



## Q32 Bio and Homology Medicines Announce Merger Agreement

November 16, 2023

--The combined company will operate as Q32 Bio Inc., advancing the development of Q32 Bio's two clinical development candidates, bempikibart (ADX-914) in Phase 2 for the treatment of atopic dermatitis (AD) and alopecia areata (AA), and ADX-097 entering Phase 2 for the treatment of complement disorders--

--Q32 Bio has re-acquired worldwide development and commercial rights to bempikibart, an anti-IL-7R $\alpha$  antibody inhibiting IL-7 and TSLP-mediated signaling, and remains on-track to report multiple topline Phase 2 results in 2H'24 --

--Concurrent \$42 million private placement investment with new and existing investors supports clinical development through multiple milestones, including key Phase 2 readouts for bempikibart, initial ADX-097 proof-of-concept data by year-end 2024 and ADX-097 topline results in 2H'25 --

--Combined company's cash balance expected to be approximately \$115 million at close, providing cash runway to mid-2026--

WALTHAM, Mass. and BEDFORD, Mass., Nov. 16, 2023 /PRNewswire/ -- Q32 Bio Inc., a clinical stage biotechnology company developing biologic therapeutics to restore immune homeostasis, and Homology Medicines, Inc. (Nasdaq: [FLXX](#)), today announced they have entered into a definitive merger agreement to combine the companies in an all-stock transaction. The combined company will focus on advancing Q32 Bio's wholly owned clinical development candidates for the treatment of autoimmune and inflammatory diseases. Upon completion of the merger, the combined company will operate as Q32 Bio, headquartered in Waltham, Massachusetts, and is expected to trade under the Nasdaq ticker symbol "QTTB".



In support of the merger agreement, Q32 Bio has entered into an agreement for a \$42 million private placement with participation from existing and new investors including OrbiMed, Atlas Venture, Abingworth, Bristol Myers Squibb, Acorn Bioventures, Osage University Partners (OUP), CU Healthcare Innovation Fund, Sanofi Ventures, Agent Capital and other undisclosed investors.

"The proposed merger with Homology Medicines and concurrent private placement is expected to provide Q32 Bio with the capital to drive development of our autoimmune and inflammatory pipeline through multiple clinical milestones," said Jodie Morrison, Chief Executive Officer of Q32 Bio. "This funding is expected to enable us to deliver two Phase 2 readouts for bempikibart in the second half of 2024, proof-of-concept data for ADX-097, a tissue-targeted inhibitor of complement activation, by year-end 2024, and topline ADX-097 clinical results in the second half of 2025."

"Following a comprehensive assessment of our strategic options, management and the Board of Directors believe the merger with Q32 Bio is in the best interest of our shareholders," said Albert Seymour, President and Chief Executive Officer of Homology Medicines. "The Q32 Bio management team's extensive track record, deep biopharmaceutical expertise and the potential of its clinical development pipeline provide a compelling opportunity to deliver meaningful treatments to patients with critical unmet needs."

Proceeds from the proposed transactions will be used to advance the clinical development of Q32 Bio's two wholly owned assets, bempikibart (ADX-914), for which Q32 Bio earlier today announced it [regained](#) all rights from Amgen, and ADX-097.

Bempikibart, Q32 Bio's lead program, is a fully human anti-IL-7R $\alpha$  antibody that re-regulates adaptive immune function by blocking signaling mediated by both IL-7 and TSLP and is currently being evaluated in two Phase 2 trials, with one clinical trial evaluating the use in atopic dermatitis (AD) and one evaluating the use in alopecia areata (AA). All data from the Phase 2 trials remain blinded and Q32 Bio remains on track to report topline Phase 2 results in the second half of 2024.

ADX-097 is based on a novel platform enabling tissue-targeted regulation of the complement system without long-term systemic blockade, a key differentiator from current complement therapeutics. Q32 Bio recently completed a first-in-human, Phase 1 ascending dose clinical study of ADX-097 in healthy volunteers. Results from the Phase 1 clinical trial demonstrated a favorable tolerability and immunogenicity profile across all single and multiple dose cohorts and weekly subcutaneous dosing met exposures for predicted complete complement inhibition in the tissue with no systemic inhibition. Q32 Bio will be commencing an open-label Phase 2 basket clinical trial, with initial data expected by year-end 2024, and a Phase 2 clinical trial in ANCA-Associated Vasculitis (AAV), with topline results from the AAV and basket trials expected in the second half of 2025.

### About the Proposed Merger

Under the terms of the merger agreement, Homology Medicines will issue to pre-merger Q32 Bio stockholders shares of Homology Medicines common stock as merger consideration in exchange for the cancellation of shares of capital stock of Q32 Bio, and Q32 Bio will become a wholly owned subsidiary of Homology Medicines. Stockholders of Q32 Bio will receive newly issued shares of Homology Medicines common stock pursuant to a formula set forth in the merger agreement. Pre-merger Homology Medicines stockholders are expected to own approximately 25% of the combined company and pre-merger Q32 Bio stockholders (including those purchasing Q32 Bio shares in the concurrent private financing discussed above) are expected to own approximately 75% of the combined company. The percentage of the combined company that pre-merger Q32 Bio stockholders and pre-merger Homology Medicines will own upon the closing of the merger is further subject to adjustment based on the amount of Homology Medicine's net cash at the time of closing. In connection with the closing of the proposed transactions, Homology Medicines stockholders will also be issued a contingent value right (CVR) representing the right to receive certain payments from proceeds received by the combined company, if any, related to dispositions of Homology Medicines' pre-transaction legacy assets.

Homology Medicines has discontinued development of its R&D programs, including HMI-103 for the treatment of PKU, and has been exploring strategic alternatives for its programs and platform technology. If Homology Medicines has not otherwise disposed of its ownership position in Oxford Biomedica Solutions, LLC (Oxford Solutions), a contract development and manufacturing organization (CDMO) jointly established by Homology Medicines and Oxford Biomedica plc, and monetized its development programs, including HMI-103 for the treatment of PKU, Homology Medicines stockholders of record will be issued a CVR for each outstanding share of Homology Medicines common stock held by such Homology Medicines stockholder prior to the closing of the proposed merger. The CVR would represent the right to receive certain cash payments from proceeds received by Homology Medicines related to the sale or license of its development programs and platform technology and the exercise of a put/call option or other sale or disposition of Homology Medicines' minority ownership position in Oxford Solutions.

The merger agreement has been approved by the boards of directors of both companies. Additional information about the transaction will be provided in a Current Report on Form 8-K that will be filed by Homology Medicines with the Securities and Exchange Commission (SEC) and will be available at [www.sec.gov](http://www.sec.gov).

Leerink Partners is serving as the exclusive financial advisor to Q32 Bio. Leerink Partners and Piper Sandler are serving as placement agents for Q32 Bio's planned private placement. Goodwin Procter LLP is serving as legal counsel to Q32 Bio. TD Cowen is serving as the exclusive financial advisor and Latham & Watkins LLP is serving as legal counsel to Homology Medicines.

## Management and Organization

Upon closing of the proposed transaction, the combined company will be led by current members of the Q32 Bio leadership team including:

- Jodie Morrison, Chief Executive Officer
- Shelia Violette, PhD, Founder & Chief Scientific Officer
- Jason Campagna, MD, PhD, Chief Medical Officer
- Saul Fink, PhD, Chief Technology Officer
- Maria Marzilli, MPH, Executive Vice President, Corporate Strategy & Program Operations
- David Appugliese, JD, Senior Vice President, Head of People

The Board of Directors of the combined company is expected to be comprised of nine members, consisting of seven members designated by Q32 Bio and two members designated by Homology Medicines. The transaction has been approved by the Board of Directors of each company and is expected to close in the first quarter of 2024, subject to customary closing conditions, including the approval of the transaction by the stockholders of each company.

## About Q32 Bio

Q32 Bio is a clinical stage biotechnology company developing biologic therapeutics targeting potent regulators of the innate and adaptive immune systems to re-balance immunity in autoimmune and inflammatory diseases. Q32 Bio's lead programs, focused on the IL-7 / TSLP receptor pathways and complement system, address immune dysregulation to help patients take back control of their lives.

Q32 Bio's program for adaptive immunity, bempikibart (ADX-914), is a fully human anti-IL-7R $\alpha$  antibody that re-regulates adaptive immune function for the treatment of autoimmune diseases. It is being evaluated in two Phase 2 trials for the treatment of atopic dermatitis and alopecia areata. The IL-7 and TSLP pathways have been genetically and biologically implicated in driving several T cell-mediated pathological processes in numerous autoimmune diseases. Q32 Bio's program for innate immunity, ADX-097, is based on a novel platform enabling tissue-targeted regulation of the complement system without long-term systemic blockade – a key differentiator versus current complement therapeutics. Q32 Bio has recently completed a first-in-human, Phase 1 ascending dose clinical study of ADX-097 in healthy volunteers.

## About Homology Medicines

Homology Medicines, Inc. is a clinical-stage genetic medicines company historically focused on transforming the lives of patients suffering from rare diseases by addressing the underlying cause of the disease. Homology Medicines has gene editing and gene therapy clinical-stage programs in PKU and Hunter syndrome (MPS II), a preclinical pipeline that includes a gene therapy candidate for metachromatic leukodystrophy and a GTX-mAb (vectorized antibody) candidate for paroxysmal nocturnal hemoglobinuria, as well as intellectual property on its family of 15 adeno-associated viruses (AAVHSCs). Homology Medicines is not currently pursuing further development of these programs and is pursuing strategic options for the Company and its programs and platform technology. Additionally, the Company has an ownership stake in Oxford Solutions, an AAV manufacturing company based on Homology Medicines' internal process development and manufacturing formed as a joint venture between Homology Medicines and Oxford Biomedica plc.

## Cautionary Statement Regarding Forward-Looking Statements

This communication contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including statements regarding the proposed transaction involving Homology Medicines and Q32 Bio, including the conditions to, and timing of, closing of the proposed transaction, the location and management of the combined company, the percentage ownership of the combined company, and the parties' ability to consummate the proposed transaction and private placement financing, including the intended use of net proceeds from the private placement financing and the expected timing of closing and completion of the private placement financing, the composition of the Board of Directors of the combined company, the expected issuance of the CVR and the contingent payments contemplated by the CVR, the combined company's expected cash and the sufficiency of the combined company's cash, cash equivalents and short-term investments to fund operations into mid-2026, the listing of the combined company's shares on Nasdaq, the expectations surrounding the potential, safety, efficacy, and regulatory and clinical progress of Q32 Bio's product candidates, including bempikibart and ADX-097, and anticipated milestones and timing, among others.

Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions among others. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: (i) the risk that the conditions to the closing of the proposed transaction are not satisfied, including the failure to timely or at all obtain stockholder approval for the proposed transaction or the failure to timely or at all obtain any required regulatory clearances; (ii) uncertainties as to the timing of the consummation of the proposed transaction and the ability of each of Homology Medicines and Q32 Bio to consummate the proposed transaction; (iii) the ability of Homology Medicines and Q32 Bio to integrate their businesses successfully and to achieve anticipated synergies; (iv) the possibility that other anticipated benefits of the proposed transaction will not be realized, including without limitation, anticipated revenues, expenses, earnings and other financial results, and growth and expansion of the combined company's operations, and the anticipated tax treatment of the combination; (v) potential litigation relating to the proposed transaction that could be instituted against Homology Medicines, Q32 Bio or their respective directors; (vi) possible disruptions

from the proposed transaction that could harm Homology Medicines' and/or Q32 Bio's respective businesses; (vii) the ability of Homology Medicines and Q32 Bio to retain, attract and hire key personnel; (viii) potential adverse reactions or changes to relationships with customers, employees, suppliers or other parties resulting from the announcement or completion of the proposed transaction; (ix) potential business uncertainty, including changes to existing business relationships, during the pendency of the proposed transaction that could affect Homology Medicines' or Q32 Bio's financial performance; (x) certain restrictions during the pendency of the proposed transaction that may impact Homology Medicines' or Q32 Bio's ability to pursue certain business opportunities or strategic transactions; (xi) the combined company's need for additional funding, which may not be available; (xii) failure to identify additional product candidates and develop or commercialize marketable products; (xiii) the early stage of the combined company's development efforts; (xiv) potential unforeseen events during clinical trials could cause delays or other adverse consequences; (xv) risks relating to the regulatory approval process; (xvi) interim, topline and preliminary data may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data; (xvii) Q32 Bio's product candidates may cause serious adverse side effects; (xviii) inability to maintain our collaborations, or the failure of these collaborations; (xix) the combined company's reliance on third parties, including for the manufacture of materials for our research programs, preclinical and clinical studies; (xx) failure to obtain U.S. or international marketing approval; (xxi) ongoing regulatory obligations; effects of significant competition; (xxii) unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives; (xxiii) product liability lawsuits; (xxiv) securities class action litigation; (xxv) the impact of the COVID-19 pandemic and general economic conditions on our business and operations, including the combined company's preclinical studies and clinical trials; (xxvi) the possibility of system failures or security breaches; risks relating to intellectual property; (xxvii) significant costs incurred as a result of operating as a public company; and (xxviii) such other factors as are set forth in Homology Medicines' periodic public filings with the SEC, including but not limited to those described under the heading "Risk Factors" in Homology Medicines' Form 10-Q for the period ended September 30, 2023. Homology Medicines can give no assurance that the conditions to the proposed transaction will be satisfied. Except as required by applicable law, Homology Medicines undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

### **Important Information about the Merger and Where to Find It**

This communication relates to a proposed transaction between Homology Medicines and Q32 Bio. In connection with the proposed transaction, Homology Medicines intends to file with the SEC a registration statement on Form S-4 that will include a proxy statement of Homology Medicines and that will constitute a prospectus with respect to shares of Homology Medicines' common stock to be issued in the proposed transaction (Proxy Statement/Prospectus). Homology Medicines may also file other documents with the SEC regarding the proposed transaction. This document is not a substitute for the Proxy Statement/Prospectus or any other document which Homology Medicines may file with the SEC. INVESTORS, Q32 BIO STOCKHOLDERS AND HOMOLOGY MEDICINES STOCKHOLDERS ARE URGED TO READ THE PROXY STATEMENT/PROSPECTUS AND ANY OTHER RELEVANT DOCUMENTS THAT ARE OR WILL BE FILED BY HOMOLOGY MEDICINES WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors, Q32 Bio stockholders and Homology Medicines stockholders will also be able to obtain free copies of the Proxy Statement/Prospectus (when available) and other documents containing important information about Homology Medicines, Q32 Bio and the proposed transaction that are or will be filed with the SEC by Homology Medicines through the website maintained by the SEC at [www.sec.gov](http://www.sec.gov). Copies of the documents filed with the SEC by Homology Medicines will also be available free of charge on Homology Medicines' website at <https://investors.homologymedicines.com/financial-information/sec-filings> or by contacting Homology Medicines' investor relations department by email at [IR@homologymedicines.com](mailto:IR@homologymedicines.com).

### **No Offer or Solicitation**

This communication is not intended to and shall not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities, or a solicitation of any vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be made, except by means of a prospectus meeting the requirements of Section 10 of the Securities Act.

### **Participants in the Solicitation**

Homology Medicines and certain of its directors and executive officers may be deemed under SEC rules to be participants in the solicitation of proxies of Homology Medicines stockholders in connection with the proposed transaction. Information regarding the persons who may, under SEC rules, be deemed participants in the solicitation of proxies to Homology Medicines' stockholders in connection with the proposed transaction will be set forth in the Proxy Statement/Prospectus on Form S-4 for the proposed transaction, which is expected to be filed with the SEC by Homology Medicines. Investors and security holders of Q32 Bio and Homology Medicines are urged to read the Proxy Statement/Prospectus and other relevant documents that will be filed with the SEC by Homology Medicines carefully and in their entirety when they become available because they will contain important information about the proposed transaction. Investors and security holders will be able to obtain free copies of the Proxy Statement/Prospectus and other documents containing important information about Q32 Bio and Homology Medicines through the website maintained by the SEC at [www.sec.gov](http://www.sec.gov). Copies of the documents filed with the SEC by Homology Medicines can be obtained free of charge by directing a written request to Homology Medicines, Inc., One Patriots Park, Bedford, MA 01730.

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