

SUMMARY OF RISK FACTORS

The risk factors described below are a summary of the principal risk factors associated with our business. These are not the only risks we face. You should carefully consider these risk factors, together with the risk factors incorporated by reference into Item 3D. of this annual report on Form 20-F and the other reports and documents filed by us with the SEC.

- As of December 31, 2021, we had never generated revenue from the therapeutic candidates within our Wholly Owned Pipeline, and we may never be operationally profitable.
- We may require substantial additional funding to achieve our business goals. If we are unable to obtain this funding when needed and on acceptable terms, we could be forced to delay, limit or terminate certain of our therapeutic development efforts. Certain of our Founded Entities will similarly require substantial additional funding to achieve their business goals.
- Our ability to realize value from our Founded Entities may be impacted if we reduce our ownership or otherwise cede control to other investors through contractual agreements or otherwise.
- We have limited information about and limited control or influence over our Non-Controlled Founded Entities.
- The therapeutic candidates within our Wholly Owned Pipeline and most of our Founded Entities' therapeutic candidates are in preclinical or clinical development, which is a lengthy and expensive process with uncertain outcomes and the potential for substantial delays. We cannot give any assurance that any of our and our Founded Entities' therapeutic candidates will receive regulatory approval, which is necessary before they can be commercialized.
- Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.
- Clinical trials of our or our Founded Entities' therapeutic candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which can affect our ability to fund our company and would have a material adverse impact on our platform or our business.
- If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Use of the therapeutic candidates within our Wholly Owned Pipeline or the therapeutic candidates being developed by our Founded Entities could be associated with side effects, AEs or other properties or safety risks, which could delay or halt their clinical development, prevent their regulatory clearance or approval, cause us to suspend or discontinue clinical trials, abandon a therapeutic candidate, limit their commercial potential, if cleared or approved, or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.
- Our clinical trials may fail to demonstrate substantial evidence of the safety and effectiveness of therapeutic candidates that we may identify and pursue for their intended uses, which would prevent, delay or limit the scope of regulatory approval and potential commercialization.
- Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the potential commercialization of therapeutic candidates.
- If we are unable to obtain regulatory clearance or approval in one or more jurisdictions for any therapeutic candidates that we may identify and develop, our business could be substantially harmed.
- Certain of the therapeutic candidates being developed by us or our Founded Entities are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business.
- If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any therapeutic candidates we may develop, we may not be successful in commercializing those therapeutic candidates if and when they are approved.
- If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial conditions could be adversely affected.
- We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any therapeutic candidates we may develop and ultimately harm our financial condition.
- We are currently party to and may seek to enter into additional collaborations, licenses and other similar arrangements and may not be successful in maintaining existing arrangements or entering into new ones, and even if we are, we may not realize the benefits of such relationships.
- We rely on third parties to assist in conducting our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing.
- If we or our Founded Entities are unable to obtain and maintain sufficient intellectual property protection for our or our Founded Entities' existing therapeutic candidates or any other therapeutic candidates that we or they may identify, or if the scope of the intellectual property protection we or they currently have or obtain in the future is not sufficiently broad, our competitors could develop and commercialize therapeutic candidates similar or identical to ours, and our ability to successfully commercialize our existing therapeutic candidates and any other therapeutic candidates that we or they may pursue may be impaired.
- We may not be able to protect our intellectual property rights throughout the world.
- Our or our Founded Entities' proprietary rights may not adequately protect our technologies and therapeutic candidates, and do not necessarily address all potential threats to our competitive advantage.
- The failure to maintain our licenses and realize their benefits may harm our business.

- If we or our Founded Entities fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or these agreements are terminated or we or our Founded Entities otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.
- Patent terms may be inadequate to protect our competitive position on therapeutic candidates for an adequate amount of time.
- Issued patents covering our Wholly Owned Programs or our Founded Entities' therapeutic candidates could be found invalid or unenforceable if challenged in courts or patent offices.
- If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.
- We and our Founded Entities may be subject to claims challenging the inventorship of our patents and other intellectual property.
- The COVID-19 pandemic has impacted, and will likely continue to impact, our business, including our clinical trials and preclinical studies, and may materially and adversely affect our business in the future.
- We may not be successful in our efforts to develop LYT-100 for the treatment of Long COVID respiratory complications and related sequelae.
- Failures in one or more of our programs could adversely impact other programs and have a material adverse impact on our business, results of operations and ability to fund our business.
- Our business is highly dependent on the clinical advancement of our programs and our success in identifying potential therapeutic candidates across the brain, immune and gastrointestinal therapeutic areas. Delay or failure to advance our programs could adversely impact our business.
- Our future success depends on our ability to retain key employees, directors, consultants and advisors and to attract, retain and motivate qualified personnel.
- The market price of our ADSs has been and will likely continue to be highly volatile, and you could lose all or part of your investment.
- Holders of ADSs are not treated as holders of our ordinary shares.
- As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with corporate governance listing standards.
- If we are unable to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ADSs.
- In connection with the audit of our consolidated financial statements in accordance with the standards of the PCAOB and U.S. securities laws, a material weakness in our internal control over financial reporting was found to exist. If we fail to implement and maintain effective internal control over financial reporting, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud.

EXPLANATORY NOTE

Pursuant to Rule 12b-23(a) of the Securities Exchange Act of 1934, as amended, the information for the 2021 Form 20-F of PureTech Health plc (the “Company”) set out below is being incorporated by reference from PureTech’s “Annual Report and Accounts 2021”, portions of which are included as exhibit 15.1 to this annual report on Form 20-F. Only the information set out below with specific reference to items and pages of PureTech's "Annual Report and Accounts 2021" is deemed to be filed as part of this annual report on Form 20-F. Other information contained within PureTech's "Annual Report and Accounts 2021" that is not specified, including graphs and tabular data, is not included in this annual report on Form 20-F and is not deemed to be filed as part of this annual report on Form 20-F. Photographs are also not included. References herein to PureTech's websites are textual references only and information on or accessible through such websites does not form part of and is not incorporated into this annual report on Form 20-F.

References below to major headings include all information under such major headings, including subheadings, unless such reference is a reference to a subheading, in which case such reference includes only the information contained under such subheading. Unless the context otherwise requires, “PureTech” and “PureTech Health” refer to the Company, which is comprised of PureTech and its Founded Entities (together, the “Group”). “Founded Entities” are comprised of “Controlled Founded Entities” and “Non-Controlled Founded Entities.” References in this annual report on Form 20-F to “Controlled Founded Entities” refer to Follica, Incorporated, Vedanta Biosciences, Inc., Sonde Health, Inc. Alivio Therapeutics, Inc. and Entrega, Inc. References to “Non-Controlled Founded Entities” refer to Gelesis, Inc., and for periods after January 13, 2022, Gelesis Holdings, Inc. as its successor, Akili Interactive Labs, Inc., Karuna Therapeutics, Inc. and Vor Biopharma Inc., and, for all periods prior to December 18, 2019, resTORbio, Inc. PureTech formed each of its Founded Entities and has been involved in development efforts in varying degrees. In the case of each of the Company’s Controlled Founded Entities, the Company continues to maintain majority voting control. With respect to Non-Controlled Founded Entities, the Company may benefit from appreciation in its investment as a shareholder of such companies.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS.

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. [Reserved]

B. CAPITALIZATION AND INDEBTEDNESS

Not applicable.

C. REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable.

D. RISK FACTORS

The information (including tabular data) set forth or referenced under the heading “Risk Factor Annex” on pages 217 to 251 of PureTech’s “Annual Report and Accounts 2021” included as exhibit 15.1 to this annual report on Form 20-F is incorporated by reference.