



 **MAINZBIOMED**

Dedicated to Saving Lives  
by Transforming At-home  
Cancer Detection

**Corporate Overview April 2024**

# Safe Harbor

This presentation contains forward-looking statements concerning our expectations, anticipations, intentions, beliefs or strategies regarding the future. These forward-looking statements are based on assumptions that we have made as of the date hereof and are subject to known and unknown risks and uncertainties that could cause actual results, conditions and events to differ materially from those anticipated. Therefore, you should not place undue reliance on forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results; expectations for development of new or improved products and services; our strategies, positioning, resources, capabilities and expectations for future events or performance; and the anticipated benefits of our acquisitions, including estimated synergies and other financial impacts.

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# Mainz BioMed Overview



## Colorectal cancer screening is the largest molecular diagnostics market

- US annual market > \$30bn by 2032<sup>1</sup>
- 3rd most-commonly diagnosed cancer<sup>2</sup>
- 2nd leading cause of cancer death globally<sup>2</sup>
- Ability to move into large, adjacent areas, including pancreatic cancer and other GI cancers



## New Gold standard for non-invasive detection of AA in development

- Early detection of advanced adenomas (precancerous lesions) could drastically reduce or even eliminate cancer
- Strong clinical performance shown with two independent studies with CRC sensitivities above 90% and AA sensitivities above 80%
- On track to start patient enrolment in 2H 2024



## Disruptive, decentralized business model

- Kit-based solution that allows the testing to be done in any lab across the United States.
- All competitors using CLIA laboratory based centralized solutions that require large investments to broadly commercialize the product nationally
- Enables the sale of ColoAlert® internationally



## First Generation CRC screening test launched in Europe (ColoAlert®)

- Highly efficacious, at-home, stool-based screening test for early colorectal cancer (CRC) detection
- Combines a FIT test for detection of human hemoglobin with the PCR results of specific tumor DNA markers
- Marketed as a CE-IVD product in Europe since 2021



## Strong team

- Experienced diagnostics team, formerly Roche, Abbott or Qiagen; took the company public in 2021
- 64 employees with headquarters in Mainz, Germany
- Strong Medical Advisory Board with renowned scientific and oncology experts



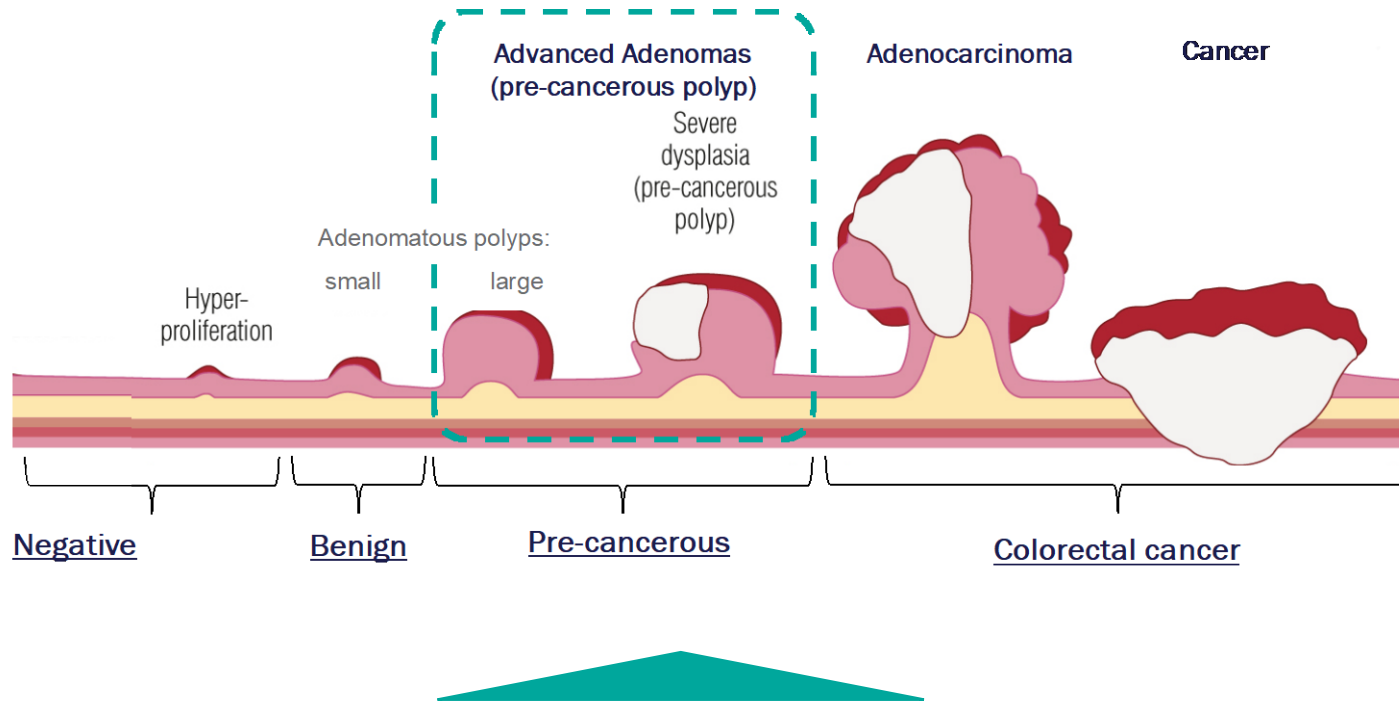
## Strong intellectual property position

- Valuable IP position, with new IP in development
- Trade secret portfolio

<sup>1</sup>Global Market Insights <sup>2</sup>The Cancer Atlas; The Burden of Cancer

# Early Identification of Colorectal Cancer (CRC) Saves Lives

## Clinical progression from colorectal polyp to cancer



*The goal of Mainz Biomed's next generation screening test is to improve the detection of advanced adenomas (precancerous lesions)*

- Almost all colorectal cancers develop from polyps over time
- With increasing time of a polyp being present, the risk of malignancy increases
- Early screening has the potential to dramatically impact the treatment and prevention of CRC, and ultimately save lives
- In a screening population  $\geq 45$ :
  - 21% sensitivity for adenomas would reduce mortality from CRC by 47%
  - 76% sensitivity for adenomas would reduce mortality from CRC by 67%

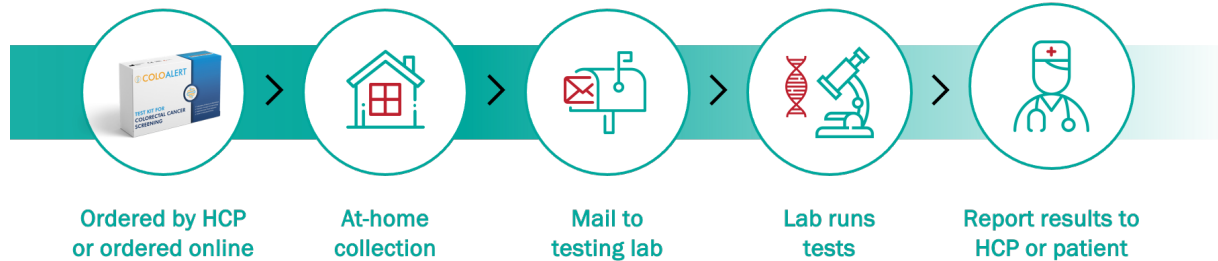
Ladabaum U, et al. Counting Advanced Precancerous Lesions as True Positives When Determining Colorectal Cancer Screening Test Specificity, JNCI: Journal of the National Cancer Institute, Volume 114, Issue 7, July 2022, Pages 1040-1043 <https://doi.org/10.1093/jnci/djac027>

Our Current Flagship  
Product

ColoAlert<sup>®</sup>

# Our Current Flagship Product – ColoAlert®

A PCR based CRC early detection stool test: simple, fast, accurate and non-invasive



- Highly accurate test (92% specificity, 85% sensitivity)<sup>1</sup>
- 98% patient satisfaction – easy product to use<sup>2</sup>
- Designed to offer affordable CRC screening solutions
- Identifies tumor DNA next to blood in stool samples
- Available through online shop, corporate health programs and networks of lab partners



*DNA stabilization tube*



*FIT tube*



<sup>1</sup> Published by: Dollinger MM et al. Clin Lab 10/2018

<sup>2</sup> 98% overall satisfaction with ColoAlert® in our internal customer survey.

# ColoAlert® - Commercialization Strategy

## Strategy

## Lab Partnerships

## Employer Corporate Health Programs (BGM)

## Online Shop



### Expansion of Lab Partnerships in Germany including the European Oncology Lab

- Focused on PKV and out of pocket patients
- Campaign targeting 16,000 private physicians



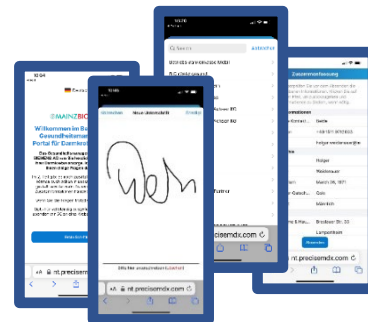
### Expansion to New Markets

- United Kingdom
- Spain
- Portugal
- Italy
- Austria
- Poland
- Romania
- Israel



### Targeting employee health-conscious German companies

- Inclusion of three new companies in corporate health program
- Bantleon and Zoeller repeat customers
- More than 500 companies targeted since the launch of BGM program



### Targeting patients and physicians

- Relaunch of ColoAlert.de website
- New online shopping experience
- Privately insured patient landing page and HCP education



Achievements

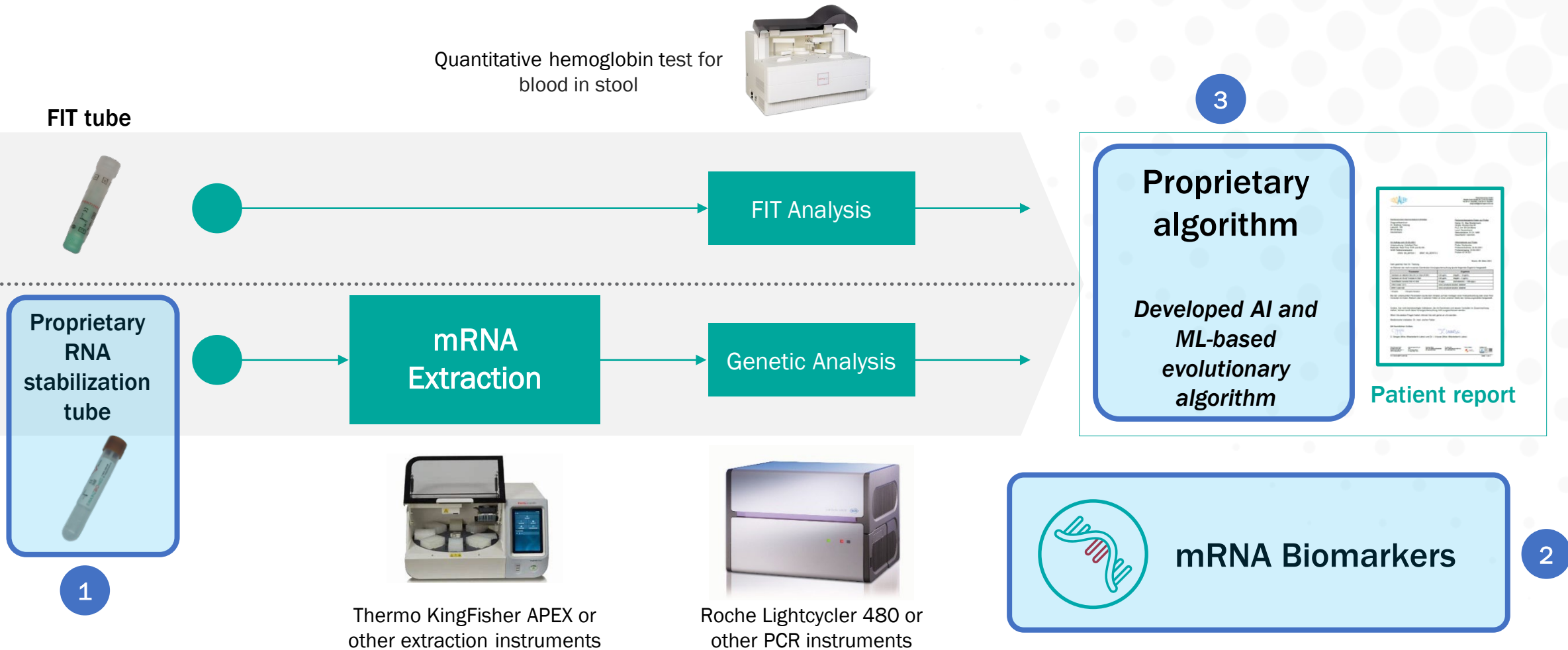
# Next Generation CRC Screening Test

*(Developing a new gold standard for non-invasive detection of advanced adenomas under development)*



# Next Generation Screening Test – mRNA Biomarkers & FIT

Combination of mRNA biomarkers & FIT expected to create leading product for AA and CRC detection



# mRNA Biomarkers are effective in detecting advanced adenomas



- mRNA testing can detect molecular changes in cells even before visible abnormalities or symptoms manifest
- mRNA biomarkers reflect the dynamic changes in gene expression that occur during the progression of adenomas to advanced stages. As adenomas evolve, certain genes may be upregulated or downregulated, and RNA biomarkers can capture these changes, providing insights into the stage of adenoma development
- mRNA biomarkers are highly specific to particular stages or types of adenomas. By targeting RNA molecules associated with the advanced stage of adenomas, these biomarkers can distinguish between advanced adenomas and less advanced forms or benign conditions
- mRNA biomarkers's sensitivity allows for the detection of even small quantities of RNA molecules associated with advanced adenomas. This sensitivity enables the detection of adenomas at early stages
- mRNA expression pattern changes can be used as an early predictor for the onset of a certain disease

# Next Generation Test: Clinical Validation and Trials (EU + US)

2023-2024

2024 - 2025

- Multi-national study (Germany, Norway, Denmark)
- 9 study sites

ColoFuture

436 patients

254 patients

eAArly DETECT Study

- US based study
- 25 study sites

Pooled Analysis

690 patients

- Pooled analysis of ColoFuture and eAArly DETECT using proprietary RNA biomarkers and & FIT test

- ReconAAsense (US, IRB approved)
  - Pivotal FDA PMA study,
  - 10-15,000 subjects across 150 study sites

# Clinical Trials Summaries and Patient information

## ColoFuture Study

- EU study (Germany, Denmark, Norway)
- 9 study sites
- Interim analysis
- Average risk patient and Dx patients

	Mean age	Control	Non-AA	AA	CRC	All groups
Male	62.2	56	6	37	23	122
Female	62.4	51	4	18	15	98
All genders	62.3	117	10	55	38	220

## eAArly DETECT Study

- US based study
- 21 study sites
- Average risk patient and Dx patients

	Mean age	Control	Non-AA	AA	CRC	All groups
Male	61.4	38	28	37	22	125
Female	59.1	65	23	28	13	129
All genders	60.3	103	51	65	35	254

## Pooled Study

- US & EU based study
- 30 study sites
- Average risk patient and Dx patients

	Mean age	Control	Non-AA	AA	CRC	All groups
Male	62.5	139	81	85	50	355
Female	61.0	180	66	61	28	335
All genders	61.8	319	147	146	78	690

# Next Generation Test: Clinical Validation and Trials

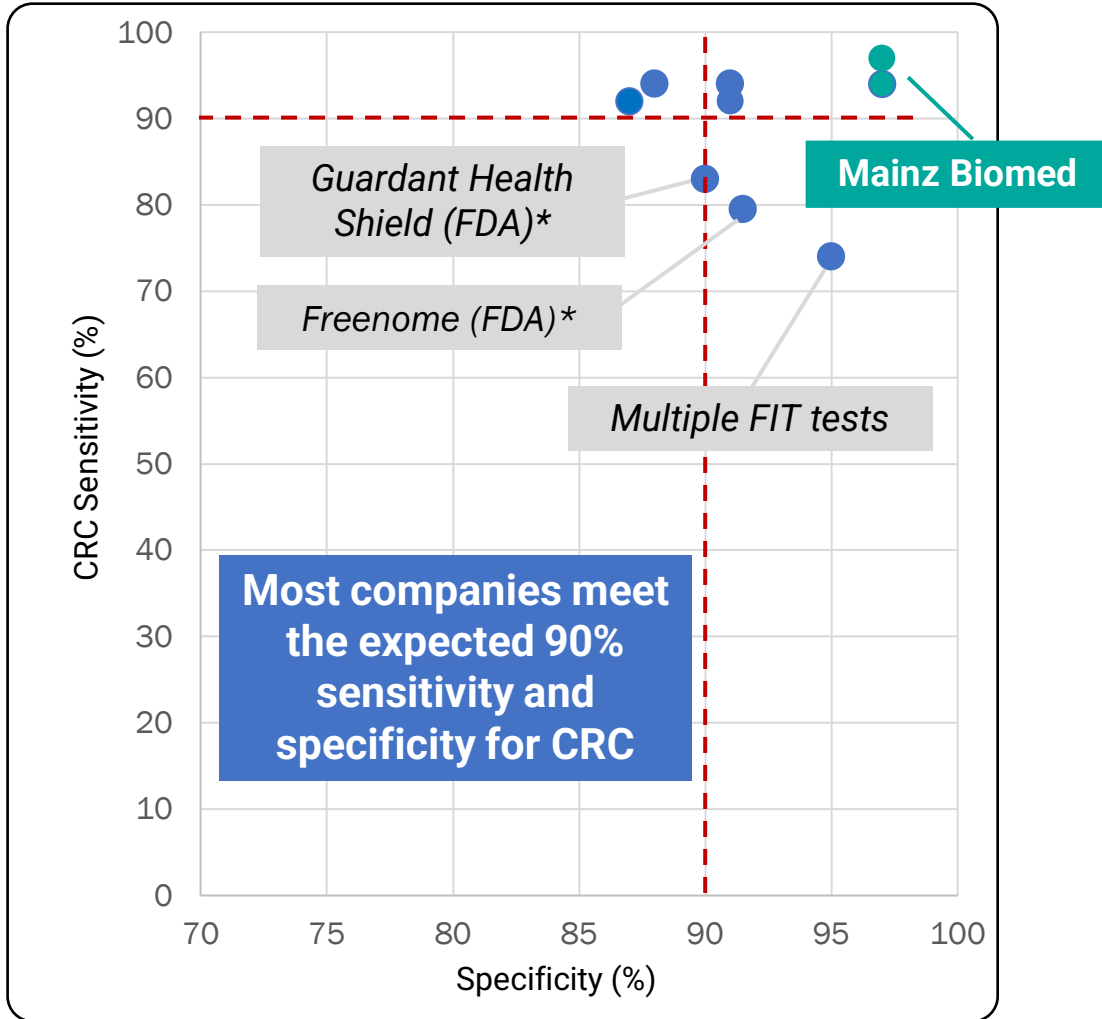
	ColoFuture	eAArly DETECT	Pooled study
CRC Sensitivity	94%	97%	92%
CRC Specificity	97%	97%	90%
AA Sensitivity	80%	82%	82%
AA Specificity	95%	97%	90%
Location	EU	US	EU & US
# of Participants	220	254	690

The industry-leading performance has the potential to enable the transition from CRC early cancer screening to CRC prevention with AA screening

- The combined analysis of data consistently demonstrated high sensitivity and specificity for both Advanced Adenomas and Colorectal Cancer.
- This strong performance across pooled studies reaffirms the reliability of the chosen mRNA biomarkers and the algorithm, **particularly noteworthy as the pooling involved two entirely separate patient cohorts.**

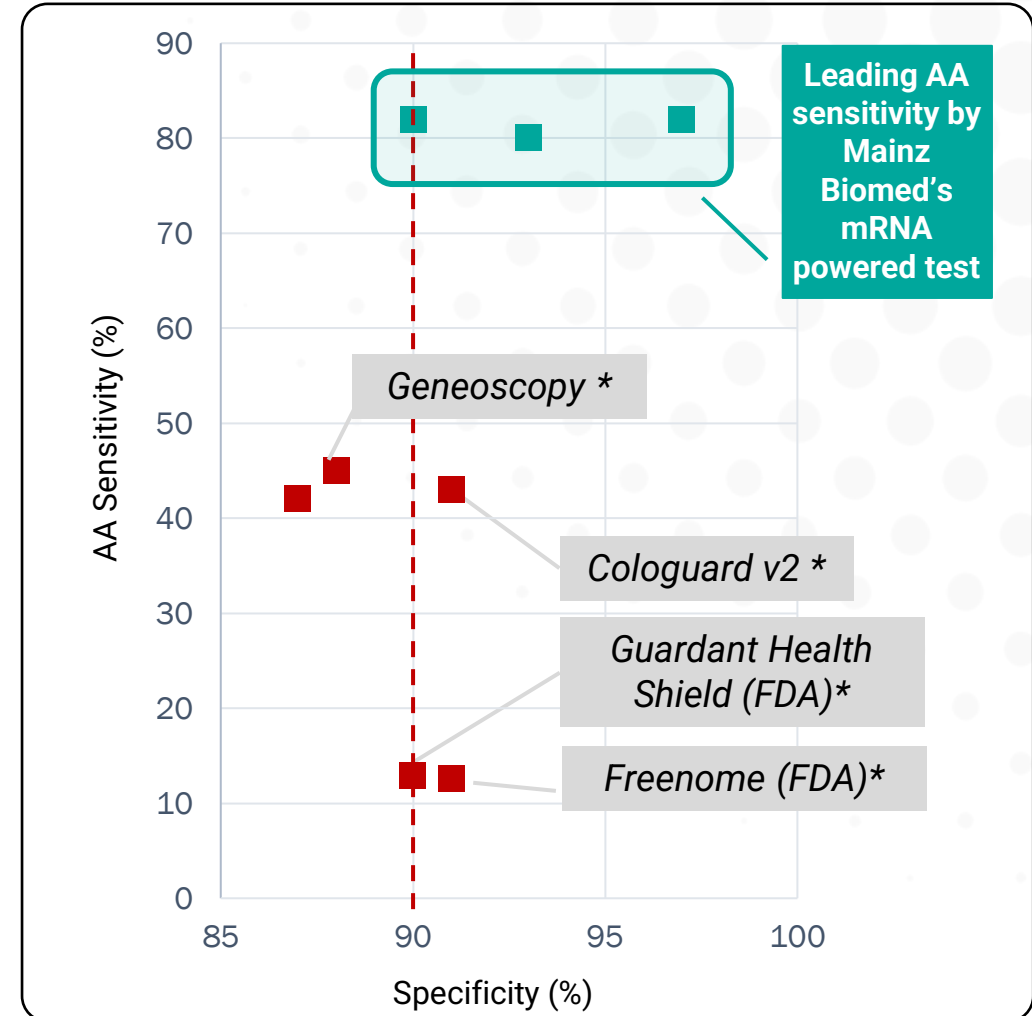
# Competition: CRC and Advanced Adenoma (AA) Sensitivity and Specificity

## CRC sensitivity



\* > 10,000 subjects screening studies

## Advanced Adenoma sensitivity

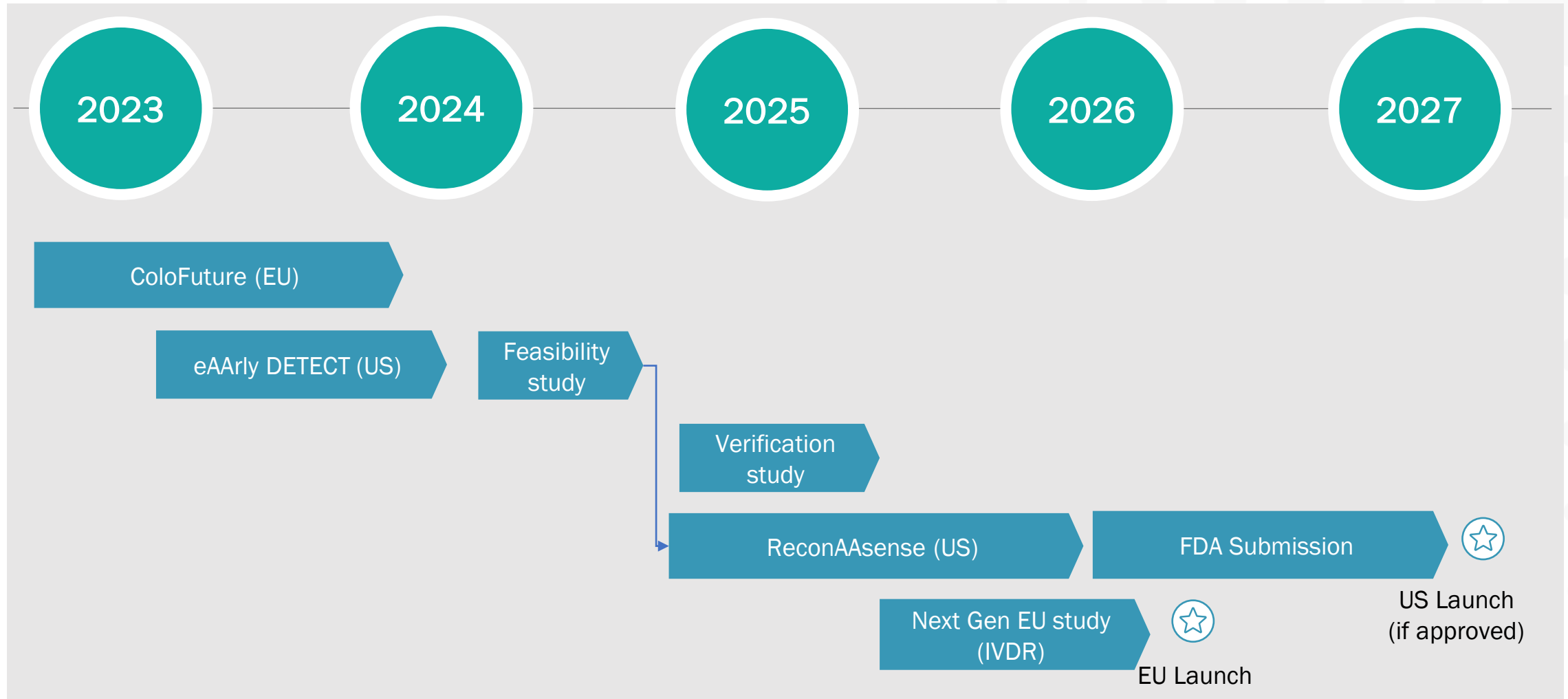


\* > 10,000 subjects screening studies

# Timeline to US Launch & Go-to Market Strategy

*Next Generation CRC Screening Test*

# US & EU Timeline for Next Generation Test





# US Go-To-Market Strategy

6-9 Months

9-12 Months

12-24 Months



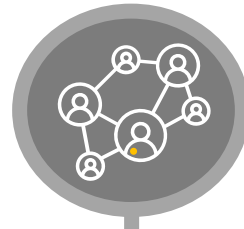
## Analytical and Clinical Validity

- Utilize current study outcomes from major medical conference abstracts to engage commercial and clinical partners
- Commence FDA study



## Clinical Utility and Value

- Deliver value-based health economic models and publications
- Develop additional tools and awareness to commence stakeholder engagement
- Commence clinical marketing studies in parallel with FDA study



## Stakeholder Engagement

- Engage key stakeholder groups including:
- **US Preventative Services Task Force**
- **Payors/CMS**
- **Clinical Organizations (HCP)**
- **Patient Advocacy groups**



## Awareness and Market Adoption

- When commercial partners have been identified, commence market awareness and adoption campaign
- Additional marketing studies including health economic, patient adherence and usability comparison versus competitors

# US Commercial Roadmap: Creating Partnerships and Awareness

## Lab Partnerships



### Target 3 tiers of Lab Partnerships

- Large National Reference Laboratories



- Regional/Specialized Reference Labs



- IDN's and Health Systems



## Payor and KOL Relationships



### Targeting Payors and KOL's

- Target key payor and reimbursement groups
- Partnerships with guideline and professional orgs
- Market access studies and KOL networks
- Health economics and clinical outcomes publications and evidence
- Partnerships with patient advocacy groups

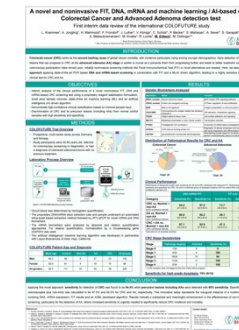


## HCP Access and Education



### Targeting and Educating HCP's

- Use lab partnerships to drive awareness within their physician networks
- HCP's accustomed to CRC screening education
- Position benefits of detecting AA's
- An improved and more convenient Cologuard test
- Clinical evidence publications focused on improved clinical outcomes



# Corporate Update

# Pipeline Development – PancAlert

AN EARLY DETECTION PANCREATIC CANCER SCREENING TEST based on real-time PCR-based detection of biomarkers in stool samples

*In early research stage*



- As GenX individuals age into their 40s and 50s they become part of the age group recommended to begin testing for CRC and more

Potential combo test with ColoAlert®

- Research program supported by a grant from Germany's Federal Ministry for Education and Research



## Microba Partnership:

- Microba and Mainz Biomed to conduct a pilot research project utilizing Microba's proprietary metagenomic sequencing technology and bioinformatic tools to potentially discover novel microbiome biomarkers for pancreatic cancer detection
- Multiple diagnostic opportunities including discovery of diagnostic and prognostic biomarkers by the explorative partnership with Microba
- Faecal microbiota-based screening also applicable to other gastrointestinal cancers

# Leadership Team

## Highly Accomplished Dx Executives



Guido Baechler  
CEO



William Caragol  
CFO



Darin Leigh  
CCO



Dr. Frank Krieg-Schneider  
CTO



Dr. Chris Von Torne  
COO



Philipp Freese  
CBO



Dr. Moritz Eidens  
CSO



Jane Edwards  
VP, Clinical Affairs



Stefan Erlach  
Head of People



Daniel Anderson  
Head of IT

# Leading Industry and Clinical Advisors

## Renowned Scientific and Oncology Experts



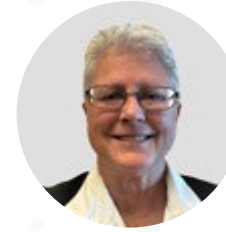
Dr. Heiner Dreismann  
Chairman of Board



Dr. Michele Pedrocchi  
Strategic Advisor



Dr. Rainer Metzger  
Strategic Advisor



Karen L. Richards  
Regulatory Advisor



Dr. Soren Thestrup-Nielsen  
Clinical Advisor



Dr. Kim Turgeon  
Clinical Advisor



Dr. Douglas Rex  
Clinical Advisor



Dr. Timothy Wang  
Clinical Advisor



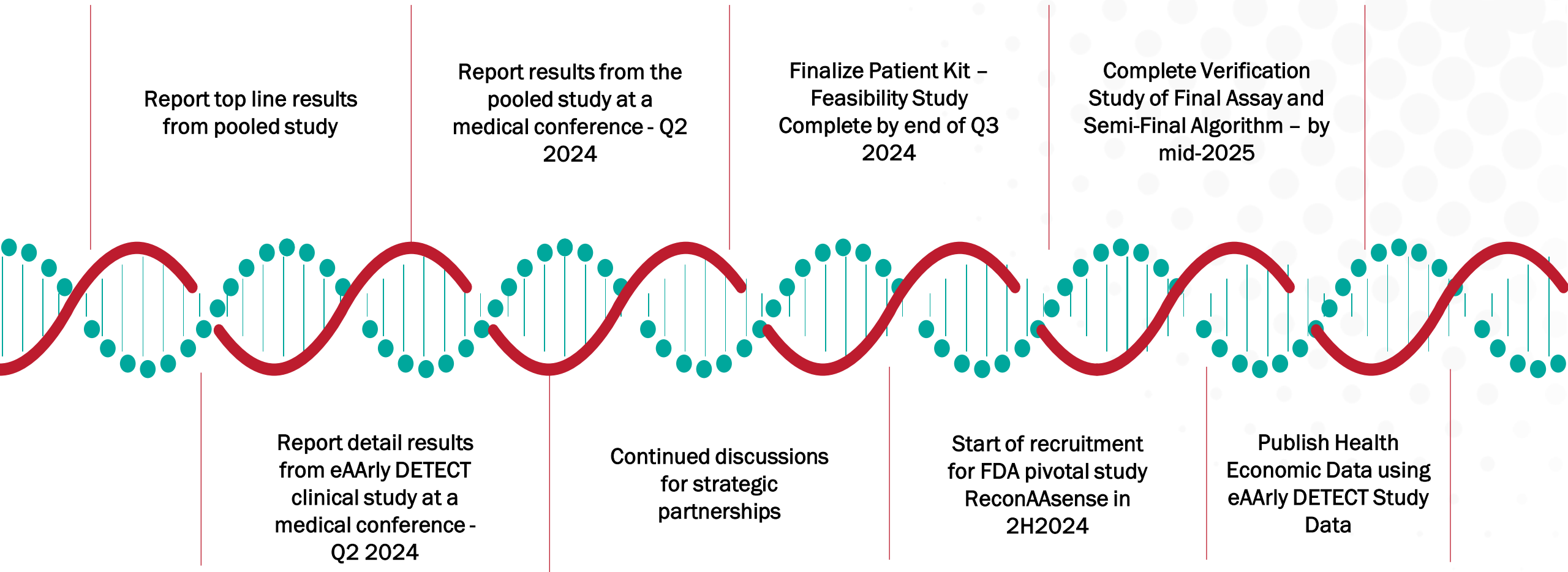
Dr. Matthias Dollinger  
Clinical Advisor



Dr. Jay Wohlgemuth  
Clinical Advisor



# Near Term Milestones



# Summary Financial Data

(unaudited), in \$	Years ended December 31	
	2023	2022
<b>REVENUE</b>		
ColoAlert® Revenue	\$895,479	\$529,877
Cost of Revenue	385,820	347,726
<b>GROSS PROFIT</b>	<b>509,659</b>	<b>182,151</b>
<b>OPERATING EXPENSES</b>		
	56.9%	34.4%
Research and Development	9,590,393	5,019,366
Sales and Marketing	6,158,477	6,396,906
General and Administration	11,405,471	15,209,919
<b>TOTAL OPERATING EXPENSES</b>	<b>27,154,341</b>	<b>26,626,191</b>
<b>NET LOSS</b>	<b>(26,295,727)</b>	<b>(26,387,336)</b>
<b>NON-CASH ADJUSTMENTS TO NET LOSS</b>	<b>4,421,512</b>	<b>10,230,740</b>
<b>ADJUSTED EBITDA</b>	<b>\$(21,874,215)</b>	<b>\$(16,156,596)</b>
<b>BALANCE SHEET DATA:</b>		
	<b>December 31, 2023</b>	<b>December 31, 2022</b>
Cash Balance	\$7,070,925	\$17,141,775
Total Debt	5,966,954	1,983,787
Stockholders' Equity	3,249,226	14,096,067

(i) As of April 15, 2024

(ii) Including ordinary share equivalents

## Capitalization:

Nasdaq Ticker: MYNZ

Basic Shares O/S : 21,886,575 <sup>(i)</sup> <sup>(ii)</sup>

Fully Diluted Shares O/S: 31,211,225 <sup>(i)</sup> <sup>(ii)</sup>



## Analyst Coverage:

Justin Walsh, Jones Trading  
 Ross Osborn, Cantor Fitzgerald  
 Yi Chen, HC Wainright



# Investment Highlights



Highly-differentiated  
flagship product (ColoAlert®)

Significant market opportunity



Disruptive, decentralized business  
model

Developing next-gen product



Strong intellectual  
property position

Strong team



Executed milestones to  
accelerate commercial roll-out



THANK YOU



MAINZBIOMED

CORPORATE PRESENTATION

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