

geneacres17

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Track 4 – Business Solutions

**SciClone Pharmaceuticals and LONZA:
Win – Win Contract Manufacturing**

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Agenda

- Introduction
 - SciClone Pharmaceuticals
 - LONZA
- The Issue
- Challenges in Resolving the Issue
- Actions
- Outcomes
- Critical Success Factors
- Conclusions

SciClone Pharmaceuticals

- Profit-Driven Enterprise
 - Solid global sales growth drives sustainable profitability
 - 2008 revenues: \$54 M; 46% increase
 - 2009 guidance
 - \$69-\$71 M revenues; initial \$60-\$62 M
 - 30% revenue increase over prior year
 - \$0.10 - \$0.14 EPS; ; initial \$0.00-\$0.02
- International Commercial Success
 - ZADAXIN marketed in more than 30 countries
 - Established business in China with ~175-person sales organization
- Rich Product Portfolio in Oncology and Infectious Disease
 - Invest in cost-efficient phase 1/2 trials; partner phase 3 trials
 - 1 marketed product; developing 3 molecules in 5 indications

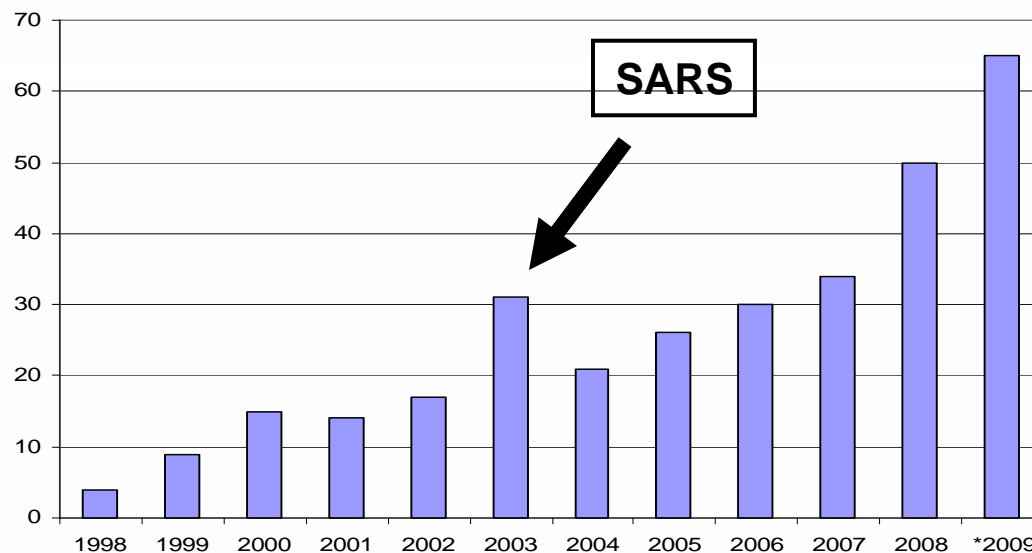
Product Pipeline

	Phase 1	Phase 2	Phase 3	Marketed
ZADAXIN				
HBV/HCV & Other Indications China, Russia & >30 other countries	[Progress bar spanning Phase 1, 2, and 3]			
H1N1 Vaccine Enhancement Italy & 12 countries; global	[Progress bar spanning Phase 1, 2, and 3]			Marketing approval targeted 1H 2010
Stage IV Melanoma U.S./Europe treat and prevent nausea and vomiting caused by chemotherapy, radiotherapy, and surgery	[Progress bar spanning Phase 1 and 2]			
DC Bead				
Liver cancer China	[Progress bar spanning Phase 1, 2, and 3]			Marketing approval expected 2010
Ondansetron RapidFilm				
Anti-nausea/vomiting (chemotherapy) China & Vietnam	[Progress bar spanning Phase 1, 2, and 3]			Marketing approval expected 2011
RP101				
Pancreatic Cancer U.S. & Canada	[Progress bar spanning Phase 1 and 2]			
SCV-07				
Oral Mucositis in Head/Neck Cancer Global (Ex-Russia)	[Progress bar spanning Phase 1 and 2]			
HCV Global (Ex-Russia)	[Progress bar spanning Phase 1]			

Product Profile

- Product was launched in China in 1996
- Thymalfasin (chemical name of Zadaxin) is a naturally occurring, 28-amino acid peptide with both direct anti-cancer and immunomodulatory activities
- Indicated for the treatment of hepatitis B and as a vaccine adjuvant
- Used for hepatitis, liver cancer, severe infections, CMV infection after organ transplantation, and other indications

Zadaxin Revenues (\$Million)



* Worldwide 2009 revenue guidance is \$69 to \$71 Million

Key Success Factors

- Built a widely recognized brand
- Competing successfully with local generics
- Broad coverage of cities, hospitals, specialties
- Long-standing Key Opinion Leader relationships

LONZA

Leading-edge Technologies

- Chemical
- Biotechnological

Full-Service Offering

- Lead development through market supply

Financially Stable

- CHF 2.9 billion (2008 sales)
- Growth: 8-12% per year

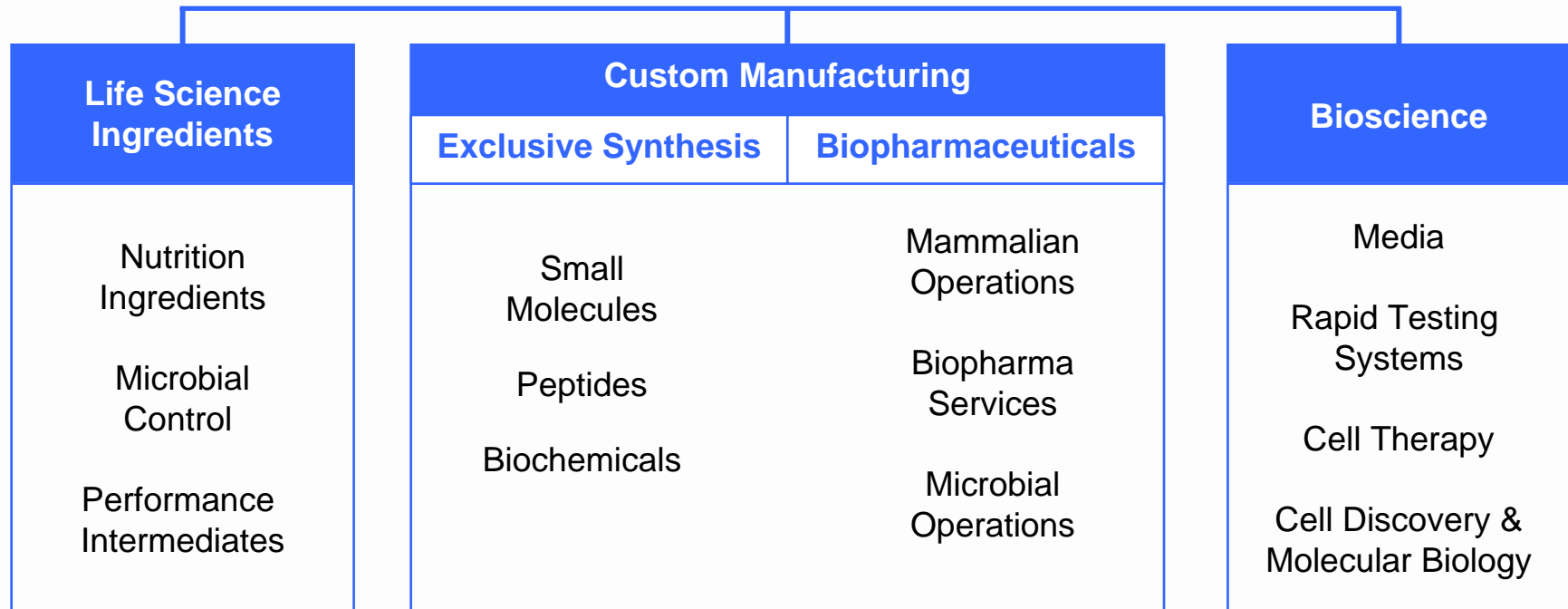
Global

- 27 facilities; 8,500 employees



LONZA's offering is designed to provide a complete yet flexible service

LONZA

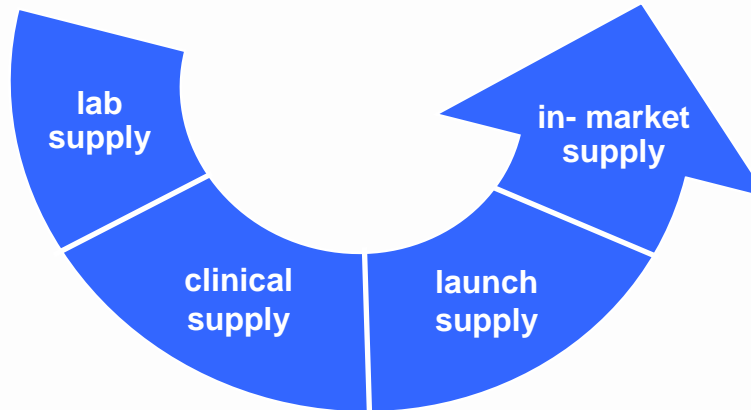


We remain focused on late-stage lead development and manufacturing



Products

- Early intermediates
- Advanced intermediates
- Bulk actives/ drug substance



A Broad Range of Production Scales

- Assists lifecycle management
- Increases flexibility
- Enables seamless scale-up

Chronology of Zadaxin Production: The Issue

- First contract signed in 1994 (with UCB Bioproducts); supply agreement renewed in 1999
- 1994 – 2005 modest annual forecasts; no issues producing material to meet SciClone's needs
- 2006 – UCB Bioproducts acquired by Lonza
- 2006 – Forecasts began to increase; Lonza found that process yields were low (<50% of 2005 yield); met increased forecasts by increasing number of campaigns
- 2007 – SciClone signalled significantly larger forecasts
- Larger forecast required a new approach to the entire process

Challenges in Resolving the Issue

- Technical
- Cultural/Organizational
- Planning

Technical Challenges

- Variable Cycle Times
- Variable Yields (Often Lower than Expected)
- Not Easy to Identify Where in Process Problems Exist
- Lack of Available Data

Cultural/Organizational Challenges

- Lonza Acquisition of UCB
- Organizational Changes
- Language (x2)
- Style of Communication

Planning Challenges

- Forecast Uncertainty
- No Rolling or Long-Term Forecast Provided
- Inventory at Less Than Desired Levels
- ERP Capabilities

Planning Challenges (Cont'd.)

- Uncertain Delivery Dates & Quantities
- Long Lead-Times
- Single-Sourced
- Raw Materials
- No Safety Stock Strategy
- Supplier Agreement

Actions

- Intensified Communication & Information Sharing
 - Direct, face-to-face communication between the parties
- Conducted Root Cause Analysis & Process Mapping
- Developed Contingency Plans
- Established Firm Ship Dates

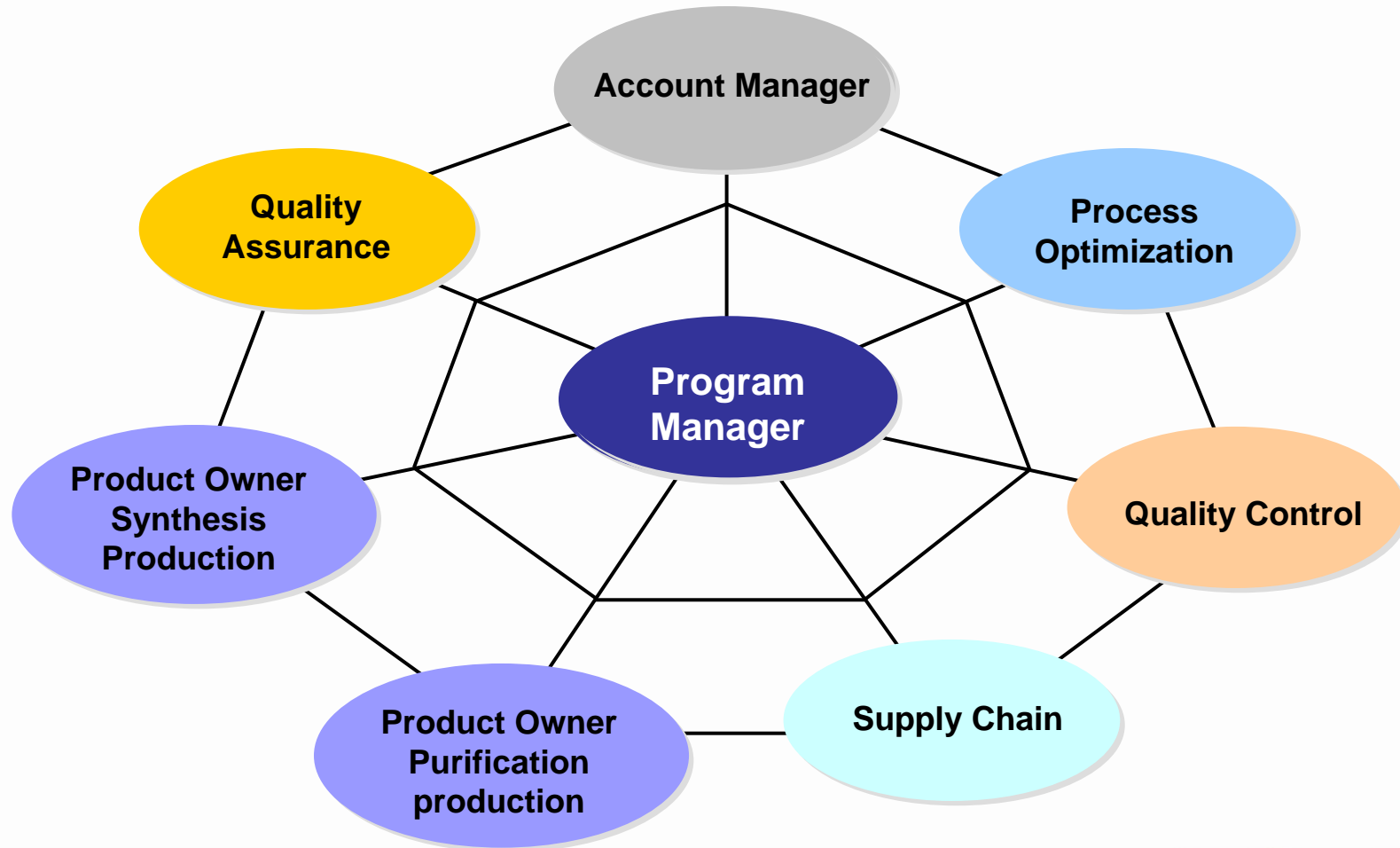
Outcomes

- Increased Process Yields → Increased Annual Productivity
- Improved Process Consistency
- Reduced Manufacturing Cycle Time
- Improved Relationship
 - Achieved Joint Safety Stock Plan
 - Agreed on “Win-Win” Contract Strategy

LONZA's View: Critical Success Factors

- Project Management Harmonization
- Account Management
- Operational Excellence
 - Liberty Project

Lonza Project Team for SciClone



Program Manager - Responsibilities

Project Management

- Lead multi-disciplinary project teams to ensure the successful delivery of customer projects on time, on budget and to the required quality
- To be the primary interface with the Customer regarding day-to-day project execution
- Responsible for controlling and monitoring the status of each project against the agreed project plan

Contract Management

- Prepare proposals and agreements in close collaboration with Sales
- Primary on-site interface for all contractual issues both internal and external
- To be the voice of the customer on site
- Financial responsibility for contracts e.g. budgeting, profitability, etc.
- Provide ongoing contractual support to Sales and Business Development.

Account Management

- Sales position stays tied to the account
- Local Representation
- Contract negotiations
 - Costs and scope from Program Manager
 - Drafts developed jointly with Program Manager
 - Feedback and support from Program Manager
 - Final decisions stay with Account Manager

Liberty Project

■ Technical Aspects

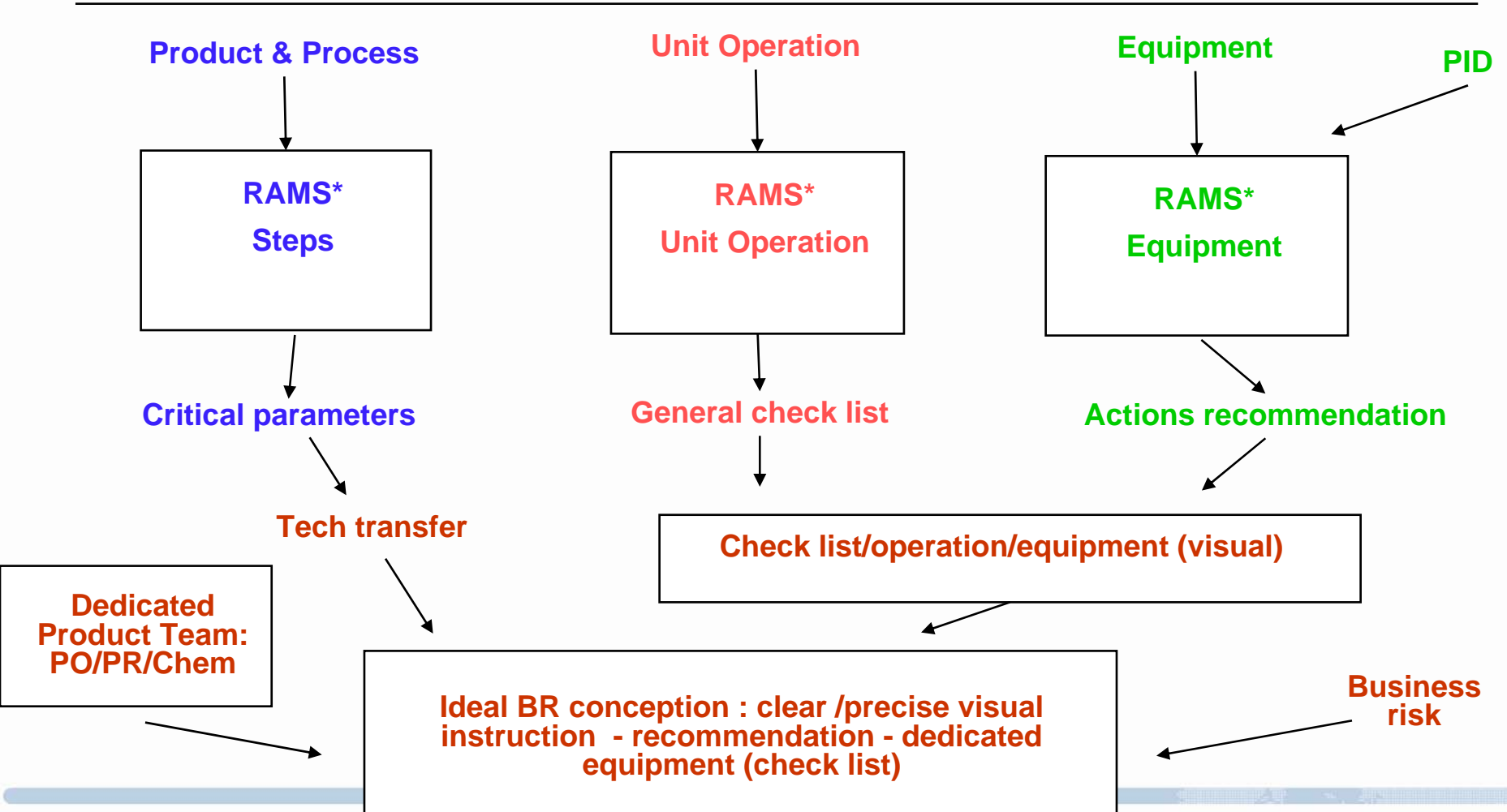
Risks Assessments Methodology System (RAMS)

- Intermediates
- Critical parameters for each step
- Equipment:
 - Dedicated/Appropriate equipment

Liberty Project

- People and Organizational Aspects
 - set-up Organization/Method : “Product Team”
 - define Ownership/Responsibilities/Roles/Tasks
 - Product Owner on field during critical operation
 - Product Responsible/Supervisor/Operators: staffing training before operations
 - Chemical Support
 - R&D: Technology Transfer SOP / Assistance ‘on-line’
 - In-Process “QA”

“Liberty Project”: Methodology



Successful Outcome: Conclusions

- LONZA and SciClone Addressed Manufacturing and Supply Issues Jointly
 - Technical
 - Effective tools used for problem solving
 - Cultural/Organizational
 - Account management
 - Operational excellence
 - Interdisciplinary project team
 - Planning
 - Defined process for forecasting & planning
 - Communication & Shared Vision
 - Openness of both parties to cooperate
 - Admitting own short comings
 - Listening to other party

Thank You

Questions?