

▶ Insights from the C-Suite: Specialty Pharma

The growing U.S. specialty pharmaceutical market comprises more than 90 companies marketing more than 550 prescription pharmaceutical products and is valued at about \$21 billion, according to MCD Group.

According to MCD Group, specialty pharmaceuticals are mainly prescribed by clinical specialists and aimed at well-defined patient groups. In many cases, specialty products address large unmet needs that often are being treated inadequately. Examples of specialty indications include but are not limited to infertility, gout, cystic fibrosis, pancreatic insufficiency, vitamin deficiencies, bipolar disorder, multiple sclerosis, and fibromyalgia.

Specialty pharmaceutical companies are generally focused on only a few therapeutic categories, and sometimes have a very narrow focus on one or two specialty indications. These companies usually have well-trained sales representatives that call on specialty physicians, such as allergists, psychiatrists, endocrinologists, or pain management physicians.

Based on MCD Group estimates, the categories with the largest number of marketed products are: women's health (about 90 products) and dermatology (about 130 products). Overall, the top-selling specialty pharmaceutical products in 2009 were products for pain, sleep disorders, opioid dependence, and ADHD. With respect to total product revenue, four therapeutic categories generated the highest sales: pain management, CNS, ophthalmics, and dermatology.

We asked executives representing several specialty pharmaceutical companies to tell us what their biggest challenges are and what opportunities may lie ahead.

CHRISTIAN SCHADE

Executive VP and
Chief Financial Officer

Omthera Pharmaceuticals Inc. is an emerging specialty pharmaceuticals company focusing its efforts on the clinical development of new therapies for dyslipidemia.

▼ For more information, visit omthera.com.



Christian Schade

According to Goldman Sachs research analysts, the specialty pharmaceutical industry's returns, and the prospects for sustained long-term value, have been clouded by "the persistent structural headwinds of rising reimbursement pressure, higher FDA hurdles, and aggressive generic challenges." Equity investors agree with this assessment. In a Credit Suisse analysis, for the last 10 years the specialty pharma sector had traded at an average premium to the S&P 500 of about 27%, which declined to a premium of just 10% by the end of 2010.

Not to oversimplify the challenges, but the

surest way for industry participants to steepen the value proposition curve is through product innovation. The historical business model relied heavily on the economics of in-licensing and product marketing as the key value drivers. Given the realities of the current environment, future value will be created on innovative product development to produce best-in-class products to face new and growing global healthcare challenges. The value of such products will be enhanced through a careful positioning of intellectual property and clinical trial designs, built not for speed with low barriers for success, but with preference for reimbursement requirements and targeted marketing goals.

According to Goldman Sachs: "The perception of sustainability extends for the combination of competitive advantages, long duration assets, and a development program that drives confidence in the long-term potential of the company."

At Omthera Pharmaceuticals, we believe we are leading this change. Omthera is developing Epanova, a patent-protected, novel, ultra-pure mixture of the free fatty acid forms of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Data for Epanova points to an improved

and more predictable bioavailability compared with the ethyl ester form found in prescription omega-3 products currently available. The market opportunity is confirmed by the growing global prevalence of severe hypertriglyceridemia, which has risen dramatically over the past decade and is largely caused by increasing rates of obesity in adults and children. Currently, about 1.7% of the U.S. population suffers from severe hypertriglyceridemia, equating to roughly 5 million Americans, fewer than 20% of whom are receiving lipid-lowering therapy. This represents a severe unmet medical need where we believe Epanova will provide the best solution to a rapidly increasing healthcare problem.

ANGUS RUSSELL

CEO

Shire is one of the world's leading specialty biopharmaceutical companies. Through its Shire Human Genetic Therapies (HGT) business, the company is pursuing opportunities on behalf of patients and families facing such rare diseases as Fabry disease, Hunter syndrome, Gaucher disease, hereditary angioedema, and metachromatic leukodystrophy. Through its specialty pharma business, Shire develops and distributes a portfolio of treatments for patients with ADHD, ulcerative colitis, and end-stage renal disease.

▼ For more information, visit shire.com.



Angus Russell

Today, specialty pharmaceutical companies must demonstrate and deliver tangible value to a broad group of stakeholders — and that is our greatest challenge.

While physicians were previously viewed as the main key to the successful commercialization of a product, patients, caregivers, advocacy groups, policymakers, regulators, and payers are all now equally important influencers with whom we must frequently engage.

Doing so enables us to not only identify and address their unique needs, but also deal with the factors that have a very real and direct impact on

MARKET ATTRACTIVENESS

- » Specialty pharma is attractive to potential buyers because of its high profile, high revenue, and high growth
- » Specialty pharma companies are becoming increasingly important in the overall pharma landscape
- » There is significant interest from Japanese pharma in U.S.-focused specialty pharma companies due to slowing domestic growth, government initiatives to increase the rate of generic use, and a strong yen

Source: Bourne Capital Partners

the success of a drug candidate, such as clinical trial design and the ability to gain reimbursement from payers.

But to effectively serve multiple stakeholders, companies must also identify and meet a need in the marketplace for a specific medicine. Addressing an unmet need — and defining the value proposition of a potentially successful product — is necessary to demonstrate the tangible value associated with a product candidate.

Delivering true value to the healthcare system through a market-driven, multi-stakeholder approach is critical in this day and age.

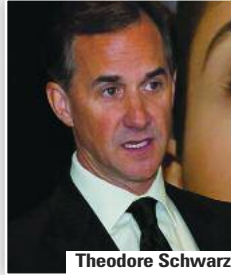
Companies that can better demonstrate and deliver value are more likely to receive the reimbursement needed to meet the high costs of developing their medicines, and therefore generate revenue to reinvest in further R&D and innovation. If we get it right, this will help multiple stakeholders and ultimately improve the overall health of society.

THEODORE SCHWARZ

President

SkinMedica Inc. is focused on developing, acquiring, and commercializing products that improve the appearance of skin. SkinMedica markets and sells to physicians, with a focus on aesthetics, both prescription and nonprescription skin care products.

▼ For more information, visit skinmedica.com.



Theodore Schwarz

As one of the leaders in physician-dispensed, scientifically based skin care, our biggest challenge is helping patients and consumers alike understand the value of insisting upon innovative, clinically supported products, and seeking those products through the assistance of a medical professional.

Patients are often overwhelmed by cosmetic and consumer companies promising them results that don't materialize, and they become cynical about topical skin care.

The SkinMedica team works hard to source innovative scientifically supported active ingredients, stabilize those ingredients in elegant formulations, and then prove the product efficacy through prescription-like clinical trials.

We then use a variety of educational and consumer awareness platforms to educate both the physician and patient on the value of using good scientifically based skin care. **PV**

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Innovations in client-side market research departments across the industry from Scott Christofferson of the consultant firm **Market Research Executive Board** and Derek Jones of **AstraZeneca**

Evolving innovations and regulatory challenges in social media from the **Digital Health Coalition** and expert panelists

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