
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 6-K

**Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934**

For the month of March 2020

Commission File Number: 001-36622

PROQR THERAPEUTICS N.V.

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The Netherlands

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(Address, Including ZIP Code, and Telephone Number,
Including Area Code, of Registrant's Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

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):

On March 31, 2020, ProQR Therapeutics N.V. (the “Company”) issued a press release titled, “ProQR Announces Positive Findings From an Interim Analysis in the Phase 1/2 trial of QR-421a for Usher Syndrome and Provides Business Update.” A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The Company hereby incorporates by reference the information contained herein into the Company’s registration statement on Form F-3 (File No. 333-228251).

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.

PROQR THERAPEUTICS N.V.

Date: March 31, 2020

By: /s/ Smital Shah
Smital Shah
Chief Financial Officer

INDEX TO EXHIBITS

<u>Number</u>	<u>Description</u>
99.1	Press Release dated March 31, 2020.

ProQR Announces Positive Findings From an Interim Analysis in the Phase 1/2 trial of QR-421a for Usher Syndrome and Provides Business Update

- QR-421a showed early and encouraging evidence of activity, with 25% of patients showing a benefit across multiple concordant outcome measures and was well tolerated with no serious adverse events
- QR-421a is the second ophthalmology program where clinical activity was predicted by translational models, further validating the platform
- COVID-19 pandemic expected to impact timelines for the pipeline
- ProQR anticipates its cash runway will fund operations into H2 2022

LEIDEN, Netherlands & CAMBRIDGE, Mass., March 31, 2020 — ProQR Therapeutics N.V. (Nasdaq: PRQR) (the “Company”), a company dedicated to changing lives through the creation of transformative RNA therapies for severe genetic rare diseases, today announces positive findings from a planned three-month interim analysis of its Phase 1/2 *Stellar* trial of QR-421a in adults with Usher syndrome and non-syndromic retinitis pigmentosa (nsRP) due to *USH2A* exon 13 mutations. The Company is also providing an update on business operations in relation to the COVID-19 pandemic. Management will host a conference call today at 8:15 am ET.

“The goal of the interim analysis of this 24 month *Stellar* trial of QR-421a was to assess safety and early signs of efficacy for the purpose of informing next steps in development and future trial strategy,” said David Rodman, M.D., Executive Vice President of Research and Development of ProQR. “We are pleased with the current safety profile and are very encouraged by early signals of target engagement and clinical activity supported by concordant benefit observed across multiple outcome measures for 25% of QR-421a-treated patients thus far in this trial. The findings support continuing the trial as planned, with both cohort expansion and dose escalation in order to identify a potential development path to registration. Importantly, these data represent the second program from our ophthalmology pipeline that is supported by preclinical predictions from human retinal organoids, providing further validation of our translational approach and platform technology.”

Phase 1/2 Three-Month Interim Analysis

The interim analysis (IA) is based on nine and three month data from the first and second dose cohorts, respectively, of the *Stellar* Phase 1/2 clinical trial of QR-421a, an investigational RNA therapy. The *Stellar* trial is a randomized, single ascending dose, global multicenter, longitudinal, 24-month study, involving active versus sham procedure. The first two cohorts include a total of 14 subjects (ranging from 24-65 years in age), of which eight received a single dose of QR-421a and six received a single sham procedure for masking. Six subjects were enrolled in the 50 µg cohort (“low dose”), of which four received treatment and two were randomized to sham; eight patients were enrolled in the 100 µg cohort (“mid dose”) of which four received treatment and four were randomized to sham. The population varied in disease characteristics with both Usher syndrome (n=6) and nsRP (n=8) affected subjects included, genetic background with both homozygous (n= 4) and heterozygous (n=10) subjects for *USH2A* exon 13 mutations, and visual impairment at baseline ranging from mild to severe.

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Key initial findings include the following:

Safety data: Across both cohorts thus far, QR-421a was observed to be generally well tolerated with no serious adverse events noted.

Efficacy data: In the six sham treated subjects (two followed for 9 months and four for 3 months), outcome measures demonstrated no consistent pattern of response above the “noise” level. In contrast, two of eight QR-421a-treated patients (one each in the 50 µg and 100 µg dose cohorts) demonstrated benefit across multiple concordant outcome measures.

- **Responder 1:** One of four treated patients in the low dose group was classified as a responder, with onset of action observed by the 3 month visit. Benefit was maintained for 6 months or longer, which is consistent with the expected half-life of QR-421a in photoreceptors. This Usher syndrome patient was homozygous for *USH2A* exon 13 mutations and had moderate visual impairment at baseline (peripheral vision affected). Concordant benefit was observed across multiple relevant measures appropriate to the severity of the patient’s disease, including full field stimulus threshold test (FST) [deterioration by 5 dB in untreated eye, treated eye stable], dark adapted chromatic (DAC) perimetry [15 dB.steradian improvement in peripheral sensitivity in treated eye, <5 dB.steradian change in untreated eye], and optical coherence tomography (OCT) assessment of photoreceptor Ellipsoid Zone (EZ area). For FST and OCT, the contralateral, untreated eye demonstrated modest deterioration while the treated eye showed stabilization. For DAC perimetry the untreated eye was unchanged, whereas the treated eye demonstrated improvement.
- **Responder 2:** One of four treated patients in the mid dose group was classified as a responder with onset of action observed by 3 months. This non-syndromic RP patient was heterozygous for *USH2A* exon 13 mutations and had severe visual impairment at baseline (peripheral and central vision affected) with baseline best corrected visual acuity (BCVA) of 33 and 36 letters (approximate Snellen equivalent: 20/250 and 20/200) in the treated and untreated eye, respectively. Concordant benefit was observed across multiple relevant measures appropriate for the stage of disease including FST (improvement by 12 dB in treated eye, no improvement in untreated eye), DAC (up to 10 dB.steradian improvement in treated eye, with deterioration in the untreated eye), and BCVA (7 letter improvement from baseline of 33 letters, which is more than one line on the ETDRS eye chart, compared to no change in the untreated eye).

Next steps: Based on the safety profile and early evidence of efficacy observed to date, the Company plans to take advantage of the adaptive design, and expand the 100 µg cohort with additional subjects who are homozygous for exon 13 mutations. Dose escalation to 200 µg (“high dose”) is planned to occur in parallel. An interim analysis of dose- and gene copy-dependent safety and efficacy will be planned once all additional subjects have reached at least 3 months of treatment.

Business Update Related to COVID-19 Pandemic

The COVID-19 pandemic is rapidly evolving and has prompted global health concerns, the duration, severity and exact impact of which are currently unknown and cannot be predicted with confidence. In consultation with the trial sites, due to the COVID-19 pandemic the Company also expects a delay in all of its ongoing and scheduled trials, including the pivotal trial of sepfarsen for Leber congenital amaurosis 10. ProQR is implementing mitigation procedures that support a rapid ramp up in enrollment as soon as the disruption resolves, including additional patient identification activities and documentation for additional site activations, while prioritizing the safety of trial participants and healthcare providers. For the trials of QR-421a and QR-1123, patients have already been identified for the next dose cohorts and the Company expects to begin dosing as soon as practical after clinical

sites are ready and able to do so. This will be the same for the start of the clinical trial for QR-504a. The Company currently does not believe that its supply chain will be affected.

Due to the COVID-19-related delays, the Company has undertaken a budget review process and now anticipates its cash runway will fund operations into the second half of 2022.

“In these uncertain times, the health and safety of patients in our trials, their caregivers, and our employees remains our top priority. We believe we have taken appropriate measures designed to limit their risk,” said Daniel A. de Boer, Chief Executive Officer of ProQR. “While we manage the challenges stemming from the COVID-19 pandemic, we remain confident in the fundamentals of our business, as demonstrated in part by the data we are sharing today from our QR-421a program. We have a productive platform, a deep pipeline of RNA therapies focused on inherited retinal diseases, and the benefit of a strong balance sheet, which positions us well to endure the current disruption and continue the important work with the communities we serve.”

Conference Call

Management will discuss the data and next steps for development during a webcasted conference call today, March 31, 2020, at 8:15 a.m. ET. The live and archived webcast of this presentation can be accessed through the Events and Presentations page on the Investors section of the Company’s website, www.ProQR.com. The dial-in details for the call are +1 631-510-7495 (US), +31 (0) 207143545 (NL), conference ID: 5986384. The archived webcasts will be available for approximately 30 days following the presentation date.

About Usher Syndrome Type 2 and Non-Syndromic Retinitis Pigmentosa

Usher syndrome is the leading cause of combined deafness and blindness. People with Usher syndrome type 2 are usually born with hearing loss and start to have progressive vision loss during adulthood. The vision loss can also occur without hearing loss in a disease called non-syndromic retinitis pigmentosa. Usher syndrome type 2 and non-syndromic retinitis pigmentosa can be caused by mutations in the *USH2A* gene. To date, there are no pharmaceutical treatments approved or in clinical development that treat the vision loss associated with mutations in *USH2A*.

About QR-421a

QR-421a is being evaluated in the Phase 1/2 *Stellar* trial and is a first-in-class investigational RNA therapy designed to address the underlying cause of vision loss in Usher syndrome type 2 and non-syndromic retinitis pigmentosa (RP) due to mutations in exon 13 of the *USH2A* gene. QR-421a is designed to restore functional Usherin protein by using an exon skipping approach with the aim to stop or reverse vision loss in patients. QR-421a is intended to be administered through intravitreal injections in the eye and has been granted orphan drug designation in the US and the European Union and received fast-track and Rare Pediatric Disease designations from the FDA.

About the *Stellar* Phase 1/2 Trial of QR-421a

Stellar, or PQ-421a-001, is a first-in-human study of QR-421a in adults who have vision loss due to mutations in exon 13 of the *USH2A* gene and is conducted at expert sites in North America and Europe. It is a double-masked,

randomized, 24-month study exploring the safety and efficacy of a single intravitreal injection of several dose levels of QR-421a and a control sham procedure into one eye.

About ProQR

ProQR Therapeutics is dedicated to changing lives through the creation of transformative RNA therapies for the treatment of severe genetic rare diseases such as Leber congenital amaurosis 10, Usher syndrome and autosomal dominant retinitis pigmentosa. Based on our unique proprietary RNA repair platform technologies we are growing our pipeline with patients and loved ones in mind.

Since 2012

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “look forward to,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions. Such forward-looking statements include, but are not limited to, statements regarding QR-421a, and the clinical development and the therapeutic potential thereof, our other programs and business operations, including timing of commencing clinical trials and enrollment of patients therein, the expected impact of the COVID-19 on our business operations, including our research and development plans and timelines and the supply chain for our clinical and development programs, and our financial position and cash runway. Forward-looking statements are based on management’s beliefs and assumptions and on information available to management only as of the date of this press release. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, without limitation, the risks, uncertainties and other factors in our filings made with the Securities and Exchange Commission, including certain sections of our annual report filed on Form 20-F. These risks and uncertainties include, among others, the cost, timing and results of preclinical studies and clinical trials and other development activities by us and our collaborative partners whose operations and activities may be slowed or halted by the COVID-19 pandemic; the likelihood of our clinical programs being executed on timelines provided and reliance on our contract research organizations and predictability of timely enrollment of subjects and patients to advance our clinical trials and maintain their own operations; our reliance on contract manufacturers to supply materials for research and development and the risk of supply interruption from a contract manufacturer; the potential for future data to alter initial and preliminary results of early-stage clinical trials; the unpredictability of the duration and results of the regulatory review of applications or clearances that are necessary to initiate and continue to advance and progress our clinical programs; the ability to secure, maintain and realize the intended benefits of collaborations with partners; the possible impairment of, inability to obtain, and costs to obtain intellectual property rights; possible safety or efficacy concerns that could emerge as new data are generated in research and development; and general business, financial and accounting risks and litigation. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and we assume no obligation to update these forward-looking statements, even if new information becomes available in the future, except as required by law.

Cautionary Note on Future Updates

The statements contained in this press release reflect our current views with respect to future events, which may change significantly as the global consequences of the COVID-19 pandemic rapidly develop. Accordingly, we do not undertake and specifically disclaim any obligation to update any forward-looking statements.

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