

3.

Immunodiagnosics

Disclaimer

In General. This disclaimer applies to this presentation and any oral comments of any person presenting it. This document, taken together with any such oral comments, is referred to herein as the “Presentation”. This Presentation has been prepared by DiaSorin S.p.A. (“Diasorin” or the “Company” and, together with its subsidiary the “Group”). This Presentation is being furnished to you for information purposes only and for use in presentations of the industrial plan of the Group.

Verbal explanation. This Presentation has to be accompanied by a verbal explanation. A simple reading of this Presentation without the appropriate verbal explanation could give rise to a partial or incorrect understanding.

No offer to purchase or sell securities. The information, statements and opinions contained in this Presentation are for information purposes only and do not constitute a public offer under any applicable legislation or an offer to sell or solicitation of an offer to purchase or subscribe for securities or financial instruments or any advice or recommendation with respect to such securities or other financial instruments.

Rounding. Due to rounding, numbers presented throughout this Presentation may not add up precisely to the totals provided and percentages may not precisely reflect the absolute figures.

Miscellanea. This Presentation has been prepared on a voluntary basis. Diasorin is therefore not bound to prepare similar presentations in the future, unless where provided by law. Neither the Company nor any member of the Group nor any of its or their respective representatives, directors, employees or agents accept any liability whatsoever in connection with this Presentation or any of its contents or in relation to any loss arising from its use or from any reliance placed upon it.



Forward-looking statements

This document contains forward-looking statements that are based on current expectations, estimates, forecasts and projections about the industries in which Diasorin operates and the beliefs and assumptions of the management of Diasorin. In addition, the management of Diasorin may make forward-looking statements orally to analysts, investors, representatives of the media and others. In particular, among other statements, certain statements regarding future financial performance, the achievement of certain targeted metrics at any future date or for any future period, trends in results of operations, margins, costs, return on capital, risk management and competition are forward-looking in nature. These statements may include terms such as “may”, “will”, “expect”, “could”, “should”, “intend”, “estimate”, “anticipate”, “believe”, “remain”, “on track”, “design”, “target”, “objective”, “goal”, “forecast”, “projection”, “outlook”, “prospects”, “plan”, or similar terms. Forward-looking statements are not guarantees of future performance and are, by their nature, subject to inherent risks, uncertainties and assumptions that are difficult to predict because they relate to events and depend on circumstances that may or may not occur or exist in the future and, as such, undue reliance should not be placed on them.

Forward-looking statements do not take into account any additional effects that may arise from impacts on the global market in which Diasorin operates and, more generally, on the macroeconomic scenario.

Actual results may differ materially from those expressed in forward-looking statements as a result of a variety of factors, including: the impact of the COVID-19 pandemic, the ability of the Group to create and launch new products successfully; changes in the global financial markets, general economic environment and changes in demand for diagnostic/healthcare/life sciences products, which is subject to cyclicality; changes in local economic and political conditions, changes in trade policy and the imposition of global and regional tariffs or tariffs targeted to the diagnostic/healthcare/life sciences industry, the enactment of tax reforms or other changes in tax laws and regulations; the Group's ability to offer innovative, attractive products; various types of claims, lawsuits, governmental investigations and other contingencies, including product liability and warranty claims, investigations and lawsuits; material operating expenditures in relation to compliance with health and safety regulations; the intense level of competition in the diagnostic/healthcare/life sciences industry, which may increase due to consolidation; the Group's ability to fund its defined benefit pension plans; the ability to access funding to execute its business plans and improve its own businesses, financial condition and results of operations; the Group's ability to realize anticipated benefits from joint venture arrangements; disruptions arising from political, social and economic instability; commercial risk due to the fact that the Group operates in a market characterized by the presence of large competitors; risk associated to the maintenance of relationship with customers and strategic partners; risks associated with relationships with employees and suppliers; increases in costs, disruptions of supply or shortages of raw materials; developments in labor and industrial relations and developments in applicable labor laws; exchange rate fluctuations, interest rate changes, credit risk and other market risks; political and civil unrest; earthquakes or other disasters.

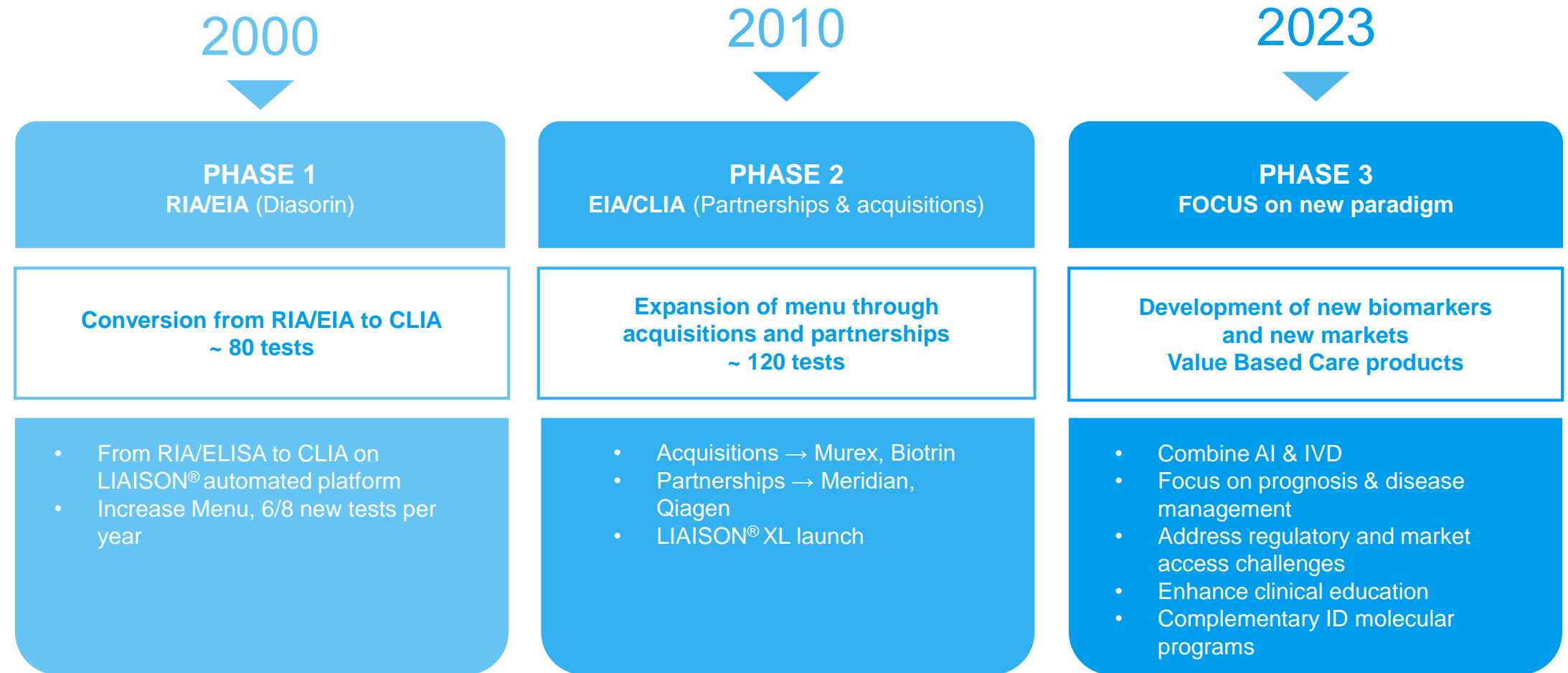
Any forward-looking statements contained in this document speak only as of the date of this document and Diasorin disclaim any obligation to update or revise publicly forward-looking statements. Further information concerning the Group and its business, including factors that could materially affect the Group's financial results, are included in Diasorin's reports and filings with CONSOB and Borsa Italiana.

No update. The information and opinions in this document is provided to you as of the dates indicated and Diasorin does not undertake to update the information contained in this document and/or any opinions expressed relating thereto after its presentation, even in the event that the information becomes materially inaccurate, except as otherwise required by applicable laws.

Non-IFRS and Other Performance Measures. This document contains certain items as part of the financial disclosure, which are not defined under IFRS. Accordingly, these items do not have standardized meanings and may not be directly comparable to similarly-titled items adopted by other entities. Diasorin management has identified a number of “Alternative Performance Indicators” (“APIs”). These APIs (i) are derived from historical results of Diasorin and are not intended to be indicative of future performance, (ii) are non-IFRS financial measures and, although derived from the financial statements, are unaudited and (iii) are not an alternative to financial measures prepared in accordance with IFRS. The APIs presented herein include EBIT¹, EBITDA², adjusted EBITDA³, Net Financial Position⁴ and Free Cash Flow⁵. These measures are not indicative of historical operating results, nor are they meant to be predictive of future results. These measures are used by the management to monitor the underlying performance of the business and operations. Similarly entitled non-IFRS financial measures reported by other companies may not be calculated in an identical manner, consequently the measures reported in this document may not be consistent with similar measures used by other companies. Therefore, investors should not place undue reliance on this data.

¹ EBIT is defined as the “Operating Result” net of interests and taxes – ² EBITDA is defined as the “Operating Result”, gross of amortization and depreciation of intangible and tangible assets. EBITDA is a measure used by the Company to monitor and evaluate the Group's operating performance and is not defined as an accounting measure in IFRS and therefore shall not be considered an alternative measure for assessing the Group's operating result performance. - ³ Adjusted EBITDA is defined as Adjusted EBITDA, excluding extraordinary costs and expenses incurred in the Luminex transaction announced on April 11, 2021 - ⁴ The Net Financial Position is defined as the algebraic sum (positive balance sheet assets and negative balance sheet liabilities) of cash and cash equivalents and other current financial assets, minus current financial liabilities and non-current financial liabilities. - ⁵ Free Cash Flow is defined as the set of means available to the Company and is equal to cash flows deriving from operating activities net of interest received or paid, and net of investments and divestments of fixed assets.

Diasorin Immunodiagnostic Menu Development

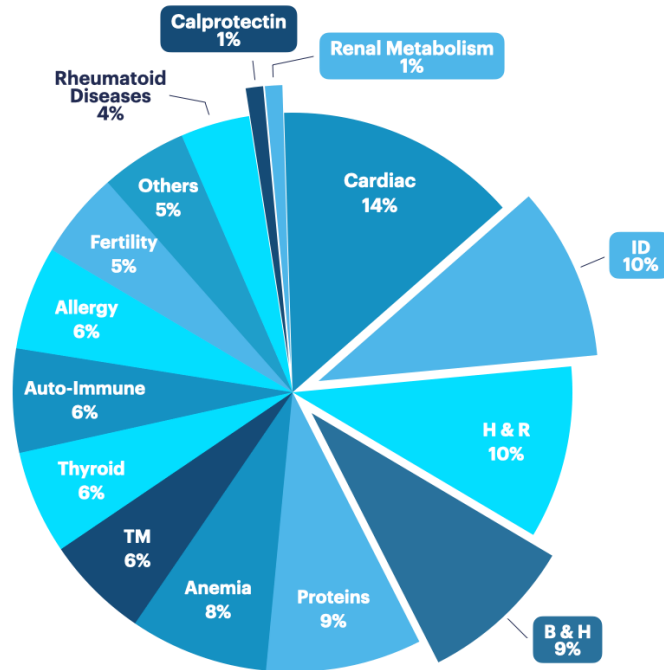


Immunodiagnostic Market, Size And Rationale For Phase 3.0

IVD market = € 60 billions (Excluding Covid)*

- Whereof 23% → Immunoassay market size = 14 €/bn
- Estimated growth: 2% on annual base

EU Immunoassay market segmentation (Q2'23 EDMA(**) Data)
(22% of total Immunoassay market)*

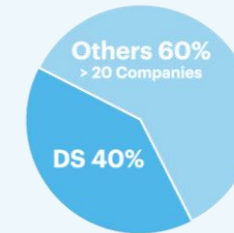


(*) Berenberg MedTech report, Nov 22

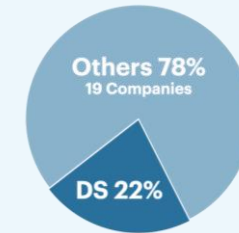
(**) EDMA: European Diagnostic Manufacturers Association

EU EDMA(**) data 12 months rolling, Q2'23

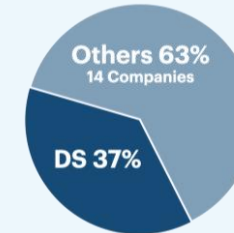
Infectious disease



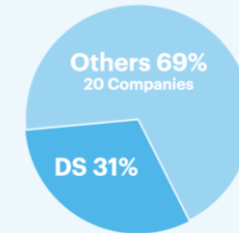
Bone & mineral



Calprotectin



Renal metabolism

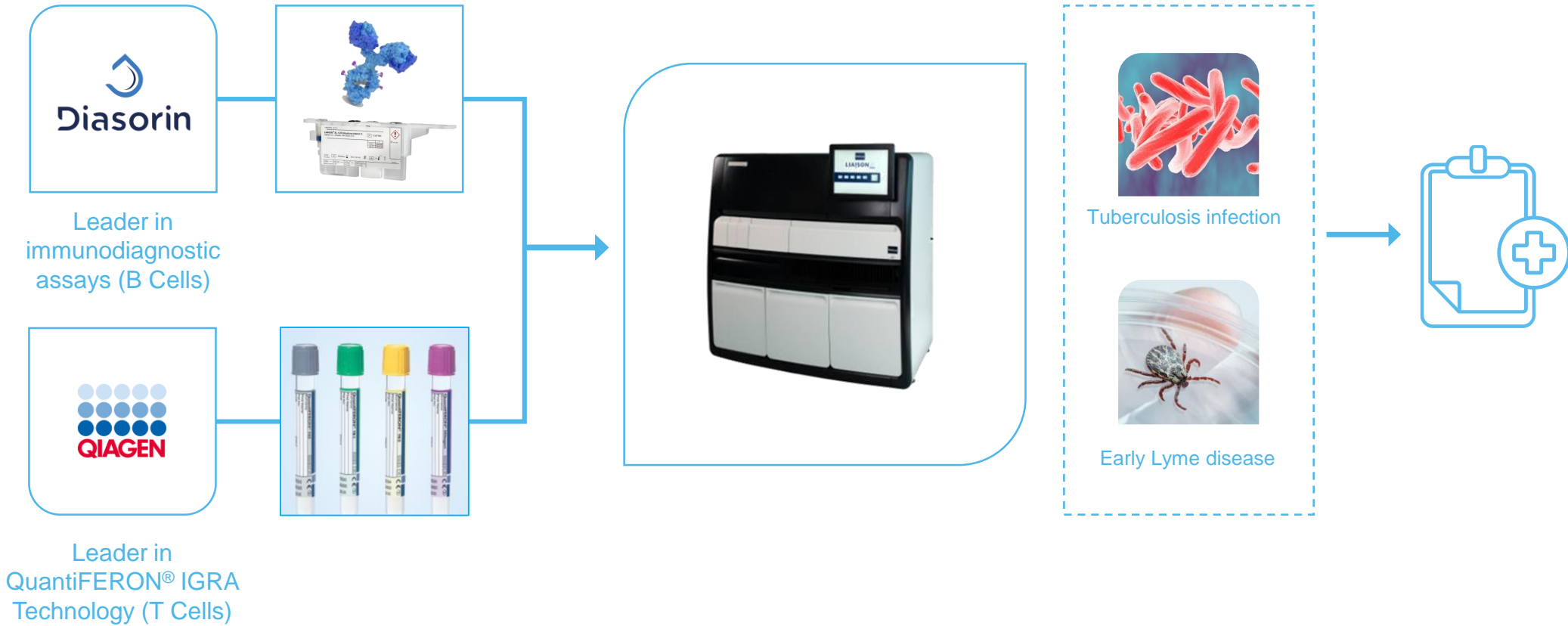


DS = Diasorin

DIASORIN STRATEGY:
Driving the market grow with 3rd generation assays in ID and GI/Stool areas

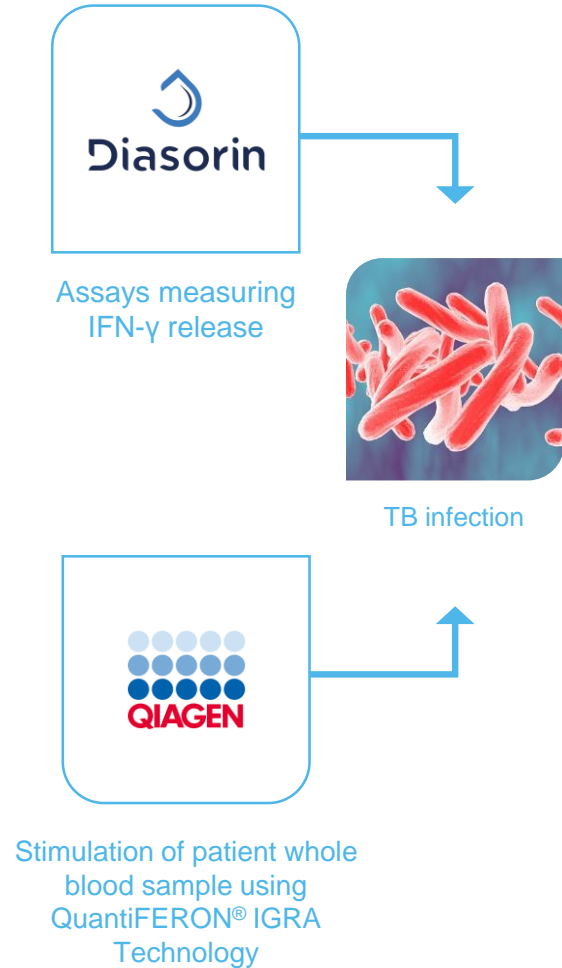
QIAGEN Partnership On QuantiFERON® Technology

QIAGEN QuantiFERON® Technology and Diasorin IVD Testing expertise combined



Tuberculosis Infection: Market And Opportunity

- Tuberculosis (TB) caused by *Mycobacterium tuberculosis* with 2 broad clinical forms:
 - Latent TB infection (LTBI)
 - Active TB disease
- LTBI can progress to active disease in patients with suppressed immune systems
- Patients with active disease can spread infection through aerosol transmission
- WHO Global Tuberculosis program goal = TB free with zero deaths, targeting:
 - Highly vulnerable population
 - Healthcare workers and beyond, such as in the fields of social protection, labour, immigration and justice
- TB testing & diagnosis
 - Skin test: injection of a small amount of tuberculin into skin
 - Blood testing (IGRA) is looking for the immune response to infection, not the pathogen itself
 - Blood testing (IGRA): searching for the immune response to *Mycobacterium tuberculosis* infection

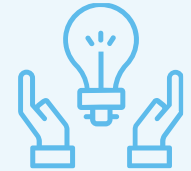


Worldwide estimated
LTBI market size ~
70-80 mln tests



North America 20 million
Latin America ~8 million
EMEA ~ 5 million
Japan ~ 7 million
China ~15 million
Asia-Pacific ~15 million

A winning partnership
solution (**IGRA
Technology +
Automation**)

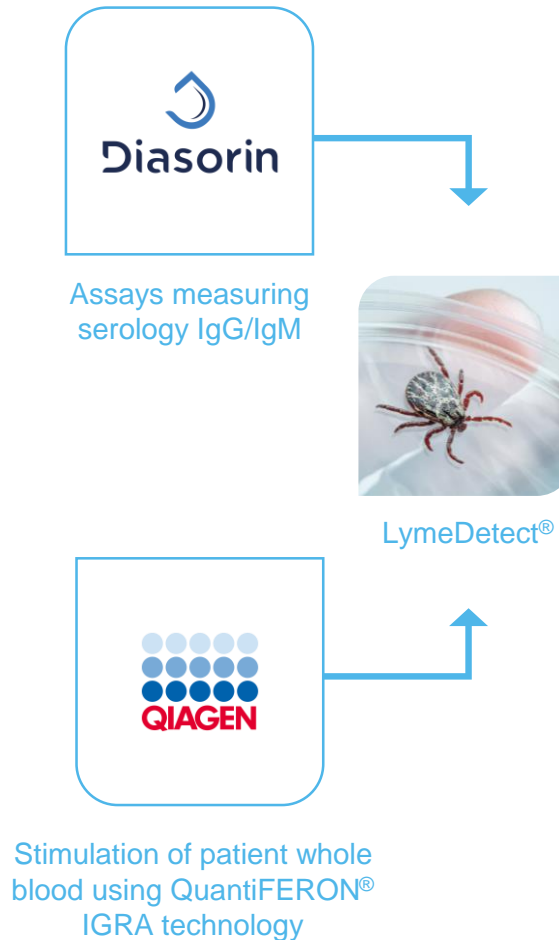


**~30% of TB testing
already converted
from skin test in last
few years**



LIAISON® LymeDetect® To Address Lyme Disease: An Emergent Challenge

- Lyme disease caused by the bacterium *Borrelia burgdorferi* transmitted to humans by infected *Ixodes* ticks
- Symptoms may appear within a few days and/or later (months), following an infectious tick bite typically during spring and summer
- Common sign of early infection: bulls eye rash (*erythema migrans*) 1-2 weeks post exposure
- If untreated, Lyme diseases can evolve into severe forms with neurological symptoms, heart problems and arthritis
- Testing & diagnosis: serology IgG and IgM (less sensitive in Early Lyme disease) cannot differentiate between past and new infections



Potential annual U.S. market for **Acute Phase** threatening: ~120 \$/mln



Algorithm leading to **increased clinical determination: >30-50%** vs. sTTT



The only test available for Acute Phase

LymeDetect®
Diagnostic Algorithm
(IgG + IgM + IGRA)

Partnership benefits:

- **Improving** early patient **identification**
- **Better** driving of **antibiotic therapy decision** and **appropriate treatment**



Focus: U.S. market, with go-to-market strategy in place.
Expected submission: Dec 2023

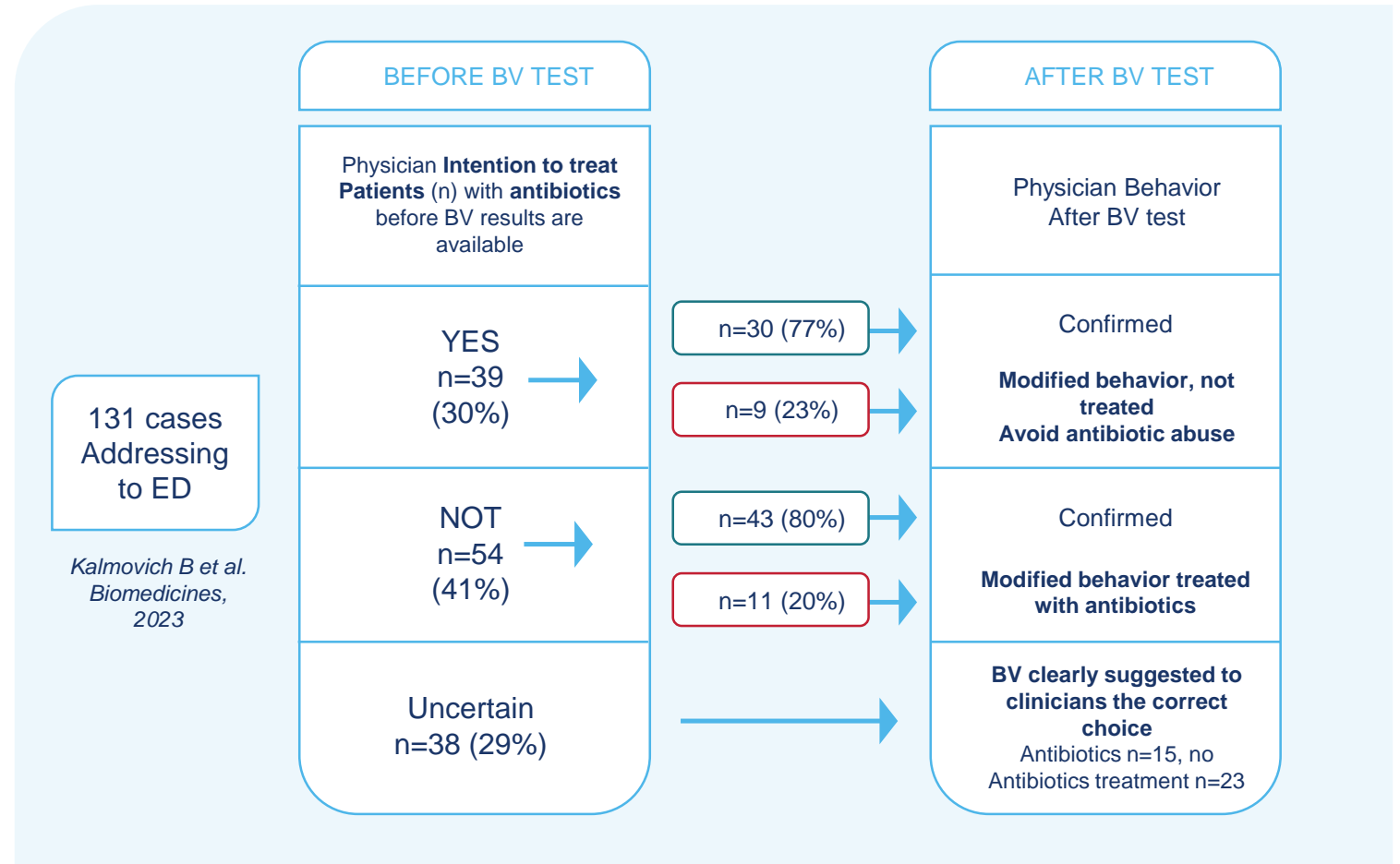
LIAISON® MeMed BV®, Solving The Clinical Dilemma: Bacterial Or Viral Infection?

- 4.7 mln of pediatric patients/year in the U.S. address to Emergency Department (ED) with suspect infections
- ED Physicians challenged to quickly decide if patients need:
 - Hospitalization, warding or safely dismissal
 - Treatment with antibiotics, considering data report showing:
 - 40% antibiotics overuse
 - 20% antibiotics underuse = risk of exacerbation



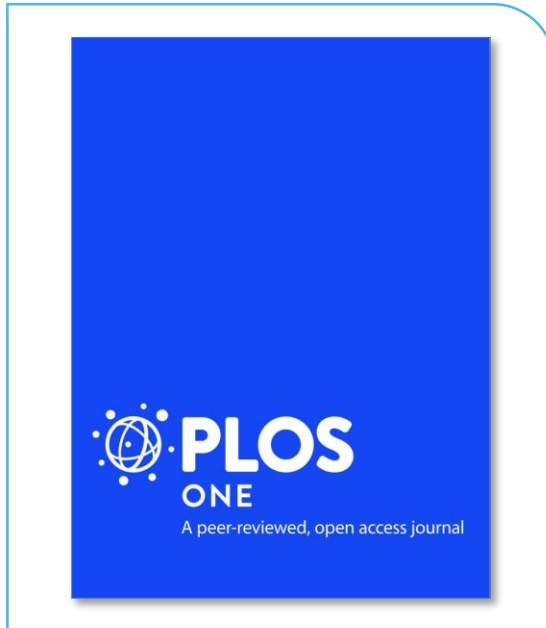
- A semi-quantitative assay test measuring 3 non-microbial (host) signature proteins (TRAIL, IP-10, and CRP)
- An algorithm defining bacterial or viral likelihood score for infection (discrimination B/V)

LIAISON® MeMed BV®: empowers clinical decision-making

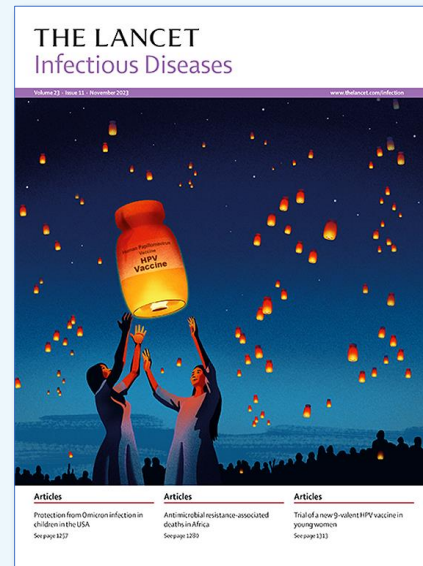


MeMed BV[®] high performance independently confirmed in select studies

Thousands of patients enrolled (2013 - 2022)



March 2015
Curiosity study



April 2017
Opportunity study



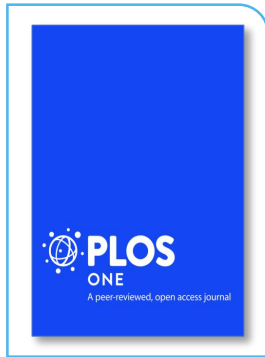
October 2017
Pathfinder study



October 2021
Autopilot study

MeMed BV[®] high performance independently confirmed in select studies

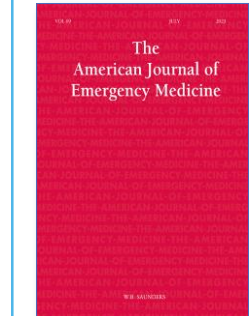
Multiple new evaluations, and real-world evidence on thousands of patients show positive results - published by customers and collaborators in 2023



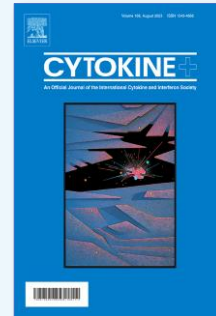
January
2023
Rosetta study



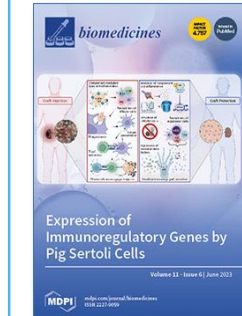
February 2023
German RWE study



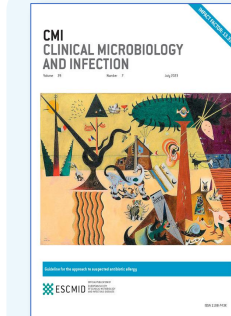
March
2023
Maimonides Operational study



May
2023
COVID Severity study



May
2023
Maccabi Pilot real world evidence study



June
2023
Observer study

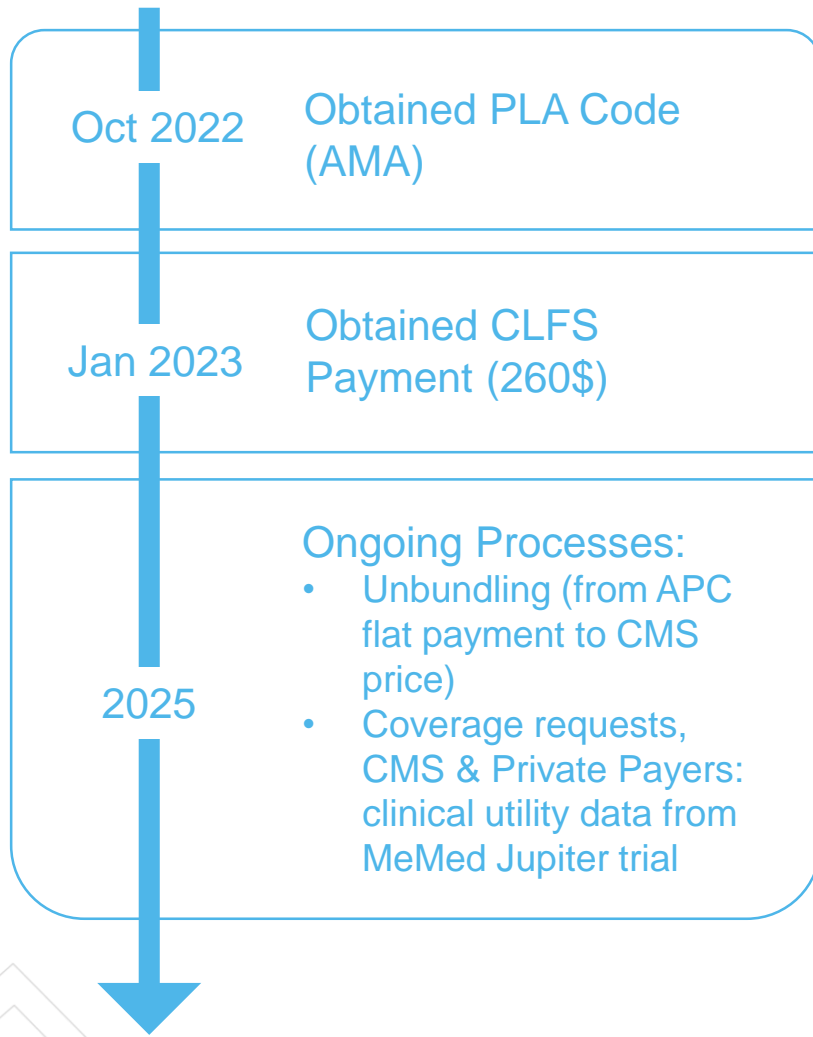


June
2023
Texas Children's Validation study



November
2023
Spirit study

Focus On U.S. MeMed Reimbursement And Market Creation



MeMed & hospital strategy



- Expanded presence to 5 regions: additional 15 sales reps + 6 scientific professionals
- Offering a complete solution for LIAISON® XL/XS on Hub centers
- Demand creation team of 11 professionals added to drive sales cycles and increase utilization rates
- Focused & Modular geo-targeting campaign in key growth regions through Doximity and Sermo platforms to create clinicians interest & leads for outside the lab

Primary U.S. Focus, potential market 400 \$/mIn
Program in place for EU

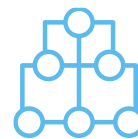
Differential Diagnosis IBD With Novel Biomarkers And Machine Learning Tools

- IBD(*) diagnosis: requires the differentiation from IBS(**) and a conclusive diagnosis is often reached by colonoscopy (invasive and costly procedure)
- Calprotectin is a “non-specific” marker for intestinal neutrophilic inflammation and is higher when IBD is present
- Low fCAL levels (<20 µg/g) = very specific in ruling out IBD, high levels (>250-300 µg/g) = likely indicative of IBD
- The challenge is to provide physicians with an assay aiming at 100% diagnostic precision overcoming the zone of diagnostic uncertainty and accelerating diagnosis time

Global Burden Of Inflammatory Bowel Disease, 2017
(*) Inflammatory Bowel Disease
(**) Irritable Bowel Syndrome



A new assay
calprotectin + 2 fecal biomarkers
to identify the IBD patients in the
less performant range



An algorithm based on
computational method will combine
the biomarkers in a single
reportable result intended to aid in
supporting rule-in/rule-out decision
for IBD/IBS

Calprotectin: growing at double-digit rate in many geographies (e.g. China & U.S)

Estimated market opportunity with Calprotectin 3.0: 140 €/mln



Machine learning tool = identifies new fecal biomarker combinations

Calprotectin 3.0: improves IBD patients identification from 70% to 99%

Calprotectin 3.0 algorithm

New Calprotectin 3.0 algorithm will:

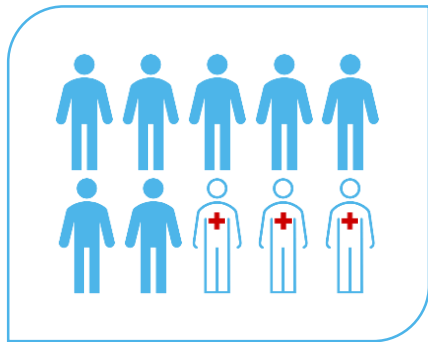
- Reduce unnecessary colonoscopies (cost saving)
- Improve patient quality of life with a timely and precise diagnosis



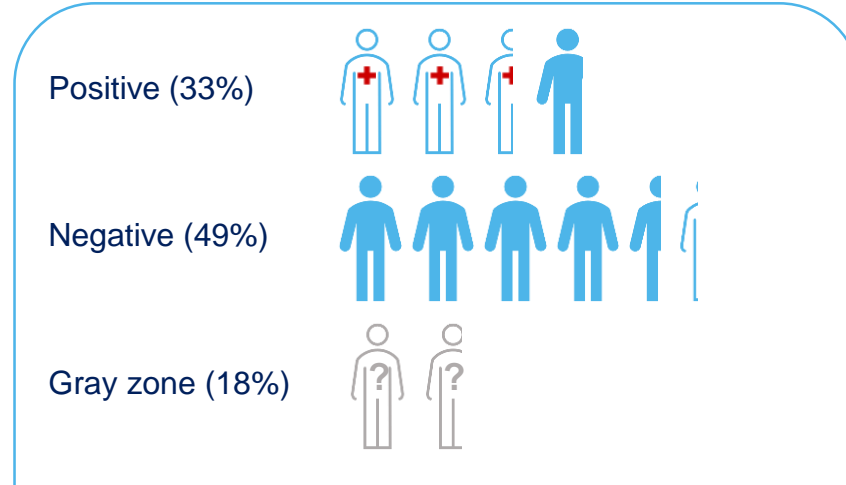
Expected submission: 2025

Impact On Patient Pathway With Calprotectin 3.0

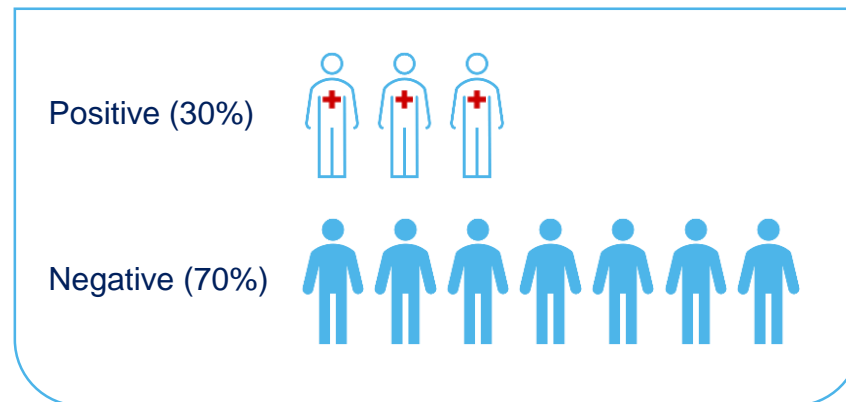
Patients presenting with chronic abdominal pain (~30% sick)



Current flow



Calprotectin 3.0 algorithm



Undesired effects

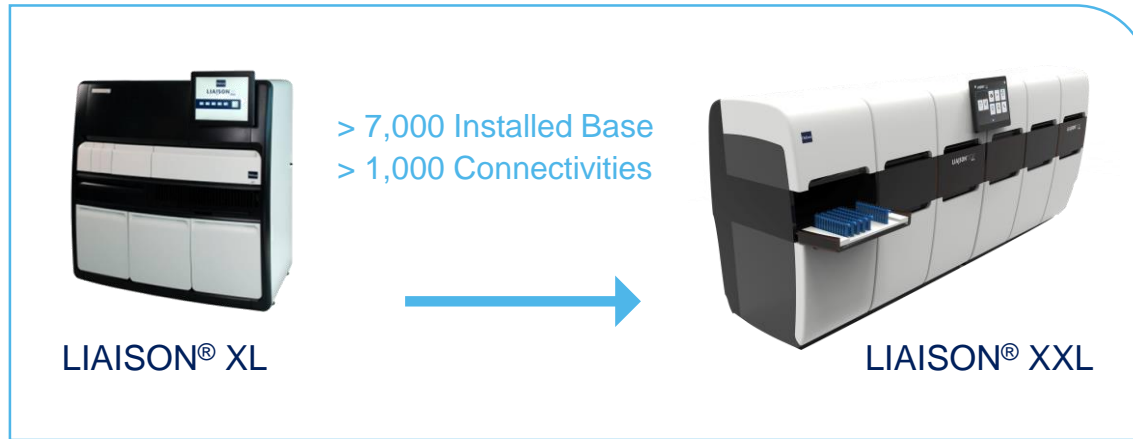
- Unnecessary colonoscopies on healthy subjects (~8% of tested subjects)
- Delayed diagnosis to sick individuals (~2% of tested subjects)
- Repeat of Calpro tests, and unnecessary colonoscopies if inconclusive (all 18% of tested subjects)

Key advantages

- Timely and accurate diagnosis
- Avoidance of unnecessary colonoscopies (invasive and costly for the healthcare systems)

LIAISON® XXL: The Next Step Forward In The Instrumentation Journey

Faster systems to increase productivity



Same cartridge
for all the
LIAISON®
solutions

XS
XL
XXL



Large labs and hospital consolidation
+
Continuous Diasorin portfolio expansion

New LIAISON® XXL platform

- Higher Productivity
- Higher footprint efficiency
- Increased throughput regardless of mix and connectivity
- Better connectivity with other suppliers
- Increased size flexibility using same cartridge technology
- Tailored customer solution, sample bay, direct water supply

- Convert gradually existing LIAISON® XL installed base to allow customer's growing needs
- **Expected submission: 2025**



Diasorin

Investor Day 2023
December 15, 2023

3.0