrangements, which were assessed to be short-term leases (with a lease term of 12 months equaling its non-cancellable period).

Depreciation expense in the six months of 2022 was  $\in$ 68,195 (2021:  $\in$ 15,048), which related to property, plant and equipment and leases and is included in the 'Other expenses' line. For the second quarter of 2022 a total of  $\in$ 35,345 (2021:  $\in$ 11,987) depreciation charge was included in 'Other expenses'.

# 5. Personnel expenses

	For the three mont	For the three months ended June 30		s ended June 30		
	2022 2021 2022		2022 2021		2022	2021
	€	€	€	€		
Wages and salaries	(3,279,593)	(1,606,969)	(5,845,176)	(2,618,645)		
Pension charges	(177,185)	(51,327)	(355,729)	(81,289)		
Other social security charges	(286,570)	(124,356)	(569,559)	(235,669)		
Share-based payments	(3,142,839)	(1,772,738)	(5,089,777)	(3,869,348)		
	(6,886,187)	(3,555,390)	(11,860,241)	(6,804,951)		

The average number of staff (in FTEs) employed by the Group in the six months ended June 30, 2022 was 47 (2021: 17).

# 6. Finance income/(expense)

	For the three mont	For the three months ended June 30		s ended June 30
	2022	2021	2022	2021
	€	€	€	€
Foreign exchange differences	11,535,811	(2,401,910)	14,971,998	3,503,986
Interest expenses over bank balances	(33,457)	(69,552)	(78,517)	(151,764)
Other finance expenses	(550)	(3,021)	(499)	(7,849)
	11,501,804	(2,474,483)	14,892,983	3,344,373

#### 7. Income taxes

Income taxes are accounted for in line with IAS 34. The interim period is considered part of a larger financial year, where the income tax is recognized in each interim period based on the best estimate of the weighted average annual income tax rate expected for the full financial year. The estimated tax expenses are determined based on a full year basis and subsequently allocated using the expected full year effective tax rate. The discrete items are recognized in full in the interim period in which they emerge. In the total interim tax charge, no distinction is made between current and deferred tax expenses/income.

	For the three months ended June 30		For the six months	ended June 30
	2022	2021	2022	2021
	€	€	€	€
Income tax expense	(2,741,102)	(2,965)	(2,779,817)	(21,554)
	(2,741,102)	(2,965)	(2,779,817)	(21,554)

The total tax expenses over the six months ended June 30, 2022 principally relates to the Dutch fiscal unity in the Netherlands, which reported an estimated tax expense of  $\in 2.7$  million during the period. During the period, the Dutch fiscal unity reported a taxable income of approximately  $\in 17.4$  million which was mainly driven by foreign exchange gains. Of the total taxable income, an amount of  $\in 7.0$  million was set off by the utilization of the accumulated losses carried forward (which were previously not recognized), resulting in a net taxable profit of  $\in 10.4$  million.

Reconciliation of income tax benefit at statutory tax rate and the income tax expense as reported in the unaudited condensed consolidated statement of profit or loss and other comprehensive income is as follows:

	For the three months ended June 30		For the six month	s ended June 30
	2022	2021	2022	2021
	€	€	€	€
Income/(loss) before tax	(9,879,966)	(15,199,807)	(25,868,281)	(21,224,095)
Income tax at statutory income tax rate in The Netherlands (25.8%)	2,549,031	3,799,952	6,674,016	5,306,024
Effect of tax rates in other countries	(3,211,414)	(1,160,468)	(6,017,458)	(3,171,956)
Temporary differences for which no deferred tax assets/liabilities have been				
recognized	_	(184,629)		(162,580)
Nondeductible expenses	(84,694)	(96,125)	(190,060)	(587)
Current period losses for which no deferred tax asset has been recognized	(1,994,025)	(2,361,695)	(3,246,315)	(1,992,455)
Income tax expense	(2,741,102)	(2,965)	(2,779,817)	(21,554)

Income tax expense is recognized based on management's estimate of the weighted average effective annual income tax rate expected for the full financial year, bearing in mind the impact of non-discrete and discrete items. Non-discrete items in the income tax expense are recognized based on management's estimate of the weighted average effective annual income tax rate expected for the full financial year. Discrete items in the income tax expense are recognized for the applicable statutory tax rate.

The (estimated) average annual tax rate used for the six months ended June 30, 2022 is 10.7% compared to 0.1% for the six months ended June 30, 2021. The estimated effective tax rate includes significant discrete tax effects relating to the tax impact (after utilization of DTAs previously not recognized) on foreign exchange gains. As foreign exchange results cannot be reliably forecasted, the effective tax rate at year end may deviate from the currently reflected estimated effective tax rate.

The Current period losses for which no deferred tax asset has been recognized consists of the expense related to the losses in Switzerland, offset by the benefit from the utilization of previously unrecognized losses carried forward in the Netherlands.

The differences in the overseas tax rates are due to the lower tax rate in Switzerland and the higher tax rate in the USA compared to the statutory income tax rate in the Netherlands.

Pharvaris N.V. is the head of the fiscal unity including Pharvaris Netherlands B.V. and Pharvaris Holdings B.V.

# **Deferred** tax

Deferred taxes have been recognized to the extent that management concludes that there is sufficient probability as per IAS 12 that there will be future taxable profits available in the foreseeable future against which the unused tax losses can be utilized.

Deferred tax assets relating to losses carried forward have not been recognized, and deferred tax assets on deductible temporary differences in excess of deferred tax liabilities on taxable temporary differences have neither been recognized in the unaudited condensed consolidated statement of profit or loss and other comprehensive income nor in the unaudited condensed consolidated statement of financial position.

# 8. Property, plant and equipment

		Office
	Notes	equipment €
Balance at January 1, 2022		108,099
Additions		49,739
Depreciation expense	4	(15,992)
Balance at June 30, 2022		141,846
Balance at June 30, 2022		
Cost		184,443
Accumulated depreciation		(42,597)
Net book amount		141,846

During the six months ended June 30, 2022, the Group acquired assets with a cost of €49,739 (December 31, 2021: €78,251). The acquisitions during the six months ended June 30, 2022 and the year ended December 31, 2021 were related to equipment, tools and installations.

#### 9. Leases

The following table provides information about the Group's right-of-use assets:

	June 30, 2022	December 31, 2021
	$\epsilon$	€
Balance at January 1	243,250	_
Addition	_	301,965
Depreciation charges	(52,203)	(58,715)
Impact of transaction of foreign currency	19,667	_
Balance at June 30, 2021	210,714	243,250

The following table provides information about the Group's lease liabilities:

	June 30, 2022 €	December 31, 2021 €
Office lease	(212,865)	(250,184)
Total lease liability	(212,865)	(250,184)
Current portion	(110,772)	(99,432)
Non-current portion	(102,093)	(150,752)

The lease agreement started on June 1, 2021 and has a lease term of three years. The average incremental borrowing rate applied to the lease liabilities was 3.12% during the six months ended June 30, 2022 (2021: 1.5%). Cash outflows related to leases during the six months ended June 30, 2022 and 2021 were  $\in$  38,428 and  $\in$  5,012, respectively.

#### 10. Receivables

	June 30, 2022	December 31, 2021
	€	€
Trade Receivables	7,920	8,451
VAT receivables	324,008	691,628
	331,928	700,079

#### 11. Other current assets

	June 30, 2022	December 31, 2021
	€	€
Prepayments	3,991,672	1,507,753
Other assets	583,895	5,699
	4,575,567	1,513,452

Prepayments mainly relate to prepaid insurance, sign-on bonus to personnel, prepaid R&D expenses and rent.

Other assets mainly consist of deferred transaction costs related to Group's in-process equity financing (refer to note 13). The company defers the transaction costs related to any in-process financing. Upon recognition of the equity instruments, the related transaction costs are deducted from share premium.

# 12. Cash and cash equivalents

Cash and cash equivalents comprise of cash in bank and are not subject to any restriction.

# 13. Equity

On June 30, 2022, the Company's authorized share capital amounted to epsilon14,100,000 divided into 58,750,000 ordinary shares and 58,750,000 preferred shares, each with a nominal value of epsilon0.12. As at June 30, 2022, a total number of ordinary shares issued was 33,765,967 (2021: 33,151,881). On June 30, 2022, the issued share capital totaled to epsilon4,051,916 (2021: epsilon3,975,432).

In March 2022, the Company filed a Form F-3 Registration Statement and prospectus with the Securities and Exchange Commission relating to an at-the-market program providing for the sales from time to time of up to \$75,000,000 of its ordinary shares pursuant to a Sales Agreement with SVB Securities LLC. During the six months ended June 30, 2022, the Company sold a total of 588,100 ordinary shares in two different transactions under the sales agreement generating total net proceeds of \$9,698,504 ( $\Theta$ 9.2 million), after deducting \$299,954 ( $\Theta$ 308,000), which was payable to SVB Securities as commission in respect of such sales.

On February 5, 2021, the Company became public by listing its ordinary shares on the Nasdaq Stock Exchange. On the same date all Preferred shares A, Preferred shares B and Preferred shares C were automatically converted to ordinary shares and 9,511,075 ordinary shares were issued. Together with the issuance of the ordinary shares, the par value of each ordinary share was increased from 0.01 to 0.12.

Ordinary shares hold the right to one vote per share.

# **Issued shares**

	June 30,	December 31,
	2022	2021
	Number of	Number of
	shares	shares
Ordinary shares	33,765,967	33,151,881
	33,765,967	33,151,881

#### 14. Trade and other payables

	June 30, 2022	December 31, 2021
	€	€
Trade payables	3,681,792	2,125,511
Tax and social security liabilities	487,163	365,061
	4,168,955	2,490,572

#### 15. Accrued liabilities

	June 30,	December 31,
	2022	2021
	€	€
Consulting, professional and audit liability	1,002,291	786,116
Clinical accrued liabilities	1,405,000	386,328
Manufacturing accrued liabilities	4,487,910	1,231,514
Pre-clinical accrued liabilities	99,000	398,468
Personnel related accruals	1,941,900	1,459,162
Other accrued liabilities	44,937	8,494
	8,981,038	4,270,082

#### 16. Risk management activities

The Group's risk management activities are the same as disclosed in note 17 of the consolidated financial statements for the year ended December 31, 2021.

#### 17. Fair values

Fair values of cash and cash equivalents, trade receivables, trade payables, and other current liabilities approximate their carrying amounts largely due to the short-term maturities of these instruments.

# 18. Share-based payments

In 2016, the Company implemented an Equity Incentive Plan (the "Plan") in order to advance the interests of the Company's shareholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with performance-based incentives that are intended to better align the interests of such persons with those of the Company's shareholders. This plan has been superseded by the 2021 long term incentive plan ("LTIP").

Set out below is an overview of changes in the Stock Options and Restricted Stock Units ("RSUs") during the six months ended June 30, 2022

	Stock Options		RSUs	
	Outstanding options	Weighted average exercise price	Outstanding RSUs	
Outstanding January 1, 2022	2,470,295	€ 9.18	259,714	
Granted	742,500	€ 16.12	345,196	
Exercised	(22,045)	€ 2.38	(5,190)	
Forfeited			(903)	
Outstanding June 30, 2022	3,190,750	€ 10.84	598,817	

On January 1, 2022, a total of 70,000 stock options were granted to members of the Board of Directors with an exercise price of \$14.39 per share with a final exercise date of December 31, 2031 unless forfeited or exercised on an earlier date. 25% of the aggregate number of share options shall vest on December 31, 2022 and thereafter 1/48th of the aggregate number of share options shall vest on each subsequent monthly anniversary of the vesting commencement date until either the option is fully vested, or the option holders' continuous service terminates.

On April 1, 2022, a total of 552,500 stock options were granted to members of the Board of Directors and key management with an exercise price of \$18.14 per share with a final exercise date of March 31, 2032 unless forfeited or exercised on an earlier date. 25% of the aggregate number of share options shall vest on March 31, 2023 and thereafter 1/48th of the aggregate number of share options shall vest on each subsequent monthly anniversary of the vesting commencement date until either the option is fully vested, or the option holders' continuous service terminates.

On June 1, 2022, a total of 120,000 stock options were granted to members of key management with an exercise price of \$17.98 per share with a final exercise date of May 31, 2032 unless forfeited or exercised on an earlier date. 25% of the aggregate number of share options shall vest on May 31, 2023 and thereafter 1/48th of the aggregate number of share options shall vest on each subsequent monthly anniversary of the vesting commencement date until either the option is fully vested, or the option holders' continuous service terminates.

During the six months ended June 30, 2022 a total of 345,196 RSUs were granted to employees that joined the Group in the same period and existing employees. The RSUs shall vest equally over a four-year period on each of the four anniversaries of the vesting start date until either the RSUs are fully vested or the RSUs holders' continuous service terminates.

The fair value of the RSUs is determined based on the share value per ordinary share at the grant date (or at the first trading day after the grant date if the Nasdaq Stock Exchange is not open on this date). The grant dates were January 1, 2022, February 1, 2022, March 1, 2022, April 1, 2022, May 1, 2022 and June 1, 2022. The share closing price was \$16.41, \$17.00, \$18.47, \$18.14, \$17.10, and \$17.98 at January 3, 2022, February 1, 2022, March 1, 2022, April 1, 2022, May 2, 2022 and June 1, 2022, respectively.

For the six months ended June 30, 2022, the Group recognized  $\in$ 5,089,777 of share-based payment expense in the unaudited condensed consolidated statement of income or loss and other comprehensive income (six months ended June 30, 2021:  $\in$ 3,869,347). For the three months ended June 30, 2022, the Group recognized  $\in$ 3,142,839 of share-based payment expense in the unaudited condensed consolidated statement of income or loss and other comprehensive income (three months ended June 30:  $\in$ 1,772,738).

As of June 30, 2022, a total number of 1,287,099 stock options are exercisable (June 30, 2021: 337,667).

The inputs and outputs used in the measurement of the fair value per option at each grant/ measurement date using the Black-Scholes formula (including the related number of options and the fair value of the options) were as follows:

	June 1	1, 2022	April 1	, 2022	Januar	y 1, 2022
Number of options	12	0,000	55	2,500		70,000
Fair value of the options	€	11.83	€	11.50	€	9.10
Fair value of the ordinary shares	€	16.78	€	16.41	€	12.67
Exercise price	€	16.78	€	16.41	€	12.67
Expected volatility (%)		80%		80%		85%
Expected life (years)		6.1		6.1		6.1
Risk-free interest rate (%)		3.0%		2.6%		1.4%
Expected dividend yield						

Expected volatility is based on an evaluation of the historical volatilities of comparable listed biotech-companies over the most recent historical period that commensurate with the expected option life. The expected life is based on Management's best estimate of when the options will be exercised. The risk-free interest rate is based on the yield on US Government bonds, with tenure equal to the expected life. The expected dividend yield is zero considering the stage of the Group.

# 19. Basic and diluted loss per share

Basic and diluted loss per share is calculated by dividing the loss attributable to equity holders of the Company by the weighted average number of issued and outstanding ordinary shares during the three and six months ended June 30, 2022 and June 30, 2021.

All of the Company's potential dilutive securities have been excluded from the computation of diluted net loss per share attributable to ordinary stockholders as the effect of including them would be antidilutive.

	For the three ended Ju		For the six months ended June 30,		
	2022	2022 2021 (*)		2021 (*)	
	€	€	€	€	
Loss attributable to equity holders of the Company	(12,710,159)	(15,202,347)	(28,728,509)	(21,243,974)	
Weighted average number of ordinary shares outstanding	33,582,171	33,126,351	33,368,220	27,646,066	
Basic and diluted loss per share	(0.38)	(0.46)	(0.86)	(0.77)	

(\*) This has been revised. Refer to Note 2.1.

# 20. Commitments and Contingencies

#### Claims

There are no material claims known to management related to the activities of the Group.

#### **Commitments**

The Group's contractual obligations and commitments as of June 30, 2022 amounted to €16 million, (December 31, 2021: €19.5 million) primarily related to research and development commitments.

The Group had no contingent liabilities and no contingent assets as at June 30, 2022 and at June 30, 2021, respectively.

# 21. Related parties

Note 1.2 provides information about the Group's structure, including details of the subsidiaries and the holding company. The following provides the total amount of transactions that have been entered into with related parties for the relevant financial period.

#### Key management personnel compensation

	For the three months ended June 30,		For the six months ended June 30,	
	2022	2022 2021		2021
	€	€	€	€
Short term employee benefits	771,241	894,878	1,520,406	1,436,106
Post employee benefits	33,177	6,622	78,559	22,099
Share-based payments	954,796	825,074	2,175,098	2,122,736
Total	1,759,214	1,726,574	3,774,063	3,580,941

A total number of 445,000 stock options and 14,216 RSUs are granted to key management during the six months ended June 30, 2022. Refer to note 18 for disclosures on the share-based payments.

The outstanding balances payable to key management personnel, or entities which they control, as per June 30, 2022 and December 31, 2021 were  $\in$ 417,760 and  $\in$ 1,157,029, respectively.

# 22. Events after the reporting period

On August 22, 2022, the Company announced that the U.S. Food and Drug Administration (the "FDA") had verbally informed it that, based on its review of nonclinical data, the agency is placing a clinical hold on the clinical trials of PHA121 in the United States (the "clinical hold"). The FDA indicated it will provide a formal clinical hold letter to Pharvaris within approximately 30 days following the verbal notice.

On September 12, 2022, the Company announced that it has received formal clinical hold letters from the FDA. The FDA requested that the Company conduct an additional long-term rodent toxicology study and update the Investigator's Brochure. The letters stated that the nonclinical observations are unlikely due to B2 receptor antagonism, the primary mechanism of action of PHA121. The Company plans to request a Type A meeting with the FDA to discuss on-demand and prophylactic proposals to address the clinical holds. In the RAPIDe-1 study, subsequent to the clinical hold in the U.S., the Company continues to evaluate PHVS416 for HAE attacks in patients enrolled outside the U.S. Given the current dataset of evaluable attacks, the Company anticipates announcing top-line data for the RAPIDe-1 study in the fourth quarter of 2022. The Company is working with country-specific regulatory authorities regarding the ongoing CHAPTER-1 Phase 2 study of PHVS416 for the prophylactic treatment of HAE attacks. The Company has notified country-specific regulatory authorities in Canada, Europe, Israel, and the UK of the U.S. clinical hold. When the Company has more clarity regarding the impact of the U.S. clinical hold and additional feedback from global regulatory authorities, the Company will provide guidance on the timing of announcing top-line data for the CHAPTER-1 trial.

Signatories to the unaudited condensed consolidated interim financial sta	tements
Leiden, September 12, 2022	
Pharvaris N.V.	
Board of Directors	
B.A.E. Modig	A.M. de Jonge Schuermans
E. Björk	R.H. Glassman
D.P. Meeker	J.G.C.P. Schikan

V. Monges