

Curetis AG

Innovative Molecular Dx for Acute Infectious Diseases

January 2012

Non-Confidential



Curetis - a Clinical Trial Stage MDx Company Targeting Unyvero™ Launch in 2012

Curetis is a molecular diagnostics company focusing on the development and commercialization of solutions for the rapid and easy identification of pathogens and antibiotic resistances associated with severe bacterial infections.

- › Founded August 2007, ISO 13485 certified, Manufacturing site opened,
- › Director Sales joined recently, recruited commercial team already
- › 30 employees (full time)

- › Over € 36 Mio Financing raised to date from strong syndicate
 - › Forbion and Roche added as new investors in successful Oct 2011 financing closing
 - › Aeris Capital, LSP, BioMed Invest, CD-Venture, KfW

- › Products:
 - › Unyvero™ instrument platform and disposables for detection of pathogens and antibiotic resistance genes for Pneumonia

- › Collaboration agreement with Sanofi Pasteur signed:
 - › regarding the potential use of the Unyvero™ platform in a future global clinical trial

Curetis' Management Team Combines Decades of Operational and Commercial MDx Industry Experience

Management Team	Key Experience
Oliver Schacht, PhD CEO	15 years in Biotech (CFO Epigenomics AG and CEO Epigenomics, Inc.)
Andreas Boos CTO	25 years R&D and management experience (Hewlett Packard, Agilent Technologies, Philips)
Johannes Bacher COO	15 years R&D and management experience (Hewlett Packard, Agilent Technologies, Philips)
Dr. Gerd Luedke Director, Bio-Assay Developmt.	20 years in assay and systems R&D (Agilent Technologies, Philips)
Dr. Anne Thews (MD) Director Marketing/Med. Affairs	20 years clinical lab and strategic/tactical mktg. (Univ. Mainz, Beckman Coulter, Philips)
Dr. Klaus Brinkmann Director Sales	15 years in IVD sales into hospital market (Becton Dickinson, Beckman Coulter, Bio-Rad)

Curetis Unyvero™ Platform Offers Fully Automated and Integrated Walk-Away Operation and Attractive Design

Unyvero Analyzer (4 units, 2 slots each)



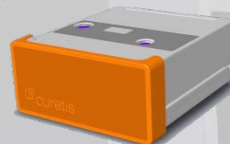
Unyvero Cockpit



Unyvero Lysator



Unyvero Cartridge



Best-in-Class Platform for Highly Multiplexed Pathogen and Antibiotic Resistance Detection

- › Unyvero™ platform: More than 10 units built
- › Unyvero™ Pneumonia Cartridge fully developed and tested
- › High unmet medical need addressed with unmatched multiplexing capabilities
- › Manufacturing scale-up established (up to 1 million cartridges p.a.)

- › Convincing clinical proof of concept data with hundreds of cartridge runs
 - » Unyvero™ finds practically everything that microbiology culture finds
 - » Unyvero™ finds significant numbers of pathogens that culture misses
 - » Opportunity to improve upon current culture-based “gold standard” deficiencies

- › Initiating prospective multi-center clinical trials in EU and USA

- › Expected commercial launch in EU in 2012

- › Maintained full strategic control over all assets

- › Upside potential from pharma partnering / companion Dx use

Unyvero™ Solution Closing a Diagnostic Gap Within 4 Hours

Severe acute infections are a huge and growing medical & economic burden

Lack of timely diagnosis leads to inadequate therapy in many cases associated with poor medical outcome

- › Clinical diagnostic practice today: culture
- › Pathogen and antibiotic resistance identification is not available when it is needed as culture typically takes 2 to 5 days
- › Forcing clinicians to initiate empiric antibiotic treatment, which is wrong in 40% of the cases

Today's molecular testing not yet a feasible alternative

- › Available test menus not adequate
 - » single/few pathogen testing only, instead of required multiparameter testing
 - » very limited products for antibiotic resistance testing
- › Highly complex technologies, require special infrastructure and skilled operators

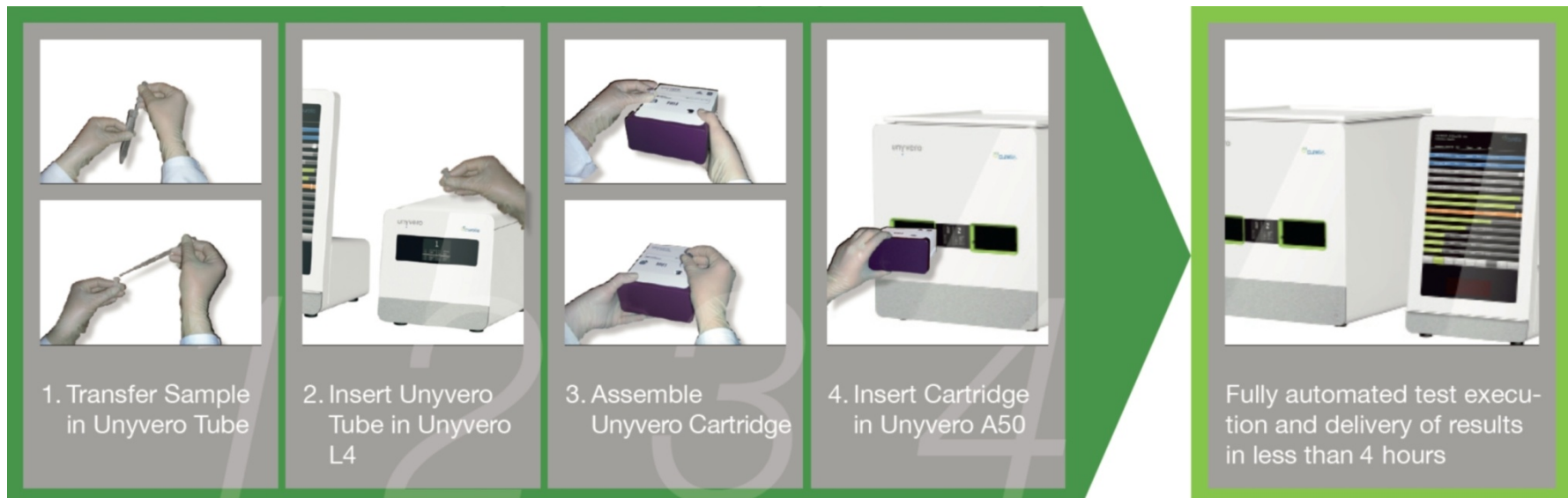
Curetis' Novel, Simplified Unyvero™ Workflow Reduces Time to Result from Several Days to Less than 4 Hours

4 steps and a few minutes of manual labor

No need for special molecular diagnostic lab

Fully automated,

unsupervised analysis



Unyvero™ Pneumonia Panel Covers all Relevant Bacteria and Resistances According to Clinical Guidelines

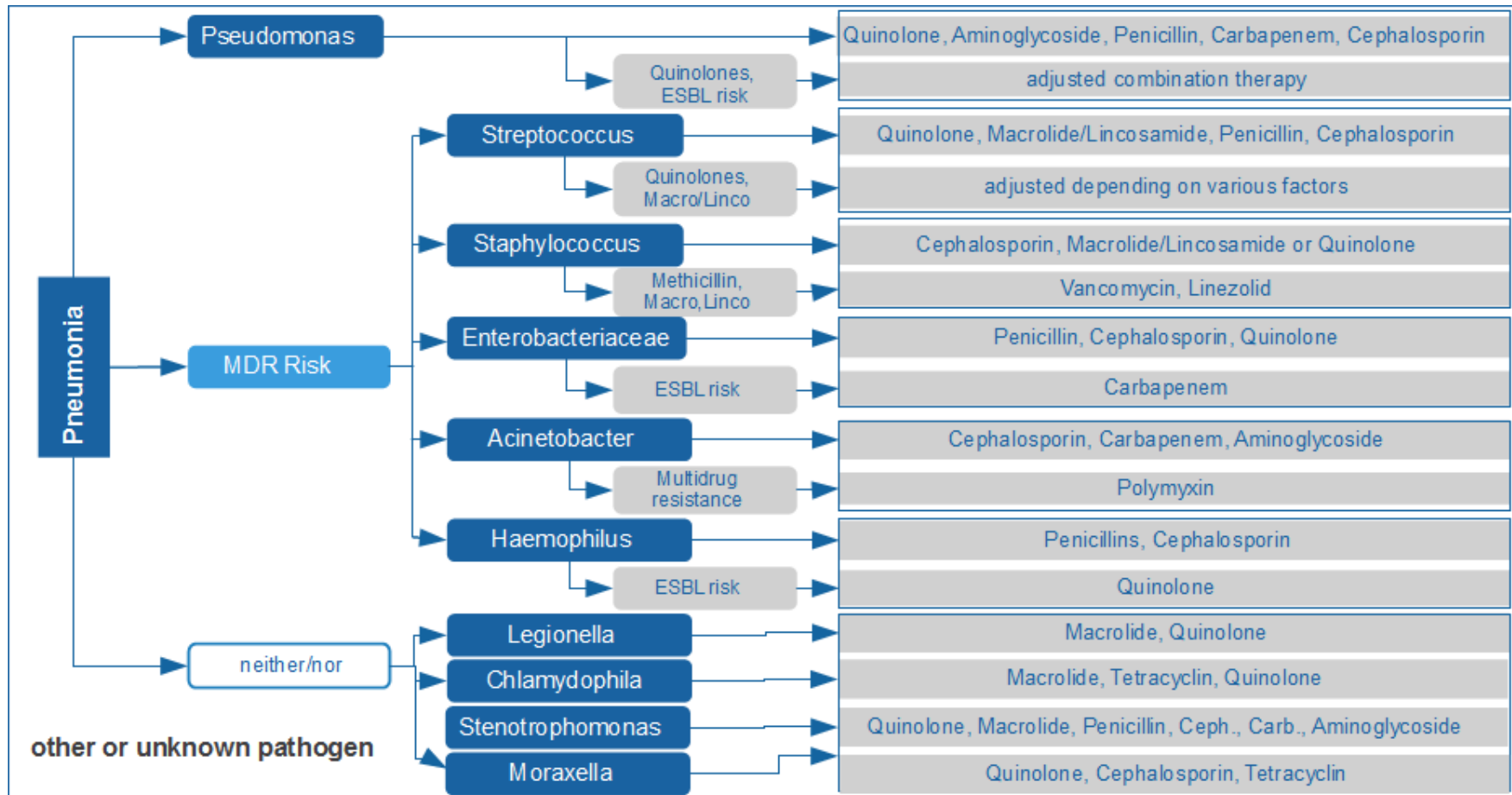


Figure: Decision tree for pneumonia therapy

* CDC: Prevention of Healthcare-Associated Pneumonia (2003), Management of mdr Organisms in Healthcare Settings (2006)
 American Thoracic Society: HAP, VAP, HCAP Guideline (2005), CAP Guideline (2007)
 Paul-Ehrlich-Gesellschaft (Germany): CAP-Leitlinie (2003), Nosokomiale Spumoni (2003)
 European Respiratory Society: Lower Respiratory Tract Infections (2005)
 Infectious Diseases Society (USA): CAP Management Guideline (2008)
 British Society of Antimicrobial Chemotherapy: HAP Guideline (2008)
 Canadian Guideline Committee: VAP Diagnosis and Treatment (2008)

Curetis Addresses a Large (€1.6 Billion) and Growing Market for MDx in Severe Infections in the EU and USA

Multiple Pipeline Opportunities	# tests US & Europe
LRTI pneumonia ¹	22.6 Mio
LRTI others ² (est.)	10 Mio
Surgical Site Infections	7.3 Mio
TB (acute)	8.1 Mio
others ³	16 Mio
Total # of cultures	64 Mio

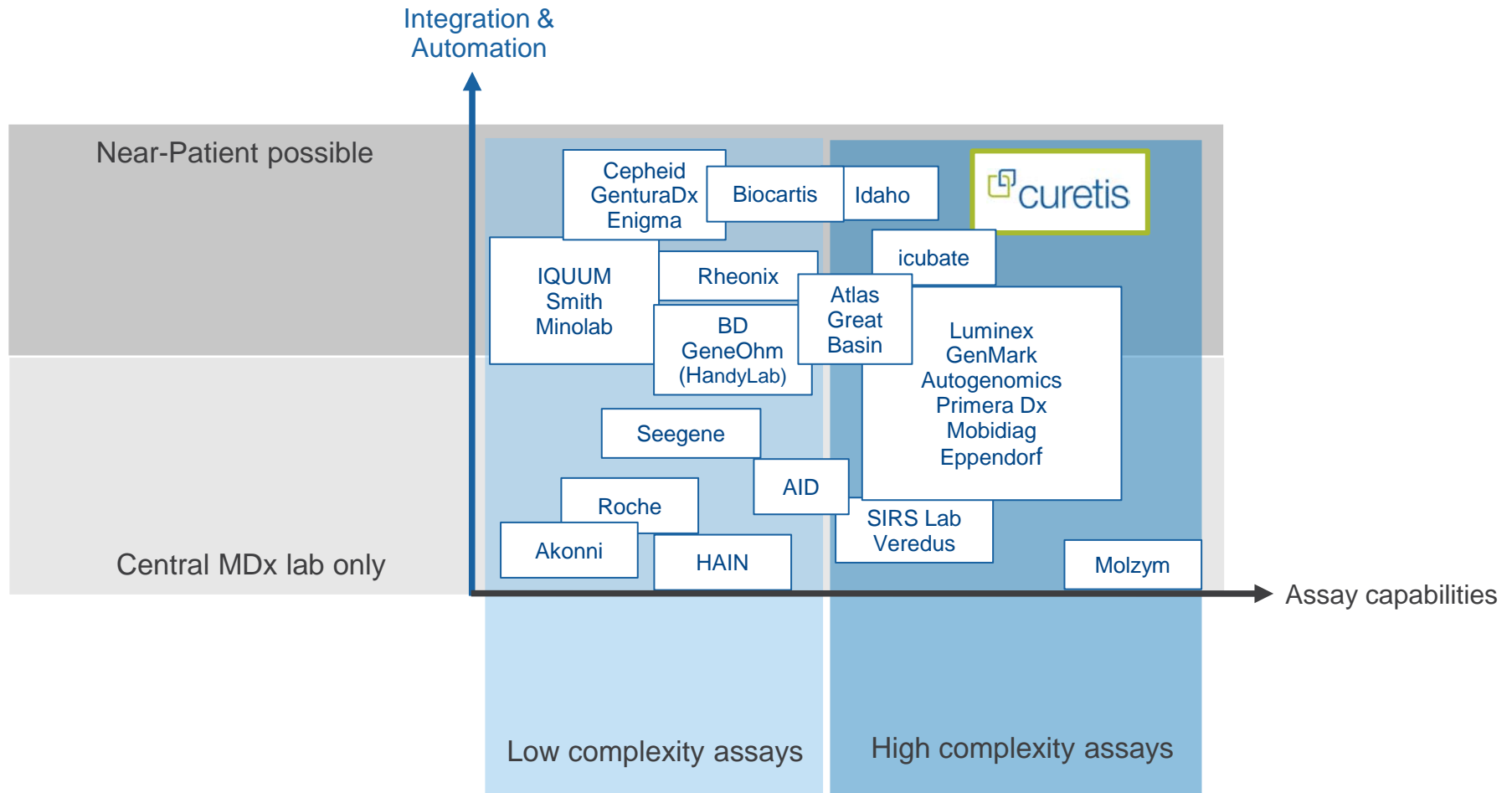
→ € 1.6 billion market today

¹ LRTI (Lower Respiratory Tract Infections) Pneumonia: HAP, VAP, HCAP, and hospitalized CAP

² other LRTI – other severe lung infections excl. TB

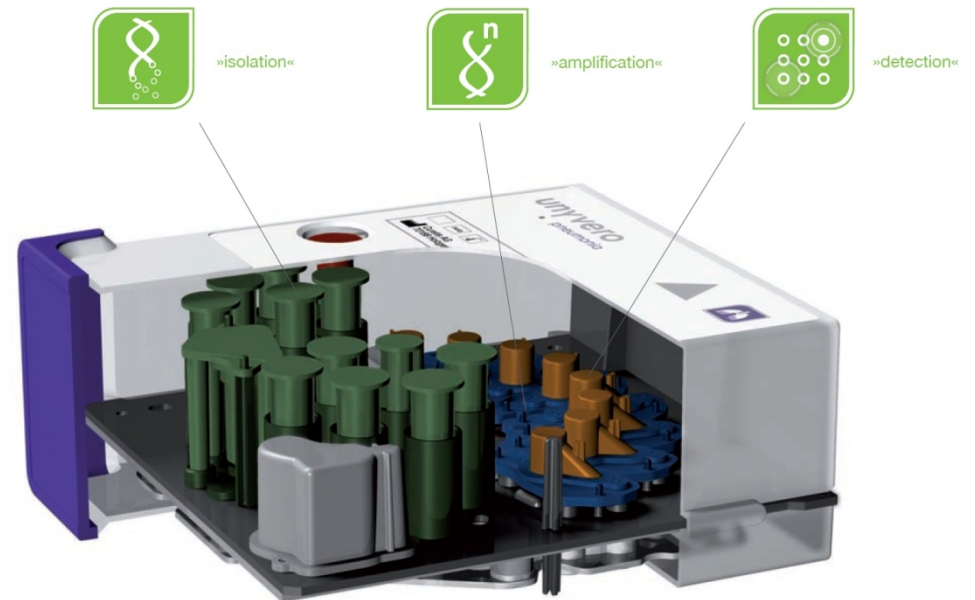
³ other infections (e.g. cellulitis)

Curetis Unyvero™ Solution: Unique Combination of Multiplexed Assays with Superior Automation & Integration for All Clinically Relevant Sample Types



Unyvero™ Solution and Cartridge Integrates all MDx Steps

- › Homogenization and liquefaction
 - » Conditions **any** clinically relevant patient sample type
- › Isolation and purification
 - » **high performance** DNA purification
- › specific amplification of multiple targets
 - » **specific** multiplex endpoint PCR
- › specific detection of amplicons
 - » **fast and specific array-based** detection



The Unyvero™ L4 Lysator Offers Unique Sample Prep

- › Key features / functions:
 - » Processes any relevant clinical sample type
 - » Up to 4 samples can be processed simultaneously
 - » Combining mechanical, thermal and enzymatic steps
 - » Rapid processing time ~ 15-30 min
- › Total of 10 instruments built
- › Lysator instrument verification and testing of biological functions completed
- › EMC pre-testing completed / CSA safety testing started



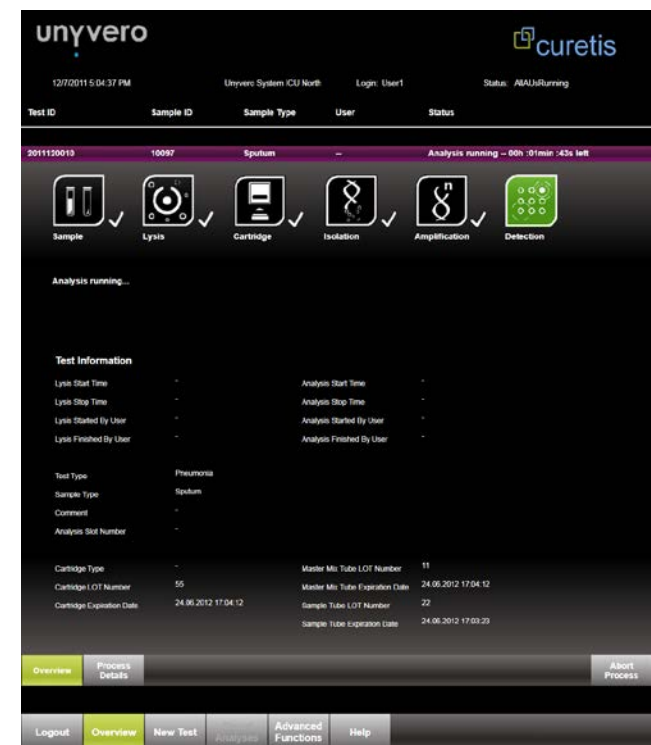
The Unyvero™ A50 Analyzer: Flexibility and Scalability

- › Total of 10 units delivered
- › Key features / functions:
 - » 2 slots for independent, random access processing
 - » Complete measurement in closed system, including sample prep, DNA isolation, specific amplification and array detection
 - » Processing time ~ 200min
 - » No manual steps, unsupervised operation
 - » EMC testing started / CSA safety testing started



Touchpad Unyvero™ C8 Cockpit Guides Users from Sample to Result

- › Key features / functions:
 - › Built in Barcode Scanner
 - › Automated results generation



Curetis' Bodelshausen Manufacturing Site Opened on 14th October 2011

- › Two ISO-8 clean-rooms installed
- › Three QC laboratories set up
- › Installation of manufacturing line equipment
- › Personnel hired and trained



Unyvero™ Pneumonia Assay: Fully Developed with Excellent Performance in Hundreds of Clinical Samples

Sample Preparation for sputum, BAL, tracheal secretion, blood and others:

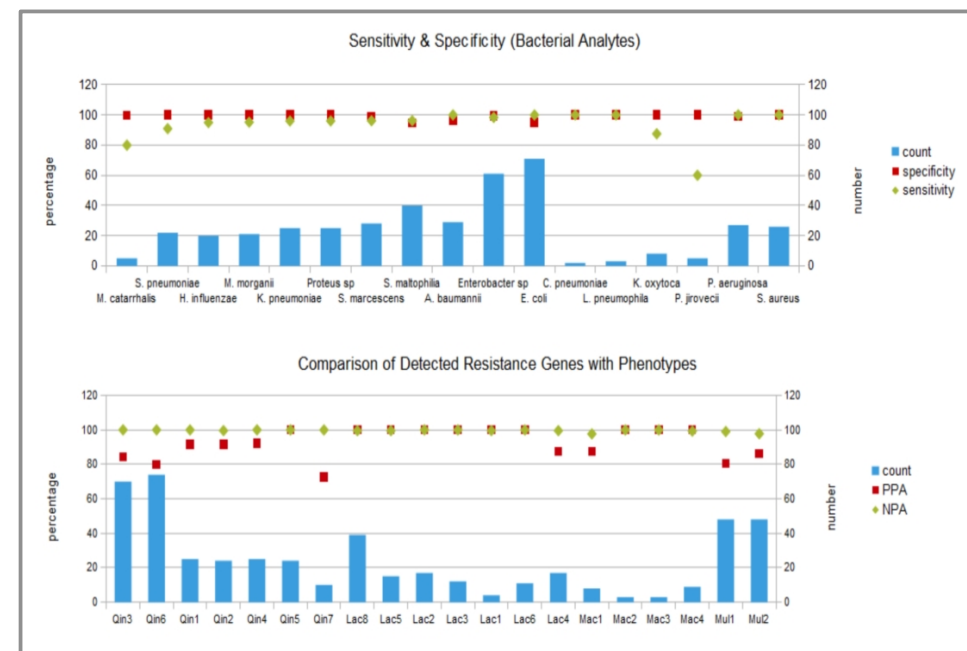
- › Hundreds of patient samples processed
- › Highly consistent extractions and amplifications

PCR assays:

- › All PCR assays for pathogens and resistances implemented as multiplex reactions
- › Tested with well characterized clinical strains and native patient samples (> 400 samples)
- › Sensitivity and specificity are both well above 90%, fully meeting clinical requirements
- › Very low cross reactivity with human and non pathogenic bacteria (normal flora)

Detection probes:

- › All probes designed and implemented
- › Tested and characterized with clinical samples



Initiating Clinical Trials – 2012 EU Launch, Expect 2013 FDA Clearance

Pre-Clinical Testing:

- › Performed on (negative) clinical samples spiked with well characterized bacteria (strains and resistances, several hundred clinical isolates available at Curetis)
- › Estimated number of tests: > 2,000 total (e.g. dilution series, sensitivity and specificity, cross reactions, repeatability)

Clinical Trials & Launch:

EU study to start in due course, performed for EU regulatory CE marking

- › At 5 sites - up to 1,000 patients, comparing results against microbiology

FDA regulatory study to start in 2012

- › At least 3 US sites - at least 2,000 patient samples, validating intended use claims
- › Extensive FDA Feedback built into trial design
- › 510(k) / de-novo 510(k) approach anticipated for instrument / assay

EU post-marketing studies to start in H2-2012

- › Demonstrating medical and economic benefits

Strong Network of Clinical KOLs in EU and USA



Prof. Dr. Ingo Autenrieth

Microbiologist
Uniklinikum Tübingen (UKT), Germany
leading expert microbiology (incl. Mdx)

- » large microbiology laboratory
 - › 160 000 samples/year, staff 100, certified Laboratory
- » 130 publications
- » chair: Genome Research Network
- » member: International Society of Microbiology
- » editor: International Journal of Microbiology



Prof. Dr. A. Torres

Clinician
Hospital Clínic de Barcelona (HCB), Spain
leading expert pneumology, intensive care

- » responsible for all pneumonia patients, HCB
- » 480 publications
- » coordinator: “Management and prevention of infectious, interstitial, and tumoral pulmonary diseases” at IDIBAPS
- » editorial Board of Pulmology, European Respiratory Journal, Thorax, Chest and Intensive Care Medicine

Network of potential EU advisors / lead-users / trial sites

Clinicians / Intensivists / Pneumologists:

- » **Prof. J-L Vincent / Brussels**
- » Prof. J. Rello / Barcelona
- » Prof. J.D. Chiche / Paris

Microbiologists / Hygienists / Laboratorians:

- » Prof. O. Denis / Brussels
- » **Prof. C. Knabbe / Bad Oeynhausen**
- » Prof. P. Gastmeier / Berlin

Network of potential US advisors / lead-users / trial sites

Clinicians / Intensivists / Pneumologists:

- » **Prof. M. Kollef / St. Louis**
- » Prof. R. Wunderink / Chicago
- » Prof. C. Burnham / St. Louis

Microbiologists / Hygienists / Laboratorians:

- » **Prof. C. Ginocchio / New York**

Curetis has Attractive Products in the Pipeline - Additional Assays Already Pre-Developed

Surgical Site Infection Cartridge:

- › ~80% of required analytes already covered by pneumonia panel
- › add Enterococci and Vancomycin resistance genes – first assays already available

TB Cartridge:

- › Multiplexed assay available and already tested with clinical samples
- › Covers wide range of mycobacteria
- › Covers all major antibiotic resistances including multidrug resistance

Expanded Pneumonia Cartridge:

- › Feasibility demonstrated for assays that cover bacteria, fungi and viruses from one sample in one cartridge

Sepsis Cartridge:

- › Considering third party content for use with the Unyvero™ platform

Dual Commercialization Strategy: Direct Sales in Major Home Markets + Sales via Distributors and Partners

Germany, Austria, Switzerland (DACH)

- › Direct Sales through Curetis' commercial organization
- › Launch scheduled for 2012 with CE marking
- › Target segment are large hospital customers
- › Currently building commercial team – key hires made

Other European Countries

- › Sales through distributor(s) and/or large laboratory organizations (key accounts)
- › Possible with CE marking from late 2012 onwards

USA & ROW

- › Sales through (global) strategic commercialization partner(s) from 2013 onwards

Pharma Partnerships

- › Sanofi Pasteur collaboration signed; potential use of Unyvero in future global clinical trial
- › Clinical trial support for Pharma - potential for companion diagnostics use later

Curetis has a Strong Business Case

- › MDx / IVD experienced management team with track record of delivering results
- › Platform fully developed and de-risked
- › Pneumonia assay fully developed, several other assays in pipeline
- › Prospective clinical trials in EU and USA being initiated
- › Commercial opportunity near term with 2012 EU launch
- › Sanofi Pasteur collaboration signed
- › FDA clearance expected in 2013
- › Upside potential from pipeline expansion and partnering deals
- › Strategic options fully maintained

Thank You !

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