The Role of Entrepreneurial Leadership and Innovation in the Future of Therapeutic Dermatology

As a highly diverse field with overlapping segments in therapeutics, aesthetics, and skin care, dermatology is an attractive area for pharmaceutical companies. The potential patient population in dermatology is large and varied because of the chronic and age-agnostic nature of many dermatological conditions, which leads to an extensive target segment from a business perspective.

It has become increasingly common for pharmaceutical companies to cover both therapeutic and aesthetic dermatology because of overlaps in customer segments and products that can often address both areas. Whether driven by dermatology companies, practitioners, or payers, this evolution is reflected in the new look of dermatology-focused pharmaceutical companies. As a result, the focus and investment of these pharmaceutical companies appear to be leaning more heavily toward the cash pay business than ever before.

To underscore this point, we can look to multiple companies, including Allergan, Galderma, and Merz, that have demonstrated that it is possible to establish a leading presence in aesthetic dermatology and retain a pharmaceutical company heritage.

Industry challenges

Despite the evidence proving that organizations can invest heavily in the cash pay side of their business and still maintain the pharmaceutical heritage upon which they built their foundation, there are a number of challenges to continued growth and success in therapeutic dermatology.

The total investment per successful drug is very large because most research and development (R&D) initiatives are unsuccessful in bringing a new product to market. On average, it will cost a company $359 million to develop a new drug from the research laboratory to the patient. Only 5 in 5,000 of the drugs that begin preclinical testing ever make it to human testing. Only one of these five is ever approved for human use (California Biomedical Research Association, 2016).

The broad patient population in therapeutic dermatology and their differing needs based on skin type and skin concern have often resulted in innovation of delivery vehicle or concentration, versus new drug development. The revenue potential of these incremental innovations is less than in the case of a new chemical entity. A relevant example of US Food and Drug Administration approvals of dermatological products due to new delivery is Fabior (tazarotene) foam, 0.1%, (Stiefel, a GSK Company, Brentford, United Kingdom), which received US Food and Drug Administration approval for the treatment of acne vulgaris in May of 2012. Tazarotene, the chemical entity that is the basis of Fabior foam, 0.1%, was first approved as a gel-based treatment for plaque psoriasis in 1997 and for the treatment of mild to moderate acne vulgaris in 2001.

Further, new chemical entities designated for only dermatological use are less common than in other specialty areas. Thus, the return on investment expected for bringing a new dermatological product to market can be further challenged. This makes regular investments into novel therapeutic dermatology programs less appealing compared with other therapeutic areas, where the return on investment is likely to be higher. One of the most appealing new chemical entities in dermatology exclusively is crisaborole topical ointment, 2%, a product in development for the potential treatment of mild to moderate atopic dermatitis in children and adults. The product has a Prescription Drug User Fee Act date of January 2017 and, if approved, will be one of the highest revenue potential, nonbiologic dermatology products to come to market in the past decade. Pfizer (New York, NY) has reported that if the product is approved, it is expected to generate $2 billion in peak year sales. This compares with new chemical entities in other categories with peak year sales in the range of $6–8 billion.

Mergers and acquisitions have significantly reduced the number of companies focusing exclusively on dermatology (Figure 1 and Table 1). R&D projects that were once targeted to dermatology are becoming part of larger portfolios, where they may have to compete for corporate resources and prioritization with molecules and indications in other therapeutic areas.

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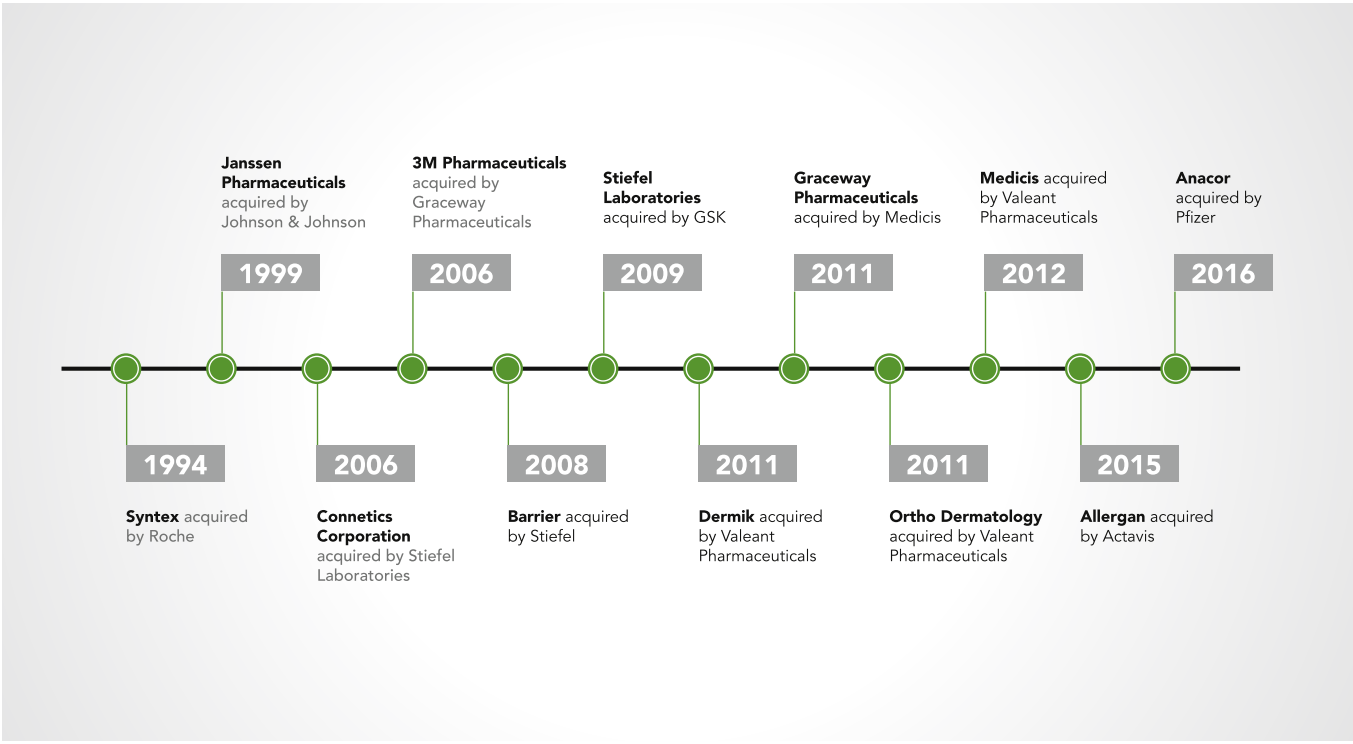

Figure 1. Selected recent acquisitions of dermatology companies. This highlights the small number focused primarily on the specialty.

In addition, as companies have consolidated, merged, and expanded their footprints in dermatology and, more specifically, aesthetics, the development pipeline has become crowded with therapeutic, over-the-counter, and aesthetic products and indications. As a result, less focus has been put on novel therapeutic products, causing therapeutic dermatology to be characterized by accidental, or "sub-blockbuster" products.

To illustrate this point, we can look to the short list of blockbuster drugs in dermatology, such as Accutane (previously manufactured by Roche Pharmaceuticals, Basel, Switzerland; isotretinoin), Epiduo (Galderma, Lausanne, Switzerland; adapalene and benzoyl peroxide) gel, 0.1%/2.5%, and Lamisil (Novartis, terbinafine). Two of these three drugs started as new chemical entities with the intent to focus on therapeutic dermatologic indications. Although they are considered blockbuster drugs in dermatology, reported peak year sales are in the range of only $760.0 million to $1.2 billion (Drugwatch, 2016). This compares with blockbuster drugs in other categories with peak year sales in the range of $6–8 billion. Further, well-known dermatology brand names like Rogaine (Johnson & Johnson, New Brunswick, NJ, minoxidil) and Propecia (Merck & Co., Kenilworth, NJ, finasteride) were not the outcome of intentional dermatological development but the result of lifecycle management of molecules approved for nondermatological use.

Table 1. Dermatology company acquisition highlights (1994–2016)

Buyer	Approximate Purchasing Company Revenues at Time of Acquisition[1]	Acquired Company	Approximate Global Revenues at Time of Acquisition[1]	Acquisition Value
Roche	$9.7 billion (1994)	Syntex	$2.1 billion (1994)	$5.3 billion
Stiefel Laboratories	—	Connetics Corporation	$184.4 million (2005)	$640 million
Graceway Pharmaceuticals	—	3M Pharmaceuticals	$350.0 million (2006) (NA and LATAM)	$875 million
Stiefel Laboratories	—	Barrier Therapeutics	$6.7 million (2006)	$148 million
GSK	$28.4 billion (2009)	Stiefel Laboratories	$900 million (2009)	$2.9 billion
Valeant Pharmaceuticals	$820.4 million (2010)	Dermik	$240 million (2010)	$425 million
Medicis	$700 million (2010)	Graceway Pharmaceuticals	$315 million (2010)	$455 million
Valeant Pharmaceuticals	$1.2 billion (2010)	Ortho Dermatology	$600 million (2010)	$345 million
Valeant Pharmaceuticals	$3.5 billion (2012)	Medicis	$150 million (2010)	$2.6 billion
Actavis	$6.4 billion (2013)	Allergan	$8.68 billion (2013)	$70.5 billion
Pfizer	$49.6 billion (2014)	Anacor	$69.7 million (2015)	$5.2 billion

Abbreviations: LATAM, Latin America; NA, North America.

[1]Purchasing company values and acquired company values are estimates based on publicly available information, referencing the full year before the close of the acquisition.