

Strange Bedfellows



Managing Technology
Partners Successfully

Today's Panelists

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Global Alliance Director
Hoffmann-La Roche

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Vice President, Alliance Management & Head
Drug Delivery Franchise
Halozyme Therapeutics

Peter D. Noymer, Ph.D.

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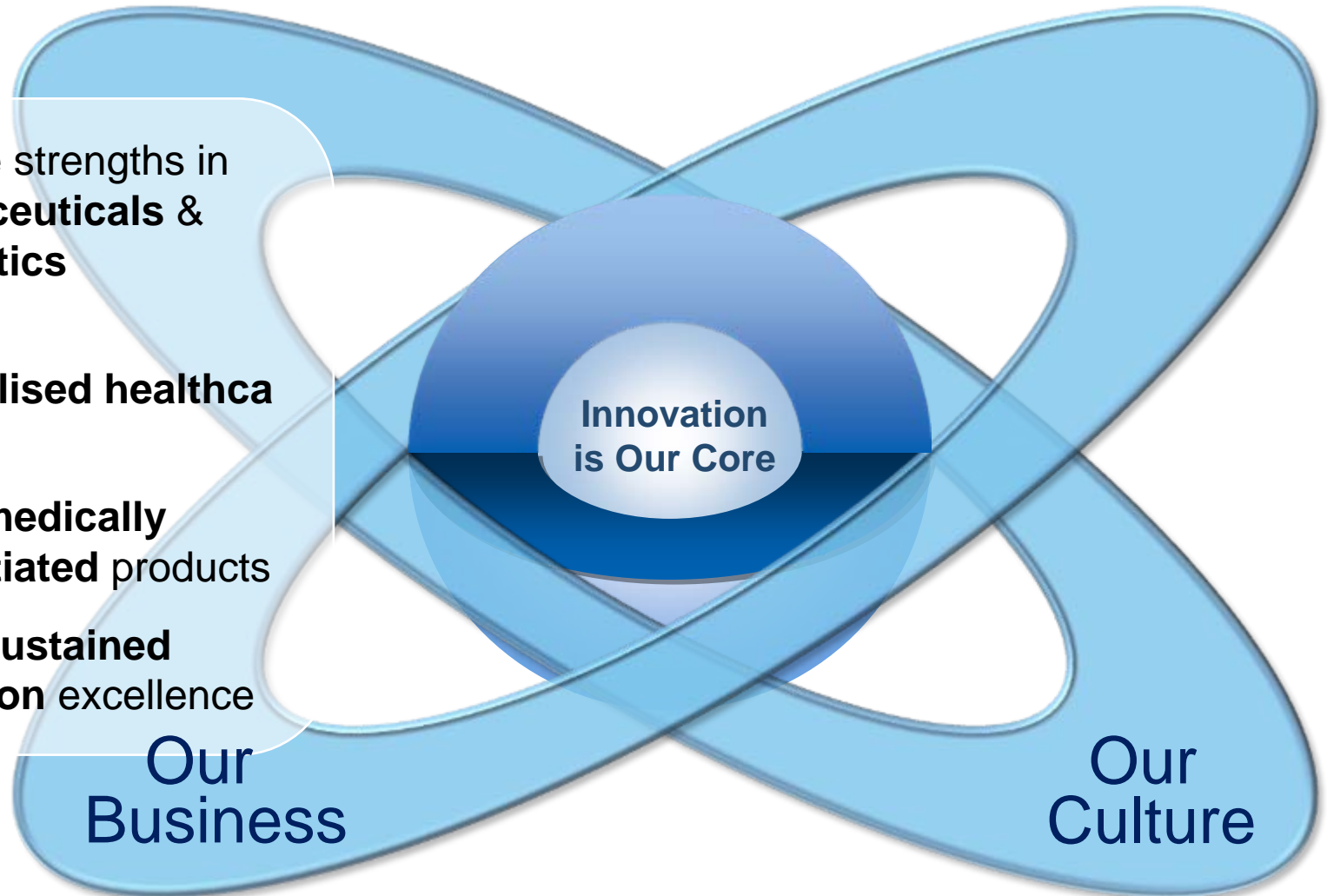
Jennifer Dent

Global Alliance Director
Hoffmann-La Roche

Roche

We innovate healthcare

- Combine strengths in **pharmaceuticals & diagnostics**
- Lead **personalised healthcare**
- Deliver **medically differentiated** products
- Deliver **sustained innovation** excellence



Partnering business functions: Want, find, get, manage



From opportunity to partnership and beyond the deal



Compact unit

- About 90 senior professionals
- Based in Switzerland, USA, Japan & China
- Decision-making authority
- Interface between Roche and external partners

Broad remit

- Research collaborations
- In-licensing collaborations
- Out-licensing collaborations
- Divestments
- M&A

Want

Defining our search

Find

Identifying partners

Get

Personalising deals

Manage

Building collaborations

Herceptin subcutaneous

An important step forward for patients



Advantages

- Potential for fewer infusion reactions
- Opportunity to decrease health care costs
- Potential for convenient self-administration
- Proprietary Roche Diagnostics-developed injection device

Program Status

- Phase III non-inferiority study, HANNAH, ongoing ex-US



Michael Haller

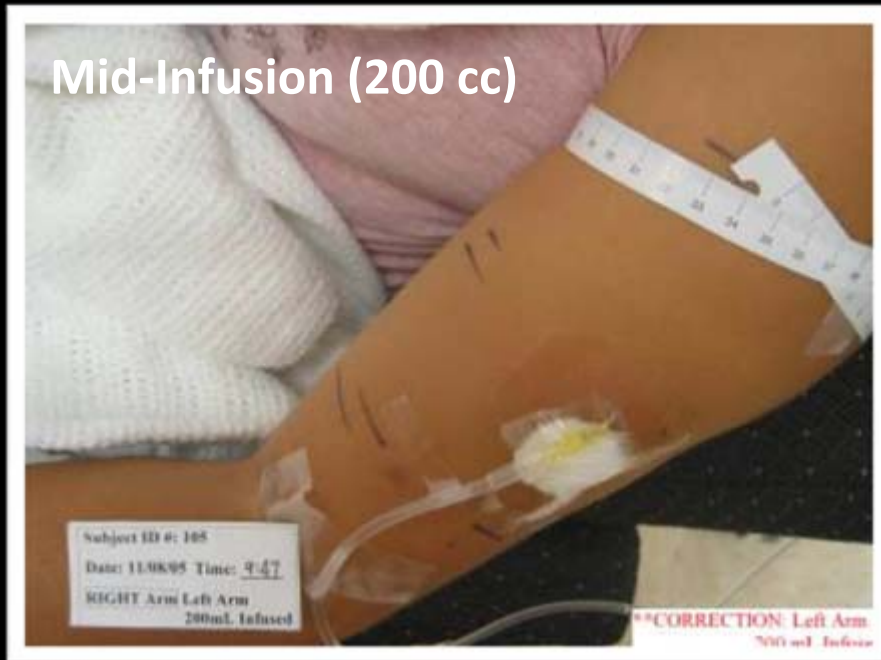
Vice President, Alliance Management & Head
Drug Delivery Franchise
Halozyme Therapeutics



- Strong technology foundation and pipeline of commercial and clinical stage assets with significant revenue potential and near-term value drivers
 - Core technology is FDA approved rHuPH20 (recombinant human hyaluronidase) enzyme (“PH20”)
 - Technology validated by partnerships with Roche and Baxter; multiple milestones plus royalties achievable; \$106 million received to date
 - Strong safety profile, IP protection, and value proposition for partnered and proprietary programs
- Robust pipeline of other multifunctional Matrix enzymes offers better treatments and patient benefits for variety of therapeutic uses to drive long-term growth

Halozyyme's PH20 Enhance™ Technology Enables Large SC Administration Volumes

Randomized controlled Phase IIIB study of subcutaneous hydration of lactated Ringer's (LR) +/- PH20 in 54 volunteer subjects



Side-by-Side Simultaneous SC Infusions

PH20 Core Technology: Targets Hyaluronan (HA) in “Matrix” for Spreading



Multifunctional PH20 Enzyme Platform Targets Over \$20 Billion in Late-Stage Product Opportunities



Partnered Programs



Roche's Herceptin[®] SC in Phase 3 pivotal trial, \$5.1B WW product, MabThera[®] SC in Phase 1, \$5.9B WW product



Baxter BioScience's GAMMAGARD[®] with PH20 in pivotal Phase 3, \$6B WW market



Baxter rollout of FDA approved HYLENEX[®] in pediatric hydration underway, \$200M addressable market

Proprietary Program

Ultrafast Insulin in Phase 2, data from three additional clinical studies available in 2010, \$3B rapid-acting analog insulin market

Peter D. Noymer, Ph.D.
Vice President, Product R&D

ALEXZA
PHARMACEUTICALS

Background – “personal pipeline”

	Pre	Ph 1	Ph 2	Ph 3	NDA	Mkt
AERx® - diabetes						
AERx® - other						
Intraject® - migraine						
Staccato® - agitation						
Staccato® - other CNS						

- **By the numbers**
 - 2 companies (Aradigm, Alexza)
 - 10+ years (since 1999)
 - One product approved (Sumavel™ Dosepro™ – Zogenix – approved July 2009)
 - One NDA under review (Staccato® Loxapine – submitted December 2009)
 - 8-10 other development candidates
- There are an additional ~20 novel drug-device combination products being developed just for inhalation at other companies

Some of the challenges ...

Engineers



Chemists



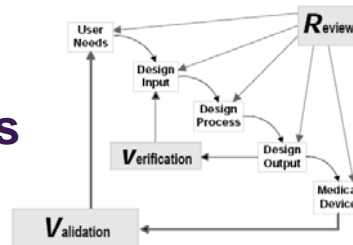
Small companies



Large companies



Device regulations



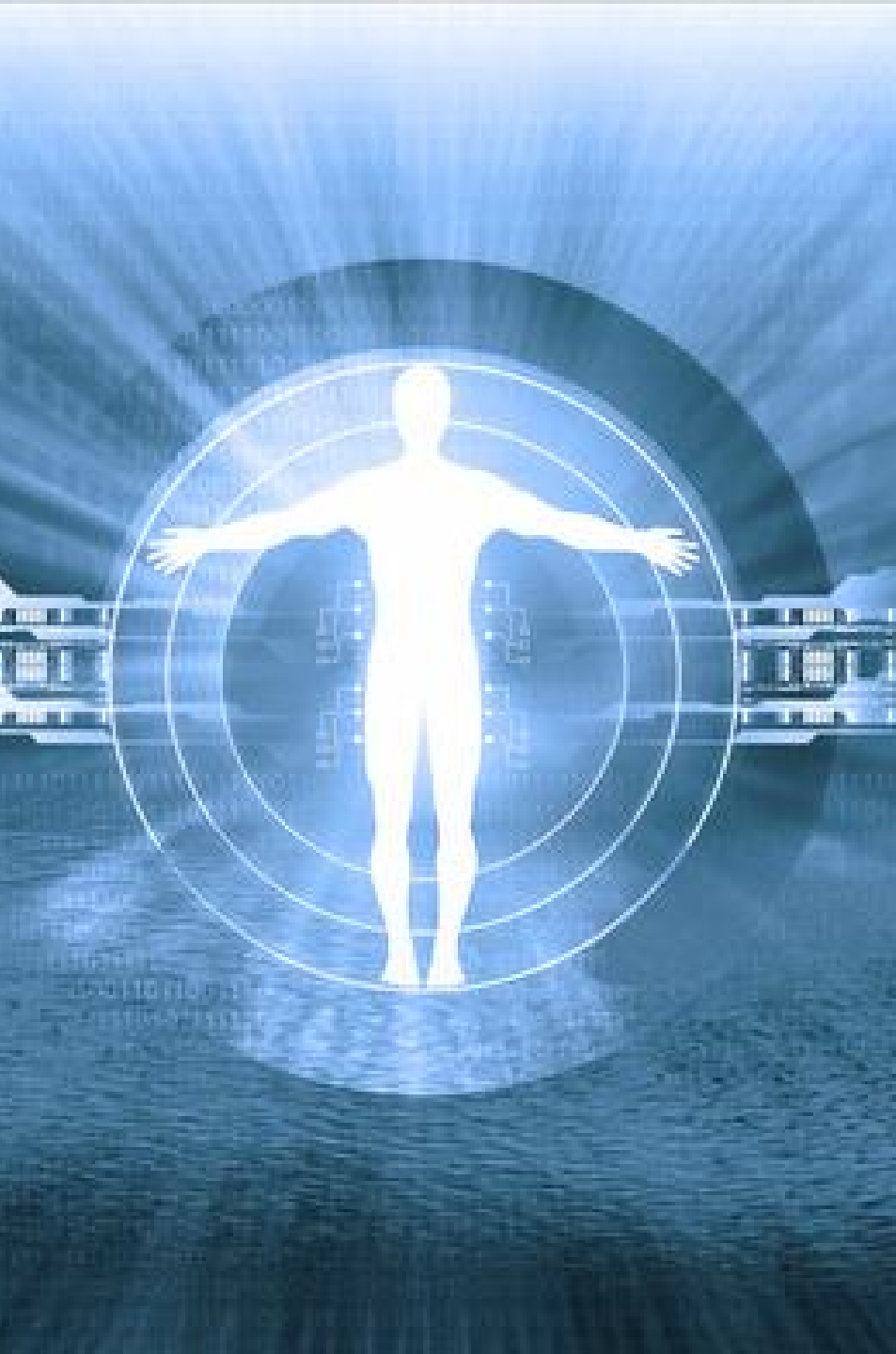
Drug regulations

Getting there from here ...

The only difference between
stumbling blocks and
stepping stones
is the way you
use them.

—Unknown





Convergent
technologies –
key to the
future of
medicine?



Combination Product Definition

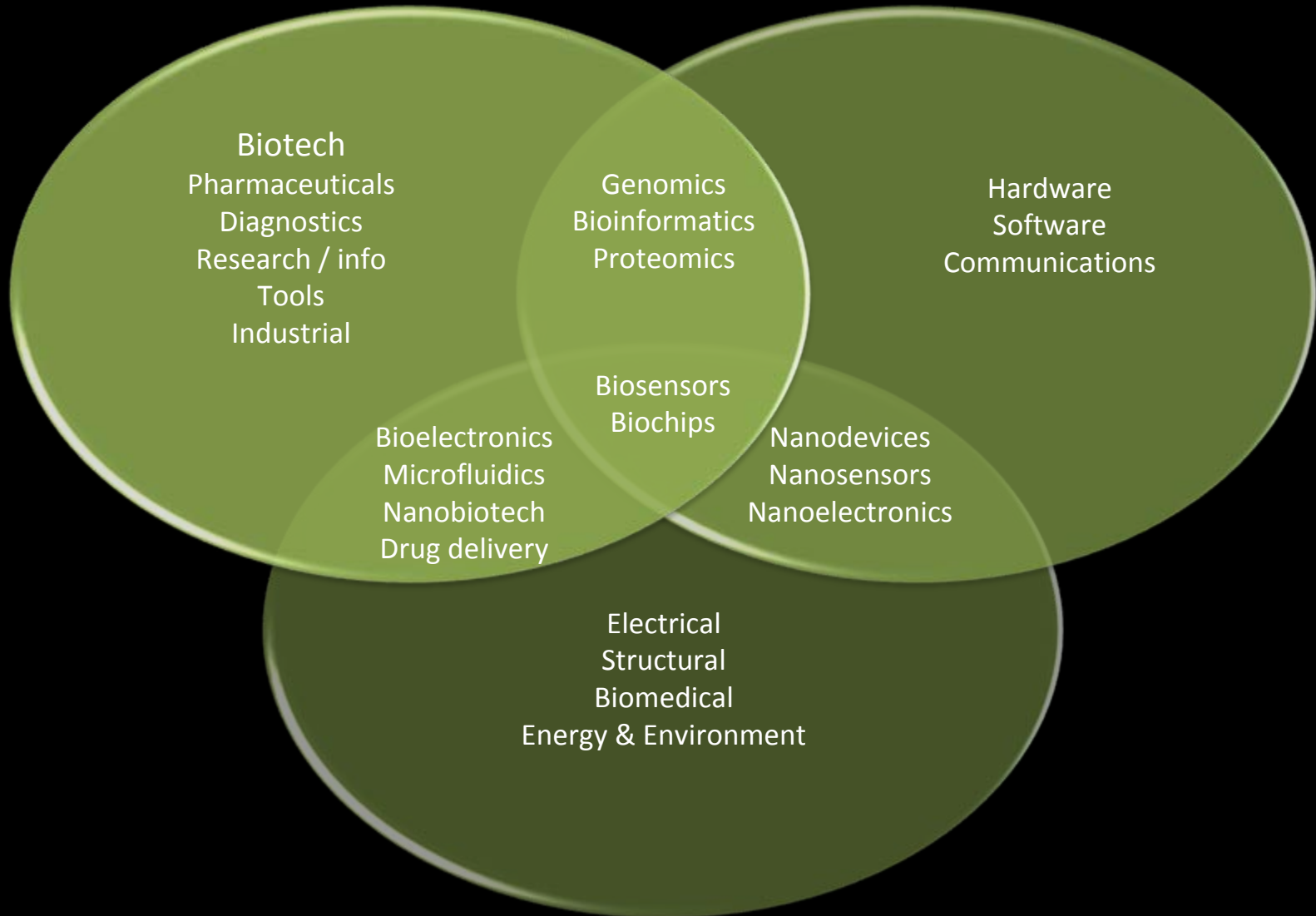
A product comprised of two or more regulated components combined or mixed and produced as a single entity

Two or more separate products in a single package

A product packaged separately that is intended for use only with an approved product where both are required to achieve the intended use

Any investigational product packaged is for use with another individually specified investigational product

The Convergence of Technologies





Drug to device



Drug to biologic



**Diagnostic to
treatment**



Device / drug with communication technologies

Bringing together two or more companies with different capabilities

Key Drivers

- Scientific / technology trends
- Economic trends



Office of Combination Products

Responsibilities for OCP

- The entire regulatory life cycle of combination products to include oversight of product jurisdiction decisions
- Specific pre-market review and post-market processes

Specific pre-market review and post-market processes

- Center for Biologics Evaluation and Research (CBER)
- Center for Drug Evaluation and Research (CDER)
- Center for Devices and Radiological Health (CDR)

Combinations Products Coalition

A group of leading companies in the drug, device and biologics industries working to improve the regulatory environment for combination products by developing and advocating policy positions on regulatory issues affecting combination products



The unique cross-industry membership enables diverse thinking that leads to sound policies. This diversity distinguishes the CPC from other industry organizations:

<http://www.combinationproducts.com/>

Business Challenges

Higher development costs

Evolving regulatory environment

Product development pathway





Integrating cultures
Facilitating decision
making

Traditional

Preventing/
resolving conflict


Challenges

Measuring and
delivering results

Complexity in Combination Products

- Clinical studies
- Changing regulatory environment
- Complexity in development pathways





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Lessons Learned

Clearing of forests, including tropical rainforests, is a major cause of climate change. It is important to protect these forests.



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