

Biotech Journey through the Phases of Commercializing a Product

HRBioTech  **CONNECT**

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 **THE Nemetz Group** LLC

Who we are

ArnzenGroup LLC

- Firm started in 2001 by Breck Arnzen who has more than 30 years of exposure in multiple industries
- Specialize in Leadership and Organization Development with start-up and large companies
- Deep experience in the biotech and pharmaceutical industry
- Expertise in consulting and coaching leaders and leadership teams through major transitions and change

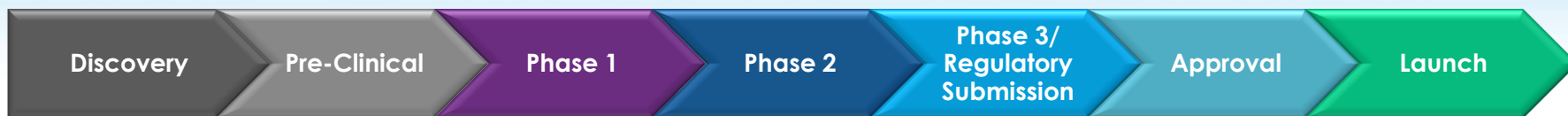
The NemetzGroup LLC

- Boutique consultancy founded in 2003
- Led by Susan Nemetz who has more than 30 years of pharmaceutical leadership experience
- A seasoned team of biopharmaceutical professionals each with 15+ years industry experience
- Deep and broad strategy and commercialization and marketing skills
- Experience spanning many therapeutic categories

Session flow

- Introductions and agenda review
- Industry trends overview
- Influence of corporate structure & strategy on commercialization focus
- Charting the commercialization journey
 - Case vignettes
- Building commercial capabilities
 - Challenges & decisions along the way
- Role of HR
- Leading the journey
- HR's levers & tools
- Action steps

Who was in the room?



Company position	Pressing aspects of the commercialization journey
2 drugs on market, + Phase 3	<ul style="list-style-type: none"> • Differentiating our products • Accessing physicians • Reorienting the company, getting comfortable with change
Pre-commercial	<ul style="list-style-type: none"> • Infusing a commercial discipline • Becoming more disciplined in line with regulatory overview
Launching a new company with existing products	<ul style="list-style-type: none"> • Building the business infrastructure
Product, + moving into Phase 3	<ul style="list-style-type: none"> • Risk of cannibalizing our existing product
Discovery	<ul style="list-style-type: none"> • Surviving check-to-check; how can we invest in early commercial activities?
Pre-launch	<ul style="list-style-type: none"> • Balancing continuing creativity & regulatory discipline
Moving into Phase 3	<ul style="list-style-type: none"> • How soon do we need to do ... what?
Late Phase 2, + Discovery	<ul style="list-style-type: none"> • Incorporating market thinking early on
Discovery, + Phase 2	<ul style="list-style-type: none"> • The push & pull around pace vis-à-vis competitors

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Overview of industry trends

Changing healthcare landscape

- Increased payer influence (e.g., value-based purchasing)
- New decision-makers and stakeholders
- Widespread use of health information technology (HIT)
- Consolidation of delivery providers

Novel Biotech/Pharma relationships

- VC funding trends
- Financing pressures
- Prevalent mergers & acquisitions

Increasing use of development outsourcing

- Strategic outsourcing partnerships
- New skill sets to define and manage critical deliverables
- Changing internal competency models
- Need to address health information technology (HIT) metrics

Evolving commercial models

- Reduced number of sales reps and high access barriers
- Increased account management orientation
- More customer centricity
- Focus on specialty products vs. primary care

Industry trends for HR professionals in various stage companies to watch

Trend	Implications for HR	Early biotech	Late stage	Commercial
Payer influence	<ul style="list-style-type: none"> Strengthen health economics competencies 	●	●	●
Downsizing	<ul style="list-style-type: none"> Manage morale Create lateral career paths 	○	○	●
Leaner field model	<ul style="list-style-type: none"> Evolve skill set & IC systems Support shift from detail rep to account manager/ science liaison 	○	○	●
Shift to specialists	<ul style="list-style-type: none"> Upgrade therapeutic skills & science background 	●	●	●
R&D outsourcing	<ul style="list-style-type: none"> Develop virtual team skills & technology 	●	●	●
Consolidation/ customer-centricity	<ul style="list-style-type: none"> Develop account management or “system” orientation to customers 	○	○	●
Health information technology	<ul style="list-style-type: none"> Develop IT skills beyond IT department 	●	●	●

- High impact
- Moderate impact
- Low impact

Company structure and strategy determines commercialization priorities

Platform

- Vision and opportunity to inform partnering strategy

Pre-IND

- Target selection
- Indication prioritization
- Business development insight

Clinical stage

- Market/customer/patient insight to inform development
- Partnering strategy
- Opportunity assessment commercial development

Product Company

- Fully integrated commercial effort
- Ongoing cross-functional life cycle management
- Adapting to changing healthcare landscape

Charting the path to commercialization

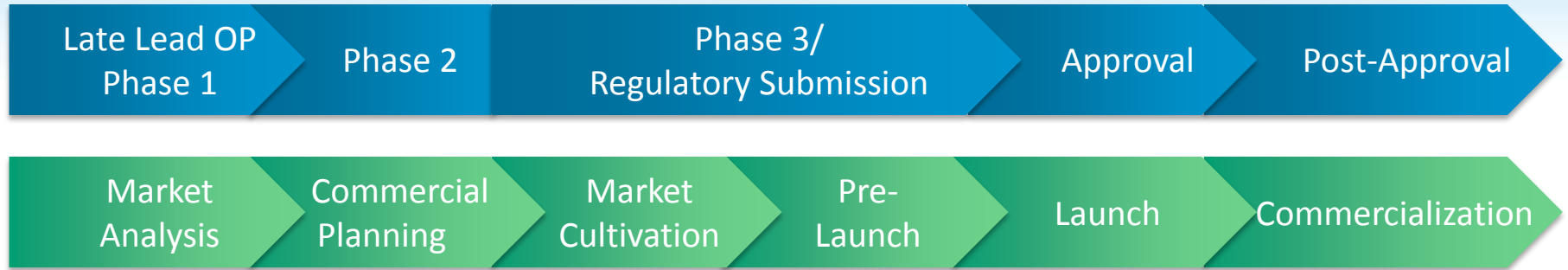
Direct implications

- Timing of commercial capability build
- Balance of internal hires vs. consultants
- Profile and role description of commercial hires
- Executive expectations regarding strategy and plans
- Development of current policies and SOPs

Indirect implications

- Creating integrated team culture
- Facilitating understanding of diverse personality profiles between R & D and commercial team
- Educating the organization about commercial role, functions and contributions
- Clarifying external relationship development – KOLs, patient advocacy groups, etc.
- Instilling trust among team members
- Managing egos

Commercial activities should be integrated into development plan and organization



Market Assessments

Indication Prioritization and TPP Development

Quantitative Market Research

Competitive Intelligence

Forecast Modeling

Message Strategy

Commercial Due Diligence for Business Development

Business Plan Development

Commercial Activity Mapping and Budget Creation

Advocacy Development

Integration with Medical Affairs

Publication and Medical Meetings Strategy

Pricing and Reimbursement Insight

Competitive Differentiation

Product Positioning

Communications Planning

Agency Selection and Guidance

Tactical Marketing Plan Development

Payer Assessment and Strategy

Sales Force Planning

Launch Planning

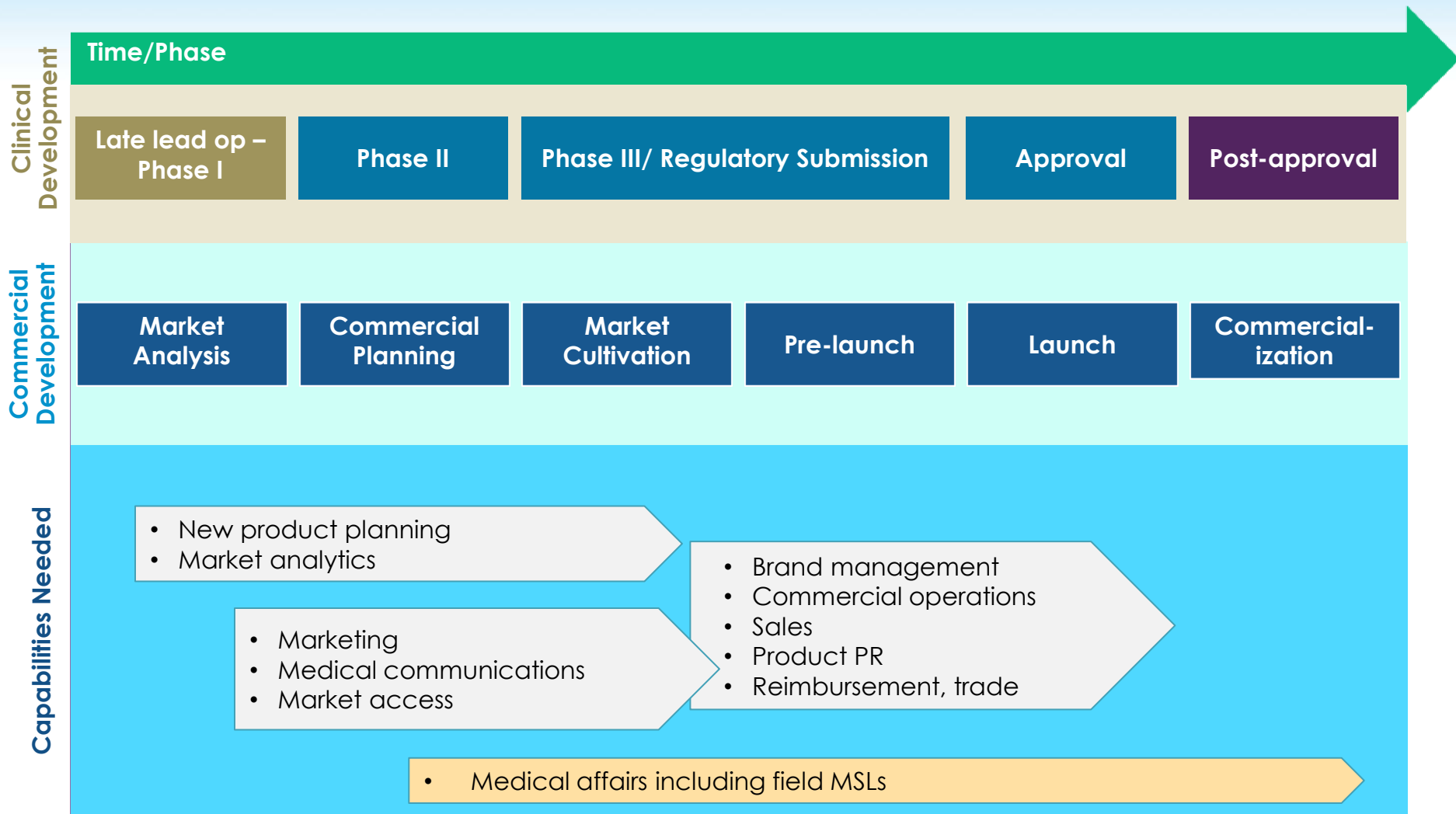
Launch Plan Execution

Sales Training Development and Implementation

Performance Analysis

Life Cycle Management

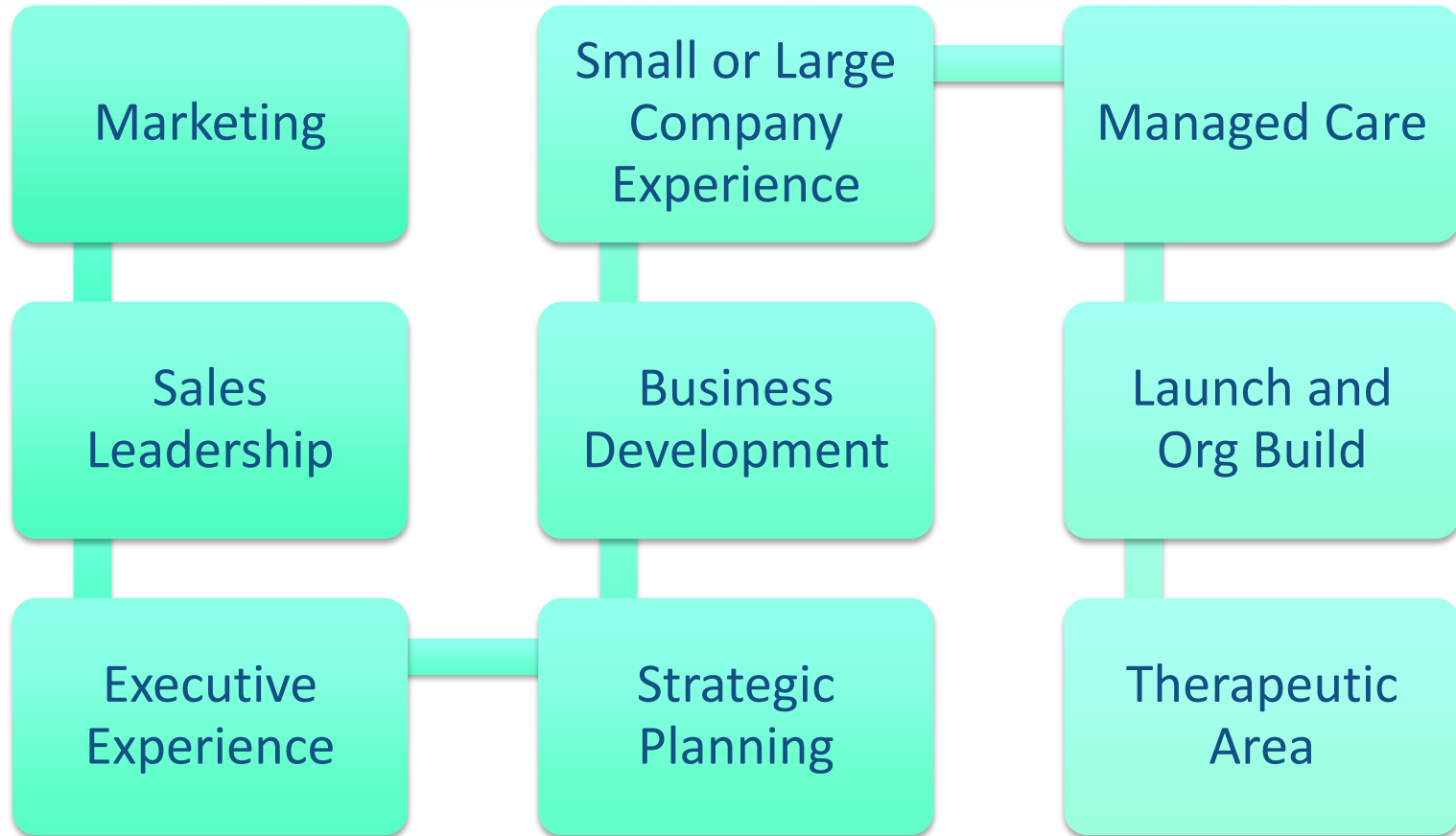
Commercial capability build is tied to development



Example resource decision: “profile” of commercial leadership role

- Need to consider company strategy, stage and priority to determine type of senior commercial hire
 - Chief business officer
 - Commercial lead focused on business development
 - Head of marketing
 - Chief commercial officer

Commercial Leader Profile Considerations



Summary

Important aspects of commercial journey

- Understand your market
- Understand the needs of that market
- Ensure an integrated program team
- Align incentives
- Bring management team along

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Human Resources' role

ANTICIPATE

- Understand the needs of your market
- Envision your expanded role and influence
- Conduct a simple audit/assessment of your HR practices
- Define commercial vision with external/customer perspective central to planning
- Balance external and internal insight, ensure time for interpretation

EDUCATE

- Bring management team along
- Ensure program/project manager values commercial insight
- Get knowledgeable resources to educate and prepare you & your leadership team
- Create opportunities for cross-functional education on each others' roles

ORGANIZE

- Establish an integrated program team early, and ensure frequent team self-assessment
- Modify processes & change responsibilities
- Align incentives

RESOURCE

- Map the needs of your business from now to full commercialization

Leading the journey

Understanding → Ownership → Commitment → Leadership

Build A Common Sense Of Urgency And Need

Engage the key stakeholders

Calibrate expectations & needs

Keep the conversation forward-looking

Develop Shared Goals and Priorities

Encourage open & divergent thinking

Explore all options

Establish shared goals & priorities

Translate Collective Commitment Into Individual Action

Focus on priorities

Build agreement to an action plan

Establish personal accountabilities

Sustain Momentum

Help individuals adapt

Consolidate & leverage progress

Align the environment

Key HR people & organization levers/tools

Symptoms & Challenges	Levers	Tools
<ul style="list-style-type: none"> • Unclear strategy, goals, governance • Delays, bottlenecks • Lack of communication & coordination • Indecision, decisions don't stick 	Aligning Teams and Organization	<ul style="list-style-type: none"> • Strategy & goal alignment • Responsibility charting (RACI) • Organization assessment • Team development
<ul style="list-style-type: none"> • Loss of critical skilled employees • Disconnect between stated values and actions • Splintered culture 	Defining and Cultivating Culture	<ul style="list-style-type: none"> • Surveys – assess & monitor • Employee involvement • Mentoring
<ul style="list-style-type: none"> • Uneven performance & results • Lack of leadership for expansion • High failure rate on promotions • Significant management distraction 	Managing Performance and Development	<ul style="list-style-type: none"> • Performance management • Rewards & incentives • Talent reviews • Succession planning • Coaching • Training 'programs'
<ul style="list-style-type: none"> • Extended searches, high % of offers declined • Poor integration of new hires • High turnover in first 18 months • Extended time-to-productivity 	Attracting, Selecting, Onboarding	<ul style="list-style-type: none"> • Competency profiles • Recruitment efforts • Hiring practices • Onboarding

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Sue Nemetz

Susan Nemetz brings nearly 25 years of corporate strategy, sales, marketing, business development and management experience in the healthcare sector. Ms. Nemetz' significant professional accomplishments include: creating international business and operating strategies for the launch of an innovative cancer therapy, growing a small nuclear medicine business into a world-class medical imaging operation, and successfully integrating two distinct therapeutic and imaging organizations into a single, cohesive cardiovascular product franchise.

Prior to establishing her consulting company, Ms. Nemetz served in commercial leadership roles at Millennium Pharmaceuticals and DuPont Pharmaceuticals.

In founding The NemetzGroup, Ms. Nemetz sought to fill an unmet need in the life sciences arena. From her extensive industry experience, Ms. Nemetz recognized that there is a critical need to help organizations envision and articulate longer-term strategy while also focusing and delivering on the near-term priorities and details of execution.

Ms. Nemetz received a BS in Business Management and Marketing from the University of Minnesota and has been actively involved in mentoring fellow businesswomen throughout her career.



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Breck Arzen

With 30 years of experience as both an internal and external business advisor to CEOs, GMs and Functional Leaders, Breck has assisted start-ups to large global corporations in the areas of organizational alignment, change management, leadership development and executive coaching in a wide variety of industries.

Breck has worked extensively in the biotech and pharmaceutical industry assisting with early stage organization development, project and program leadership, process improvement and post-acquisition integration as examples. Prior to his role as an external consultant and coach, Breck held the position of Vice President of Leadership and Organization Development at Avery Dennison Corporation. He has also held senior management positions with SmithKline Beecham (now GlaxoSmithKline) and Digital Equipment Corporation (now HP).

Breck has a BA in International Relations from Colby College and a master's degree in Human Resource Management from Boston University.



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