



Understanding Value Creation in Bioscience

Gap Filling Assistance

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?

- Help define and assess the likelihood of success of a specific business initiative for your bioscience company
- Determine the most appropriate path to technical, clinical, regulatory, reimbursement, and commercial success
- Assess market sizes, adoption rates, market segments and other market parameters currently and in the future
- Assess the competition today and tomorrow; many of us probably worked with them or for them
- Assist in implementation or audit of a quality system, clinical study design, regulatory filings, CLIA lab establishment, etc.
- Estimate financial requirements based on many years of operating experience in similar companies
- Get executive management excited about new ideas, initiatives and product expansion opportunities

Potential

Path to Success

Market

Competition

Specific Needs

Financials

Presentation

Halteres Associates: What Is Your Challenge?

You need to complete a specific task, but...

- Due to bandwidth limitations, qualified people within your organization do not have time to conduct the analysis or assessment
- Your organization does not have the internal expertise required to conduct the analysis or the assessment
- You need an independent expert analysis or assessment or a confirmation of your internal findings



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

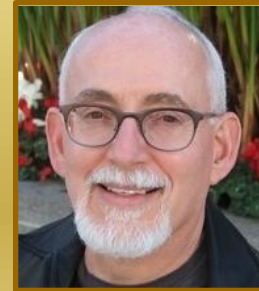
SANTA CLARA, Calif., December 8, 2008 – Affymetrix, Inc. (Nasdaq: AFFX) today announced the completion of its acquisition of Panomics, Inc., a privately held, Fremont, Calif.-based company which offers a powerful suite of assay products...

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

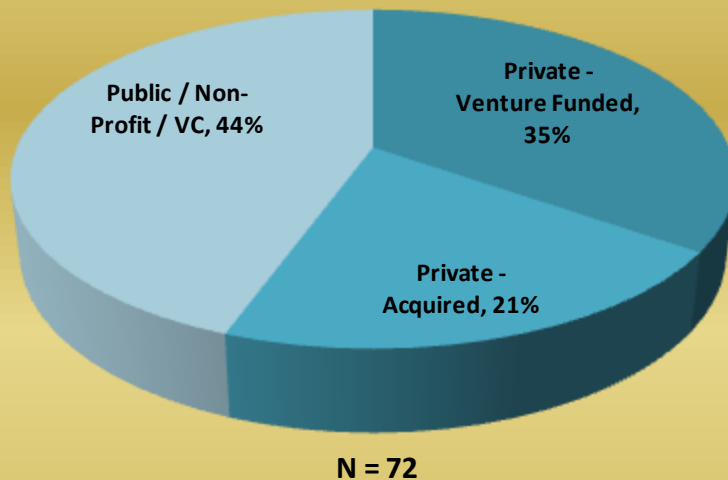


Team Member	Company/Organization	Experience
Mickey Urdea, PhD	Tethys, Catalysis Foundation for Health, Bayer, Chiron	Entrepreneur, Scientist, Diagnostics Executive/Expert, Inventor
Paul Neuwald, PhD	AcroMetrix, Chiron, Abbott, NIH	Program Director, Scientist, Entrepreneur, Quality Systems, Product Development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

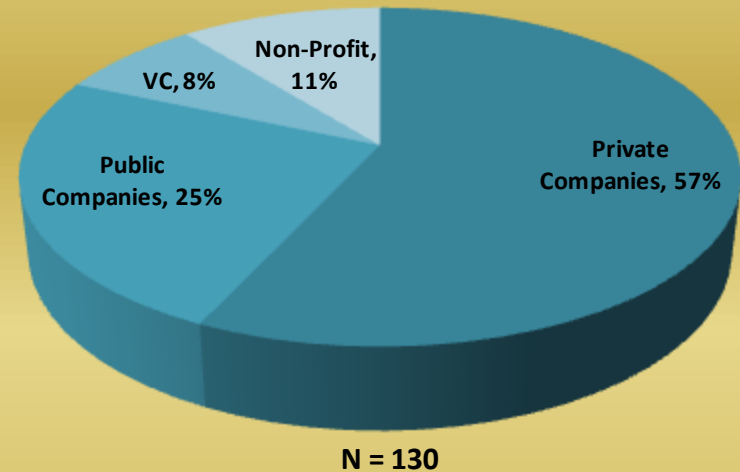


Halteres Associates: Client and Project Summary

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



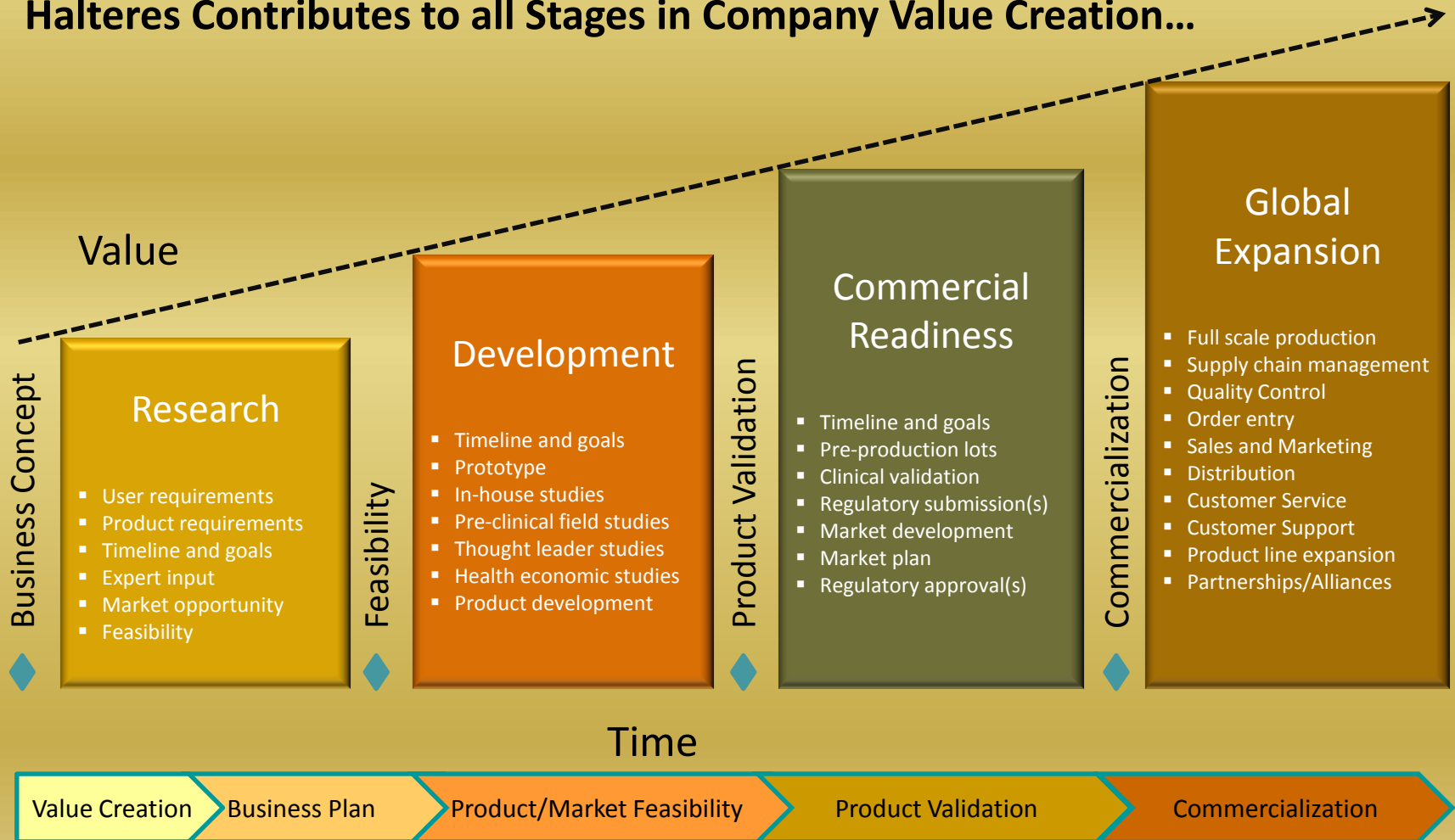
Foundations

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



Halteres Associates: What We Bring to the Table

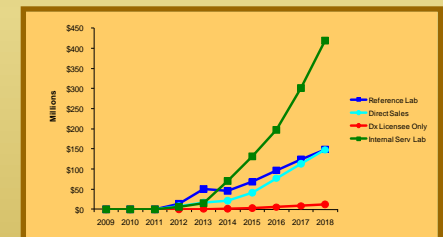
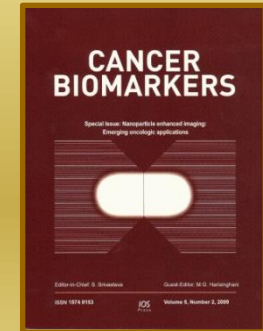
Halteres Contributes to all Stages in Company Value Creation...



Halteres Associates: How We Have Helped our Clients

Examples include...

- 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 major molecular diagnostics companies
- Conducted health economic analyses determining product value and establishing value-based reimbursement levels
- 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: How We Have Helped our Clients

Examples include...

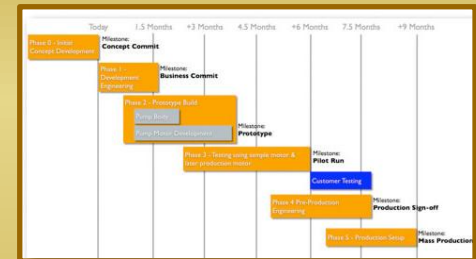
- Helped establish credibility and market awareness by setting up relationships between clients and key opinion leaders within their market space
- Designed clinical studies to validate the client's product, and identified the sample banks required to complete those studies
- Prepared clients for product 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: 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 it takes to successfully run a bioscience company; we've done it ourselves
- We understand what is driving domestic and global bioscience markets today, including emerging markets
- 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 assessment
- 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
Total	9,786		37,071	\$17,985,758

“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

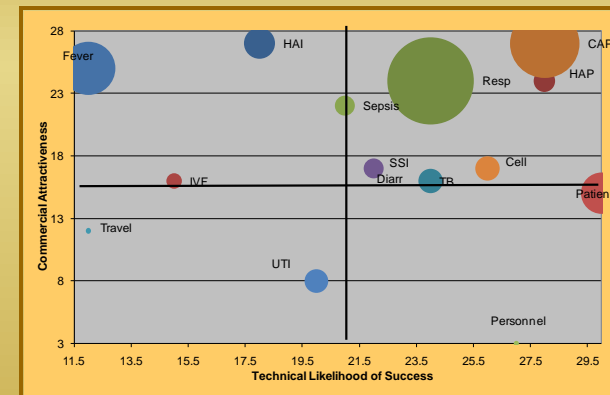
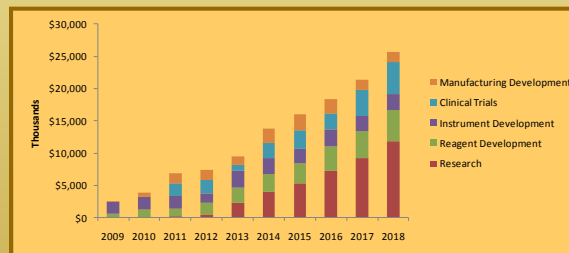
- Identify most attractive diagnostic applications and markets
- Determine value proposition (health economics and business modeling)
- Generate and refine investor presentation
- Review and provide feedback on business plan

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

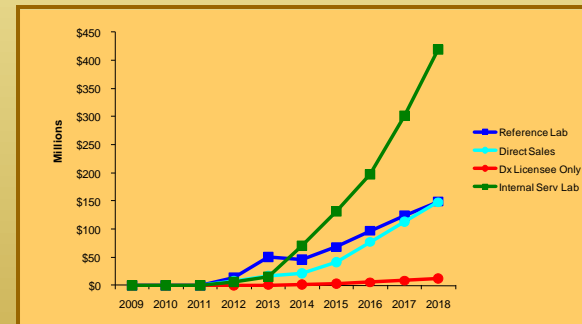
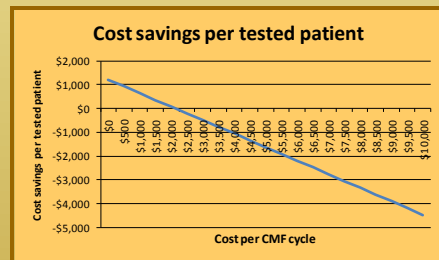
- Determine medical need and identify most attractive applications
- Assess market and competitive landscape
- Determine value proposition (health economics and reimbursement)
- Generate business and financial models

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)

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Competition

Specific Needs

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Presentation

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