



# *Understanding the Application of Bioscience Global Health Organizations Halteres Associates*

**July 2011**



Halteres from Ancient Greece  
National Archaeological Museum in Athens

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# Halteres Associates: What We Can Do For You?

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- Evaluate and compare healthcare practices in resource-limited settings within the developed and developing world
- Help identify and assess unmet healthcare needs and user requirements in the developed and developing world
- Determine the most appropriate products required to address unmet healthcare needs and user requirements
- Determine what will be required to discover, develop and validate new biomarkers and technologies for the developed and developing world
- Determine the types of organizations and partnerships required to deliver new healthcare products to end users
- Estimate the financial requirements for discovering, developing and delivering new healthcare products
- Get sponsors and healthcare leaders excited about the prospects of addressing unmet global healthcare needs

Healthcare

Unmet Needs

Solutions

Development

Delivery

Financial Needs

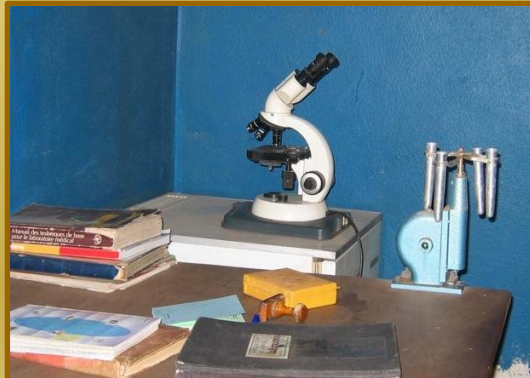
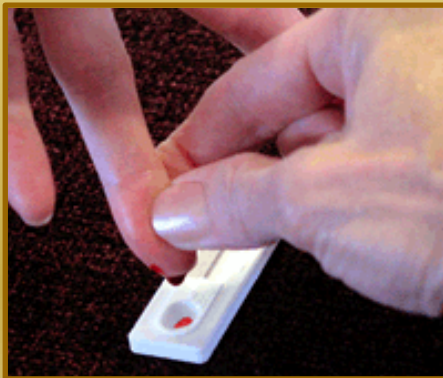
Presentation

# Halteres Associates: What Is Your Challenge?

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**You are committed to improving global health, but...**

- Your organization requires assistance assessing unmet healthcare needs in the developed and developing world, as well as potential innovative solutions
- Your organization does not have the operational business expertise needed to understand what will be required to discover, develop, validate and deliver innovative new products designed to address global health needs
- Specialized assistance is required in areas of knowledge or expertise that are not available to your organization at this time



# Halteres Associates: Company Overview

## Our approach works...

Halteres was formed in 2002 to help bioscience and global health organizations deliver innovative new products that address unmet medical needs worldwide

- Managing partner and just two full-time employees
- Access to over 100 professionals with extensive direct operating experience
- Customized executive-level consulting teams that best meet unique client needs
- Synthesis of ideas and best practices results in actionable work products

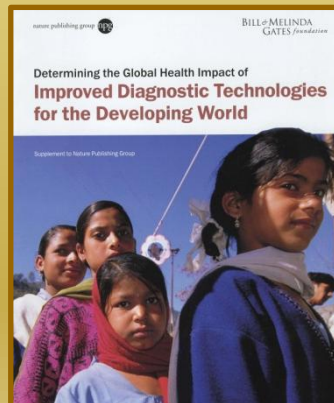
### Biomarkers for Infectious Disease Diagnostics in the Developing World

Diagnosis of *Giardia lamblia*, *Cryptosporidium parvum*, and  
Enteroaggregative *Escherichia coli* in Children with Diarrhea as  
a Surrogate of Stunting

Laura Penny, Paul Neuwald, and Mickey Urdea

August 2006

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### Requirements for high impact diagnostics in the developing world

Authors: Mickey Urdea<sup>1</sup>,  
Laura A. Penny<sup>1</sup>,  
Stuart S. Olmsted<sup>2</sup>,  
Maria Y. Giovannini<sup>3</sup>,  
Peter Kaspar<sup>4</sup>,  
Andrew Shephard<sup>5</sup>,  
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Steven Buchsbaum<sup>8</sup>,  
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Deborah C. Hay Burgess<sup>9</sup>

#### PREFACE

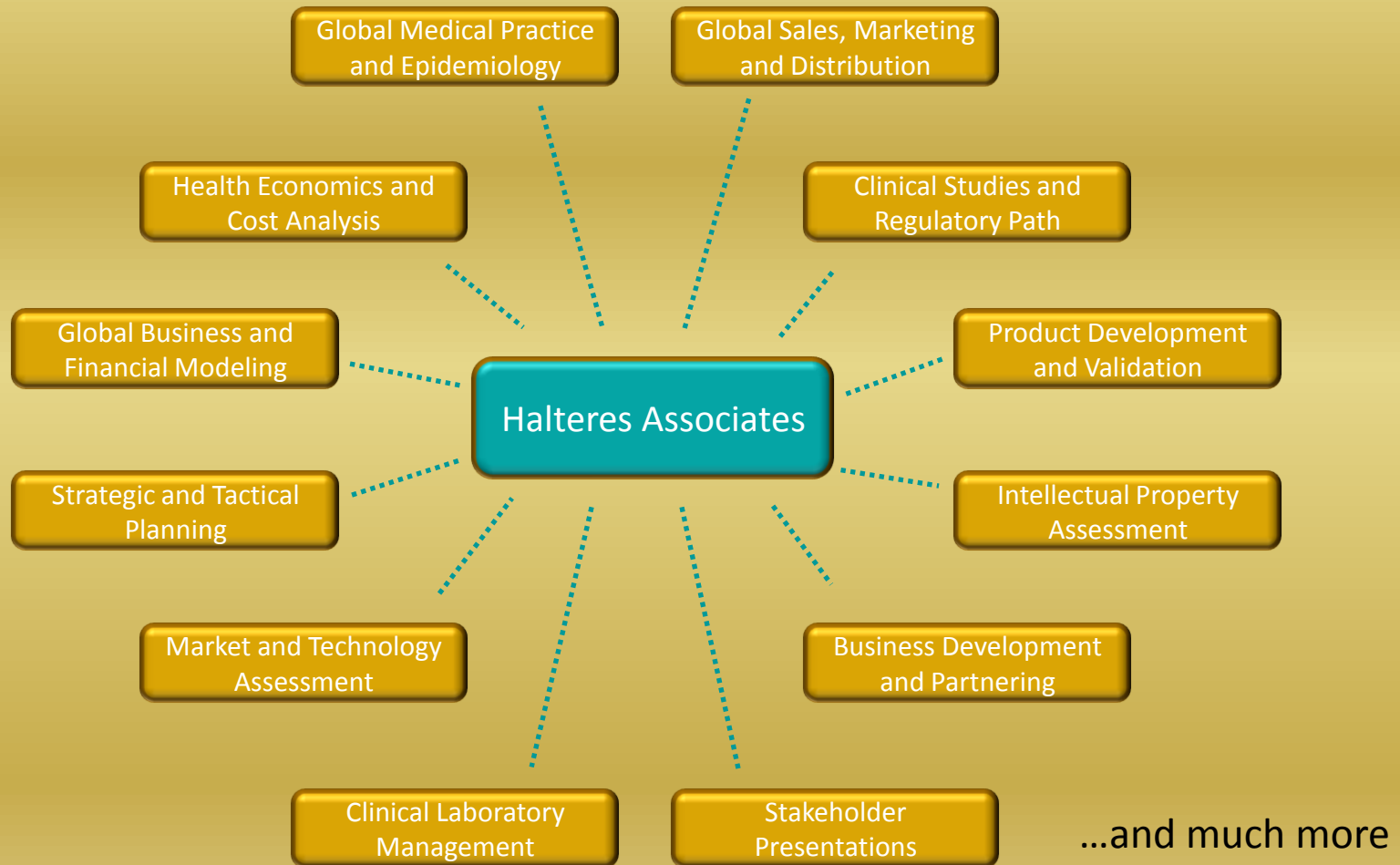
Infectious diseases continue to devastate the developing world. One crucial factor in the lack of diagnostic tests that can be performed at low-infrastructure sites, which serve most of the global population, without these diagnostics, health-care workers do not know who should be treated and, just as importantly, who should not be treated. A detailed understanding of the resource limitations in testing locations will have a great impact on the design of diagnostic tests — sometimes in surprising ways.

#### INTRODUCTION

Despite recent advances in the availability of powerful drugs, infectious diseases that are largely treatable continue to take a massive toll on the populations of developing countries. Many previously published analyses have provided estimates of the burden posed by specific diseases. For instance, recent estimates reported by the World Health Organization (WHO) of the proportion of childhood deaths attributed to pneumonia were 21% in the Africa region, 21% in the eastern Mediterra-

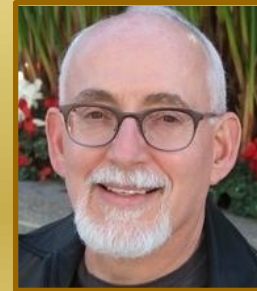
born to infected women will acquire HIV infection during the first year of life<sup>1</sup>. In 2005, an estimated 2.3 million children worldwide were living with HIV-acquired immunodeficiency syndrome (AIDS), 2 million of whom were in sub-Saharan Africa<sup>2</sup>. In the developing world, syphilis remains a significant health concern during pregnancy; its prevalence among pregnant women attending antenatal centres in Africa ranges from 3 to 19%<sup>3</sup>. Infections of *Neisseria gonorrhoeae* and *Chlamydia trachomatis*, which are the causative bacteria of gonorrhoea and chlamydia, respectively, remain significant health concerns. In Africa, the prevalence rates for these infections are up to 66% in high-risk populations (for example, commercial sex workers) and up to 40% even in low-risk populations<sup>4</sup>. Estimates of the impact of diarrhoeal diseases around the world range from 1 billion to 4 billion diarrhoeal episodes every year among children aged <5 years in developing countries, causing ~2.5 million deaths, of which ~85% occur in the poorest parts of the world<sup>5</sup>. In some countries, diarrhoeal diseases account for >20% of all deaths in children aged <5 years.

# Halteres Associates: Depth of Team Experience



# Halteres Associates: Meet Our Professionals

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...and many more

# Halteres Associates: Introducing the Core Team

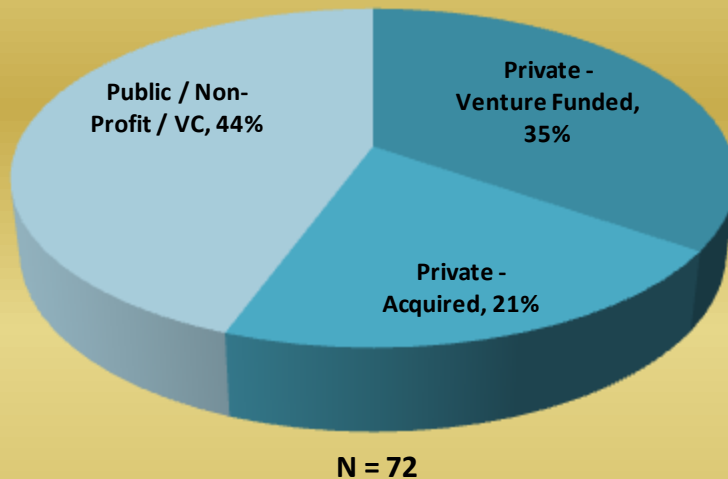


Team Member	Company/Organization	Experience
Mickey Urdea, PhD	Tethys, Catalysis Foundation for Health, Bayer, Chiron	Entrepreneur, Scientist, Diagnostics Executive/Expert, Inventor
Paul Neuwald, PhD	AcroMetrix, Chiron, Abbott, NIH	Program Director, Scientist, Entrepreneur, Quality Systems, Product Development
Rich Thayer, MBA	Catalysis Foundation for Health, Roche, Praxsys, Chiron	Entrepreneur, Diagnostics Business Executive, Strategy and Programs
Dave Hendricks, PhD	Bayer, Chiron, Gene-Trak Systems	Clinical Studies, Market & Product Development, Scientist, Professor
Lou Riceberg, PhD	BioBridge Strategies, Chiron, Ciba Corning, BBC	Strategy and Business Planning, Market Development, International Business
Harald Rinde, MD, MBA	BioBridge Strategies, Novartis, Ciba Geigy	Medical Practice, Health Economics, Pharma-Dx Interface
Katherine Tynan, PhD	Vitra Bioscience, Applied Biosystems, Oncogenetics, Datagenetics	Business Development, Equity Investment, Strategic and Business Planning, Marketing
Laura Penny, PhD	Pharsight, GeneLogic, Quintiles, Sequana	Technology Assessment, Market Research, Medical Genetics, Scientist
Dave Chernoff, MD	Elan, Chiron, UCSF Medical Center	Medical Practice, Pharma-Dx Interface
Others (>100 total)	Large and Small Diagnostics, Life Sciences, Devices and Pharma Companies	Subject Matter Experts, Diagnostics, Pharma, Med Devices, Bioscience

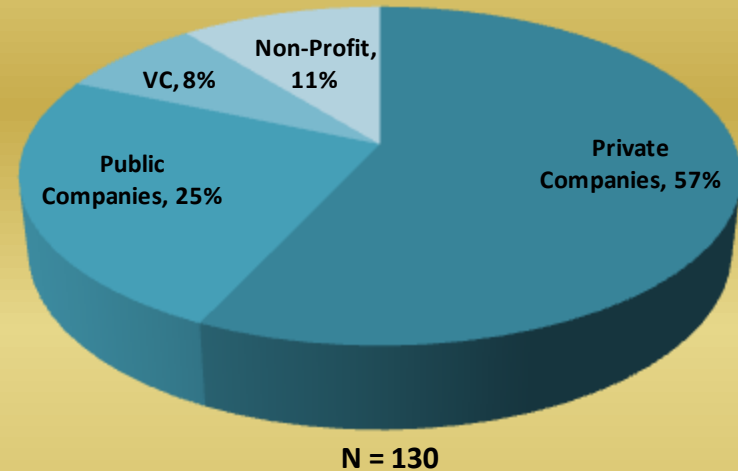


# Halteres Associates: Client and Project Summary

## Clients



## Projects



- The majority of our clients are venture-backed private companies, 38% of which were acquired (21% of total clients)
- Other institutions include non-profit foundations, private investment firms and publically traded companies
- A significant number of our clients come back to us requesting that we do follow-on projects (customer satisfaction is key!)

# Halteres Associates: Venture and Foundation Clientele

## Venture Capital Firms

- aeris Capital AG
- CMEA Ventures
- InterWest Partners
- Kleiner Perkins Caufield & Byers
- Longitude Capital Management
- Mohr Davidow Ventures
- Morningside Technology Advisory
- Skyline Ventures



## Foundations

- Catalysis Foundation for Health
- The Bill and Melinda Gates Foundation



# Halteres Associates: Public and Private Clientele

- Aclara Biosciences, Inc. (acquired by Monogram)
- Adamas Pharmaceuticals, Inc.
- Advanced Cell Diagnostics, Inc.
- Affymetrix, Inc.
- Angelica Therapeutics, Inc.
- Artemis Health, Inc.
- Bayer Diagnostics
- CELlective Dx Corporation (renamed On-Q-ity)
- Chembio Diagnostics, Inc.
- Chiron Diagnostics
- Compugen Limited
- Crescendo Bioscience, Inc.
- Curetis AG
- DiscoverRx Corporation
- DNAR, Inc. (renamed On-Q-ity)
- Dow Chemical Company
- Eos Biotechnology, Inc.
- Epoch Biosciences (acquired by Nanogen)
- GE Healthcare
- Genelex Corporation
- GeneNews Corporation
- Genentech USA, Inc.
- Genomic Health, Inc.
- Glycominds Ltd. (acquired by Savyon Diagnostics)
- GPB Scientific, LLC
- Ibis Biosciences, Inc. (acquired by Abbott Molecular)
- Iconix Biosciences, Inc. (acquired by Entelos)
- ID Biomedical Corp. (acquired by GSK)
- Idun Pharmaceuticals, Inc. (acquired by Pfizer)
- Integrated Diagnostics, Inc.
- Intel Corporation

# Halteres Associates: Public and Private Clientele



- Invenux, Inc.
- Investigen, Inc.
- Johnson & Johnson Research Pty, Ltd.
- Life Technologies Corporation
- LJI BioSystems, Inc. (acquired by Molecular Devices)
- Luminex Corporation
- Metabolex
- Molecular Staging, Inc.
- Nanōmix, Inc.
- Nodality, Inc.
- Norwood Abbey, Ltd.
- Novartis, Inc.
- NuGEN Technologies
- Panomics, Inc. (acquired by Affymetrix)
- ParAllele Bioscience (acquired by Affymetrix)
- Pathwork Diagnostics, Inc.
- Predicant, Inc. (acquired by Pathwork Diagnostics)
- Quantum Dot Corp. (acquired by Invitrogen)
- Roche Molecular Systems, Inc.
- Satoris, Inc.
- Sensovation AG
- Siemens Healthcare Diagnostics, Inc.
- Singulex, Inc.
- Sirius Genomics, Inc.
- SRU Biosystems, Inc.
- Tethys Bioscience, Inc.
- UCLA Dental Research Institute
- Ventana Medical Systems, Inc. (acquired by Roche)
- Visible Genetics, Inc. (acquired by Bayer)
- Whatman, Plc. (acquired by GE Healthcare Sciences)



# Halteres Associates: How We Have Helped our Clients

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## Examples include...

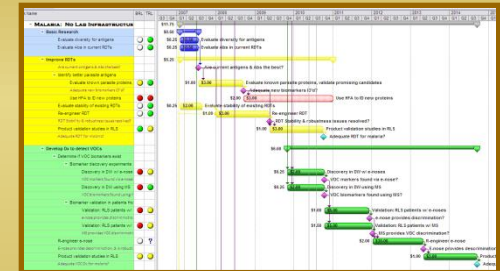
- Helped establish credibility and market awareness by establishing relationships between clients and key opinion leaders within their market space
- Designed clinical studies to validate innovative products, and identified the sample banks required to complete those studies
- Prepared clients for product manufacture by assessing compliance with international regulatory and quality requirements
- Helped clients establish, license and manage CLIA-compliant clinical diagnostic testing laboratories
- Evaluated the impact of innovative products on healthcare costs through health economic analyses



# Halteres Associates: How We Have Helped our Clients

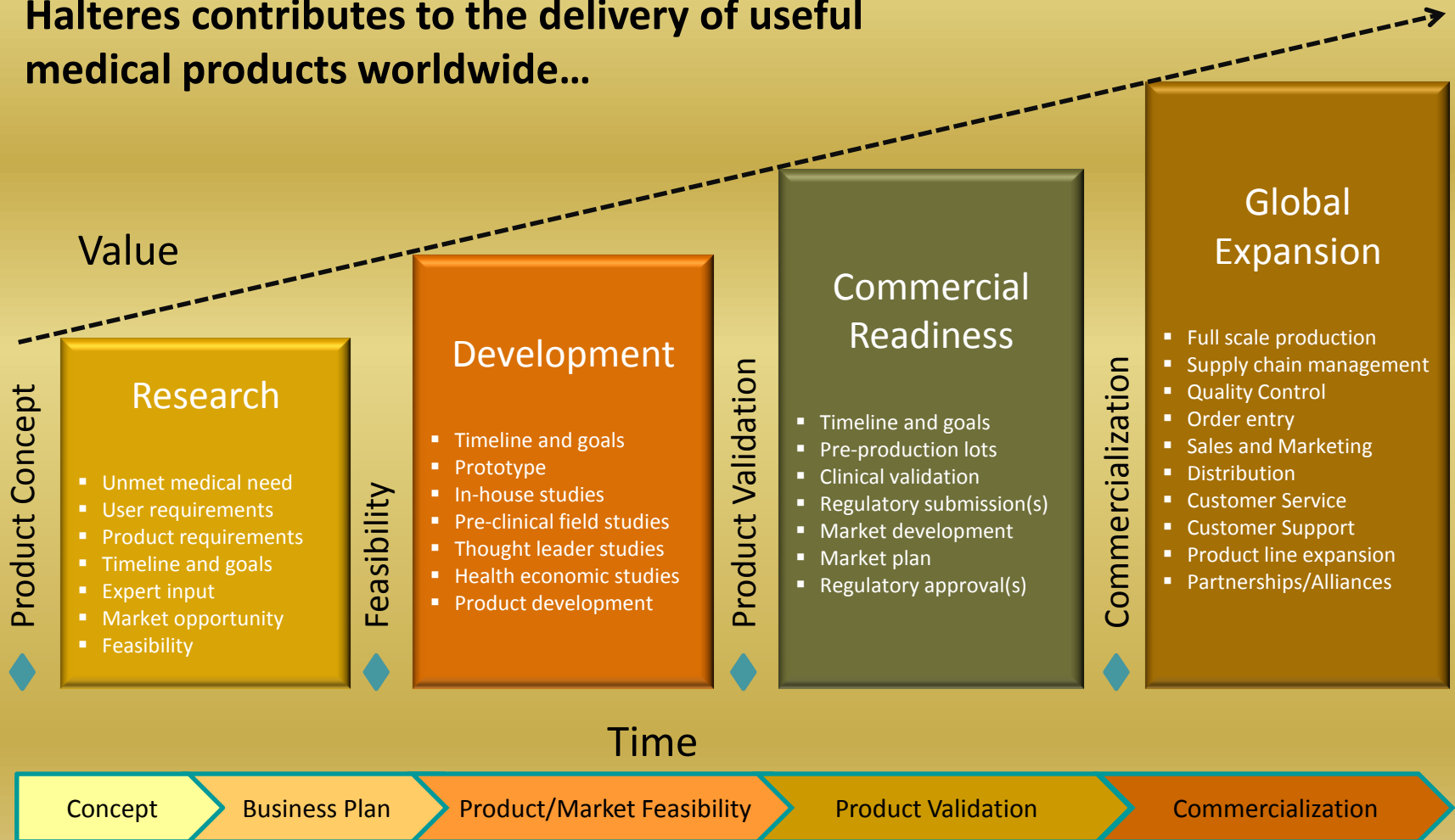
## Examples include...

- Identified and evaluated potentially useful biomarkers and technologies for application to diagnostic products for resource-limited settings within the developing world
- Developed a detailed roadmap, including estimated costs, risks, gaps and timing, for the discovery, development and validation of important infectious disease biomarkers
- Evaluated factors affecting the supply of diagnostic products to the developing world (demographics, medical practice, logistics, financial considerations, business models, etc.)
- Developed detailed business models showing what will be required to deliver useful diagnostic products to resource-limited settings within the developing world
- Assessed, first-hand, medical practices in Africa, Latin America, India and China and developed case studies



# Halteres Associates: What We Bring to the Table

Halteres contributes to the delivery of useful medical products worldwide...



# Halteres Associates: What We Bring to the Table

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## General Capabilities...

- We understand how to assess biological, technical and business risks, formulate strategic plans, and recommend business models and partnership options for companies and non-profit organizations
- We advise on program plans from initial discovery research to post-commercialization follow-up activities
- We understand what is driving domestic and global bioscience markets today, including emerging markets
- We understand what it takes to successfully start and run a bioscience company; we've done it ourselves
- We've worked with start-up, venture-backed, private and public companies, and non-profit organizations
- We understand funding requirements in the global market



# Halteres Associates: What We Bring to the Table

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## Gap-filling Needs...

- Partner opportunity assessments
- Market and competitive analyses
- New market expansion opportunities
- Business plan reviews and risk assessments
- Business and market sustainability programs
- Assessment of trends in global diagnostic markets
- Disease area-specific clinical and medical practices
- Clinical laboratory start-up (licensure and execution)
- Cost analyses for diagnosis, treatment and prevention
- Temporary executive assistance (e.g., Acting Chief Medical Officer)



# Halteres Associates: Case Study #1 – Dx Supply Assessment

## Client

- Non-profit organization focused on making improvements in global health
- Funds programs aimed at delivering diagnostic products to the developing world

## Need / Deliverable

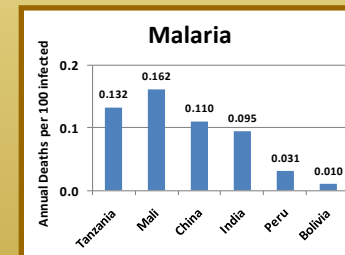
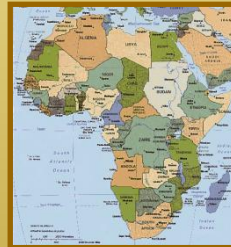
- Evaluate what will be required to deliver infectious disease diagnostic products to resource-limited settings in Africa, Latin America, India and China
- Develop case studies showing potential risks, barriers and solutions
- Generate sustainable business models for delivering useful diagnostic products

## Duration

- 18 months

## Outcome

- Halteres recommendations will be used in future client diagnostic programs



“I would like to extend my thanks to the entire Halteres team for a very productive (final project review) meeting today. We...came to some key recommendations which I know the Foundation will find very useful as we go forward in our future diagnostic programs.” – Senior Program Officer at a Non-profit Organization (Access to Diagnostics Assessment Project)

# Halteres Associates: Case Study #2 - Market Assessment

## Client

- Molecular diagnostic division of a major publically traded company
- Interested in entering new diagnostic market sector

## Need / Deliverable

- Determine US market segments, landscape and size for new diagnostic testing area
- Compare and contrast major players in this field and their products
- Determine unmet clinical needs and how the client's products address these needs

## Duration

- 1 month

## Outcome

- Client decided not to enter the new sector due to relatively small market size

Factors for Estimation of Market Size	Number of Patients	Additional Individuals Sequenced for Match	Total Number of Specimens Sequenced	Revenues
Unrelated Allogeneic Transplants	3,500	6	24,500	\$10,584,000
Related Allogeneic Transplants	6,286	1	12,571	\$5,431,968
Instrumentation				\$1,000,000
Reagents for Determining Sequences				\$970,900
<b>Total</b>	<b>9,786</b>		<b>37,071</b>	<b>\$17,985,758</b>

“Thanks so much for this excellent analysis. The pleasure was ours!”  
– International Business Leader at a major diagnostics company (HLA Testing Market Analysis Project)

# Halteres Associates: Case Study #3 - Strategic Assessment

## Client

- European diagnostics startup company with seed funding and MDx technology

## Need / Deliverable

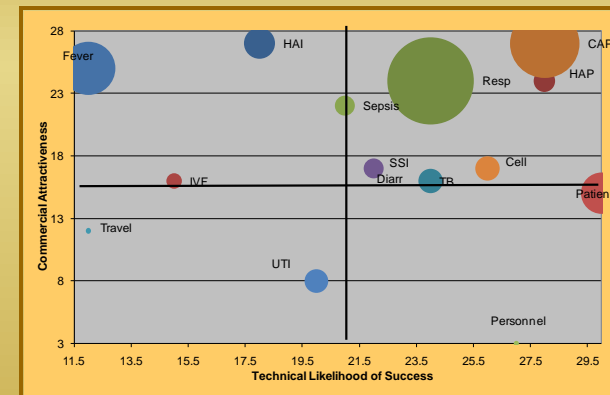
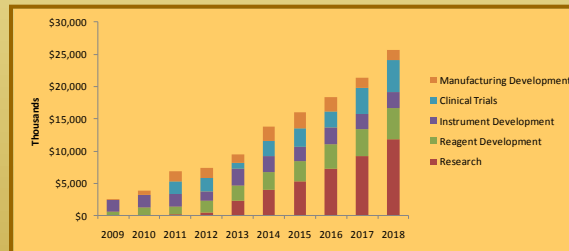
- Identify most attractive diagnostic applications and markets
- Determine value proposition (health economics and business modeling)
- Generate and refine investor presentation
- Review and provide feedback on business plan

## Duration

- 3 months

## Outcome

- Secured Series A funding from European investment firm



“We were positively impressed by the productivity and depth of knowledge contributed by each of the Halteres team members. As renowned specialists with tremendous individual expertise in the IVD market and healthcare industry, they helped us to develop a sound business plan and to optimize our business strategy, on time and on budget. We thoroughly enjoyed working with them.” – Managing Director of a European diagnostics startup company (Strategic Assessment Project)



# Halteres Associates: Additional Client Feedback

“For a diagnostic startup company like ours, the first product is of life or death importance, and you have only one chance to get it right. Halteres’ unique methodology and thorough process takes the guesswork out of selecting the optimum market opportunity thus maximizing the chances of success.”

– President and CEO of a molecular diagnostics startup company (Strategic Assessment Project)

“I wanted to thank you and the team for a great experience. I think that we have an extraordinary technology that you all have made far more extraordinary by defining where we can best derive value. Frankly, I wish I had called you even earlier than I did.”

– Chief Financial Officer at a mid-stage diagnostics company (Strategic Assessment Project)

“Thank you for joining us for the NIH grant program review. Your presence was important to me and my team. I look forward to interacting with you again in the near future.”

– Prof. & Chair, School of Dentistry and Director, Dental Research Institute at a major university (Grant Review Support Project)

“Our colleague... (an) HIV physician and head of Clinical Affairs, was very pleased with the team’s work. In his words, you ‘nailed it.’”

– Director, Technology Management at a major diagnostics company (HIV POC Market Analysis Project)

“Halteres has consistently provided our company with the expertise we needed when we needed it. With depth and breadth – a one stop consultant shop.”

– President and CEO of a therapeutics startup company (Pharmaceutical Market Assessment Project)

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# Halteres Associates: Contact Information

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