

Building a Commercial Platform

HC Andersen

October 22, 2024



Forward-looking Statements

References herein to this presentation shall mean and include this document, any oral presentation accompanying this document provided by BioPorto A/S (the “Company” or “BioPorto”), and any further information that may be made available in connection with the subject matter contained herein. By viewing or receiving or reading this presentation or attending any meeting where this presentation is made, you agree to be bound by the limitations, qualifications and restrictions set out below.

This presentation contains forward-looking statements. Words such as “believe”, “expect”, “may”, “plan”, “strategy”, “estimate”, “target” and similar expressions identify such forward-looking statements. Statements other than historical facts included in this presentation concerning our plans, objectives, goals, future events and performance are forward-looking statements. They involve risks, uncertainties and other factors, which may cause actual results, performance and achievements to differ materially from the results discussed in the forward-looking statements. These include numerous assumptions, risks and uncertainties, many of which are beyond BioPorto’s control. These risks and uncertainties are described from time to time in BioPorto’s Announcements and in its 2023 Annual Report under Risk Factors. We undertake no obligation

to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date of this presentation.

This presentation is for information purposes only and does not constitute an offer to sell or a solicitation of any offer to buy any securities issued by the Company in any jurisdiction. The information contained herein is not for distribution in the United States of America. This document does not constitute, or form part of, an offer to sell, or a solicitation of an offer to purchase, any securities in the United States. The Company’s securities have not been and will not be registered under the U.S. Securities Act of 1933, as amended (the “Securities Act”) and may not be offered or sold within the United States absent registration or pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act. There is no intention to offer or solicit an offer to buy any securities in the Company in the United States or to make a public offering of the securities in the United States. Company securities may be sold only to qualified institutional buyers (as defined in Rule 144A under the Securities Act) in reliance on Rule 144A.

Agenda

How NGAL moves from research to clinical use

1. Product & Market
2. Commercial Strategy – Making a market
3. Commercial Tactics
4. US Traction
5. ROW Traction
6. Partnerships
7. Going Forward

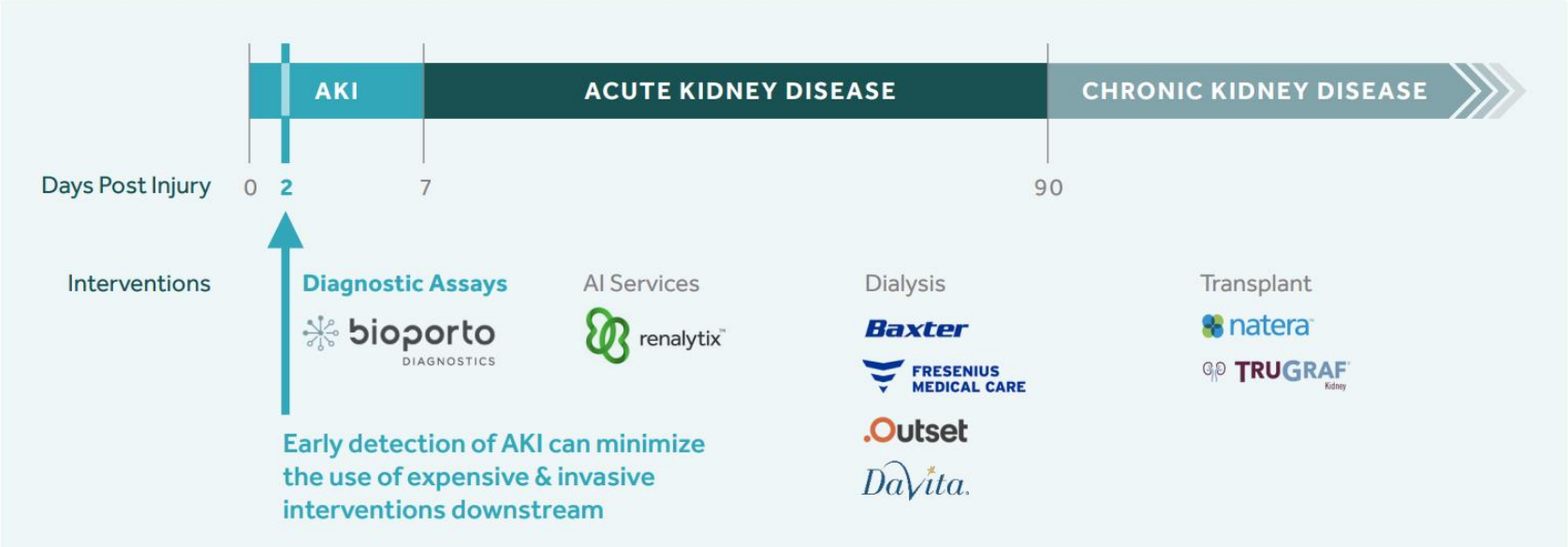


SVP Global Marketing and
US Commercialization

Product & Market



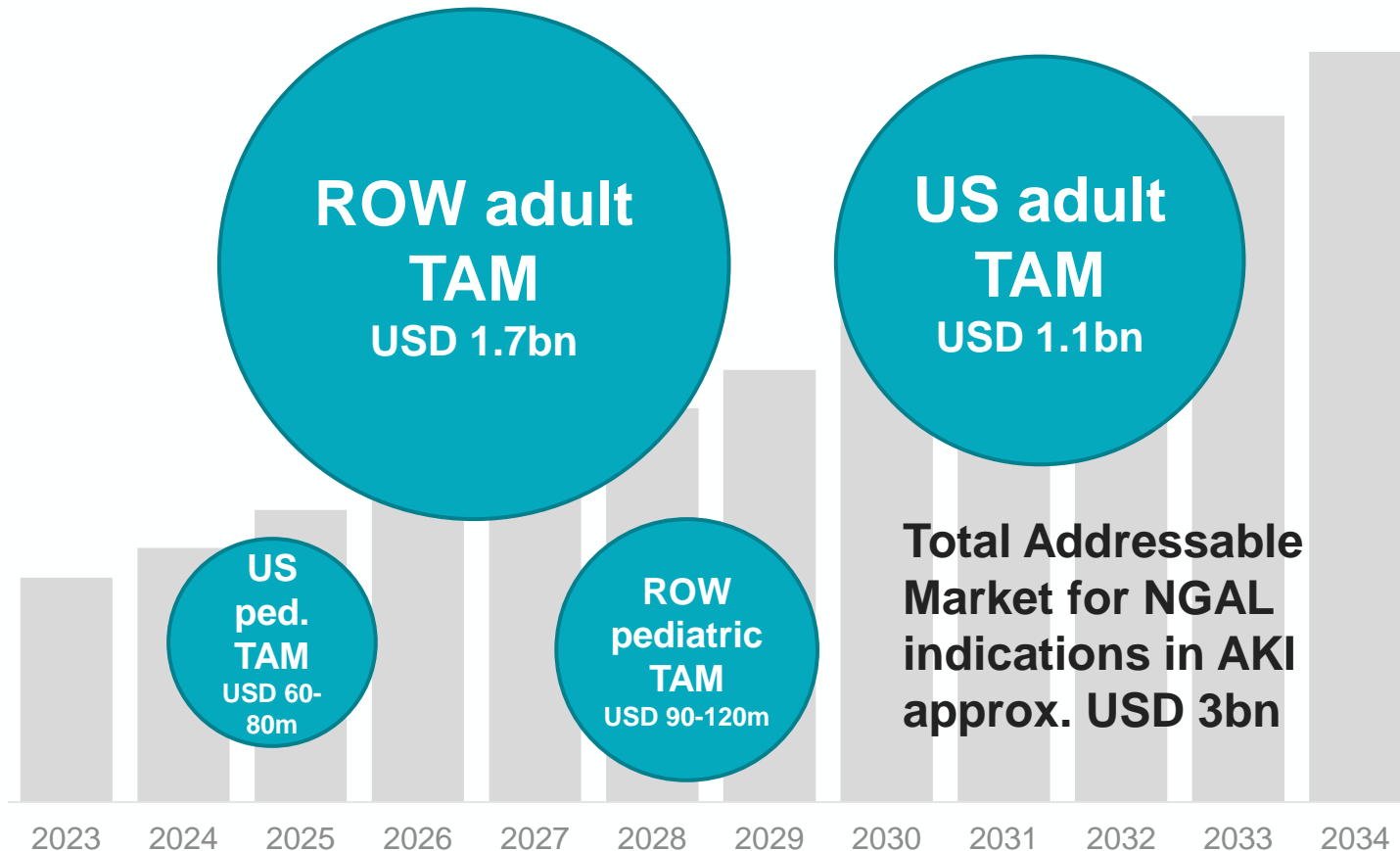
Kidney Investments are a new growth area



Biomarkers in the space which have a similar offering:

PenKid from Shingotec	KIM1	Cystatin C
<ul style="list-style-type: none"> Functional, commercially available POC in EMEA, technical agreement with BC 	<ul style="list-style-type: none"> Research ELISA only, part of the Renalytix product = send out test for CKD evaluation 	<ul style="list-style-type: none"> Functional, commercially available on Big 5 clinical chem, CKD evaluation

AKI Diagnostics Market Growing at +5% yearly driven by changing paradigm



- The AKI market is driven by advances in early detection and diagnostic technologies. McKinsey notes a need to move to preventative care.
- Recent advancements are transforming paradigm from Serum Creatinine to earlier and more accurate diagnosis, crucial for improving patient outcomes.
- Recent development of novel biomarkers and diagnostic assays that offer greater sensitivity and specificity in detecting AKI such as Kidney Injury Molecule-1 (KIM-1), Neutrophil Gelatinase-Associated Lipocalin (NGAL), and Interleukin-18 (IL-18) are gaining prominence.



Our Product: NGAL Improves the Standard of Care in AKI – MARKET MAKER

SCr is Inadequate

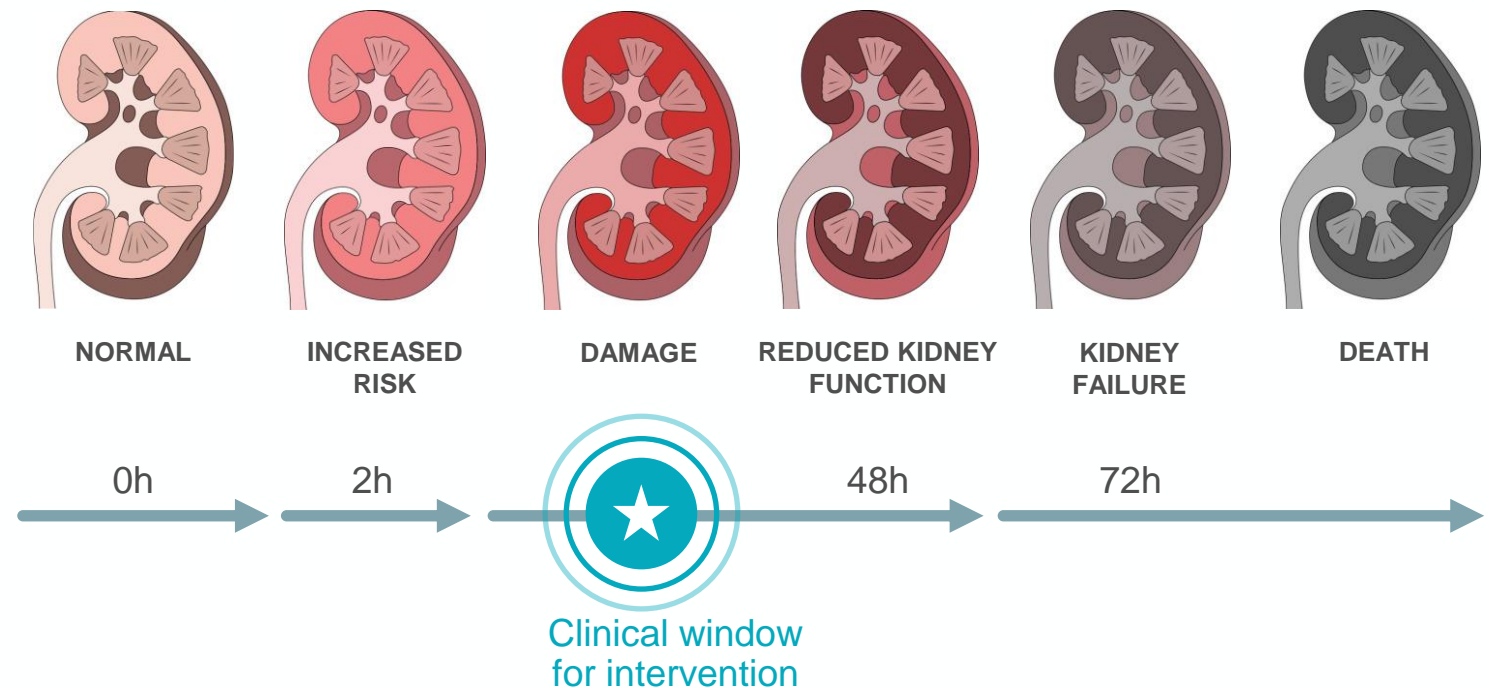
- 2-3 days delayed¹
- 43% of patients missed using SCr alone²
- 66% of AKI misclassified³
- 70% of clinicians believe they are missing AKI⁴

The NGAL Test/ProNephro AKI

Actionable Results within 2 Hours

Standard of Care Serum Creatinine (SCr)

48-72 Hours to respond



NGAL assays designed to run on major clinical chemistry instruments



High-Value Diagnostic Price Point

No investment in capital equipment

High margins even at today's scale



Validation of agnostic assay, laboratorian view



David Alter, MD

Director of clinical chemistry,
Department of Pathology, and
associate professor of
pathology and laboratory
medicine, Emory University
School of Medicine, July 2024

*“The **real winners** over time will be independent companies like **Bio-Porto Diagnostics**, which developed an **NGAL assay** and worked closely with IVD companies so the assay could be adapted to Roche, Olympus, Beckman, Siemens, and so forth. People are uncomfortable being tied down to a platform because there are a few assays they can’t find anywhere else. I was impressed that Emory brought the NT-proBNP onboard to address the concerns of the cardiologists because we were lucky enough to have another site that had the ability for the assay. “*

Commercial Strategy



BioPorto Commercial is on plan

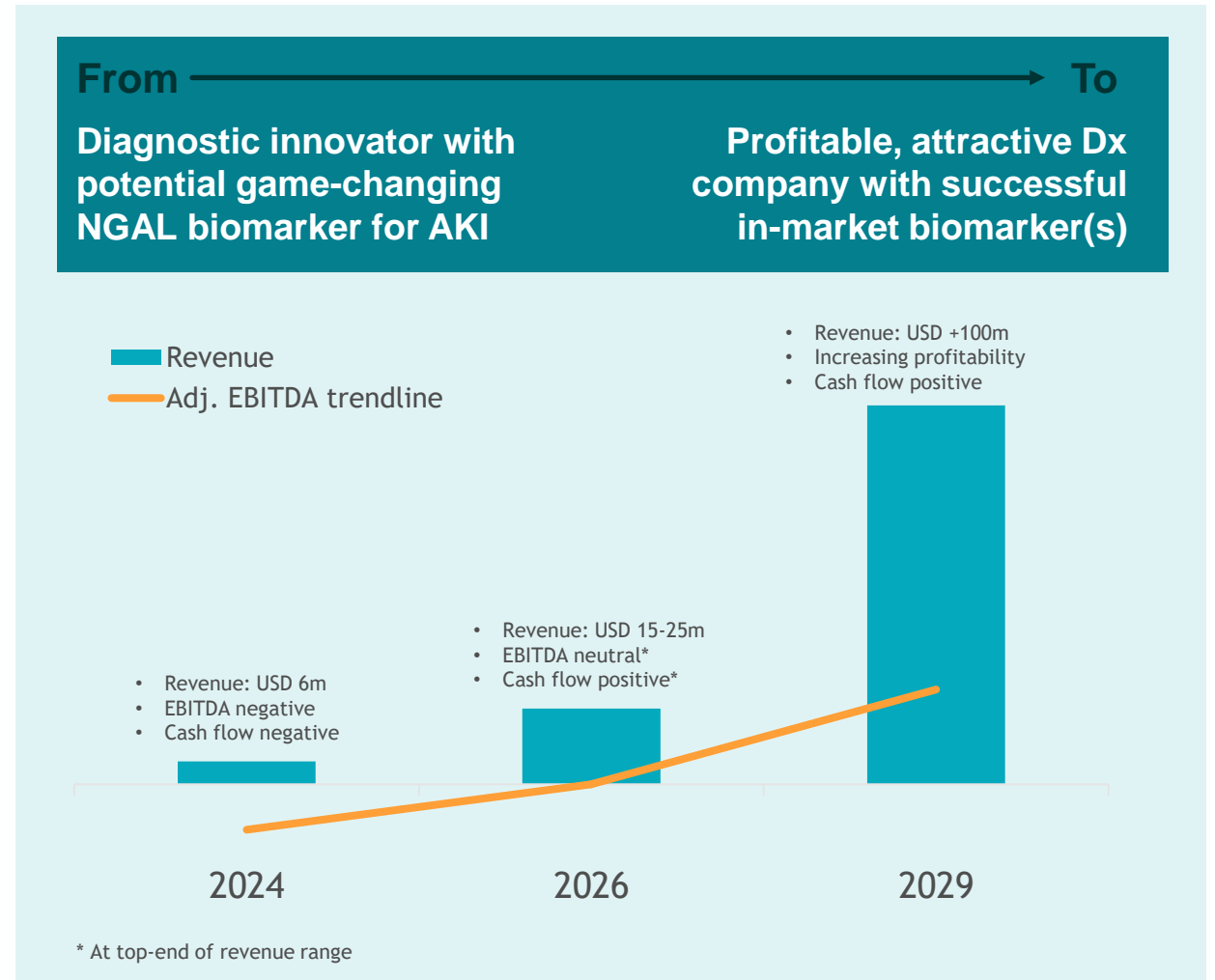
BioPorto is the **NGAL Market Maker**

Current Key Commercial Objectives

- Grow usage in Pediatrics/Young Adults (US)
- Initiate clinical usage in RoW
- Expand strategic partnership portfolio

Keys to succeeding

- Direct sales team to drive clinical engagement
- Build instrument partnership relationships
- Biomarkers/NGAL in Guidelines
- Build foundation for US adult launch



Commercial Strategy for US

	2024 – June 2025	July 2025 –December 2026	2027-2029
	Pediatric Indication Approved	Pediatric Instrument Expansion Executed	Clearance Adult Indication (FDA IVDR)
Go-to-Market Model	<ul style="list-style-type: none"> Direct sales to pediatric ICU Distribution via partnership with Roche to pediatric ICU RUO (pediatrics and adult) 	<ul style="list-style-type: none"> Direct sales to pediatric clinics and hospitals Indirect sales via partnership with Roche Distribution via new instrument partnerships Direct RUO 	
Target Customers	<p>Target Accounts: Large ped hospitals/centers</p> <p>Target customers: Nephrologists; Cardiologists; Intensivists; CV Surgeons; Laboratory directors</p>	<p>Target Accounts: Large integrated hospital centers; Mid-size ped hospitals</p> <p>Target Customers: Nephrologists; Cardiologists; Oncologist Intensivists; CV Surgeons; Laboratory directors</p>	<p>Target Accounts: Large integrated hospital centers; Heart centers, Oncology centers</p> <p>Target customers: Nephrologists; Cardiologists; Oncologist Intensivists; CV Surgeons; Laboratory directors</p>
US Sales Organization & Partners	<ul style="list-style-type: none"> Add sales reps 1 additional distribution partnership 	<ul style="list-style-type: none"> Ramp up sales organization Add distribution partnerships 	<ul style="list-style-type: none"> Enhance sales organization Add distribution partnerships

Commercial Strategy for ROW

	2024 – June 2025	July 2025 –December 2026	2027-2029
	Pediatric Indication Approved	Pediatric Instrument Expansion Executed	Clearance Adult indication (FDA IVDR)
Go-to-Market Model	Distributor (Primary focus) <ul style="list-style-type: none"> + local demand generation Primary: IT, DE, ES, KR, Secondary: Benelux, GR, IL, EU, MY, MX, IN 		Distributor + local demand generation (<i>Primary focus</i>) <ul style="list-style-type: none"> Primary: IT, DE, ES, FR, KR, GB, EU, Secondary: Benelux, GR, IL, MY, ID, MX, IN, Middle East, BR
Target Customers	<ul style="list-style-type: none"> Adult patients ICU Cardio and Pulmonary Pre and post surgery patients ; Transplantation patients Ped ICU patients 	<ul style="list-style-type: none"> Adult patients: ICU Cardio and Pulmonary Adult ED patients: Cardio and Pulmonary Pre and post-surgery, transplantation, sepsis Ped ICU patients 	<ul style="list-style-type: none"> Adult patients: ICU Cardio and Pulmonary Adult ED patients: Cardio and Pulmonary Pre and post-surgery, transplantation, sepsis Ped ICU patients
RoW Sales Organization & Partners	<ul style="list-style-type: none"> Sales reps 2 strategic partnerships 	<ul style="list-style-type: none"> Sales reps Additional strategic partnerships 	<ul style="list-style-type: none"> Sales reps Additional strategic partnerships

Commercial Tactics





FDA approval triggered initiation of Marketing and Medical tactics to drive clinical engagement in 2024 in US and RoW



Industry

- Publications (GUIDANCE, TakingFocus2)
- Guidelines
- Podiums/ Special Events



Internal Processes

- Website updates
- Forecasting in SFDC
- Sales & MSL Training
- Reimbursement Dossier



Promotion

- Congresses
- Webinars
- Social Media
- Emails
- Press/Media



Education

- Corporate – MSA websites with integrated collateral
- FDA special controls
- Partner training
- On label and off label

- Forward events that create sales opportunities to create pipeline
- Quiet periods worldwide before FDA clearance, have built actions in USA, Europe and Korea beginning in 2023
- Goals to expand beyond the core AKI community



Education Process to NGAL market awareness and adoption



Congresses

- Podiums
- Special sessions
- Webinars on unique topics
- Fireside chats with Prasad

Sales Mkt Clinical

Lab – Roche, oUS Distribution

Regional Blitz

- Local KOL(s)
- Luncheon or dinner
- BioP + KOL speakers
- Post event surveys

Sales Mkt Clinical

Roche US S&M

Single Institution

- Quality metric update
- Grand Rounds
- Unit Dept mtgs
- AKI current situ mtg
- Changes in use?
- Re-education?

Sales Clinical

Coalition building

- Nephrology SME training
- Grand Rounds
- Unit Dept mtgs
- AKI current situ mtg
- 3+ specialties Med Director(s), champion

Sales Clinical

Value Analysis/ Use Plan

- Value Analysis – pubs, use plan, NGAL specifics
- Neph Response training
- 3 part PPT for kickoff
- Off label expected interest: NICU preemies, Onco, NINJA, congenital heart defects

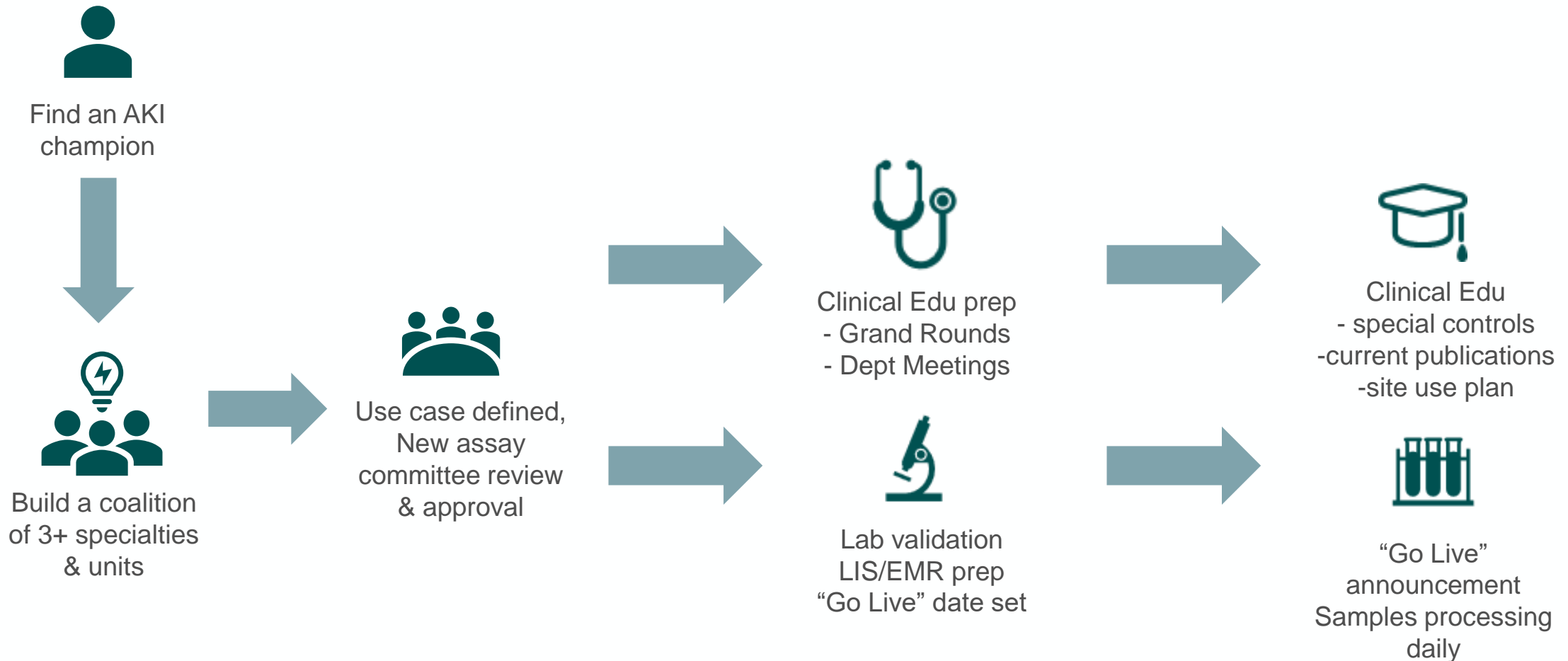
Sales Mkt Clinical

Roche US S&M



Sales Process at Hospitals

Focus on high acuity, high volume hospitals with PICU and ICU with outreach to ICU teams, nephrology, pharma, transplant, oncology and then lab.



Sales as point, MSL as resource, Roche overlay where possible, Roche/distribution as vendor to lab

US Traction



Nationwide - USA

Focus on high acuity, high volume hospitals with PICU and ICU with outreach to ICU teams, nephrology, pharma, transplant, oncology and then lab.



Find an AKI champion

Cardiac Surgeon
Fellow at CCHMC
Research using NGAL
Negotiated NGAL in contract



Cardiac surgery, ICU AKI management



Build a coalition of 3+ specialties & units



Use case defined,
New assay
committee review
& approval

Cardiac Surgery
Intensive Care
Nephrology team



Clinical Edu prep
- Grand Rounds
- Dept Meetings



Clinical Edu
- special controls
-current publications
-site use plan



Lab validation
LIS/EMR prep
"Go Live" date set



"Go Live"
announcement
Samples processing
daily

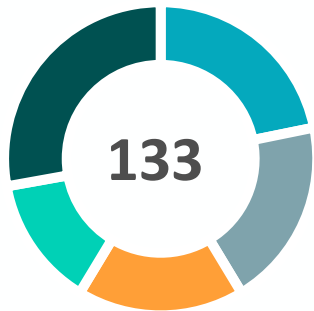
Ortho platform, three years to set up
LDT, validation in '22

Live in '22

US Commercial: Acute Hospital Targets

■ Customer ■ Active Sales ■ Pending FDA ■ Prospecting ■ Not Engaged

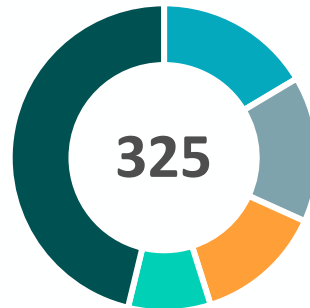
Phase 1 - Priority 133



- 14+ PICU beds & fellowship
- **Risk Strat ≥3mo - 22yr**
- Call points: CC, Neph, Pharm, Lab

- BioPorto: 4 Field Sales & 2 MSL
- Clearance: Peds on Roche c501
- Partners: Roche

Phase 2 - PICU 325



- Any # PICU beds
- **Risk Strat ≥3mo - 22yr**
- Market Awareness: Adult
- Call points: CC, Neph, Pharm, Lab + CVSurg?

- BioPorto: 4-6 Field Sales & 2-4 MSL
- Clearance: Peds on Roche c501 +
- Partners: Roche +

Phase 3 - Adult 5000



- All hospitals, systems
- **Risk Strat ≥3mo - 65+**
- Call points: CC, Neph, Pharm, Lab + CVSurg, Cirrhosis

- BioPorto: 4-6 Field Sales & 2-4 MSL
- Clearance: Peds on Roche c501 +
- Partners: Roche +

Those noted as customers are using RUO The NGAL Test

US market share 2023/2024 Roche 26-27%, Siemens 26-27%, Abbott 19%

BioPorto's NGAL presence today

US News Best Children's Hospitals 2024-2025 Honor Roll



- ✓ Boston Children's Hospital
- ✓ Children's Hospital Colorado
- ✓ Children's Hospital of Philadelphia
- ✓ Cincinnati Children's
- ✓ Nationwide Children's Hospital
- ✓ Rady Children's Hospital
- ✓ Seattle Children's Hospital

Children's Hospital of Los Angeles

- ✓ Children's National Hospital
- ✓ Texas Children's Hospital

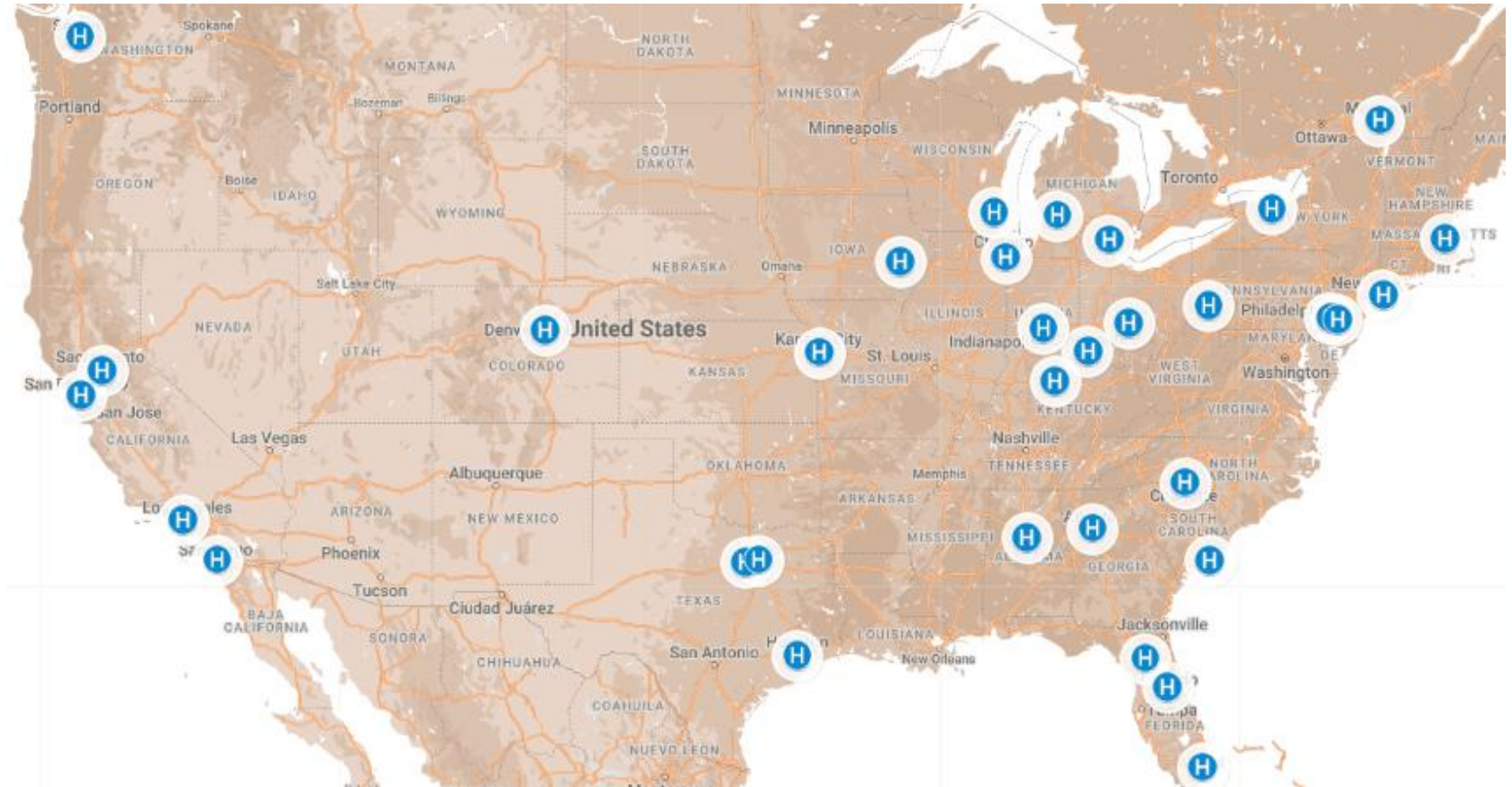
**7 Current
NGAL Users**

2 Implementing NGAL

The NGAL Test, Research Use Only, implemented as a Lab Developed Test

Increasing NGAL RUO customer base in US

- 20+ hospitals, various uses and patient populations
- RUO use as LDT of The NGAL Test - clinical and clinical research use
- Number of tests monthly ranges from a few to 100s
- Transition from RUO to ProNephro AKI once assay is available on instrumentation, and through sales channel (direct or Roche, etc.)



Study sites champion the message to the market

Customers now:

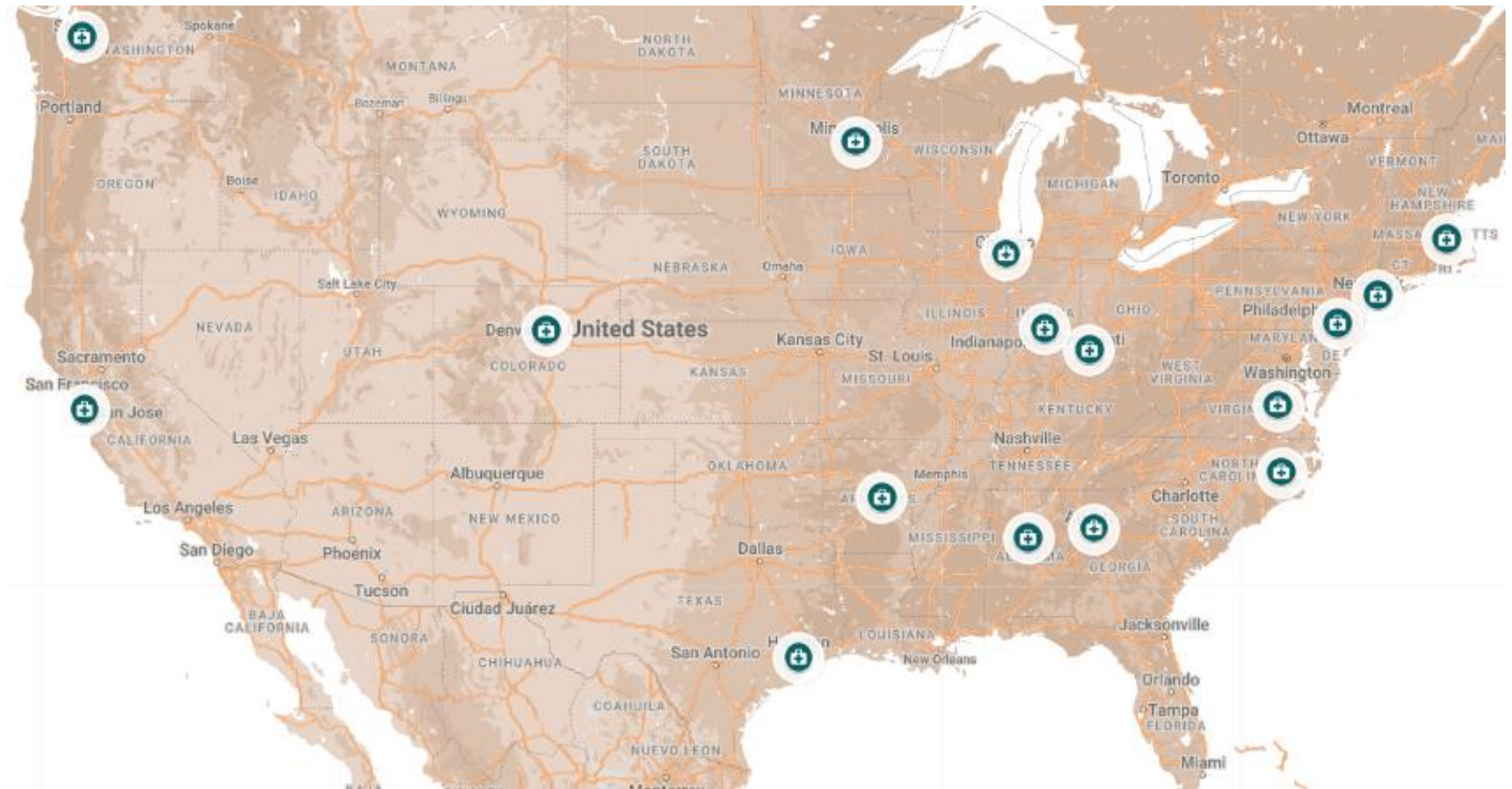
- Cincinnati Children's
- Boston Children's
- Colorado Children's
- Children's of Atlanta
- Rady Children's
- Riley Children's

Recent or Validating now :

- Children's H of Philadelphia
- Texas Children's
- Seattle Children's

Awaiting FDA cleared:

- Children's of Alabama
- Stanford
- VCU
- Arkansas
- Lurie Children's



US Clinical Trial Sites, EARNEST & GUIDANCE



Defining success in the US market

Needed to complete the “sale”

- A champion – time and political clout
- A coalition across specialties and hospital units
- An institutional use plan of “Which patients, When, What to do with the results”
- Big 5 clinical chemistry analyzer access
- Published protocols for reference (Goldstein’s RAI, TakingFocus2, Stanski’s phenotyping, Varnell’s 5 cases, NINJA)

Challenges we are addressing

- Regulatory clearance and LDT regulation
- Reimbursement – in patient DRG “all in one” payments for initial claim
- Protocols for additional patient populations and guidelines

ROW Traction



CHUM - Montreal



Find an AKI champion

Nephrologist
Fellow in Dublin with KOL '21
Research using NGAL

Non-ICU ward,
medication review & AKI
management



Build a coalition
of 3+ specialties
& units

Use case defined,
New assay
committee review
& approval

Hospitalist (owns the patient)
Pharmacy, for drug review
Nephrology team

Focus on high acuity, high volume hospitals with PICU and ICU with outreach to ICU teams, nephrology, pharma, transplant, oncology and then lab.

Presentations to CHUM team '21, '22
Presentation in Europe '21 & USA congresses '23
Submission to province for reimbursement



Clinical Edu prep
- Grand Rounds
- Dept Meetings



Clinical Edu
- special controls
- current publications
- site use plan



Lab validation
LIS/EMR prep
"Go Live" date set

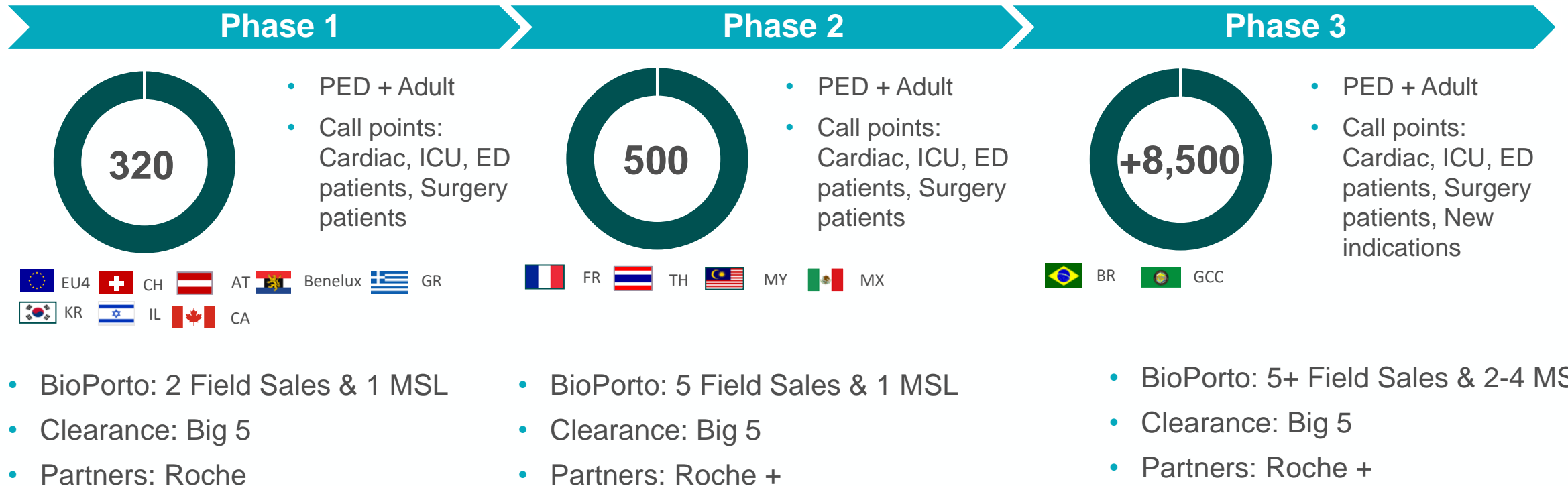


"Go Live"
announcement
Samples processing
daily
Live in '22

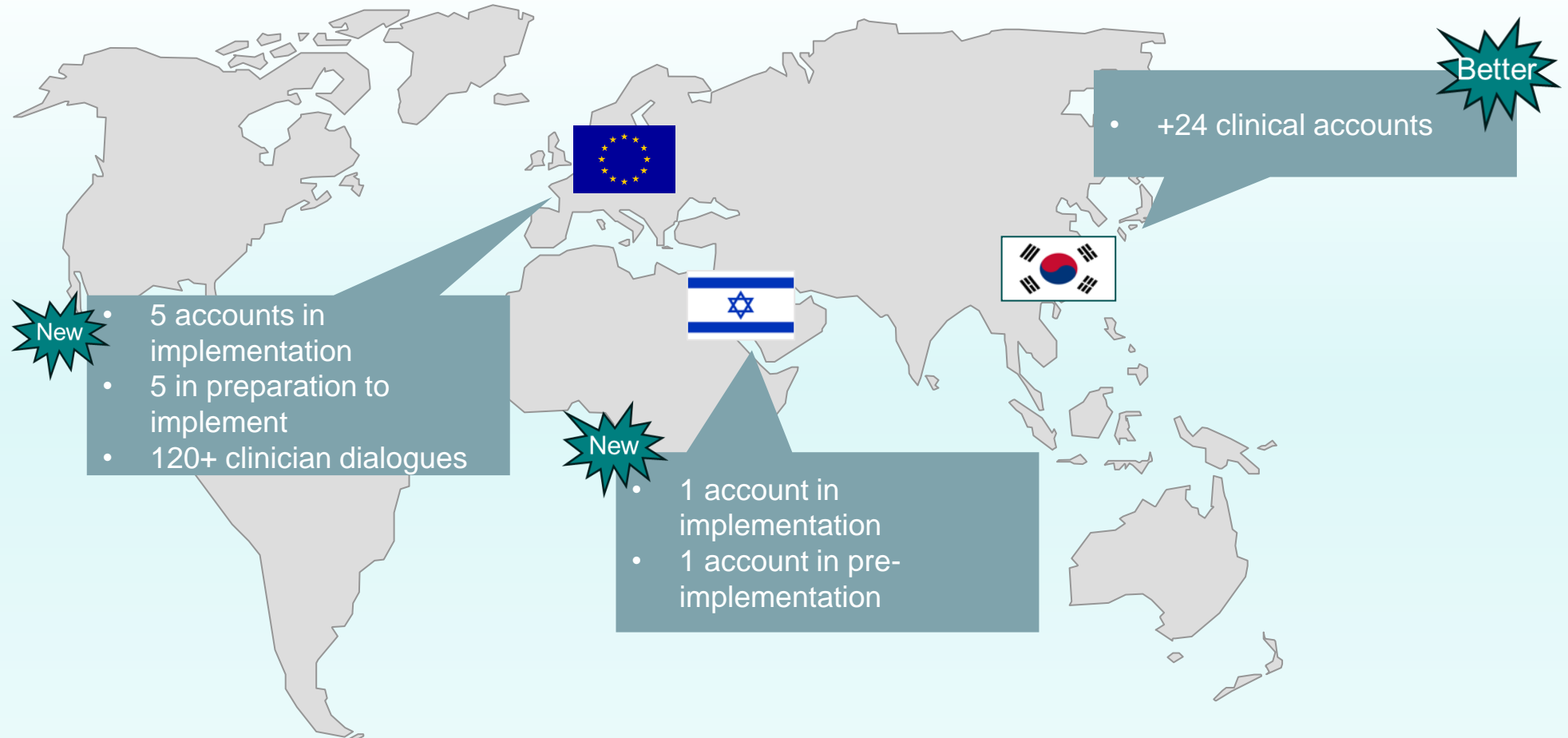
Roche platform, negotiated discount to support research '22, '24

RoW key countries and indications

Targeting large medical centers with high procedure volume



RoW NGAL Clinical usage



Partnerships





Distribution Partnerships

Instrument Vendors as Distribution Partners

(E.g. Roche, Abbott, Siemens, Beckman)

- Supplies full solution to clin chem laboratories
- Preferred vendors with established lab relationships
- Through Reagent Rental model controls / influences lab's ability to add non-native tests to open channels on instruments.
- Speeds up purchase and validation process for own/partnered tests.

Distribution Partners

- Import product, respond to hospital bids.
- Support hospitals and commercial users.
- Mostly non-clinical sales.

Current Partners

Instrument Distribution Partners

- Roche
 - Distributes The NGAL Test™ globally for c501, responsible for local registration.
 - Will distribute ProNephro AKI (NGAL) in the US for c501.

Distribution Partners

- Korea
- Italy
- Spain
- Czech Republic
- Belgium
- Germany
- Israel



Market Partners

To impact protocol use of Biomarkers for AKI



Acute Disease Quality Initiative (ADQI)
Consensus meetings on specific topics
Feed into guidelines

Allow industry partners access to view the process from the sidelines



International Pediatric Nephrology Association (IPNA)
Pediatric guidelines working group to meet in January 2024
Industry will have role, as yet undetermined



Kidney Disease KDIGO
2012 AKI guidelines under revision, group of 20 worldwide KOLs
Public comments submitted by BioPorto in 2023

GUIDELINES

- Impact protocol usage
- Allow for quicker uptake of new methods and tests
- Can be worldwide, or more regional
- Different specialties have different guidelines

Going Forward



Going into 2025

- Promotional presence in major markets with “feet on the street” and at congresses using case examples to show practical usage of NGAL
- Key milestones
 - USA 133 forecasted for product availability and clinical readiness
 - EU 320 clinical use customer targets
- Patient Populations: Pediatrics, Adult ICU/Cardiac Surgery/Cirrhosis with opportunistic support for Emergency Departments and Oncology
- Adult USA FDA clinical study support

“We are building a platform for future growth”

Contacts:

Niels H. Nielsen CFO (nhn@bioporto.com)
Tim Eriksen, IR (tee@bioporto.com)

Phone: +45 4529 0000
www.bioporto.com

