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In addition, non-GAAP financial measures are included in this presentation. Please see table in appendix for reconciliation to the most directly comparable GAAP measure.



# Gold standard in hematology MRD and immune receptor discovery

Strategic Review: maximizing value for patients, employees and shareholders



## **Rationale**

MRD & IM: two compelling businesses with key differences

- Stages of maturity
- Investment requirements
- Value drivers



# Process & Diligence

- Working with outside advisors
- Management and Board reviewing structural alternatives



# **Outcome Timeline**

 On track to communicate outcome by end of Q1'24







# MRD

A commercial stage diagnostics business

# clonoSEQ® is the gold standard in hematology MRD



<sup>1</sup> Includes covered lives in ALL and MM. CLL and DLBCL covered lives are 195M and 75M respectively



<sup>2</sup> Primary endpoint in 9 trials, secondary endpoint in 66 trials

<sup>3</sup> US clinical patients

# clonoSEQ captures the synergistic value of clinical diagnostics and pharma



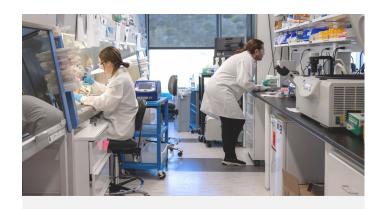
# **Clinical testing**

Monitor response to treatment via serial quantification of disease burden

Pharma supports lifecycle expansion which drives clinical use



Clinical usage drives inclusion as an endpoint in pharma trials

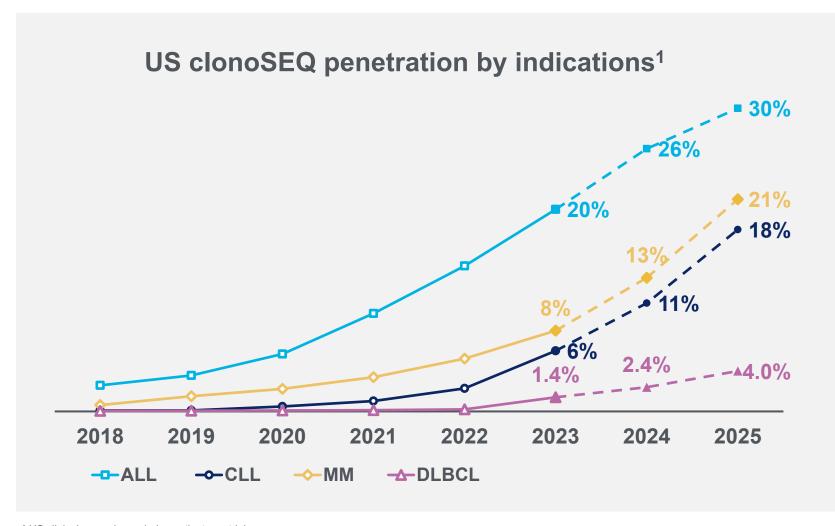


#### **Pharma trials**

Accelerate drug development and commercialization by using MRD as a clinical endpoint



# Significant opportunity in clinical testing ahead in current indications



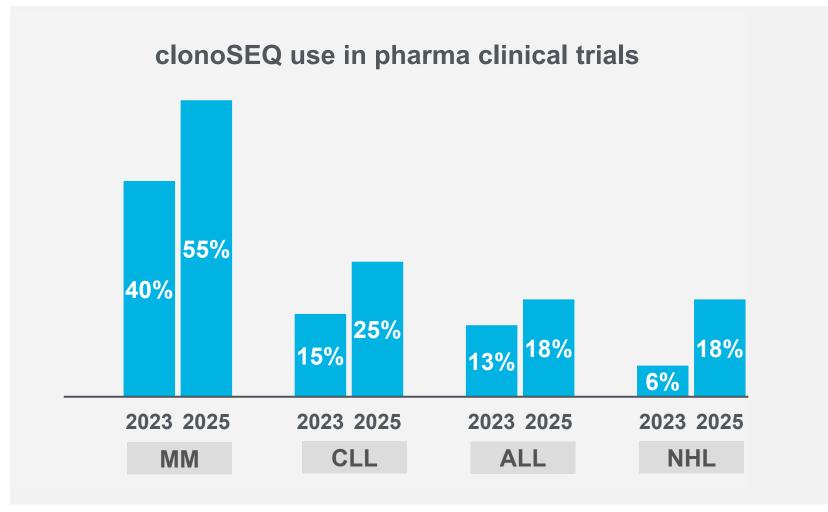
MM driving short to medium-term growth, followed by newer indications: CLL and NHL

- 5 yr. prevalence used for ALL & DLBC; 10 yr. prevalence used for MM and CLL,
- Penetration excludes patients on clinical trials
- Peak penetration shown; penetration based on clinical utility, evolving clinical landscape, HCP research and internal team think
- Indolent and non-treated CLL patients excluded from calculations; penetration purely based on patients who are treated, and their disease needs to be monitored.



<sup>&</sup>lt;sup>1</sup> US clinical use only, excludes patients on trials

# Significant room for expansion in our pharma business



Focus on expanding presence in NHL and CLL trials

#### **Potential tail-wind:**

FDA acceptance of MRD as a primary clinical endpoint in trials



# Key priorities to grow the business while reaching profitability

# Key Priorities Increase testing in blood Increase testing in blood Expand into newer indications Expand patient use cases Workflows Figure 1 Figure 1 Figure 2 Figure 2 Figure 2 Figure 3 Figure 3 Figure 4 Figure 4

**Improve Margins** 

Coverage expansion / ASP increase



Production lab efficiencies

**Ongoing evidence generation/studies** 



**OPEX** leverage





# Mounting evidence on MRD clinical & research utility presented at ASH 2023







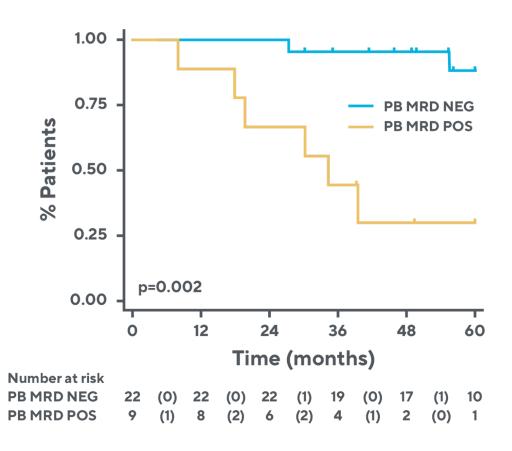


# MRD status in blood predicts PFS in MM early in treatment

#### **ATLAS (University of Chicago)**

"We're encouraged to see the results of MRD testing with clonoSEQ in peripheral blood, which suggest that it is a prognostically significant assessment early in treatment."

Ben Derman, MD, Assistant Professor of Medicine at the University of Chicago



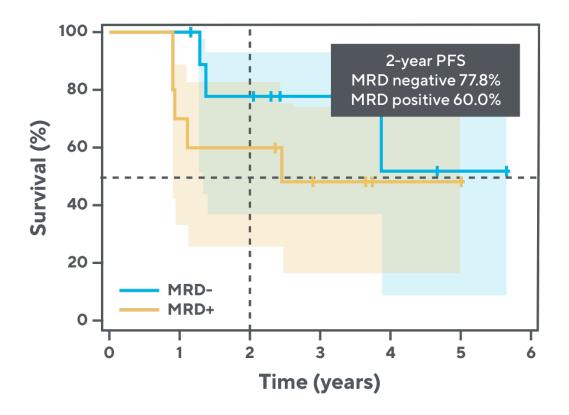
Presented at ASH 2023: "Early Peripheral Blood Minimal Residual Disease Status By NGS in Patients with Newly Diagnosed Multiple Myeloma (MM) on a Phase 2 Trial Receiving Elotuzumab, Carfilzomib, Lenalidomide, and Dexamethasone (Elo-KRd)"





# **Exploring the role of MRD in informing management in MCL**

#### PFS by PB MRD Status Post Consolidation



#### **Wisconsin Oncology Network Study**

"The prognostic power of MRD has been well-substantiated, and now, a growing set of evidence supports the use of MRD to adapt approaches to therapy, with potentially meaningful implications on patients' quality of life."

Julie Chang, MD, Associate Professor, Hematology/Oncology Faculty, University of Wisconsin-Madison School of Medicine and Public Health

Presented at ASH 2023: "Minimal Residual Disease (MRD) Testing By Next Generation Sequencing (NGS) after Two Cycles (CY) of Non-Intensive Chemoimmunotherapy Is Predictive of Remission Duration and Need for Maintenance Therapy (MT) in Previously Untreated Mantle Cell Lymphoma (MCL): A Wisconsin Oncology Network Study"





# **Growing our foothold in NHL**

## Target key milestones to accelerate our expansion in the largest lymphoid market

#### **DLBCL**

- DLBCL enhanced assay available for pharma
- FDA submission in 2024

### MCL

- Active MCL pharma trials+ prospecting in progress
- Medicare reimbursement
   & commercial launch in
   1H 2024

#### CTCL

- Enhanced T-cell assay (TCRBG) in development
- Medicare reimbursement
   & commercial launch by
   YE 2024



# Relentless focus on improving margins



# **Increasing clonoSEQ ASP**



#### **OPEX** leverage

- 1 Reduce out-of-policy claims
- 2 Reduce non-contracted claims
- 3 Optimize revenue cycle management

- 1 Production lab efficiencies
- 2 Commercial economies of scale
- 3 G&A optimization

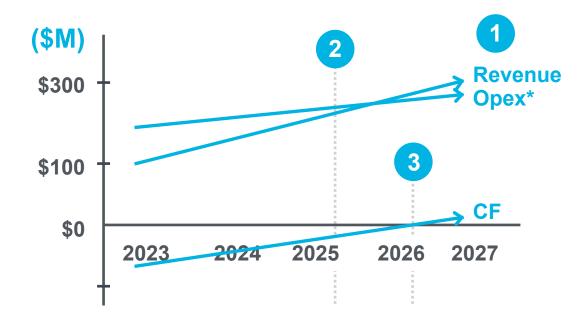


# Financial outlook and path to profitability for MRD business

#### Path to profitability/cashflow breakeven

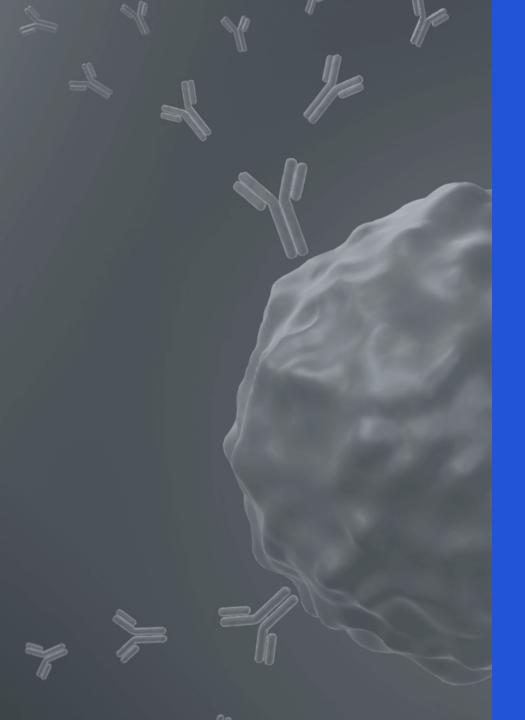
- 1 Revenue CAGR from 2023-2027 to be 25-30%
- 2 Adj EBITDA¹ positive 2H 2025
- 3 Cash Flow Breakeven 1H 2026

#### **Est 3 yrs. P&L progression (illustrative)**



<sup>\*</sup> Opex in this chart excludes stock comp, depreciation and amortization Chart not at scale







# Immune Medicine (IM)

An immune-driven drug discovery business

# We are the gold standard in immune receptor discovery

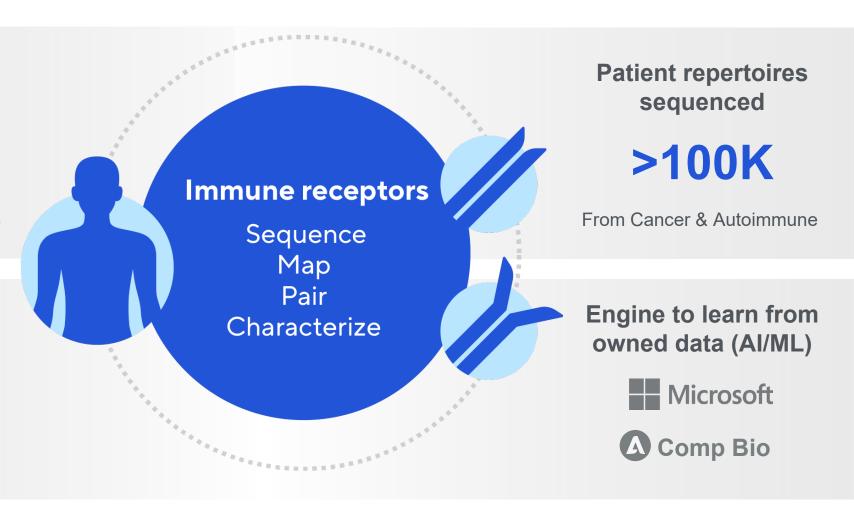
Full TCR functionally matched to an HLA presented antigen

~500K

Vs <40,000 available worldwide

Strong IP and patent portfolio

245+



TCR: T cell receptors HLA: Human leukocyte antigens



# Advancing transformative therapies in cancer and autoimmunity

#### Solving for TCR-antigen discovery and mapping

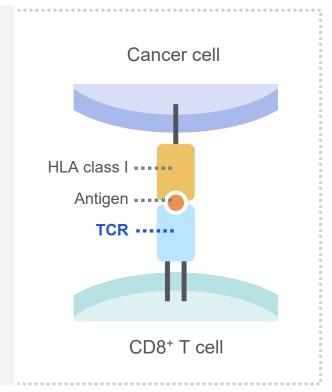


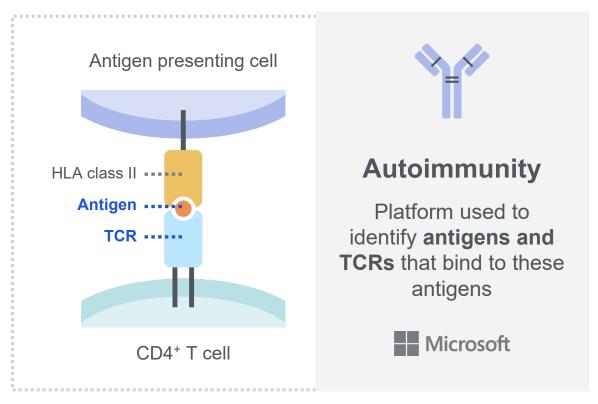
#### Cancer

Platform used to generate library of **TCRs that bind** to known antigens

Genentech

A Member of the Roche Group





Developing 1st **fully personalized** cell therapy product

Driving **immune-driven precision medicine** with novel targets





# **GNE** partnership: advancing into the clinic with the 1<sup>st</sup> product candidate

Identifying optimal TCR candidates in two product categories



#### **Shared Product**

- ✓ IND cleared for 1<sup>st</sup> candidate
- ✓ 2 additional TCR data packages
- In 2024: support GNE to enter the clinic with 1<sup>st</sup> candidate

Developing neoantigen-directed T-cell therapies



A Member of the Roche Group

Individual neoantigens
Patient tumor sequencing

Tumor neoantigen candidates

#### **Personalized Product**

- ✓ Completed POC (+100 patients)
- Built workflow in SSF lab under regulated conditions
- In 2024: complete end-to-end testing for future clinical readiness





# Advancing in autoimmune with 1st novel target in Multiple Sclerosis (MS)

## Why focus on MS?



Current treatments have limited efficacy and significant side effects



T-cells play a causative role



Self-antigens involved, but unknown

#### What did we find?

- Identified specific TCRs that are shared and clustered in MS patients
- Used these TCRs to find the self-antigen likely causing the immune response in MS
- This self-antigen is the focus of our lead drug candidate program

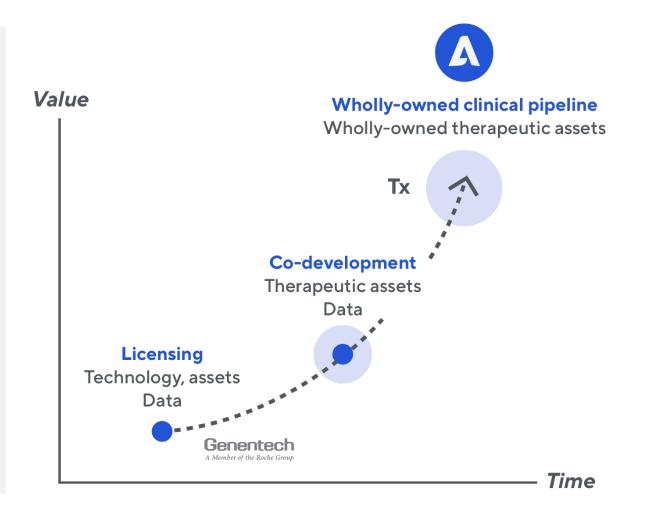
#### What is next?

- In 2024: validate target using in vitro and in vivo disease models
- Assess antibodies developed from our platform as lead modality



# IM is well-positioned to deliver on key priorities in the next couple of years

- Support GNE's development of cancer cell therapy products
- Designate therapeutic candidate (MS) and enter the clinic
- Scale target discovery in additional autoimmune indications (T1D, RA)
- Gate R&D investments on catalysts that achieve strategic priorities





# **Key Takeaways**

#### **MRD**

- ✓ Gold standard MRD test in blood cancers
- Clear execution path to drive clinical volume growth and improve margins
- Clear line of sight to profitability

## IM

- ✓ Leaders in immune receptor discovery and characterization
- ✓ Expected to enter the clinic with 1<sup>st</sup> cell therapy product candidate in oncology
- ✓ Target identified in MS with focus on preclinical development of a future drug candidate

## Strategic review ongoing to maximize value of both businesses



