

3,000,000 Shares



Ordinary Shares

uniQure is providing updated information related to the public offering of its ordinary shares pursuant to our preliminary prospectus supplement dated April 7, 2015.

The following risk factor on page S-16 of the preliminary prospectus supplement has been revised to reflect information received on April 8, 2015, with respect to the ongoing post-approval review of our Glybera program by the European Medicines Agency. The revised risk factor reads as follows:

We are subject to potentially costly post-approval obligations, review and other regulatory requirements for Glybera in the European Union, and any of our product candidates for which we obtain marketing approval in the future could be subject to similar requirements, which may restrict or eliminate the commercial success of Glybera or our other product candidates.

Glybera and any of our product candidates for which we obtain marketing approval in the future, as well as the manufacturing process, post-approval studies and measures, labeling, advertising and promotional activities for such products, will be subject to continued requirements of and review by the FDA, EMA and other regulatory authorities.

As part of our marketing approval under exceptional circumstances in the European Union, the EMA has imposed ongoing requirements for a potentially costly post-approval study and market surveillance activities. Specifically, as a condition to approval of Glybera we are required to complete a post-approval clinical trial and implement a disease registry for long-term surveillance of patients, as well as implement risk management procedures, distribute educational materials to healthcare professionals and patients, implement an additional manufacturing process step, comply with certain notification obligations and undergo annual reassessment, any negative outcome of which could potentially lead to a withdrawal of marketing approval for Glybera. The expense and uncertain result of these post-approval requirements may delay, limit or terminate our commercialization plan for Glybera and adversely affect our financial position, particularly in light of the relatively small market for this orphan indication. Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties.

In addition, we have submitted several Type II variations to the EMA, which seek to update the summary product of characteristics, SmPC, of Glybera to include additional six-year follow-up

and other clinical data. Following our submission of the Type II variations, and a voluntary disclosure of accidental destruction of some historical source data at a site in Canada, the EMA requested a good clinical practices, or GCP, inspection of our Glybera trial program. The Dutch and UK regulatory authorities conducted the inspection on behalf of the EMA in early 2015. The inspectors reported to the EMA on the quality control mechanisms that were in place in our company during data acquisition and processing in 2009 and 2010 with respect to maintaining patient and trial data obtained prior to approval of Glybera, and the integrity of the historical trial data as a whole. We have already implemented corrective quality control actions to rectify the oversight issues identified by the inspection and continue to refine our quality system. We believe that the events in the past do not materially affect the previously reported results of our historical trials. The inspection team also concluded “that the quality of the data and the level of GCP compliance both are acceptable” and that the trial data can be used for the submitted Type II variations.

As part of the ongoing variation procedure, the EMA is currently reviewing the benefit-risk analysis of Glybera in light of the additional six-year follow-up data we provided and the findings of the GCP inspection. On April 8, 2015, we received a copy of an assessment report prepared by the rapporteur designated by the Committee for Advanced Therapy Medicinal Products, or CAT, which is the committee that advises the EMA’s Committee for Human Medicinal Products for Human Use of the EMA, or CHMP, on gene therapies. The CHMP is comprised of 32 members and the report represents only the views of the rapporteur and does not bind the CAT or the CHMP in any way. Based on our final clinical study report including the six-year follow-up data, the assessment report states that the rapporteur considers that Glybera lacks efficacy and therefore that the benefit-risk balance of Glybera is negative. However, the rapporteur recommends that our application for variations be subject to a request for supplemental information before a final recommendation can be made.

The report will be submitted to the CAT for review and consideration at meetings scheduled to be held on April 16-17, 2015, and then to the CHMP for review and consideration at meetings scheduled to be held on April 21-23, 2015. These committees will reach their own conclusions, which may or may not be in line with those of the rapporteur. After the April meetings, we anticipate receiving a final assessment report, which may include requests for additional information as part of the variation procedure and may require a further response from us to support our position.

We are preparing the supplemental information requested by the rapporteur, and continue to believe that the clinical data from our Glybera development program, including the six-year follow-up data, support a positive benefit-risk balance and the marketing authorization under exceptional circumstances we have received. We can provide no assurance, however, that the EMA’s final conclusion will differ from that set forth in the rapporteur’s assessment report.

Any adverse outcome of this review could require us to expend significant further resources to support our conclusions, including potentially conducting further post-approval studies, or could potentially result in revocation of the marketing approval for Glybera in the European Union.

Should we receive FDA approval of Glybera or any of our other product candidates in the future, the FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, also closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved label.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. The occurrence of any event or penalty may inhibit our ability or that of our collaborators to commercialize Glybera and any other products and generate revenues or may lead to withdrawal of marketing approval, which would have a material adverse effect on our business.

Forward-Looking Statements

This document 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. Forward-looking statements are based on management’s beliefs and assumptions and on information available to management only as of the date of this document. These forward-looking statements include, but are not limited to, statements regarding the outcome of the European Medicines Agency’s assessment described above. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, without limitation, risks associated with regulatory oversight and the risks, uncertainties and other factors described under the heading “Risk Factors” in uniQure’s 2014 Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 7, 2015. 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.
