

SPECIALTY PHARMA

Strategies For
Business Development

Vol. 2 No. 3

May/June 2006

Rebirth of Molecules

Market Drivers for Analgesics

POSTNET STD
U.S. Postage
PAID
Permit 262
Mechanicsburg, Pa.

www.specialtypharma.com



Kenneth W. Locke, PhD

A Case Study in
Accelerating Product
Commercialization

pg.18



Michael T. Sheckler, MBA

Discussing the Boon
for Analgesics

pg.40



Wallace K. Reams

Staying the Course
on Transdermal Drug
Delivery & Therapeutics

pg.44

Special Roundtable

Emerging Trends in Specialty Pharma Growth

By: Jean Male, President & CEO,
Emp-Higher Performance Development, Inc.

Introduction

Peter Drucker was quoted as saying "Knowledge has to be improved, challenged, and increased constantly, or it vanishes." This virtual roundtable assembled a group of 10 leading-industry thought leaders who weigh-in on emerging trends in Specialty Pharma. Their broad cross-section of knowledge is sure to challenge what you think you know about Specialty Pharma and inspire you to consider innovative, out-of-the-box ideas as you develop business plans for the coming quarter. The diverse group represents multitudinous functions within, and adjunct to, Specialty Pharma. The vigorous discussion addressed Specialty Pharma growth as it relates to the pipelines, people, portfolio and profits, market penetration challenges, innovation, compliance, and ROI. The group is composed of: Peter Lankau, President & CEO, Endo Pharmaceuticals, Inc.; Julia Amadio, VP, Marketing & Marketing Services, Daiichi Pharmaceutical Corporation; Jane Chin, PhD, President, Medical Science Liaison Institute, LLC; Shellie Caplan, President, Caplan Associates; Paul W. Allen, VP, Managing Partner, Life Sciences, Clarkston Consulting; Charlene Prounis, Managing Partner, Flashpoint Medica; Keith McCormack, PhD, Head of Research McCormack Group,

Medical Information Officer, Off-Label Ltd; Jack Gordon, CEO, AccuPoll Research, Inc.; and Steve Woodruff, VP, Business Development, Pedagogue Solutions.

Growth

Q: What growth trends are you seeing or experiencing around pipeline, people, portfolio, profits, etc.?

Peter Lankau: Many companies have focused more on acquiring on-market products for revenue generation than building a pipeline. Endo was a bit fortunate in coming out of the DuPont Merck organization in the late 1990s. We had a litany of products to develop a revenue stream allowing us to reinvest those profits into building a pipeline. With this freedom of movement, we have taken the approach to invest very heavily in our pipeline to build sustainability. In Specialty Pharma, the one-hit-wonder approach is one that can be very lucrative if you hit, but disastrous if you don't. We were able to build from the legacy of a brand name like Percocet[®] and continue to generate new life-cycle extensions of the product, extending its ability to generate profits such that we could build our pipeline. A pipeline built through acquisition is more likely to become

strained as time goes on. Therapeutic area focus also has been very important for our growth because we have been able to create a leadership position within that space. Endo has been very concentrated in its therapeutic focus in the area of pain, enabling us to be in a market where the kinds of pain products that we bring to market are typically not being sought after by Big Pharma competitors. Our ability to dominate in the pain niche market has been very important to our success.

Julia Amadio: For Daiichi, one of the initial challenges was that we were clearly looking at development in a Specialty Pharma arena. We had our antibiotic J'loxin[®] Otic and Lvoxac[®] for Sjogren's. However, oncology, which was out-licensed at the start, had enabled us to truly create a commercial business in the US. The biggest portion of the pipeline has been in the oncology arena, which to Peter's point, a lot of Specialty Pharma companies start with one or two products and look at driving the development, but then look externally for other fillers. We had a very late-stage oncology product that was looking very good even at interim Phase III that then died at the very end. That may have helped spark some of the impetus for the merger.

Keith McCormack: We seem to be in an unprecedented era. Before 2008, it's estimated that globally \$70 billion worth of drugs will come off patent and 80% of that will come from the US market. In the past, this would have been a great opportunity for the generics market. Now, the generics market, particularly in India, is seeing some very hard times; so the opportunities for Specialty Pharma seem to be tremendous. I wonder, however, if Specialty Pharma is about to undergo a transition and evolution into a sort of second era, a "super" Specialty Pharma. From where I sit as Director of Off-Label.com,

those companies and proven recruiters is definitely becoming more prevalent to avoid making big hiring mistakes.

Jean Male: I'm surprised by how much the hiring profile keeps coming up, yet is often overlooked, understated, or an underexploited aspect of return on assets. I can't underscore it enough. Employees are vital to differentiation; able to exceed revenue projections for relative commodities, and conversely, shortfalls for products that could otherwise have a marketplace edge.

Charlene Prounis: When it comes to return on investment, the trend toward ever-increasing direct-to-consumer (DTC) budgets simply misses a gold mine opportunity. "If only a small percent of these budgets were deployed to support the doctor patient encounter (DPE) — the most critical flashpoint — patients would be prepared, involved, and supported in a way that makes every dollar work harder and meets the needs of all stakeholders.

Keith McCormack: We shouldn't lose sight of the fact that the drug industry is only 100 years old and that there have been many, many cycles. This may sound outrageous, but I see a "new" Big Pharma growing out of Specialty Pharma. Specialty Pharma should not lose sight of the experiences of Big Pharma. Innovation is never-ending, and once you stop changing, you'll be changed.

Jean Male: Yes, and standing still in the tar pit didn't bode well for the dinosaurs either. ■



Jean Male

*President,
Emp-Higher
Performance*

Ms. Jean Male has been driving revenue in Specialty Pharma for nearly two decades through sales, product management, business development, training, and performance improvement. In 1989, Ms. Male spearheaded expansion, human performance initiatives, and training programs directly linked to revenue generation and subsequently adopted as the international benchmark for specialty biopharma success. Since 1997 as President of Emp-Higher Performance, Ms. Male has been providing first-person perspective and keen insight to create hiring profiles, protocols, and performance initiatives for Specialty Pharma companies during acquisition, commercialization, and expansion.



Peter Lankau

*President &
CEO, Endo
Pharmaceuticals,
Inc.*



Julia Amadio

*VP, Marketing
& Marketing
Services, Daiichi
Pharmaceutical
Corporation*



Jane Chin, PhD

*President,
Medical Science
Liaison Institute,
LLC*



Shellie Caplan

*President,
Caplan
Associates*



Paul W. Allen

*VP, Managing
Partner,
Life Sciences,
Clarkston
Consulting*



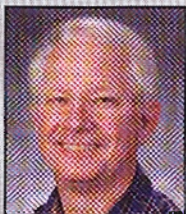
Charlene Prounis

*Managing
Partner,
Flashpoint
Medica*



Keith McCormack, PhD

*Head of Research
McCormack Group,
Medical Information
Officer, Off-Label Ltd*



Jack Gordon

*CEO, AccuPoll
Research, Inc.*



Steve Woodruff

*VP, Business
Development,
Pedagogue
Solutions*