

# ***Understanding Value Creation in Bioscience***

## ***Early Stage Companies***

### ***Halteres Associates***

**July 2011**



Halteres from Ancient Greece  
National Archaeological Museum in Athens

This document contains the proprietary information of Halteres Associates, LLC . It is distributed to the recipient for informational use only and may not be reproduced in any form without the express written permission of Halteres.

# Halteres Associates: What We Can Do For You?

---

- Help define and assess the likelihood of success of the business proposition for your early stage bioscience company
- Determine the most appropriate path to technical, clinical, regulatory, reimbursement, and commercial success
- Assess the competition today and tomorrow; many of us probably worked with them or for them
- Think like the management team of a startup; offer advice on your organization strengths, needs, and talent gaps
- Estimate the financial requirements based on many years of operating experience in similar companies
- Help position the company to maximize value
- Get investors and Board members excited about the prospects of the new product opportunities for the company

Potential

Path to Success

Competition

Management

Finance Needs

Value

Presentation

# Halteres Associates: What Is Your Challenge?

---

**You are committed to building a successful new bioscience business, but...**

- Your organization requires assistance assessing potential product applications, markets, competitors, pricing, business and financial models, etc.
- Your organization does not have the internal business expertise to properly position or present the company, its technology or your value proposition to potential investors or Board members
- Specialized assistance is required in functional areas where you are not properly staffed at this stage in your growth



# Halteres Associates: Company Overview

---

## Our approach works...

Halteres was formed in 2002 to help maximize client value creation by providing strategic and tactical consulting services to bioscience organizations and investors

- 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 sets us apart from other consulting firms

Following a Halteres project, every one of our clients has achieved their goals

- Those who wanted to be acquired, were
- Those who sought funding, obtained it

**SANTA CLARA, Calif., December 8, 2008 – Affymetrix, Inc. (Nasdaq: AFFX)** today announced the completion of its acquisition of Panomics, Inc., a privately held, Fremont, Calif.-based company which offers a powerful suite of assay products...

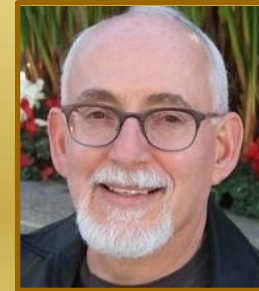
**NEW YORK, NY, September 2, 2009 – Advanced Cell Diagnostics (ACD)** said Tuesday that it has raised \$5.4 million in a Series A financing from Morningside Ventures. The company plans to use the funding to develop diagnostic tests based on its RNAscope technology...

# Halteres Associates: Depth of Team Experience



# Halteres Associates: Meet Our Professionals

---



...and many more

# Halteres Associates: Introducing the Core Team

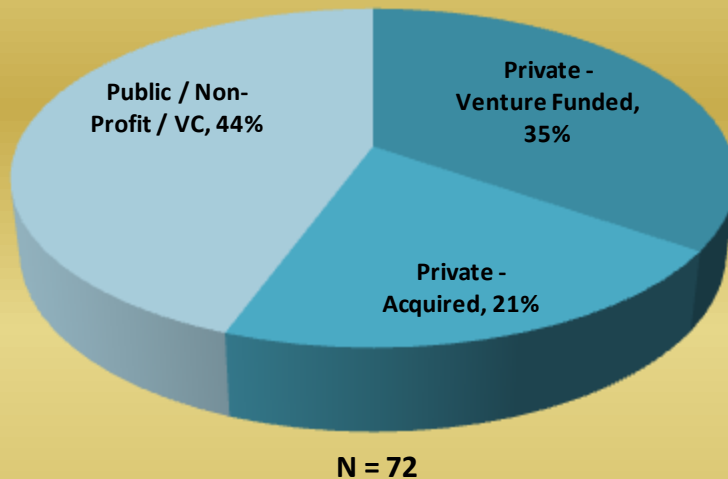


Team Member	Company/Organization	Experience
Mickey Urdea, PhD	Tethys, Catalysis Foundation for Health, Bayer, Chiron	Entrepreneur, Scientist, Diagnostics Executive/Expert, Inventor
Paul Neuwald, PhD	AcroMetrix, Chiron, Abbott, NIH	Program Director, Scientist, Entrepreneur, Quality Systems, Product Development
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

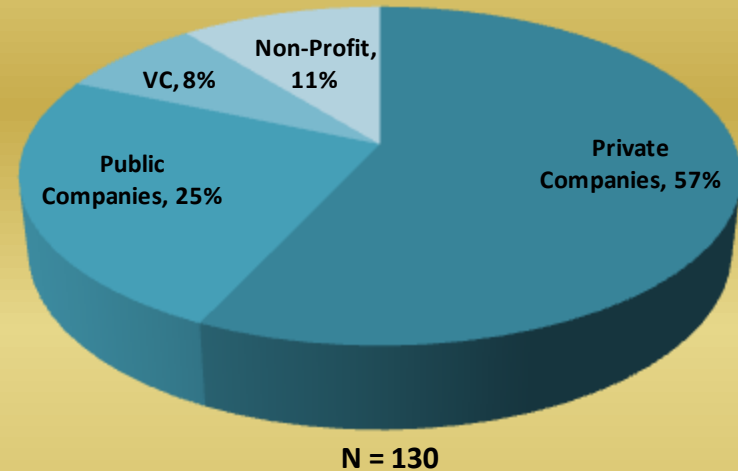


# Halteres Associates: Client and Project Summary

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: 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: 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



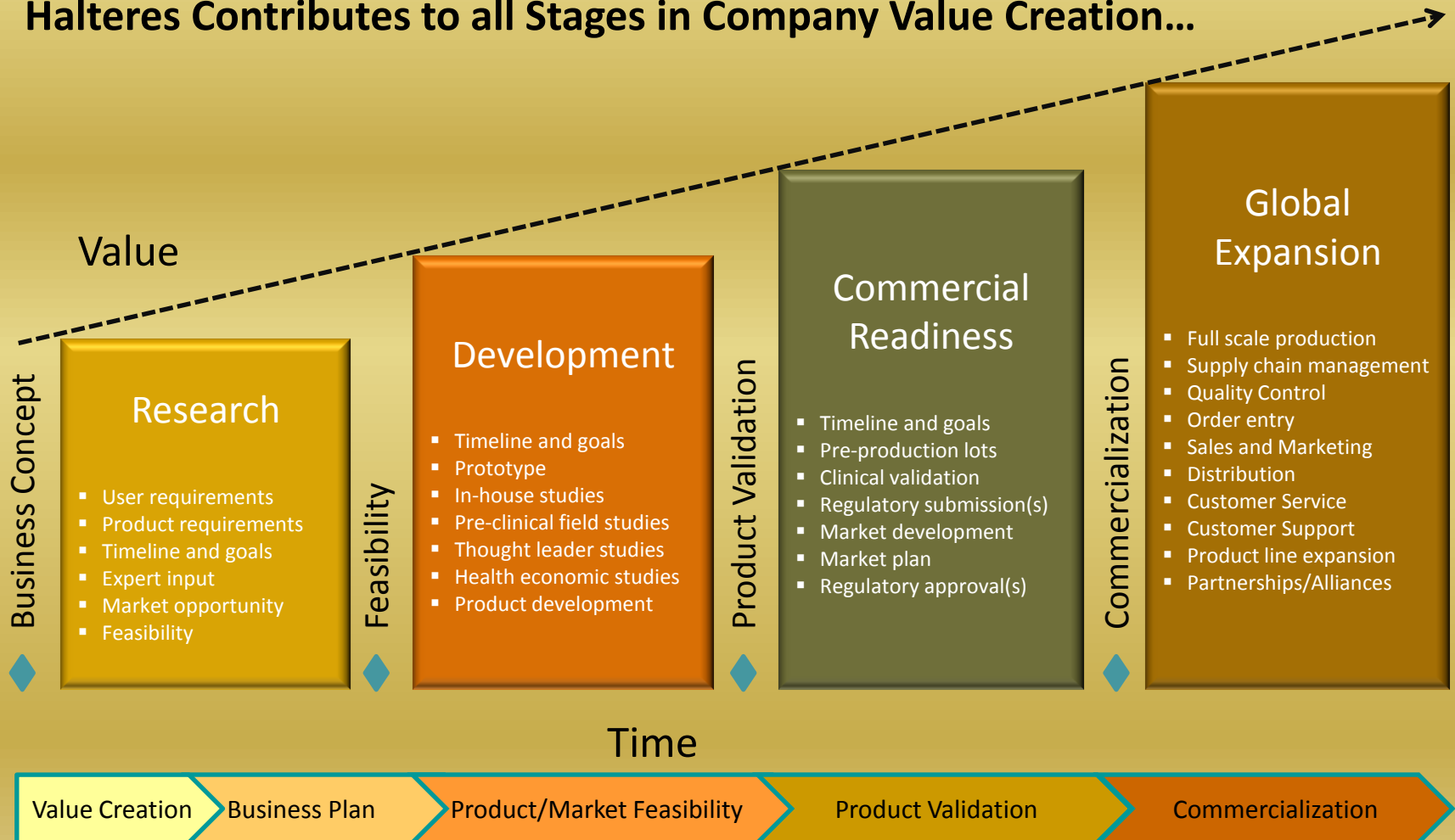
## Foundations

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



# Halteres Associates: What We Bring to the Table

Halteres Contributes to all Stages in Company Value Creation...



# Halteres Associates: How We Have Helped our Clients

---

## Examples include...

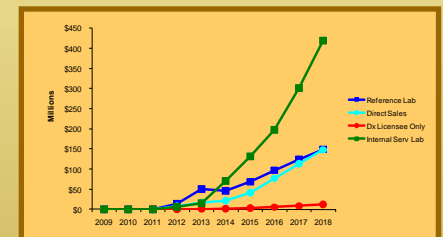
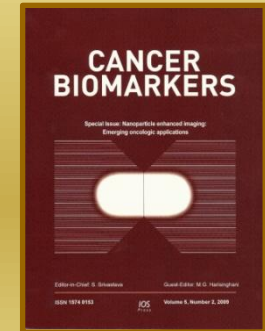
- Helped establish credibility and market awareness by setting up relationships between clients and key opinion leaders within their market space
- Designed clinical studies to validate the client's product, and identified the sample banks required to complete those studies
- Prepared clients for product manufacture by assessing compliance with international regulatory and quality requirements
- Helped clients establish, license and manage CLIA-compliant clinical diagnostic testing laboratories
- Established value-based pricing of client's products through health economic analyses



# Halteres Associates: How We Have Helped our Clients

## Examples include...

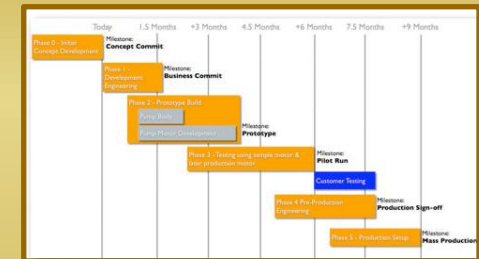
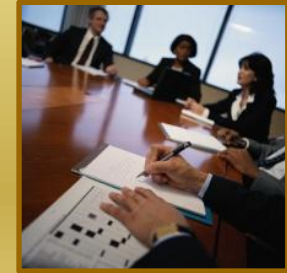
- Identified the unique, and potentially most valuable, market opportunities for several clients for biomarkers and/or technologies
- Conducted market assessments for potential new product offerings by early stage firms as well as major molecular diagnostics companies
- Conducted competitive assessments for potential new product offerings targeted for specific market segments
- Developed detailed business and financial models showing investments and operating expenses required to achieve positivity
- Prepared clients for the next round of funding (Series A, B, C, etc.) by developing compelling slide presentations



# Halteres Associates: What We Bring to the Table

## General Capabilities...

- We understand how to assess technical and business risk, formulate strategic plans, and recommend business models and partnership options
- 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 today's market



# Halteres Associates: What We Bring to the Table

---

## 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
- Disease area-specific clinical and medical practices
- CLIA laboratory start-up (plan, licensure and execution)
- Reimbursement strategy for complex molecular testing
- Assessment of market growth trends in molecular diagnostics
- Temporary executive assistance (e.g., Acting Chief Medical Officer)



# Halteres Associates: Case Study #1 – Product Development

---

## Client

- Venture-funded molecular diagnostics company focused on oncology testing
- Develops products and delivers tests through its CLIA-certified laboratory

## Need / Deliverable

- Provide advice on technical development plan for new test offering
- Advise on requirements for CLIA lab as well as IVD clearance through FDA
- Assist in design, development and review of protocols, plans and procedures

## Duration

- 4 months



## Outcome

- Client successfully launched the new test offering through its CLIA-certified lab



“I wanted to second the feelings of everyone here and thank you for all of your help in what has been an extraordinarily valuable project for us. And that value will only increase with time, as we bring the manufacturing of our products into compliance with the QSR.” – CFO at a mid-stage diagnostics company (ISO and QSR Compliance 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

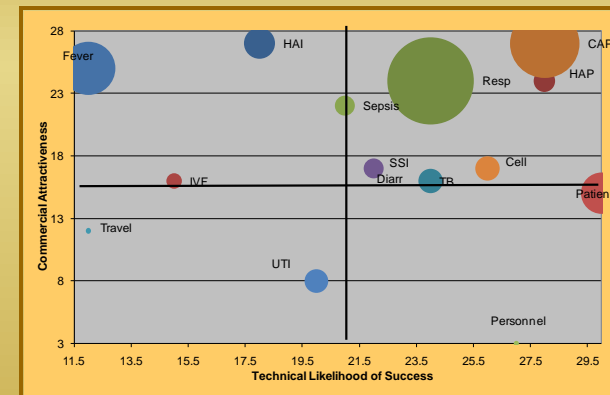
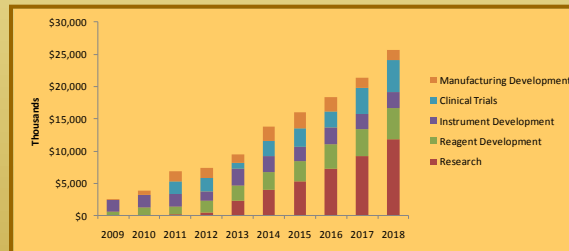
- Identify most attractive diagnostic applications and markets
- Determine value proposition (health economics and business modeling)
- Generate and refine investor presentation
- Review and provide feedback on business plan

## 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: Case Study #4 - Strategic Assessment

## Client

- American diagnostics startup company with seed funding and MDx technology

## Need / Deliverable

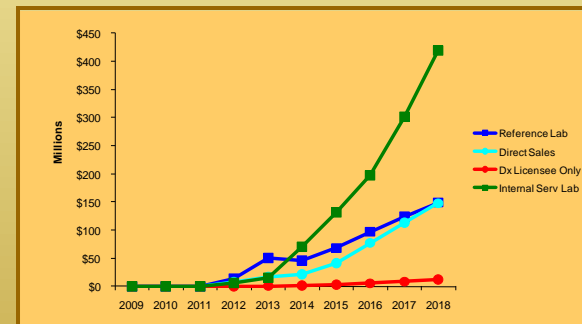
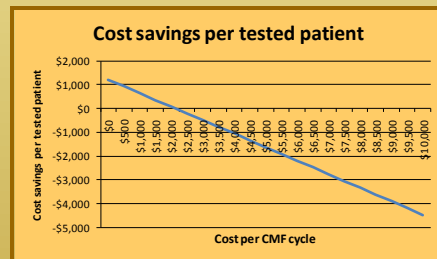
- Determine medical need and identify most attractive applications
- Assess market and competitive landscape
- Determine value proposition (health economics and reimbursement)
- Generate business and financial models

## Duration

- 3 months

## Outcome

- Secured Series A funding from off-shore VC investment firm



“The team from Halteres has been helpful to me in every aspect of our business planning, from initial feasibility and market sizing, to product development, all the way through how we are going to get the product adopted and paid for.”  
– President and CEO of an American 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)

# Halteres Associates: What We Can Do For You?

---

- Help define and assess the likelihood of success of the business proposition for your early stage bioscience company
- Determine the most appropriate path to technical, clinical, regulatory, reimbursement, and commercial success
- Assess the competition today and tomorrow; many of us probably worked with them or for them
- Think like the management team of a startup; offer advice on your organization strengths, needs, and talent gaps
- Estimate the financial requirements based on many years of operating experience in similar companies
- Help position the company to maximize value
- Get investors and Board members excited about the prospects of the new product opportunities for the company

Potential

Path to Success

Competition

Management

Finance Needs

Value

Presentation

# Halteres Associates: Contact Information

---



**Mickey Urdea, Managing Partner:** 510-708-7478  
[murdea@halteresassociates.com](mailto:murdea@halteresassociates.com)



**Paul Neuwald, Principal & Contracts Manager:** 925-586-0486  
[pneuwald@halteresassociates.com](mailto:pneuwald@halteresassociates.com)



**Richard Thayer, Principal:** 925-487-3247  
[rthayer@halteresassociates.com](mailto:rthayer@halteresassociates.com)

**Web Site:** [www.halteresassociates.com](http://www.halteresassociates.com)

This document contains the proprietary information of Halteres Associates, LLC . It is distributed to the recipient for informational use only and may not be reproduced in any form without the express written permission of Halteres.