

# **@MAINZBIOMED**

Dedicated to Saving Lives by Transforming At-home Cancer Detection

**Investor Presentation April 2025** 

### Safe Harbor

This presentation may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including those concerning our expectations, anticipations, intentions, beliefs or strategies regarding the future. We intend all forward-looking statements to be covered by the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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 presents a significant opportunity in the molecular diagnostics market.

- US annual market > \$30bn by 20321
- 3rd most-commonly diagnosed cancer<sup>2</sup>
- 2nd leading cause of cancer death globally 2
- Ability to move into large, adjacent areas, including pancreatic cancer and other GI cancers



#### **Developing novel 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%



#### 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
- 25 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>&</sup>lt;sup>1</sup> Global Market Insights <sup>2</sup> https://www.who.int/news-room/fact-sheets/detail/cancer

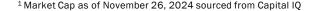
### Recent Developments – Agreements with Thermo Fisher and Quest

## **Thermo Fisher**

- Thermo Fisher Scientific Inc. (NYSE: TMO; Market Cap<sup>1</sup>: \$202.58B) is in serving science, with annual revenue over \$40 billion
- Mainz Biomed entered into a Collaboration Agreement with Thermo Fisher Scientific in November 2024
- Mainz intends to develop its Next Generation assays on the Thermo Fisher Extraction (King Fisher) and PCR (QuantStudio) platforms; Thermo Fisher will contribute development resources to the partnership
- Thermo Fisher is providing Extraction and PCR instrumentation and consumables during development at significant discounts to market



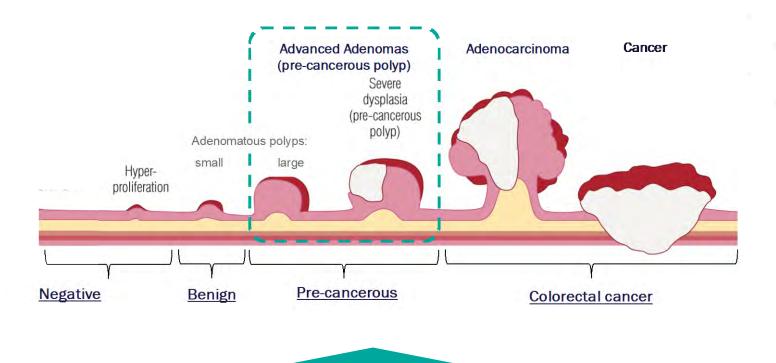
- Quest Diagnostics (NYSE: DGX; Market Cap<sup>1</sup>: \$18.16B), with revenue over \$9 billion in 2023, is a national reference lab serving one out of every three adult patients in the U.S.
- Mainz also entered into Agreements with Quest Diagnostics in November 2024
- Quest will be a lab partner for our pivotal study and will have a semi-exclusive distributor option right in the U.S. for eighteen months from the time of our FDA PMA





### 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)

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- 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 >= 45:
  - 21% sensitivity for adenomas would reduce mortality from CRC by 47%<sup>1</sup>
  - 76% sensitivity for adenomas would reduce mortality from CRC by 67% <sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Ladabaum U, et al. Counting Advanced Precancerous Lesions as True Positives When Determining Colorectal Cancer Screening Test Specificity, JNC. Journal of the National Cancer Institute, Volume 114, Issue 7, July 2022, Pages 1040-1043. https://doi.org/10.1093/jnci/djaco27



### 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
- Fast result turnaround time (3d after sample receipt)





DNA stabilization tube



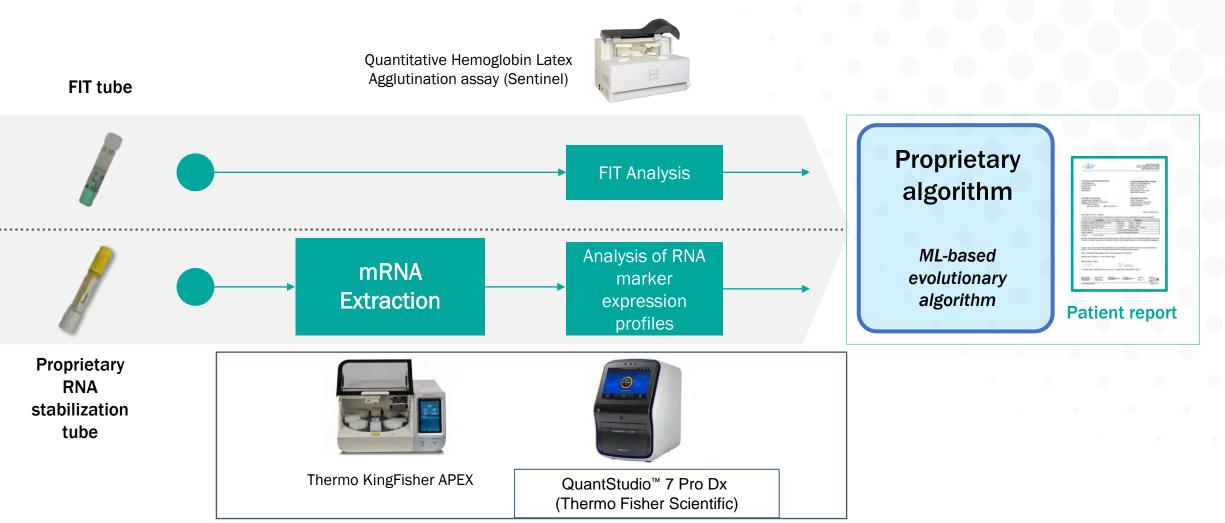
FIT tube

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

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

### Next Generation Screening Test – mRNA Biomarkers & FIT

Combination of mRNA biomarkers & FIT creating 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

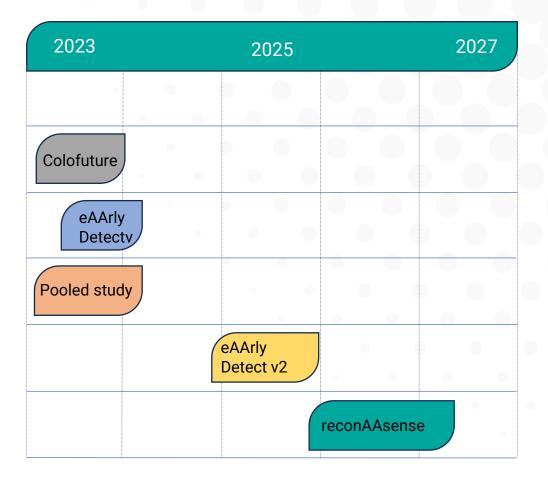
mRNA biomarkers reflect the dynamic changes in gene expression that occur during the progression of adenomas to advanced stages. As adenomas evolve, certain genes may be upregulated or downregulated, and RNA biomarkers can capture these changes, providing insights into the stage of adenoma development

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- 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 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**

Study name	Patient population type	Study size	Study location
ColoFuture	Enriched	436	EU
eAArly Detect	Enriched	254	US
Pooled study	Enriched	690	EU & US
eAArly Detect v2	Average risk	2,000	US
reconAAsense	Average risk	15,000	US



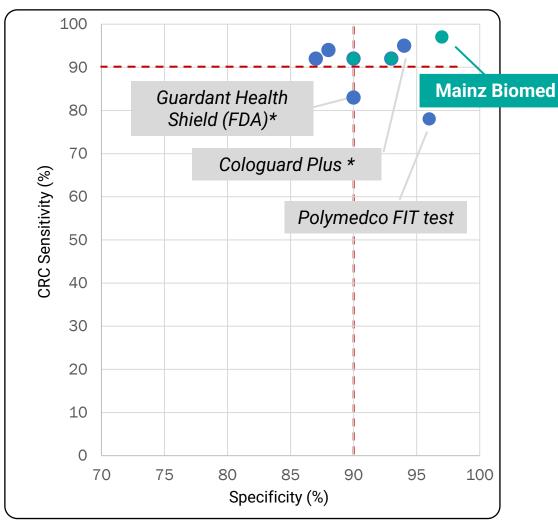
### **Next Generation Test: Clinical Validation and Trials**

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ColoFuture	Enriched	436	EU
eAArly Detect	Enriched	254	US
Pooled study	Enriched	690	EU & US

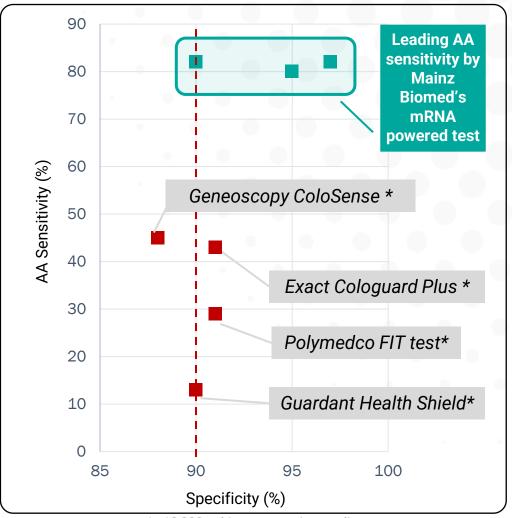
CRC sensitivity	CRC specificity	AA sensitivity	AA specificity
94%	97%	80%	95%
97%	97%	82%	97%
92%	90%	82%	90%

### Leading advanced precancerous lesion sensitivity

#### **CRC** sensitivity



#### **Advanced Adenoma sensitivity**



\* >10,000 subjects screening studies



### Pipeline Development - Next-generation Pancreatic Cancer Detection

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 <sup>1</sup>

Potential combo test with ColoAlert®

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



World renowned advanced bioanalytics platform company

#### Pancreatic Cancer Blood-Test:

- Mainz has partnered with Liquid Biosciences to develop the next-generation detection test for pancreatic cancer
- We have entered into a license and option agreement with Liquid Biosciences to access novel mRNA biomarkers for early detection of pancreatic cancer via blood test
- Independent validation of the algorithm-biomarker combination showed 95% sensitivity and 98% specificity

<sup>1</sup> American Cancer Society (ACS) - Updated their guidelines in 2018 to recommend starting CRC screening at age 45.



### Leadership Team, Board members and advisors



Guido Baechler CEO, Director



William Caragol **CFO** 



Dr. Chris Von Törne COO



Tarrin Khairi-Taraki **VP Commercial** 



Dr. Heiner Dreissmann Chairman & non-**Executive Director** 



Hans Hekland Director



**Gregory Tibbitts** Director

#### Clinical & Strategic advisors



Dr. Michele Pedrocchi Strategic Advisor



Dr. Jay Wohlgemuth **Clinical Advisor** 



Dr. Kim Turgeon **Clinical Advisor** 



Dr. Soren Thestrup-Nielsen **Clinical Advisor** 



Dr. Timothy Wang **Clinical Advisor** 



Dr. Matthias Dollinger **Clinical Advisor** 

### **Summary Financial Data**

	Year Ended December 31	
(unaudited), in \$	2024	2023
REVENUE		
ColoAlert® Revenue	\$893,991	\$895,479
Cost of Revenue	319,108	385,820
GROSS PROFIT	574,883	509,659
OPERATING EXPENSES	64%	57%
Research and Development	5,839,033	9,590,393
Sales and Marketing	6,581,333	6,158,477
General and Administration	6,849,925	11,405,471
TOTAL OPERATING EXPENSES	19,270,291	27,154,341
NET LOSS	(21,650,663)	(26,295,727)
NON-CASH ADJUSTMENTS TO NET LOSS	4,508,906	4,421,512
ADJUSTED EBITDA	\$(17,141,757)	\$(21,874,215)
BALANCE SHEET DATA:	December 31, 2024	December 31, 2023
Cash Balance	\$6,235,670	\$7,070,925
Total Debt	\$2,125,254	\$5,966,954
Stockholders' Equity	\$6,046,543	\$3,249,226

#### **Capitalization:**

Nasdaq Ticker: MYNZ

Basic Shares O/S: 3,439,853(i)

Fully Diluted Shares O/S: 7,400,990(i)



(i) As of March 31, 2025



### **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







#### INVESTOR PRESENTATION

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