UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 26, 2024

HOMOLOGY MEDICINES, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

001-38433 (Commission File Number)

47-3468154 (I.R.S. Employer Identification No.

One Patriots Park Bedford, MA (Address of principal executive offices)

area code)

01730

(Zip Code)

(781) 301-7277

Not Applicable rmer address, if changed since last report.) (Former

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

X Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

(Registra

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered	
Common Stock, \$0.0001 par value per share	FIXX	The Nasdaq Global Select Market	

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company \Box

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \Box

Item 7.01. Regulation FD Disclosure.

On November 16, 2023, Homology Medicines, Inc. (the "*Company*"), Kenobi Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("*Merger Sub*"), and Q32 Bio Inc., a Delaware corporation ("*Q32*"), entered into an Agreement and Plan of Merger (the "*Merger Agreement*"), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Q32, with Q32 continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger (the "*Merger*").

The Company is furnishing an investor presentation that may be used by Q32 (the "*Investor Presentation*") as Exhibit 99.1 to this Current Report on Form 8-K (the "*Current Report*") and is incorporated into this Item 7.01 by reference.

The information in Item 7.01 of this Current Report, including Exhibit 99.1 attached hereto, is intended to be furnished and 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 (the "*Securities Act*"), or the Exchange Act, except as expressly set forth by specific reference in such filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

Important Information about the Merger and Where to Find It

This Current Report relates to a proposed transaction between Homology and Q32. In connection with the proposed transaction, Homology filed a registration statement on Form S-4 that includes a preliminary proxy statement of Homology and constitutes a prospectus with respect to shares of Homology's common stock to be issued in the proposed transaction (the "*Proxy Statement/Prospectus*"). Homology 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 may file with the SEC. The registration statement has not yet become effective. After the registration statement is effective, the Proxy Statement/Prospectus will be mailed to stockholders of Homology. INVESTORS, Q32 STOCKHOLDERS AND HOMOLOGY STOCKHOLDERS ARE URGED TO READ THE PROXY STATEMENT/PROSPECTUS AND ANY OTHER RELEVANT DOCUMENTS THAT ARE OR WILL BE FILED BY HOMOLOGY 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 stockholders and Homology, g32 and the proposed transaction that are or will be filed with the SEC by Homology through the website maintained by the SEC at www.sec.gov. Copies of the documents filed with the SEC by Homology website at https://investors.homologymedicines.com/financial-information/sec-filings or by contacting Homology's investor relations department by email at IR@homologymedicines.com.

No Offer or Solicitation

This Current Report 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, Q32 and certain of their respective directors and executive officers may be deemed under SEC rules to be participants in the solicitation of proxies of Homology stockholders in connection with the proposed transaction. Information regarding the persons who may, under SEC rules, be deemed participants in the solicitation of proxies from Homology's stockholders in connection with the proposed transaction is set forth in Homology's proxy statement on Schedule 14A for its 2023 Annual Meeting of Stockholders, which was filed with the SEC on April 28,

2023 and the Proxy Statement/Prospectus included in the registration statement on Form S-4 initially filed with the SEC on December 18, 2023, and any amendments thereto as filed with the SEC. Investors and security holders of Q32 and Homology are urged to read the Proxy Statement/Prospectus and other relevant documents that will be filed with the SEC by Homology carefully and in their entirety because they contain important information about the proposed transaction. Investors and security holders may obtain free copies of the Proxy Statement/Prospectus and other documents containing important information about Q32 and Homology through the website maintained by the SEC at www.sec.gov. Copies of the documents filed with the SEC by Homology are request to Homology Medicines, Inc., One Patriots Park, Bedford, MA 01730.

Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this filing may be considered 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 and Q32, 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 contingent value right (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'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," "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 and Q32 to consummate the proposed transaction; (iii) the ability of Homology and Q32 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, Q32 or their respective directors; (vi) possible disruptions from the proposed transaction that could harm Homology's and/or Q32's respective businesses; (vii) the ability of Homology and Q32 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's or Q32's financial performance; (x) certain restrictions during the pendency of the proposed transaction that may impact Homology's or Q32'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'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; (xxii) effects of significant competition; (xxiii) infavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives; (xxiv) product liability lawsuits; (xxv) securities class

action litigation; (xxvi) 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; (xxvii) the possibility of system failures or security breaches; (xxviii) risks relating to intellectual property; (xxi) significant costs incurred as a result of operating as a public company; (xxx) whether the Company will meet the Minimum Bid Price Requirement during any compliance period or otherwise in the future, whether the Company will otherwise continue to meet the Nasdaq listing standards and whether the Company would be successful in any Nasdaq appeal process and (xxxi) such other factors as are set forth in Homology's periodic public filings with the SEC, including but not limited to those described under the heading "Risk Factors" in Homology and the registration statement on Form S-4 filed by Homology with the SEC. Homology can assurance that the conditions to the proposed transaction will be satisfied. Except as required by applicable law, Homology 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number Description

- 99.1 Investor Presentation dated January 2024.
- 104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 hereunto duly authorized.

HOMOLOGY MEDICINES, INC.

By:	/s/ Paul G. Alloway, Ph.D.
Name:	Paul G. Alloway, Ph.D.
Title:	President, Chief Operating Officer and Secretary

@32 BIO

Building The Future of Immune Therapeutics Company Overview

January 2024



Important Information for Investors

This confidential presentation (Presentation) is for informational purposes only and is being provided to interested parties solely in their capacity as potential investors for the purpose of evaluating a potential private offering of securities (the Purpose) by Q32 Bio Inc. (Q32) in connection with a potential business combination between Homology Medicines, Inc. (Homology) and Q32 (the Proposed Transaction). By accepting this Presentation, you acknowledge and agree that all of the information contained herein is confidential, that you will distribute, disclose, and use such information only for such Purpose and that you sual not distribute, disclose, and use such information only for such Purpose and that you sual not distribute, disclose, and use such information contained herein does not purport to be all-inclusive and none of thomology or Q32. The information contained herein does not purport to be all-inclusive and none of thomology. Q32 and Leerink Partners LLC and Piper Sandler & Co. (together, the Placement Agents), nor any of their respective affiliates or respective control persons, officers, directors, employees or representatives makes any representation or warranty, express or implied, as to the accuracy, completeness or reliability of the information contained herein does not purpore, business contending the presentation. You solud consult your own counsel and tax and financial advisors as to legal and related matters described herein, and, by accepting this Presentation, you confirm that you are not relying upon the information contained herein to make any decision.

Private Placement

This Presentation and any oral statements made in connection with this Presentation shall not constitute an offer to sell or the solicitation to buy any securities, nor the solicitation of a proxy, consent, or authorization in connection with the Proposed Transaction in any jurisdiction; nor shall there be any sale of securities in any jurisdiction in which the offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any jurisdiction.

ANY SECURITIES TO BE OFFERE IN ANY TRANSACTION CONTEMPLATED HEREBY HAVE NOT BEEN AND WILL NOT BE REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE SECURITIES ACT), OR ANY APPLICABLE STATE OR FOREIGN SECURITIES LAW. ANY SECURITIES TO BE OFFERE IN ANY TRANSACTION CONTEMPLATED HEREBY HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES EXCHANGE COMMISSION (THE SEC), ANY STATE SECURITIES COMMISSION OR OTHER UNITED STATES OR FOREIGN REGULATORY AUTHORITY, AND WILL BE OFFERE IN ANY TRANSACTION CONTEMPLATED HEREBY HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES EXCHANGE COMMISSION (THE SEC), ANY STATE SECURITIES COMMISSION OR OTHER UNITED STATES OR FOREIGN REGULATORY AUTHORITY, AND WILL BE OFFERE IN ADVINCIDAD DO DISAPPROVED OR THE SECURITIES EXCHANGE COMMISSION (THE SEC), ANY STATE SECURITIES COMMISSION OR OTHER UNITED STATES OR FOREIGN REGULATORY AUTHORITY, AND WILL BE OFFERE IN ADVINCIDAD DO DISAPPROVED OR STATES ON ONES AND REGULATION FOR OTHER UNITED STATES OR FOREIGN STATIS ON FOREIGN STATES OFFERE AND REGULATION OF AND FERSION OF AND THE SECURITIES ACT AND RULES AND REGULATIONS PROMULGATED THEREUNDER (INCLUDING REGULATION DO NO REGULATION SUNDER THE SECURITIES ACT). THIS DOCUMENT DOES NOT CONSTITUTE, OR FORM A PART OF, AN OFFER TO SELI OR THE SOLUCITATION OF AN OFFER TO BULY IN ANY STATE OR OTHER JURISDICITON TO ANY PERSON TO WHOM ITS UNLAWFUL TO AMAKE SUCH OFFER OR SOLUCITATION OF AND FERSON TO SUND TO CONSTITUTE, OR FORM A PART OF, AN OFFER TO SOLUCITATION OF AND FERSON TO THE AUTHORIZED OFFER OR SOLUCITATION OF AND FERSON TO AND TO ANY ESCURTIS AND ANY STATE OF OTHER JURISDICTION TO ANY PERSON TO WHOM ITS UNLAWFUL TO AMAKE SUCH OFFER OR SOLUCITATION Forward Looking Statements

Provide looking statements sensitive in this Presentation may be considered forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act 1995, including statements are prayeding the Proposed Transaction, including the intended of the combined company, the expected issuance of the combined company, the expectations surrounding the potential, safety, efficary, and regulatory and clinical progress of Q325 product candidates, including bempkibart and ADX-Og7, and anticipate mests for the approxed transaction and not statement. Forward-looking statements are alward the combined company, 's expect "anticipate" "and". "Inde," "anticipate" "anticipate" "anticipate" and the ability of exist on the obiging of the Proposed Transaction and the ability of exist of Homology and US2 to consummation of the Proposed Transaction and the ability of exist of Homology and US2 to consummation of the ability of themelogy and US2 to consummation of the ability of themelogy and US2 to consummation of the ability of themelogy and US2 to consummation of the ability of themelogy and US2 to consummation of the ability of themelogy and US2 to consummation of the ability of themelogy and US2 to consummation of the ability of themelogy and US2 to consummation of the ability of themelogy and US2 to consummation of the ability of themelogy and US2 to consummation of the ability of themelogy and US2 to consummation of the ability of themelogy and US2 to consumation of the ability of themelogy and US



Important Information about the Proposed Transaction and Where to Find It

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Participants in the Solicitation

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Industry and Market Data

Certain information contained in this Presentation relates to or is based on studies, publications, surveys and Q32's own internal estimates and research. In this Presentation, Q32 relies on, and refers to, publicly available information and statistics regarding market participants in the sector in which Q32 competes and other industry data. Any comparison of Q32 to any other entity assumes the reliability of the information available to Q32. Q32 obtained these information and statistics from third-party sources, including reports by market research firms and company filings. In addition, all of the market data included in this Presentation involve a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while Q32 believes its internal research is reliable, such research has not been verified by any independent source and Q32 has not independently verified the information.

Trademarks

This Presentation may contain trademarks, service marks, trade names and copyrights of other companies, which are the property of their respective owners. Solely for convenience, some of the trademarks, service marks, trade names and copyrights referred to in this Presentation may be listed without the TM, SM © or * symbols, but Q32 will assert, to the fullest extent under applicable law, the rights of the applicable owners, if any, to these trademarks, service marks, trade names and copyrights.

Confidentiality Notice

This Presentation is intended exclusively for the individual or entity to which it is addressed. This Presentation and the accompanying communication may contain information that is proprietary, privileged, confidential or otherwise legally exempt from disclosure. If you are not an intended recipient, you are not authorized to read, print, retain, copy or disseminate this Presentation or any part of it. If you have received this Presentation in error, please notify the sender immediately and delete all copies of this Presentation.



Both Homology and Q32 are subject to various risks associated with their businesses and their industries. In addition, the Proposed Transaction, including the possibility that the Proposed Transaction may not be completed, poses a number of risks to each company and its respective securityholders. All references to "we," "us" or "our" refer to the business of Q32 prior to the consummation of the Proposed Transaction. The risks described below make up a non-exhaustive list of the key risks related to Q32 strains at the factors that could cause actual results to differ from the forward-looking statements described in this been prepared solely for potential private placement investors in connection with the Proposed Transaction of rorn y other purpose. You should carefully consider these risks and uncertainties, as well as factors set forth in the section entitled "Risk Factors" in Homology's most recent quarterly report on Form 10-Q, its most recent annual report on Form 10-K and its other SEC filings. You should also carry out your own due diligence and consult with your own financial and legal advisors concerning the risks and subality of an investment in this private placement transaction before making an investment decision. The list below is qualified in its entirety by disclosures contained in future documents filed or furnished in respect of the Proposed Transaction with the SEC:

- Our limited operating history make it difficult to evaluate our future prospects and the risks and challenges we may encounter. We have incurred significant losses since inception, we have not generated any revenue from product sales to date and may never do
 so.
- Our product candidates are in clinical development and we do not yet have any product candidates approved for commercial sale
- * Even if the Proposed Transaction and the proposed private placement transaction are successful, we will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate our development and pre-clinical programs, current or future clinical trials or future commercialization efforts.
- Our expectations regarding our cash runway and ability to reach data inflection points are based on numerous assumptions that may prove to be untrue; we may be required to raise capital sooner than anticipated and our exposure to certain contingent liabilities and contractual obligations may be greater than anticipated. For example, our assumptions relating to the amounts of Homology's cash available to us at the closing of the Proposed Transaction, including amounts that may be required to negotiate costs associated with the closing of the Proposed Transaction, may prove to be incorrect, and as a result any additional amounts we would be required to spend may be material and significantly impact our cash runway and ability to achieve our inflection points without significant additional capital.
- We operate in an intensely competitive market that includes companies with greater financial, technical and marketing resources than us.
- Failure to manage our growth effectively could cause our business to suffer and have a material adverse effect on our ability to execute our business strategy, as well as operating results and financial condition.
- As our costs increase, we may experience fluctuations in our operating results, which could make our future operating results difficult to predict or cause our operating results to fall below analysts' and investors' expectations.
- We are substantially dependent on the success of our most advanced product candidates, ADX-097 and ADX-914 and our clinical trials of such product candidates may not be successful. If we are unable to advance such product candidates through clinical development for safety or efficacy or other reasons, or commercialize our product candidates, if approved, or experience significant delays in doing so, our business will be materially harmed.
- Our current or future product candidates may cause adverse or other undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following
 marketing approval, if any.
- If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad or we are delayed in bringing product candidates to market such that those products have a shorter period of patent exclusivity than we expect, our competitors could develop and commercialize technology and product candidates similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.
- * We may be subject to intellectual property rights claims by third parties, which are costly to defend, could require us to pay significant damages and may disrupt our business and operations.
- We are party to license agreements with third parties pursuant to which we obtained licenses for certain intellectual property rights utilized in the development of our product candidates; termination of these rights or the failure to comply with obligations under these agreements could materially harm our business and prevent us from developing or commercializing our product candidates.
- The conditions to complete the Proposed Transaction may not be satisfied, we may not realize the expected benefits of the Proposed Transaction, or we may uncover liabilities following consummation of the Proposed Transaction that we had not anticipated.
- The shares acquired in the proposed private placement transaction will be subject to registration with the SEC, and upon registration, the share price may be volatile due to a variety of factors, such as changes in the competitive environment in which we operate, the regulatory framework of the industry in which we will operate, developments in our business and operations and changes in our capital structure.

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Q32 Mission: Building The Future of Immune Therapeutics

	IL-7Rα Antagonist Antibody	 Bempikibart (ADX-914): Dual inhibitor of IL-7 and TSLP signaling, designed to provide broad control of T cell-mediated pathological processes in autoimmune diseases Ph1 data show attractive PK/PD profile, favorable tolerability w/Q2W SC dosing; Ph2 PK run in confirmed Ph2 dose Topline efficacy data from two Ph2 studies expected 2H24 	
	Novel Tissue-targeted Complement Platform with Clinical Asset	 Differentiated, proprietary approach to address complement dysregulation directly at the site of impacted tis ADX-097: Designed to catalytically degrade alternative pathway convertases, gaining control of the amplificat loop and all 3 complement pathways Ph1 ADX-097 data show attainment of dose-dependent target PK/PD, favorable tolerability and good immunogenicity profile with Q1W SC dosing Initiate ADX-097 Ph2 in 1H24 	
	Near Term Value Creation Potential	 Bempikibart Ph2 topline results across two indications (Atopic Dermatitis, Alopecia Areata) expected in 2H24 ADX-097 topline results from two clinical programs expected across 2024 and 2025 	
	Exceptional Team and Investors	Management team with extensive public biotech experience Orep complement therapeutics and inflammatory/autoimmune expertise Blue chip investor syndicate	
0	32 BIO		

Transaction Summary: Q32 Bio Merger with Homology Medicines (NASDAQ: FIXX)

	Overview	 Homology Medicines, Inc. (NASDAQ: FIXX) to acquire 100% of the outstanding equity interests of Q32 Bio Inc., structured as a tax-free reorganization and by means of a reverse triangular merger of a wholly-owned subsidiary of Homology with and into Q32 Bio, with Q32 Bio surviving as a wholly owned subsidiary of Homology Concurrent private placement to be consummated immediately prior to close via shares issued by Q32 Surviving entity name: Q32 Bio
	Transaction Summary	 \$317M pro forma equity value of combined company \$195M value of Q32 \$80M value of Homology¹ Assuming \$42M private financing \$115M pro forma cash balance for combined company² Pro forma ownership split³: ~61.5% Q32 Bio, ~25.2% Homology, ~13.2% private financing investors CVR agreement provides additional consideration to Homology stockholders The Boards of Directors of both companies have approved of and recommended the Proposed Transaction, which is subject to stockholder approval and other customary closing conditions
	Use of Proceeds, Timing, and Management	 Pro forma cash runway expected to mid-2026 with potential for multiple value-driving near-term clinical catalysts, including: Bempikibart (ADX-914) topline Phase 2 results across two clinical trials expected in 2H24 ADX-097 topline results from two clinical programs across 2024 and 2025 Combined board to consist of 9 members – 7 designated by Q32 Bio and 2 by Homology Q32 management to stay in place
03	2 BIO	1. Assuming \$60M net cash at close. 2. Assuming closing mid-1Q 2024. 3. Assuming Homology has \$60M net cash at close, and a \$42M private financing

Q32 Management Team: Experienced Public Company Leadership Team with Deep Drug Development Experience



Q32 Pipeline: Poised to Deliver Multiple Near-term Clinical Readouts

Program	Indication	Discovery/ Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
<u>IL-7/TSLP PROGRAM</u> Bempikibart	Atopic Dermatitis					Topline Ph2
Bempikibart (ADX-914) ¹	Dermatitis Alopecia Areata					Topline Ph2 results 2H24
COMPLEMENT INHIBITO	R PLATFORM					Packet
ADX-097	LN/IgAN/ C3G AAV					interim YE24; topline 2H25 AAV: Part A topline 2H25

Note: AAV = Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis; IgAN = IgA Nephropathy; LN = Lupus Nephritis; C3G = C3 Glomerulopathy.
 (1) Full rights to ADX-914 re-acquired from Amgen (formerly Horizon) in November 2023.



Bempikibart (ADX-914): Novel Investigational Therapy for T-cell Mediated Inflammatory and Autoimmune Diseases Delivering Two Phase 2 Readouts in 2024

IL-7 TSLP ADX-914 ADX-

Bempikibart: IL-7Rα antagonist antibody blocks IL-7 and TSLP signaling
IL-7

- Potent regulator of pathogenic T_{eff}/T_{mem} survival and proliferation
- Suppresses T_{reg} cells
- Activates TfH cells to induce B-cell mediated antibody production

TSLP

- Central regulator of DC differentiation and TH2 cytokine production
- Activates TH1, sensory neurons, mast cells, eosinophils, basophils and ILC2

Clinical Data Completed to Date

- Ph1: Durable SC PK/PD and tolerability
- Ph2 AD (Atopic Dermatitis) Part A: Confirmatory PK/PD; efficacy data currently blinded

Topline Clinical Efficacy Data Expected 2H24

- Ph2 AD Part B
- Ph2 AA (Alopecia Areata)

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IL-7 and TSLP are Central Drivers of Inflammation and Autoimmunity

Pathogenic Immune Response	Ligand/Receptor Activation	Preclinical Evidence
Induction of pathogenic T-eff/ T-mem and ILC2 cells Inhibition of T-reg function Increased Th-helper cell mediated antibody production	 Elevated IL-7 and sIL-7Rα in disease Increased TSLP signaling in disease Increased IL-7 and TSLP transcriptional signature in disease 	 Overexpression of IL-7 or TSLP recapitulates disease pathology Blocking IL-7 & TSLP pathways exerts protective effects in multiple models
 Activation of TH2 immune response 		 Potential for long-term, durable responses and remittive therapy

Blockade of IL-7 and TSLP has the potential to provide protection in a broad range of inflammatory and autoimmune diseases including AD, AA, UC, RA, SS, NIU, MS and others

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 $\label{eq:AD-atopic dermatitis, AA-alopecia areata, RA-rheumatoid arthritis, NIU-non-infectious uveitis, MS-multiple sclerosis, UC-ulcerative colitis$

Re-Acquisition of Bempikibart (ADX-914)

- In November 2023, Q32 regained full worldwide rights to Bempikibart (ADX-914) from Amgen
- Per the terms of the agreement:
 - Q32 retains the initial consideration and all development funding received (total \$55M)
 - Q32 will pay Amgen a milestone upon the first regulatory approval and subsequent downstream commercial milestones based on annual net sales thresholds
- Current Phase 2 development program for Bempikibart in AD and AA funded with proceeds previously received via Amgen partnership



ADX-914: Phase 1 Clinical Data Support Rapidly Advancing Clinical Development



ADX-914 Phase 2 AD Part A Data Supports Development Program

Part A Evaluated 2 mg/kg and 3 mg/kg Q2W SC for 12 weeks

- PK/Dosing: Both dose groups maintained target PK threshold > 5 ug/ml (dose predicted to achieve full target engagement in tissue); supports administration of 200 mg SC flat dosing (~2.7 mg/kg)¹ in AD Part B & AA
- PD: 100% of both dose groups achieved maximal RO (>90%) by day 3, maintained through entirety of dosing period (graph below)
- Absolute lymphocyte counts: No CTCAE grade ≥3 lymphopenia observed
- ADA: Low titer ADA, with no impact on PK observed
- Safety: To date, no lymphopenia associated AEs including viral infections observed
- Efficacy: Part A remains blinded. Part B blinded through topline data readout.



By Virtue of its Dual MOA, We Believe ADX-914 Has the Potential to Modulate Immune Cells Important in Both Acute and Chronic AD Pathogenesis



ADX-914-202 SIGNAL-AD: Phase 2 Atopic Dermatitis POC Clinical Trial

Atopic Dermatitis	Design/Timeline
 Atopic dermatitis is the most common chronic inflammatory skin disease Prevalence in children ranges from 2%-20%^{1,2,3} Prevalence in adults ranges from 2% to 5%^{1,2} Multiple pathways beyond the classical "T helper cell (TH)2" pathway are important in pathogenesis⁴⁻⁷ Despite recent therapeutic advances, a large AD population remains suboptimally treated Dupilumab was a breakthrough and set benefit/risk precedent for systemic biologic therapy, but up to 30% of patients fail to achieve adequate disease control^{8,9} Does not address importance of Th1/Th17 pathway in more mature, chronic disease Utility of JAK inhibitors hindered by safety concerns Development of remittive therapies gaining interest, e.g., OX40-targeting options ADX-914 has the potential to affect OX40L through TSLP and exert remittive effect via IL-7 axis 	 12-week treatment (n= ~102 patients) PK Run in completed: Dose selected for continued study SC dosing, placebo controlled Key assessments: Primary: Mean % change from baseline to week 12 week in EASI score, power > 80%, alpha 0.05 Key Secondaries: Time to EASI change, proportion of patients achieving EASI thresholds Proportion of patients achieving an AD-IGA of 0 or 1 with a ≥2 grade improvement Timeline: Topline efficacy data expected in 2H24

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1. Weidinger et al. Nat Rev Dis Primers. 2018; 2. Bieber et al. Nat Rev Drug Discov 2022; 3. Based on studies conducted globally 4. Sims et al. Exp Dermatol 2021; 5. Thijs et al. J Allergy Clin Immunol 2017; 6. Gittler et al. J Allergy Clin Immunol 2017; 7. Carnowicki et al. J Allergy Clin Immunol 2020; 8. Bieber et al. Nat Rev Drug Discov 2022; 9. Patrizi et al. J Dermatolog Treat 2021.

ADX-914: Evaluating Potential to Block TH1 and TH2 Driven Disease Pathology In AA

Hair Follicle Immune Dysregulation in Alopecia





ADX-914 is designed to inhibit IL-7 signaling and could potentially benefit alopecia areata patients by blocking CD8+ T cell-driven inflammation

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ADX-914-202 SIGNAL-AA: Phase 2 Alopecia Areata POC Clinical Trial

Alopecia Areata	Design/Timeline
Alopecia Areata is common, and psychosocially	24-week treatment (n= ~40 patients)
debilitating; scalp and face commonly impacted	 SC dosing, placebo controlled
 Approximate prevalence of 2%, most before age 50 	Key assessments:
 Up to 40% of patients develop chronic disease; 10% progress to complete loss of scalp* and/or body hair** 	 Primary: Mean % change from baseline in SALT score at Week 24; power > 80%, alpha 0.05
Psychological comorbidities common and result in major impact on patients' lives	 Key Secondaries: Time to SALT change, proportion of patients achieving SALT thresholds
Despite recent first approved therapy, there remains	 Proportion of patients achieving an AA-IGA of 0 or 1 with a ≥2 point improvement
a lack of options for inducing remission and avoiding life-long treatment	 Change from Baseline in Clinician Reported Outcome (ClinRO) for Eyebrow and Eyelash Hair Loss
 JAK inhibitors require chronic treatment as hair loss reoccurs with treatment cessation or taper; 	 Timeline: Topline efficacy data expected in 2H24
particularly challenging given class safety warnings	

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*Alopecia Totalis; **Alopecia Universalis



Proprietary Tissue-targeted Platform: Building The Future of Complement Therapeutics



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Q32 Tissue-targeted Platform Value Proposition: Designed to Enable Clinical Profile Superior to Systemic Complement Inhibitors

	The Unmet Need		The Opportunity
•	Limited activity: Reliant on systemic blockade for impact on affected organ	•	Enhanced activity through tissue targeting: Differentiated approach to driving efficacy by inactivating convertases directly at site of destruction
•	High doses, frequent administration required: High abundance, rapid turnover of most target complement proteins	•	Reduced treatment burden : SC route with QW dosing; potential for Q2W
•	Infection risk: Complement plays critical role in combating infection; systemic blockade increases risk	•	Improved risk/benefit profile: Designed to maximize therapeutic index while maintaining intact immune surveillance; broader indication potential

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ADX-097 (C3d targeted antibody – fH₁₋₅ fusion protein)

ADX-097 Lead Bivalent Fusion Protein: Designed with Unique MOA to Drive Localized, Complement Re-regulation For Enhanced Activity and Tolerability

ADX-097 Design: C3d antibody – fH₁₋₅





ADX-097 Preclinical and Ph1 Data: Robust data package supports desired PK and PD with favorable tolerability and good immunogenicity profile

Preclinical Data

- Tissue distribution and target binding
- Durable (>7 days) tissue PK/PD after SC dosing
- Reduction in key proof of mechanism (POM)/proof of concept (POC) biomarkers including proteinuria and albuminuria
- >40X safety margin for planned Ph2 clinical dosing

Ph1 Clinical Data

- Favorable tolerability and good immunogenicity profile across all SAD/MAD doses
- Weekly SC dosing met desired exposures for predicted complete tissue inhibition (based on preclinical modeling) with no systemic inhibition
- Proximal POM supports in-vivo ADX-097 integrity

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ADX-097 Preclinical Data: Supports POM, POC, PK/PD Dosing Model and Indication Rationale

Milestone ¹	Organ System	Species	Model
Target validation in human disease	✓ Kidney✓ Skin✓ Liver	✓ Human	IHC of human disease biopsies (multiple disease-types for kidney, skin & liver)
Biodistribution of drug to tissue	✓ Kidney✓ Skin✓ Liver	✓ Mouse✓ Rat✓ NHP	fH -/- mice, EBA mouse model, PHN rat model, NHP UVB
<u>Proof of Mechanism (POM)</u> : Durable inhibition of complement in tissue, absent systemic blockade	✓ Kidney✓ Skin✓ Liver	✓ Mouse✓ Rat✓ NHP	fH -/- mice, EBA mouse model, PHN rat model, NHP UVB
<u>Proof of Concept (POC)</u> : Targeted activity at low mg/kg SC administration	🗸 Kidney	✓ Rat	PHN rat model

Drug levels of 0.3 - 3.2 ug/ml predicted to provide maximal tissue targeted complement inhibition and activity based on preclinical data

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1. Not all milestones were assessed in every organ system in every species

fH -/- Mouse Model of Human C3G with Uncontrolled Complement Activation: Showed Robust and Durable Tissue PK/PD in Absence of Circulating Inhibition of Complement



 ✓ Robust tissue PK/PD and activity at doses of 1 − 3 mg/kg, SC or IV

- Tissue PD EC90 = circulating concentration of 0.3 ug/mL
- Long term, durable kidney PK/PD in absence of systemic complement inhibiting activity
- Supports dosing every 1 to 2 weeks

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Passive Heymann Nephritis Rat Model of Human Membranous Nephropathy: Showed Robust Effect on POM and POC Endpoints



ADX-097-001 Phase 1 Study: Complete with Primary Goals Achieved

ADX-097-001 SAD/MAD (n= 56 Healthy Volunteers) Explored Single Doses of 0.1 - 30 mg/kg IV and/or SC and 450 mg SC Multiple Dose Cohort (~6 mg/kg)					
Primary Goals	Achieved	Results			
Confirm planned Ph2 dose/route/schedule	~	 Attained expected dose-dependent PK/PD Once weekly SC dosing provided desired exposure for predicted complete tissue inhibition with no concomitant systemic inhibition 			
Evaluate proximal POM to establish <i>in-vivo</i> ADX-097 integrity	~	PK levels aligned with predicted Wieslab alternative pathway inhibition			
Characterize safety profile	\sim	No serious or severe AEs or discontinuations due to AEs			
Characterize immunogenicity risk	~	 No AEs related to immunogenicity Minimal anti-drug antibodies (ADA) detected across SAD/MAD; low level titers 			

450 mg selected for starting Ph2 SC dose based on favorable tolerability profile and desired exposure

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ADX-097 Phase 1 PK Data: Weekly SC Dosing Met Desired Exposures for Predicted Complete Tissue Inhibition With No Concomitant Systemic Inhibition



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Updated to include cohorts SAD 6b and SAD 8

ADX-097: Significant Market Potential in Priority High Unmet Need Indications



Estimates reflect total US prevalence27

1. Watts et al. Nat Rev Rheum 2022; 2. Estimated using U.S. and Norway incidence study results, and Norway prevalence study results as applied to U.S. population; 3. Berti et al. Arthritis Rheum 2017; 4. Q32 qualitative research; 5. Specks et al. N Engl J Med. 2013; 6. Severe disease patients are those with a high risk of progression to ESRD, among other factors; 7. Hoover et al. Kidney Int 2016; 8. Pryor et al. Rheum Dis Clin North Am. 2021; 10. Kwon et al. J Health Econ Outcomes Res. 2021; 11. Swaminathan et al. Clin J Am Soc Nephrol 2006; 12. Berthoux FC, et al. Semin Neph 2008; 13. Bomback et al. Kidney Int 2014; A. Smith et al. Ansint et al. Natur Rev Nephrol 2009; 19. Course ret al. Clin J Am Soc Nephrol 2006; 14. Smith et al. Ansint et al. Natur Rev Nephrol 2009; 19. Course et al. Clin J Am Soc Neph 2017; 21. Umehara et al. Mod Rheum 2012; 22. Uchida et al. Int J Rheum 2012; 23. Estimated using Japan prevalence study results as applied to U.S. population; 24. Brito-Zerón et al. Medicine 2016; 25. Moderate-severe patients are those who require pharmacological, primarily gluccorticoid treatment; 26. ACR clinical guidelines 2018; 27. Based on 2020 Census population;

LN, IgAN, C3G Unmet Need		Planned Design
GIO Lupus Nephritis 100K (US) ^{18,19} GIO IgA Nephropathy 185K (US) ^{20, 21} GIO C3 Glomerulopathy 3K (US) ²²	 6-fold mortality risk increase vs general population^{1,2} Up to 30% develop kidney failure requiring dialysis or kidney transplant within 15 years of diagnosis^{3,4} Up to 40% develop ESRD w/in 20 years of diagnosis^{5,6}, and patients have 10 years reduced life expectancy^{7,8} ~70% not adequately controlled w/supportive care^{5,9} Up to 50% of adult, 70% of pediatric patients progress to kidney failure within 10 years¹⁰⁻¹³ >70% experience recurring disease; ~50% experience allograft loss w/in 10 years of kidney transplant^{10,14-17} 	 Basket design (n= up to 30) Designed to assess safety, tissue pharmacology and magnitude/timing of treatment effect with focused dose-ranging Open-label with interim data readouts SC dosing with duration of treatment TBD (prior regulatory discussions support up to 24 weeks) Key assessments: Drug localization and impact in tissue, biomarkers (including surrogate endpoint biomarkers proteinuria and eGFR) for assessment of ADX-097 activity Anticipated to provide data for key regulatory discussions



1. Mahajan et al. Lupus 2020; 2. Cervera et al. Medicine 2002; 3. Maroz et al. Am J Med Sci 2013. 4. Ward et al. J Rheumatol 2009; 5. Habas et al. Medicine (Baltimore) 2022. 6. Berthoux et al. Semin Nephrol 2008; 7. Pitcher et al. Chi Nour of Amer Soc Neph 2023. 8. Hastings et al. Kidney int Reg 2018; 9. Plaun et al. N Engl J Med 2015; 10. Heiderscheit et al. Am J Med Genet C Semin Med Genet 2022. 11. Smith et al. J Am Soc Nephrol 2007; 12. Servais et al. Kidney int 2015; 13. Smith et al. J Am Soc Nephrol 2007; 12. Servais et al. Kidney int 2015; 10. Heiderscheit et al. BMC Nephrolg 2015; 15. Sahadori et al. UMT 2016; 17. Regunathan-Shenk et al. AKD 2019 18. Hoover et al. Kidney int 2015; 19. Pryor et al. Rheum Dis Clin North Am. 2021; 20. Braun et al. Int Urol Nephrol 2015; 11. Ancurat et al. Kidney int. 2013; 22. Bomback et al. Kidney int. 2018; 3. Chi North Am. 2021; 20. Braun et al. Int Urol Nephrol 2015; 11. Chi Lupart et al. MUT 2016; 12. Savdori et al. MUT 2016; 13. Pryor et al. Rheum Dis Clin North Am. 2021; 20. Braun et al. Int Urol Nephrol 2015; 21. Savdori et al. MUT 2016; 13. Pryor et al. Rheum Dis Clin North Am. 2021; 20. Braun et al. Int Urol Nephrol 2015; 21. Savdori et al. MUT 2016; 2016; 2017; 22. Servais et al. Kidney int 2016; 19. Pryor et al. Rheum Dis Clin North Am. 2021; 20. Braun et al. Int Urol Nephrol 2015; 21. Savdori et al. MUT 2016; 22. Savdori et al. Sinder et al. BMC 2015; 20. Bomback et al. SMC 2019; 21. Savdori et al. Sinder et al. SMC 2015; 21. Savdori et al. MUT 2016; 22. Savdori et al. Sinder et al. SMC 2019; 21. Savdori et al. Sinder et al. SMC 2019; 21. Savdori et al. SMC 2019; 21. Savdori et al. Sinder et al. SMC 2019; 21. Savdori et al. MUT 2016; 21. Savdori et al. MUT 2016; 21. Savdori et al. Sinder et al. SMC 2019; 21. Savdori et al. Sinder et al. SMC 2019; 21. Savdori et al. Sinder et al. SMC 2019; 21. Savdori et al. Sinder et al. SMC 2019; 21. Savdori et al. Sinder et al. SMC 2019; 21. Savdori et al. Sinder et al. SMC 2019; 21. Savdori et al. SMC 2019; 21. Savdori et a

AAV Two-part Phase 2: Expected to Deliver Key Biomarker Data & Evaluation of Reduction of Steroids

AAV Unmet Need	Planned Design
 More effective induction and maintenance With treatment, 5-year mortality 10-30% overall¹⁻³ 5-year mortality with renal disease - 20-50%¹⁻³ Relapse is substantial issue: Up to 50% of patients relapse within 5 years, often 12-18 months of IST discontinuation⁴⁻⁸ 	 Ph2 design informed by avacopan Ad Com roadmap Part A (funded FPI 1Q25) : 12-week treatment (n= up to 20 patients) Designed to evaluate safety and early treatment effect IV loading dose followed by SC dosing as adjunct to SOC Key assessments: ADX-097 localization and impact in tissue, PV/SE biomarkers for early accessment of ADX 097 activity.
 Reduction/Elimination of Glucocorticoids (GCs) IST, particularly GC side effects, account for significant early treatment related morbidity and mortality, primarily due to infection⁹ Avacopan approved in 2021, but due to limitations in development program label states, "does not eliminate GC use" and guides to 	 Anticipated to provide data for key regulatory discussions Part B (planned 2026): 24-week treatment (n= ~65 patients) Designed to evaluate ability to reduce CC use (evangeure while
avoid use in "active, serious infection" ¹⁰	 Designed to evaluate ability to reduce GC use/exposure while maintaining same or better remission rates Key assessments: BVAS, ADX-097 localization and impact in tissue, biomarkers for assessment of ADX-097 activity
ANCA Associated Vasculitis (AAV) 100K (US) ^{8, 11-13}	tissue, biomarkers for assessment of ADX-097 activity

1. Tan et al. Ann Rheum Dis 2017; 2. Heil et al. RMD Open 2017; 3. Q32 Internal estimates. 4. Samman et al. Int J Rheumatol 2021; 5. Tan et al. Ann Rheum Dis 2017; 6. Walsh et al N Engl J Med 2020; 7. Demiselle et al. Ann Intensive Care 2017; 8. Kitching et al. Nat Rev Dis Prince-Beauport et al. BMC Nephrol 2018 10. Tarveos POAlabel: 11. Berti et al. Arthritis Rheumatol 2017; 12. Watts et al. Nephrol Dial Transplant 2015; 13. Watts et al. Nat Rev Dis Pointes 2020; 7. Demiselle et al. MAT Rev Dis Pointes 2020; 7. Demiselle et al. BMC Nephrol 2018 10. Tarveos POAlabel: 11. Berti et al. Arthritis Rheumatol 2017; 12. Watts et al. Nephrol Dial Transplant 2015; 13. Watts et al. Nat Rev Rev Rheumatol 2022

IST: immunosuppressive therapy BVAS: Birmingham Vasculitis Activity Score (planned Phase 3 endpoint)



Looking Ahead

Merger Positions Q32 Bio to Unlock Significant Near-term Value-creation *

	Pro forma runway through multiple value-driving Phase 2 clinical readouts		
Use of Proceeds	 To fund the continued development of pipeline candidates, other ongoing research and development activities, and for general corporate purposes 		
Cash Runway	 Q32 has current cash runway into 1H24 Following the merger and concurrent private financing, Q32 expects to have pro forma cash balance of ~\$115M¹, providing expected cash runway to mid 2026 		
Merger Supports Potential Achievement of Numerous Anticipated Milestones	 2H24: Topline results from bempikibart (ADX-914) Phase 2 studies in AD and AA YE24: Interim data from planned ADX-097 Phase 2 renal basket 2H25: Topline results from planned ADX-097 Phase 2 Part A AAV and renal basket 		



1. Assuming closing mid-1Q 2024.

* Based on current management estimates

Q32 Mission: Building The Future of Immune Therapeutics

	IL-7Rα Antagonist Antibody	 Bempikibart (ADX-914): Dual inhibitor of IL-7 and TSLP signaling, designed to provide broad control of T cell-mediated pathological processes in autoimmune diseases Ph1 data show attractive PK/PD profile, favorable tolerability w/Q2W SC dosing; Ph2 PK run in confirmed Ph2 dose Topline efficacy data from two Ph2 studies expected 2H24
	Novel Tissue-targeted Complement Platform with Clinical Asset	 Differentiated, proprietary approach to address complement dysregulation directly at the site of impacted tissue ADX-097: Designed to catalytically degrade alternative pathway convertases, gaining control of the amplification loop and all 3 complement pathways Ph1 ADX-097 data show attainment of dose-dependent target PK/PD, favorable tolerability and good immunogenicity profile with Q1W SC dosing Initiate ADX-097 Ph2 in 1H24
	Near Term Value Creation Potential	 Bempikibart Ph2 topline results across two indications (Atopic Dermatitis, Alopecia Areata) expected in 2H24 ADX-097 topline results from two clinical programs expected across 2024 and 2025
	Exceptional Team and Investors	Management team with extensive public biotech experience Orep complement therapeutics and inflammatory/autoimmune expertise Blue chip investor syndicate
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Thank You!



Several Disease Models (Mouse, Rat and NHP) Establish Drug Levels Anticipated for Maximal Tissue PD & Activity



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Several disease models demonstrate maintaining drug levels of 0.3 - 3.2 ug/ml provides maximal tissue targeted complement inhibition and activity

ADX-097-101: Plasma ADX-097 Concentrations and % of Baseline Wieslab AP Activity After Single Dose IV ADX-097



C_{max} increased dose-proportionally following 0.1 to 30 mg/kg IV dosing; Tmax achieved within 80 minutes after IV infusion

• 30 mg/kg IV ADX-097 resulted in AP activity at or below the LLOQ of the assay at *end of infusion*; AP activity began to recover after 7 days and returned to baseline by 14 days postdose

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ADX-097-101: Plasma ADX-097 Concentrations and % of Baseline Wieslab AP Activity After Single/Multiple Dose SC of ADX-097



- Tmax achieved within 1-3 days after SC dosing
- After single dose 10 mg/kg SC ADX-097, AP activity decreased to 65% of baseline at 1 day and returned to baseline by 7 days postdose
- No change in AP activity observed following 450mg SC weekly dosing

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ADX-097-101: Key Pharmacology Takeaways

ADX-097 showed nonlinear PK with a saturable clearance mechanism

- Detectable plasma ADX-097 concentrations in all PK-evaluable participants
- T_{max} achieved within 80 minutes after IV infusion and within 1 to 3 days after SC injection
- C_{max} increased dose-proportionally following 0.1 to 30 mg/kg IV, whereas AUC increased dose-proportionally from 0.1 to 1 mg/kg IV and greater than dose-proportionally at doses greater than 1mg/kg
- Terminal T_{1/2} was dose-dependent for SC dosing
- Mild accumulation was observed after 450 mg SC QW dosing
- Bioavailability of SC administered ADX-097 estimated via population PK modeling as ~50%

ADX-097 showed dose dependent fluid phase AP activity inhibition, with more sustained inhibition at increasing IV and SC doses

- Highest dose, 30 mg/kg IV ADX-097, resulted in AP activity at or below the LLOQ of the assay (35% of baseline Wieslab activity) at end of infusion; AP activity began to recover after 7 days and returned to baseline by 14 days postdose
- After single dose 10 mg/kg SC ADX-097, AP activity decreased to 65% of baseline at 1 day and returned to baseline by 7 days postdose
- No change in AP activity was observed following 450mg SC weekly dosing

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