Viewpoint 25

Paul Edick, CEO of MedPointe, says specialty pharma companies are looking for new drugs in their own labs—an R&D paradigm that takes them...

Back to the Future

Photograph by Bill Bernstein

As *Pharmceutical Executive* celebrates is 25th anniversary, the specialty pharmaceutical sector can reflect on 15 years of history. The story starts in 1991, when the landscape was dominated by the likes of Merck, Glaxo, Bristol-Myers Squibb, Ciba Geigy, SmithKline Beecham, and Sandoz. It was a golden age. New chemical entities for the treatment of unmet medical needs were plentiful, and FDA approvals nearly so. The low hanging R&D fruit was largely unpicked. The reimbursement environment was easy. The impact of the independent generics firms was still slight, and the havoc they wreaked on branded franchises was but a glimmer of what it has become today. Profit margins, which routinely exceeded 25 percent of net sales, were fat. The top ten pharma companies controlled 32 percent of global sales. Jobs were being created; globalization was in full swing; investors reaped handsome returns from soaring share prices.

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Pioneers

At the same time, specialty companies were emerging from infancy. The movement was led by Alza, the drug delivery pioneer, and Medeva and Elan, two brash Anglo roll-ups founded and led by former Big Pharma executives. These firms joined a smattering of precocious upstarts, such as Medicis (which was founded through a merger in 1988) and King Pharmaceuticals, to anchor a new age. They joined or were followed by KOS, Endo, Forest Laboratories, and many others of odd shapes and sizes that didn't fit neatly among the pantheon of industry giants.

For many of these young, rapidly-growing firms, the early 1990s was a time of a new but fundamentally flawed strategy that played itself out over the next decade: achieving high-octane growth via acquisitions. Many companies demonstrated prowess at acquiring marketed, branded pharmaceuticals products and using these drugs to build field sales capacity and infrastructure, reach specialists and primary care physicians, and generate phenomenal sales growth and returns for investors. The problem, however, was that this business model was finite—without a concurrent investment in the R&D pipeline, it was unsustainable.

Wanted: Big Pharma's Cast-Offs

As Big Pharma entered a period of sustained corporate consolidation throughout the '90s, specialty pharma began clamoring to acquire the "non-core, non-strategic" products to which the larger companies were unable to pay an appropriate level of attention. These were the expendable, underpromoted assets that sucked up Big Pharma's management time and dragged on top-line growth. Within specialty pharma, the race was on to see who could acquire these assets the fastest.

And therein lay the problem: The growth and profitability expectations that were created as more specialty companies entered the race became unachievable. It seemed as though venture capitalists were creating a new specialty pharma firm a month. The prices for Big Pharma's divested assets grew higher, challenging the acquirer's ability to a decent ROI. The days of cozy, backroom product acquisitions were replaced by professionally managed, investment banker-led auctions, openly seeking the highest bidder.

The pace of divesting assets, which by 1993 had been a torrent, had dwindled to a trickle by the early to mid-2000s. The corporate consolidations had largely run their course. Big Pharma was getting fewer new products through the FDA approval process, changing the perception of slow-growth assets. These formerly non-core products were now cash cows that covered pressure on operating cash flows—at least so long as the threat of generic encroachment could be minimized.

Further Competition

Beyond acquiring new assets, the competitive environment for specialty pharma has undergone enormous change: Paragraph IV certifications, reimportation, managed care practices, wholesaler inventory management programs, shorter product lifecycles, and armies of sales reps competing for physician attention are but a few of the new obstacles that have emerged over the past 10 years. Collectively, they have mandated strategic change in the specialty pharma business model.

At MedPointe, a specialty company descended from the leveraged buyout of Carter-Wallace, we've changed our model to reflect these dynamics. Today, we acquire and license marketed products, but also conduct R&D, expenditures which have grown from four percent of net sales in 2003, and will exceed 12 percent of net sales in 2006.

While the early days in specialty pharma yielded a bonanza for companies that grew quickly through inorganic means, the pendulum has swung in the other direction. In many respects, it's back to the future. A blend of acquisitions—both product and technology—and internal , organic growth through new product innovation is the way forward.