

A SPECIAL BREED OF LEADER

BY ELISABETH PENA AND TAREN GROM

THE FUNDAMENTALS OF THE
SPECIALTY PHARMACEUTICAL INDUSTRY
REMAIN STRONG WITH SOLID RESULTS
RELATIVE TO OTHER SECTORS.

These companies capitalize on opportunities through a unique competency in therapeutic expertise, knowledge of geographic markets, and physician specialties. Financial-community projections predict that this currently underdeveloped segment of the pharmaceutical industry will continue to demonstrate strong growth for the foreseeable future.

I got into this business with the ultimate objective to help people. I can't think of a better way to begin every day. The minute I get in the car and start driving to work I get excited because I know what I am doing is ultimately going to make a difference.

THOMAS MCLAIN



Nabi Biopharmaceuticals

High-profile mergers regularly occur in the industry as a whole, as large pharmaceutical companies continue to consolidate to maximize research capacity and marketing power. According to industry sources, the 10 largest pharmaceutical firms accounted for more than 58% of total prescription drug sales in 2002.

The very success of these mega-pharmaceu-

tical companies leaves attractive openings for a breed of smaller, specialty pharmaceutical companies that target proven products that may be lacking attention from their developers. Many of these products have become available to specialty companies for sale and/or licensing, and more are expected to appear. Specialty pharmaceutical companies are acquiring some of these products

as part of a multidimensional growth strategy. In addition, a growing number of specialty companies have internal development capabilities. They may not go back to the molecule, but they are taking well-known products and reformulating them through proprietary technologies and reintroducing them into niche or specialty markets with great success.

THE MANAGEMENT TEAM

ADRIAN ADAMS. President and CEO, Kos Pharmaceuticals Inc., Miami; Kos Pharmaceuticals is a fully integrated specialty pharmaceutical company engaged in developing, commercializing, manufacturing, and marketing proprietary prescription products for the treatment of chronic diseases. For more information, visit kospharm.com.

CAROL A. AMMON. CEO, chairman, and director; Endo Pharmaceuticals Inc., Chadds Ford, Pa.; Endo is a fully integrated specialty pharmaceutical company with market leadership in pain management products. For more information, visit endo.com.

VICENTE ANIDO JR., PH.D. President and CEO, Ista Pharmaceuticals, Irvine, Calif.; Ista is a specialty pharmaceutical company focused on the development and commercialization of unique and uniquely improved ophthalmic products. For more information, visit istavision.com.

ROBERT J. BITTERMAN. President, Dermik Laboratories Inc., VP, Aventis Dermatologicals, Berwyn, Pa.; Dermik provides product innovations to treat a wide range of skin problems, including acne, nail fungus, precancerous lesions, dermatitis, eczema, psoriasis, and rosacea. For more information, visit dermik.com.

JOHN H. BULLION. CEO, Orphan Medical Inc., Minnetonka, Minn.; Orphan Medical acquires, develops, and markets products of high medical value for patients within selected market segments. For more information, visit orphan.com.

J. MELVILLE ENGLE. President and CEO, Dey LP, Napa, Calif.; Dey is a specialty

pharmaceutical company focused on the development, manufacturing, and marketing of prescription drug products for the treatment of respiratory diseases and respiratory related allergies. Dey is an affiliate of EMD Inc., which is part of Merck KGaA. For more information, visit dey.com.

MICHAEL FRIEDMAN. President and CEO, Purdue Pharma LP, Stamford, Conn.; Purdue Pharma and its independent U.S. associated companies are known for their pioneering research on a principal cause of human suffering: persistent pain. For more information, visit purduepharma.com.

JAMES R. HOWARD-TRIPP. President and CEO, Labopharm Inc., Laval, Quebec, Canada; Labopharm is an international specialty pharmaceutical company focused on the development of drugs incorporating the company's proprietary advanced controlled-release technology, Contramid. For more information, visit labopharm.com.

A.J. KAZIMI. CEO, Cumberland Pharmaceuticals Inc., Nashville, Tenn.; Cumberland Pharmaceuticals is a specialty pharmaceutical company with a mission to acquire rights to branded prescription products and grow them through marketing to targeted physician segments. For more information, visit cumberlandpharma.com.

THOMAS H. MCLAIN. President and CEO, Nabi Biopharmaceuticals, Boca Raton, Fla.; Nabi discovers, develops, manufactures, and markets products that power the immune system to help people with serious, unmet medical needs. For more information, visit nabi.com.

BRUCE A. PEACOCK. President and CEO, Adolor Corp., Exton, Pa.; Adolor is a

late-stage biopharmaceutical company committed to the development and commercialization of novel products to relieve pain and reduce the side effects of currently marketed narcotics. For more information, visit adolor.com.

RICHARD F. POPS. CEO, Alkermes Inc., Cambridge, Mass.; Alkermes is an emerging pharmaceutical company developing products based on sophisticated drug-delivery technologies to enhance therapeutic outcomes. For more information, visit alkermes.com.

JONAH SHACKNAI. Chairman, CEO, and founder, Medicis, Scottsdale, Ariz.; Medicis is a leading independent specialty pharmaceutical company in the United States focusing primarily on the treatment of dermatologic, pediatric, and podiatric conditions. For more information, visit medicis.com.

DENNIS L. SMITH. President and CEO, INO Therapeutics Inc., Clinton, N.J.; INO Therapeutics, a division of AGA Linde Healthcare, is a global specialty care pharmaceutical company committed to developing and marketing treatments in the areas of heart and lung function. For more information, visit inotherapeutics.com.

PHILIP S. TABBINER. President and CEO, aaiPharma Inc., Wilmington, N.C.; aaiPharma is a science-based specialty pharmaceutical company that is focused on acquiring, improving, and marketing well-known, branded medicines in pain management, gastroenterology, and critical care. For more information, visit aaiPharma.com.

I walk the talk. I highly respect people. I believe that every individual in the organization has equal value. Employees are paid different salaries because of different levels of accountability and competencies, but everybody can be equally valued. Senior management creates the environment.

CAROL AMMON



Specialty companies have been successful and will be successful in the future because of their focus and dedication to a few products; and specialty companies have to be careful not to lose that focus.

JOHN BULLION

Orphan Medical Inc.

Endo Pharmaceuticals Inc.

An Executive Perspective

KAZIMI: Information moves much faster now than it did 10 years ago and there is certainly much more available. A key challenge for a CEO is to sort through all of the data being provided from multiple sources and to focus time and energies on the information that is most valuable to the company.

POPS: The biggest difference I see in running a public company during the past 10 years is the short-term focus of the stock market and the resulting change in the nature of the ownership of these companies. Previously our stocks were owned by institutional investors who were interested in owning the stock for long periods of time and were willing to invest alongside the company and watch it build and make good on the promises of its technologies or its business plan. Today the market is much more oriented to short-term trading driven by near-term milestones in the company. It is a much more frantic capital market environment.

SHACKNAI. A strong orientation toward sales, marketing, and research and development is critical to understanding the profit centers — present and future — within a

pharmaceutical company. Possessing strong leadership skills, which can take many forms and faces, are critical to success in any important position.

MCLAIN. For success today, the entrepreneurial spirit is very important and it needs to be a key part of driving every organization. A successful CEO also needs to understand the financial drivers of the business to maximize the cash flow return. Increasingly, for CEOs in the public market arena, it's also very important to be aware of what investors' needs are in terms of information. It's also important that investors understand strategy and the direction that the company is taking. Finally, CEOs need to talk to investors about what the company is trying to accomplish and build understanding and support for the strategy going forward.

BITTERMAN. For me, success is building a company that can last through good times and bad times. To keep a company growing, the most important thing is to have a balance between short-term and long-term strategies. We've been able to sustain our growth, particularly in the past eight years, because we have planned for the future. Products have life cycles and these life cycles have to be managed.

We have to anticipate where to place bets for the future given the very long lead times, and that means managing time, cost, and risk to bring new products to market. And at the same time, maintaining a focus on the day-to-day operations is critical to ensure that we get the most out of our current product line to fund the future. This is clearly a balancing act. Having a vision of where the business needs to go and what is required to get there while supporting the current franchise is challenging. The future is always filled with ambiguity. Analysis must be combined with experience and instinct to guide the process. It's difficult to know what you don't know; uncertainty is always around the corner.

FRIEDMAN. Being a teambuilder is the No. 1 attribute of a successful CEO. Aside from that, one has to be patient and resilient. A CEO has to rely upon people who are experts in diverse fields. One has to deal with science, technology, regulatory affairs, quality control and assurance, sales and marketing, as well as markets that are increasingly complex, involving managed care and state and government formularies. A CEO has to break down the walls between these various departments and get them working together in one direction.

ADAMS. A successful CEO has to have a broad understanding of all the different functions of the business. And in particular, he or she must have very good financial acumen, strong commercial expertise, a focused eye on innovation, and a clear view of the future. In addition, a CEO, as well as the entire leadership team, must always concentrate on the big picture in relation to driving the business forward while focusing on the financial metrics of today. At Kos, successfully balancing these crucial factors of our business has been one of the many strategies that has led to our robust revenue growth and sustained, tremendous financial performance. We call this “changing the fan belt of the business while the engine is running.”

SHACKNAI. I spend a preponderance of my time on issues involving marketing, sales management, and research and development. Many of the other issues that involve operations of the company are handled directly by other senior executives, who with me make up the company’s executive committee. I have found that concentrating my efforts on the present profit centers as well as the search for profit centers for the future is the best possible use of my time.

ENGLE. CEOs need to be, above all else, ethical, close to their customers and employees, and they must set an example by “walking the talk.”

MCLAIN. What typifies my approach to business is knowing what the company can do uniquely and understanding how to deliver value. Then I focus that knowledge on what can be accomplished on a multiyear basis on the strategy and big business objectives and then translate that back into what needs to be accomplished in the near term to ensure that the company can be successful on those multi-year objectives. The other thing that is critical to success is not only to focus on what the company is setting out to accomplish but how to accomplish those goals. With a business plan, I can say with certainty that things are going to change. And a CEO can’t always achieve the goals the way the plan was originally built. A CEO needs to be able to react to challenges and take advantage of every opportunity. And that’s where organization, people, process, culture become absolutely essential to the success of a company. A CEO can have the greatest ideas, the greatest products, the greatest research, the greatest people working in the organization, but if the CEO hasn’t focused on the way to get everyone to work together, the company will never reach its full potential. What I hope to bring to Nabi and to its investors is not only the understanding and appreciation of the business model and the industry in which the company operates, but

also the focus that I can bring to the people, the process, the culture, and the organization that are going to be essential to our success going forward.

AMMON. First and foremost, as a CEO, it’s very important to have sensitivity and respect for employees. Employees are the people who make a company very successful or not so successful. As a CEO, if one can have a respect for all employees and then do the right things by them, then the company will be very successful. A CEO also needs to have a clear vision about the organization that employees can grab hold of and believe in. A CEO then needs to be able to communicate this vision to employees so they believe they are making a

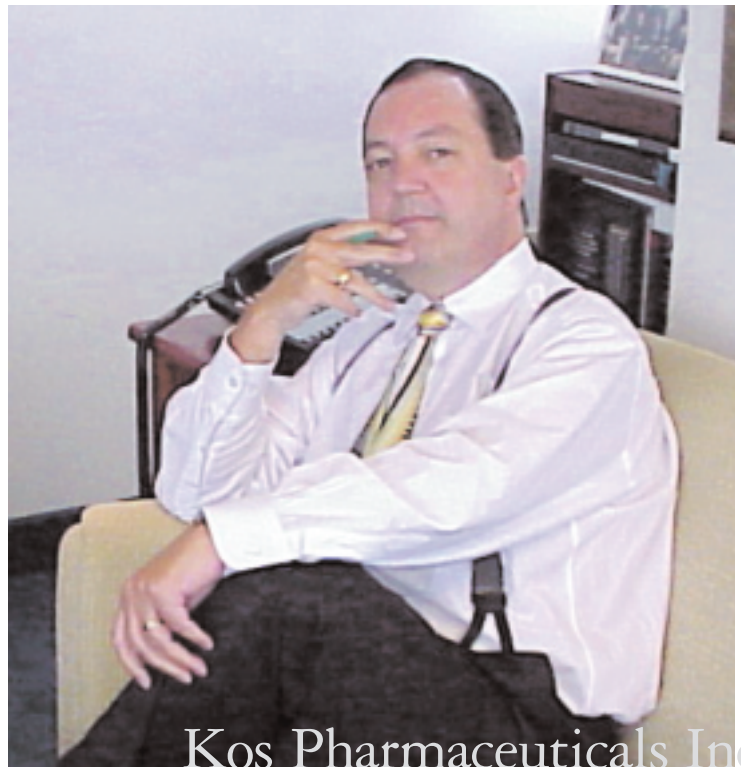
difference. The CEO is responsible for setting the type of environment that allows for the hiring of good people and then letting those people do what they do well. It all comes down to people — hire the right people, reward them appropriately, and create an environment that allows them to succeed.

BITTERMAN. Leadership starts with creating a culture that fosters specific values that we want people to adhere to and embrace, a purpose for existence, and a vision for the future. Sound values are incredibly important, especially as a company grows and new people are brought in. If the leadership is not careful, an influx of new people can dilute the original core values or beliefs, and the company



My philosophy is to have a people-centric approach — an organization that is structured with the right people who hold the right competencies. Reward, recognition, and a winning culture will cultivate teamwork, dedication, quality and, subsequently, long-term success. People are strategic, not just doers!

ADRIAN ADAMS



dynamics can change before we know it, and maybe not in the direction we wish. Our leadership team has been very deliberate at looking at these values in the people we hire. There has to be somewhat of a spiritual effect in this process; it's more than a mechanical process of hiring people to just do a job. We have to rally people around a common purpose and a core set of values. They also have to have a vision as to what the future of the company holds for them and their customers. At the same time, we need to infuse enough diversity of thought so that there is stimulation for creativity and innovation.

SMITH. I believe CEOs should be people-oriented. This is particularly important in being able to develop and foster teamwork within an organization and providing the leadership necessary to direct the business and the team effectively. This starts with having strong, talented, competent leaders in key positions within the company and then empowering them so they understand their roles and responsibilities and are appropriately motivated to achieve the company's goals and to manage their areas of responsibility as autonomously as possible.

A Special Passion

TABBINER. I'm thrilled with the fact that we have built up a part of the organization that didn't exist before — the commercial, sales and marketing, and the pharmaceutical management side of the business. We've hired not only great sales reps, but great managers and

great leaders. For me the exciting part that has arisen from this transformation is the ideas and compelling enthusiasm that they have brought to the entire organization. And this has been more dynamic and more creative than I could have imagined.

AMMON. I have more passion now than I did on day one, and I had tremendous passion then. Being able to have Endo bring new products to market is tremendously exciting. We are able to make a difference in people's lives by the types of products we offer. Seeing the company grow and seeing employees develop and have growth opportunities within the company as we get larger is very rewarding. We have a community of employees who are excited by what they do. As the company grows it's satisfying to see our employees grow. The good things that happen to people, whether it's in making a difference in people's lives or making a difference in our employees' lives, are what excite me.

MCLAIN. I got into this business with the ultimate objective to help people. And what truly excites me about Nabi is the areas in which we are focused, particularly our development products for Staph bacterial infections and nicotine addition. The people who have these healthcare challenges today don't have any good answers. When we look at the clinical results that we have had to date, we have every confidence that these unique approaches are going to make a life-and-death difference for millions of people. I can't think of a better way to begin every day. The minute I get in the car and start driving to work I get excited



Good executives must surround themselves with very good people. Putting the right people in place who treat the business like owners and who are truly involved with everything that goes on is essential. If the right people are in place, then there is a strong likelihood of putting together a good strategy, based on sound judgment, creating a culture that strives to achieve.

ROBERT BITTERMAN

because I know that what I am doing is ultimately going to make a difference.

SHACKNAI. Being among the most highly esteemed companies within our market base, which is dermatologists and pediatricians, is what excites me about our business. To be the most highly regarded company we have to have the most highly valued sales organization. Our marketing efforts, of course, have to promote our brands, but they also have to support the specialty through increased educational opportunities for physicians. And our research program has to yield products that will be highly appreciated by physicians and their patients.

BITTERMAN. My passion is to continue to create and build because of, or in spite of, market forces. Our challenge is to always think about what we need to do differently to make the business continue to grow while providing a stimulating work environment. For me, facing that challenge and bringing together a number of people in the organization who have a common sense of purpose and similar values to get the job done is what drives me. That's the creation process and it's never ending; it's only limited by imagination and energy.

SMITH. I get satisfaction from seeing the organization achieve goals through the efforts and involvement of our employees working together. All businesses today face significant challenges and demands. By being able and willing to work through issues and problems as a team, we can achieve things way beyond what any one individual would be capable of.

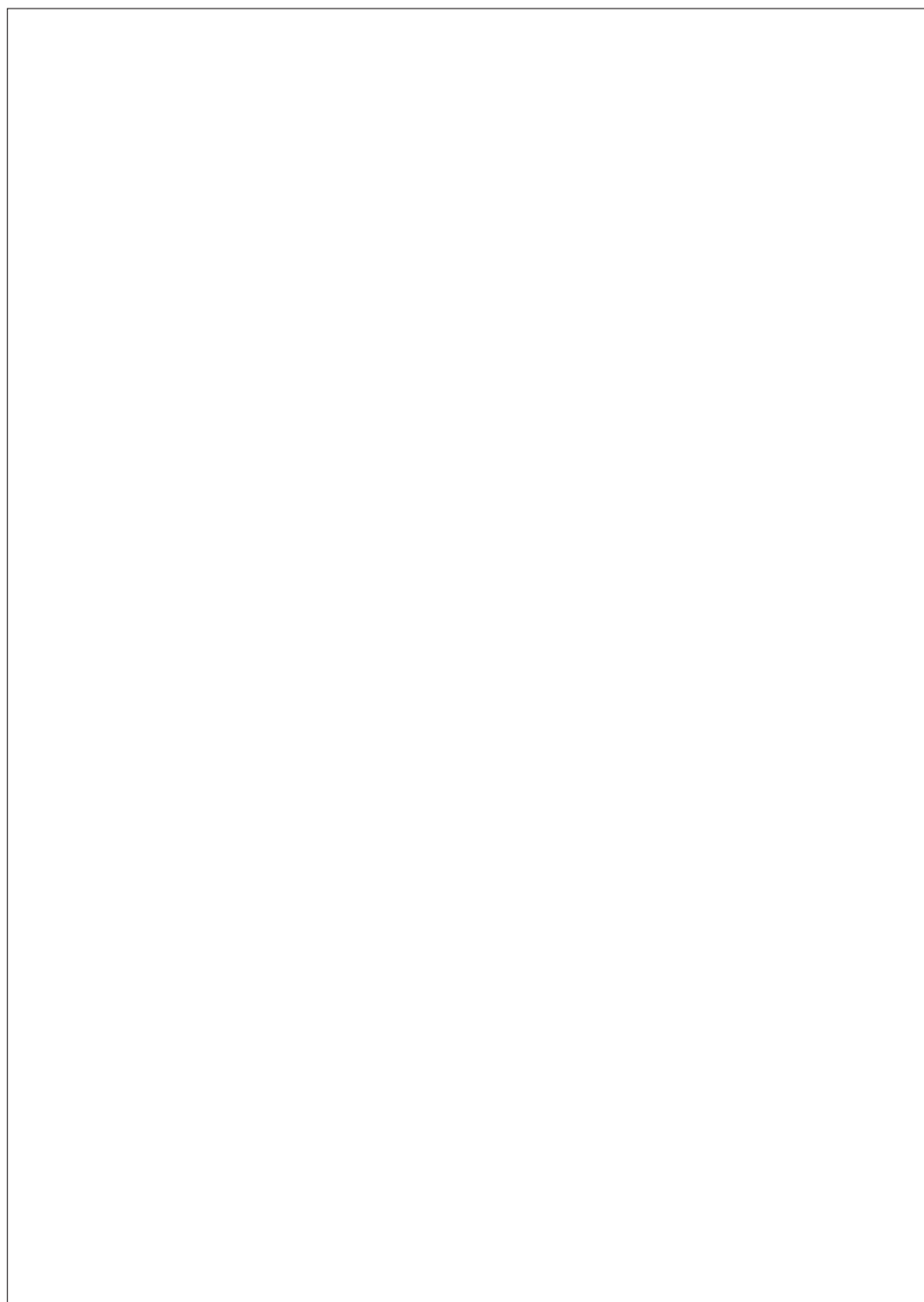
A Model Approach to Business

AMMON. Specialty pharma is a sector that is made up of a cross-section of companies that have a number of different business models. Some specialty pharma companies are R&D focused only, some are commercial only, some are acquisition only. If I were to look at specialty pharma as a whole, we face a number of unique challenges. For example, many of the products are in the late-stages of their life cycles so there is little to no patent life left. Therefore, a specialty pharmaceutical company needs to develop proprietary products to be able to diversify its revenue base and find a way to provide sustainable growth and minimize the dependence on generics and line extensions. A specialty company needs diversity in the types of products in its portfolio, including some with longer patent protection. Also, specialty pharmaceutical companies need to find the right balance between internal development and acquisitions and licensing opportunities.

TABBINER. Specialty pharma has long been seen as a sector that simply buys products and remarkets them. As a result, there has been some question as to whether this is a successful strategy. The unique aspects of aaiPharma are that our strategy goes beyond that usually seen within specialty pharma. Because of our science base, we have the ability to acquire products and reintroduce these products, but, more importantly, we can reinvigorate these products by putting them through our R&D process to either improve the molecule or the drug-delivery technology applied to that molecule. We can relaunch them into the marketplace as significant innovations and with significant improvements that help patients and physicians. We look for flagship brands in

the therapeutic areas that we focus in. And we use that well-known brand's moniker to relaunch the innovation. We want to use the fact that physicians know the brand name, value the product, and trust it.

SMITH. Organic growth versus growth from acquisitions starts with a company's strategy and determining its desired or required rate of growth for sales and earnings. Of course, many variables will affect a firm's organic growth; these factors include market size, market growth rate, promotional levels, pricing, investments, approval for new indications, in-kind competition/new technologies, and a firm's own new products all drive organic growth. If the influence factors for organic



The type and size of a company's specialty focus and the research and development being done by other firms in that area are critical factors in influencing the number and type of product opportunities that will be available for acquisition. The lack of control of the pipeline is a limiting factor for the specialty company.

DENNIS SMITH



The focus of the large companies, especially as they consolidate, continues to be on blockbuster products.

In turn, we see a growing number of smaller products that are no longer a strategic fit for those companies and may be available to specialty pharmaceutical companies.

A.J. KAZIMI



Cumberland Pharmaceuticals Inc.

JNO Therapeutics

growth are positive and sustainable over the planning period, there may be less need to supplement this growth with acquisitions to achieve the strategic goals.

SHACKNAI. Medicis is different from other specialty companies insofar as we have an intense focus on research. We are not at all dependent on externally developed products either through acquisition or licensing to grow the business at a comfortable rate. We have more than 11 significant products in development, and we expect those to be the catalyst for even more significant growth going forward. We believe that maintaining as low an overhead structure as possible is critical to our success. This provides us with one of the highest operating margins in the pharmaceutical industry. This also gives us the flexibility to move quickly if something is going better than expected or not as well as expected. Without a large, lumbering overhead, we have the ability to be far more nimble than some of our competitors. On the other hand, we also do a significant amount of licensing of developmental projects. We do periodically acquire products. But we don't have a dependency on these methods of growth.

TABBINER. We have been transforming aaiPharma from a services business that did research only for other companies to a company where we provide those services and have our own products in the marketplace. We are not only helping peoples' lives by the virtue of the work we do for others, but we are influencing peoples' lives by the virtue of a touch by our own people in the marketplace. This gives our people a sense of an emotional attachment to the work we are doing and gives them a stronger sense of commitment to the challenges of making this transformation work.

HOWARD-TRIPP. The specialty pharma business model is fast — we can make and execute decisions quickly. In big pharma there are many inefficiencies of a huge system. One has to question whether the "bigger is better" approach that big pharma has been adopting is in fact the right one.

BITTERMAN. Dermik is semi-autonomous. Our parent company, Aventis, has been mindful of our business model. Unlike other large companies that try to homogenize and centralize everything, Aventis has looked at the essence of what has made Dermik tick. Aventis recognizes that Dermik operates in a differ-

ent prescription pharmaceutical segment than its other areas of focus. Dermatologicals are a relatively small segment of the overall pharmaceutical business in the United States, representing about 5% of the total market. Aventis has allowed us to develop a model that not only lets us address our primary customers but gives us enough flexibility to determine how our growth is going to take place by giving us discretion in our investment activities in new product development. Dermik's relationship with Aventis has been quite compatible compared with many of our competitors' relationships with their parents. Other large pharmaceutical companies that had a dermatological franchise saw the derm segment as too small to make a difference to them. When their products neared the end of their life cycle, the parent company abandoned the business and customers. In contrast, Aventis has made a serious commitment. Aventis considers our business to be targeted and profitable, with acceptable risk and good growth prospects. Therefore, Aventis lets us do what we do best to service our customers and, in turn, satisfy the company's ROI objectives.

SMITH. Being a small, single-focused company means our employees are closer to the busi-

Building vibrant companies is where the excitement is. If a CEO can get the right people, the right team, and the right strategy in place, it is incredibly exciting to watch a specialty company grow.

JAMES HOWARD-TRIPP



ness and can make a difference in our company. We also are able to more easily have simultaneous interactive live communication with the majority of our employees around the world. Another pro is that we can remove or lessen bureaucracy and streamline our decision-making processes. The primary cons include a lack of critical mass of human and financial resources. Senior managers often are spread too thin because of heavy travel requirements and multiple business responsibilities placed on them.

AMMON. Endo has had a fairly unique business model since its inception — self-development of products as well as acquiring products. We have been able to build expertise on the development side, attract partners for late-stage development products, as well as build commercial expertise and credibility within a therapeutically focused area. All of these things combined make Endo somewhat differentiated.

BITTERMAN. With regard to our product development activity, we are essentially autonomous. Within Dermik Laboratories we have our own formulation and analytical laboratories. We take responsibility for all of our own clinical development, medical activities, and regulatory actions. We make our own bets in terms of what products to develop. We live and die by our choices. Our operational relationship with our parent is more along the lines of a consultative connection, but I would like to stress that we are tightly aligned with the corporate commitment to quality and integrity. We strive to live by common values.

ADAMS. Kos has been successful in keeping focused on the key areas of our business while carving out sustained market-share penetration in the huge cardiovascular and diabetes markets over time. But, we are an entrepreneurial company and if business or product opportunities arose outside our current therapeutic areas, we would critically assess those opportunities to determine whether they fit well, both strategically and financially, with our current portfolio to drive future growth. Nimble, flexible thinking is an important part of entrepreneurship.

KAZIMI. A particularly attractive strategy combines both acquisition and organic

growth. Product portfolios can be built through a strong continuous acquisition program, while growth and profitability can be enhanced by the development and commercialization of new products with competitive advantage. While acquired products have the advantage of brand names with established recognition, those that are internally developed can provide better margins and the increased value associated with innovation.

BITTERMAN. Our business model is different from big pharma. We don't discover new products. Rather we take existing compounds and make them better, wrapping them with intellectual property. We then launch a targeted and concentrated marketing and sales effort to promote those products to the specialty audiences. This is very different from the big pharma model, where companies invest billions of dollars in discovery and research in search of the next big blockbuster. Our approach is essentially to hit the singles and doubles and steal a couple of bases to sustain good growth.

AMMON. Through products such as Percocet, which is considered a gold standard in treating acutely moderate to severe pain, we were able to leverage the brand. Physicians knew right away what Percocet was. But we had to be smart about adding products to our portfolio so that we would be credible when we said we want to be the pain-management company. It was important that we brought forth a stream of new products and that's what we did in the first few years.

SMITH. Our initial product is a therapeutic drug in gaseous form that requires a safe and effective delivery device and is used in a hospital critical-care setting. The business model had to be innovative and unique and we had to provide a high-level of customer support. The traditional pharmaceutical customer-service and distribution models were not able to meet the needs of this dynamic and life-impacting drug offering. These and other factors resulted in a business model that measures the time during which our drug is used and the corre-

sponding charges are determined from that time multiplied by an hourly fee.

ANIDO. A serial product acquisition model is an opportunistic strategy and it is one that can lend itself to fluctuations in pricing. It becomes difficult to make money when a company has to pay four to five times the value of a drug because of increased valuation. A more balanced approach, and certainly one that is less risky, is when a company blends acquisitions with some internal research, which allows the company to get some of its own products out the door.

SMITH. I believe the opportunities for specialty pharma companies to source products from large pharmaceutical companies will diminish as it becomes more challenging for specialty companies to access highly attractive innovative products and provide incremental value to customers and payers. The opportunities lie in companies that can focus on one or more niche segments and provide innovative products and services that add value to customers.

AMMON. To sustain growth with an acquisition-only strategy, a company has to keep getting bigger and bigger. Whereas if there is a balance with internal development, a company has a bit more control over those products and has more control over its growth.

MCLAIN. The issue of focus can be a challenge for the specialty business model, but that focus can be a source of strategic advantage. We have developed what I think is a unique business model and approach that has positioned us well, both in terms of the products that we market today and the products that are in our pipeline that will generate a high return for our investors in the future. This focus has allowed us to position ourselves to be the mar-



Increasingly, governmental regulation at both the state and federal levels is having a significant impact on business outcomes. Therefore it is important that senior executives within our industry have a keen appreciation of the nuances of the regulatory process — whether this involves the FDA, the FTC, the Medicare/Medicaid system, as well as state agencies that seem to have great interest in the pharmaceutical industry.

JONAH SHACKNAI

ket leader and to truly have the products that set the pace and make the difference in patients' lives.

AMMON. From the beginning, Endo took a business model strategy approach to fund two engines — a R&D engine and a commercial engine. This allowed the company to drive revenue and put as much money as needed back into R&D to build a sophisticated and robust pipeline so the company has patent protection on many of its pipeline products.

TABBINER. One of the good things in terms of servicing other pharmaceutical companies on their product development challenges is that we have a broad experience set. We've worked on more than 3,000 molecules and have done more than 3,500 clinical trials for other companies. This gives us a considerable breadth and depth of experience and a level of insight that isn't found at other pharmaceutical companies. We were able to use that insight to determine the product opportunities for acquisition. We took a strategic and opportunistic approach to create therapeutic areas of interest, which are pain management, critical care, and

gastrointestinal disease. Pain is probably the best illustration of our strategy, our therapeutic interest, and our approach to the market. We have a product in the pipeline called Proso-rb-D; we then looked for a flagship brand that was already on the market to be able to connect to prescribing physicians. We found that Darvon and Darvocet-N were available because Eli Lilly wanted to divest those well-known brands. These are big brands that were launched in the 1950s. We acquired these products, began promoting them, and immediately began working on line extensions. Early this year, we launched the first line extension and we expect to be able to bring two more to market later this year. Through the reintroduction of promotion, we were able to stop the decline of this older brand because of generic penetration, and we have actually increased the use of the product. As we develop the line extensions we'll create greater uplift of the brand. This provides a wonderful forum as we then bring out other analgesics or pain products in different positions across the marketplace. This gives aaiPharma great leverage. Our goal is to have product offerings across the analgesic frontier over the next four years.

AMMON. The difference in terms of acquisition and partnering opportunities between specialty pharma and big pharma is that a \$100 million product to a specialty pharma company is very different from a \$100 million product to a mega-pharmaceutical company. Specialty pharma can treat that product as the important brand in the portfolio, whereas a company with a \$30 billion market cap would treat this product differently. Specialty pharma companies treat \$100 million or \$200 million brands as very important products.

FRIEDMAN. We are actually a smaller version of big pharma in the sense that we have internal discovery, clinical development, and a long-term focus on proprietary products. One of the principal differences of smaller specialty companies is that they tend to focus on fewer areas. A big pharmaceutical company may focus on five or 10 therapeutic fields. As a specialty company we may focus on only two or three.

SMITH. To have a strong organic pipeline is terrific, and if a specialty pharmaceutical company has that all is well in the world. But for most specialty pharmaceutical companies, that's not likely the case because they don't typically have their own full research and development capabilities.

The Crystal Ball

ADAMS. It is going to be interesting to see how the dynamics within the pharmaceutical

industry shake out in the next five to 10 years, especially in terms of continuing big pharma consolidation. I believe that much of the dynamic revenue growth and strong performance is going to be derived from companies within the biotechnology and specialty pharma industry, mainly because of the impressive innovation that continues to emerge from within these sectors.

MCLAIN. In the next five years, because of our focus we are going to be able to drive tremendous growth for the company and we will realize a lot of benefit for our investors. But when we start to look at a 10-year or 15-year plan for our company, we are as aware as anyone else from a technology standpoint and from a product focus standpoint that we will have to diversify.

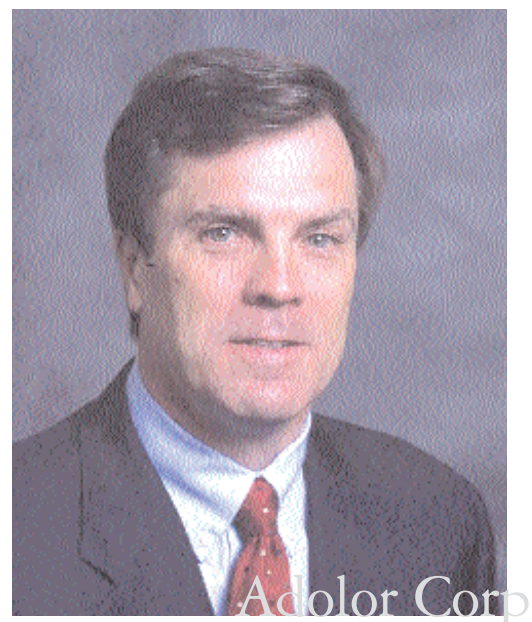
AMMON. Last year, Endo was nearing its five-year anniversary and we evaluated what the next five years should look like. We saw that we were being successful in pain management but we also recognized that there was an opportunity to branch out beyond pain management. We have chosen to address complementary therapeutic areas. For example, we acquired BML Pharmaceuticals in July 2002. BML was working on a supportive-care oncology product for oral mucositis, which we have subsequently taken into Phase III clinical trials. Because we call on physicians who write a variety of products, we looked at how the company could stay focused within complementary areas and then leverage the relationships that we had built to bring more products to the marketplace and expand our focus. To that end, we became the marketing partner with SkyePharma at the end of last year to bring to the marketplace critical-care drugs that SkyePharma is developing.

BULLION. The economies of scale that the bigger companies use to drive mergers will certainly be applied to smaller and midsized companies. The opposite side of that is that specialty companies have been successful and will be successful in the future because of their focus and dedication to a few products; specialty companies have to be careful not to lose that focus. The question is going to be how do specialty companies evolve and grow? There are some good examples of specialty companies that have been successful.

POPS. The key issue facing most specialty pharma companies is the viability of their pipelines over an extended period of time. Certain specialty pharma companies have built their initial valuation on the growth of a limited number of products, if not one product. But, it takes more than one product to build a sustainable pharmaceutical company. The key challenge for a specialty pharma company is

Specialty companies need to be the nimble mice at the feet of the elephant. We need to be responsive and we need to be able to have very quick communication among the disciplines within the organization.

BRUCE PEACOCK



how to become a real pharma company that can experience long-term, consistent growth by developing innovative products.

Risk Assessment

BULLION. A unique challenge of the specialty sector is how to continue to grow in certain areas and how to leverage development expertise and sales presence. Companies that are focused on a specialty therapeutic area have to diversify at some point as a risk-management contingency. They also are forced to do so because they cannot source more products for their area of focus. For a company to rely on a single product obviously entails risk. The challenge is how to manage or decrease that risk.

FRIEDMAN. Large companies have more access to new molecular entities. We have to be extremely careful and diligent to obtain access to new molecular entities (NMEs) that meet unmet medical needs and/or have unique benefits for patients. Because of our size, we have to work even harder to realize an adequate return on either discovering our own NMEs or acquiring these technologies in shorter and shorter time frames. We don't have the resources to pursue as many parallel paths as some of the larger companies or to invest as extensively in each NME we pursue. Therefore we have to make some tough decisions earlier.

ANIDO. There are specialty pharma companies that are not really in niche markets and some that are. Some specialty pharma companies are specialty from a definitional point of view, but are really going after massive audiences and have to field salesforces of 500 to 1,000 people to address the general practitioner or internal medicine audiences. The risk associated with those companies is huge. First, these companies have to buy a product that is big enough to sustain a large salesforce. Then they need to have complementary products to maintain growth. That competitive model is very difficult because a company is constantly coming up against some fairly huge players that also are interested in buying \$100 million, \$200 million, and \$300 million drugs. Whereas there are other niche players in specialty pharma that do well buying \$30 million and \$50 million products.

There is a distinction between the specialty pharma companies that are going after broad audiences and those that are going after truly niche businesses.

ENGL. Being specialized limits the "portfolio approach." Big pharma companies, if they have a failure, can always switch to another product category that might be outside one particular disease entity's focus. When a company operates in a niche, it generally has to be successful almost every time it commences a product development activity as there are usually fewer options in the portfolio.

SHACKNAI. Specialty pharma is not pharma without the risk. The ability to maintain a focused and lower overhead structure reduces some risk. Not conducting basic research also reduces risk of research failure, although there is a corresponding detriment in revenue opportunity. We have a reasonably high degree of confidence that most of the products we are developing will make it to market. If we were involved in basic research at the molecular level or the genomic level, our level of confidence would be much lower. Although when we hit a target the revenue opportunity would be explosive. We are in the business of hitting singles, doubles, and occasionally a triple, but home runs are not part of the lexicon with the specialty industry, and we accept that.

BITTERMAN. Risk is everywhere. Ultimately developing pharmaceutical products is risky business because the development process to substantiate safety and efficacy leaves much room for coming up short. Is our risk the same risk as throwing a billion dollars in a couple of specialty areas to try to come up with a product that will generate a billion dollars? That's certainly higher risk. But with higher risk, the higher the rewards. We generally look at compounds that have been discovered and try to make them better. We realize they probably won't generate a billion dollars. There only has been one dermatological product that has generated more than about \$600 million in the U.S. market, and that product is Accutane from Roche, which is the equivalent of a miracle drug for cystic acne.

SMITH. Specialty pharma is not pharma with-

out the risk. For a firm to be attractive to customers, employees, and investors over a mid-to long-range time period, investments must be made and a sound strategy must be successfully implemented. There are still product development risks as well as regulatory, legal, and product liability risks. The product life cycle also must be well-managed to provide maximum value and ongoing investments are needed as well. Thus, the risks are different from traditional pharmaceutical companies but are still very real.

ANIDO. For the most part specialty pharma is big pharma without the risk. Specialty pharma companies do not take anywhere near the risk, especially with early-stage compounds, that the big pharma players do. Most specialty companies buy products that are already on the market, so they are just taking a market risk. Or they buy products where the proof of concept already has been established. These are products that have completed Phase II trials; then the specialty company completes the Phase III trial. This approach is considerably less risky than going all the way back to developing small molecules that hit a particular target and going through the 10-year clinical process.

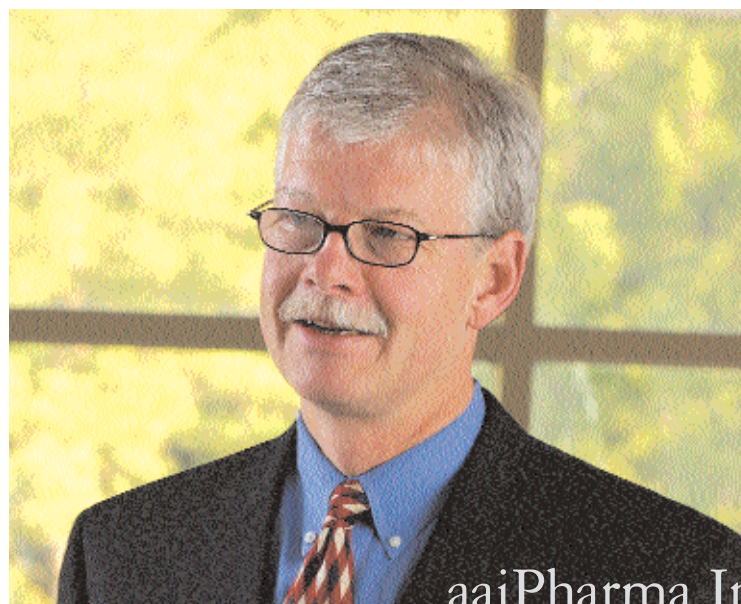
KAZIMI. Specialty pharma companies don't have the same risks as a company that has a large R&D infrastructure and associated costs. Furthermore, through the acquisition of approved products, a specialty company can avoid many development and regulatory hurdles. The potential for nonperformance of acquired products is less if these products have been marketed for a number of years. On the other hand, there is the risk that new products might displace an older product and, of course, there is the threat of generic competition.

BULLION. Every business faces risk. The question is what is the relative value of those risks? Big pharma's risk is one of having to

The strategy we have chosen plays very well within a more price-constrained environment, which I think will exist into the next decade.

We aren't focused on breakthrough products and new chemical entities, and we aren't focused on generics. We are focused on well-known brands and making them better.

PHILIP S. TABBINER



aaiPharma Inc.

Being a teambuilder is the No. 1 attribute of a successful CEO. A CEO has to rely upon people who are experts in diverse fields. A CEO has to break down the walls between various departments and get them working together in one direction.

MICHAEL FRIEDMAN



Purdue Pharma LP

find blockbuster drugs that can move a company's valuation. Specialty pharma has the unique risk of building or maintaining a meaningful presence in a specific or a specialty therapeutic area. Is the opportunity big enough? Are there enough opportunities? And if not, what other specialty areas can the company go into that have synergy with its current focus? Growth is ultimately a challenge to both big pharma as well as specialty pharma, but it is a different type of risk.

BITTERMAN. The key to long-term growth is to create a sustainable difference or advantage and for the company to work that difference to the best of its ability.

POPS. All businesses have risks. In the specialty pharma business the risk is more oriented toward portfolio selection, identifying the right products to put promotional and development energies behind, and then executing on those plans. That is in contrast to the new molecule discovery risk that big pharma is comfortable with.

Meeting the Challenges

SHACKNAI. The greatest challenge relates to the recruitment and retention of talented employees. We exist in a very competitive market for talent, whether it is at the sales level, the marketing level, or the research and development level. I spend a great deal of my time, as do my colleagues, in interviewing prospective candidates, and making sure that successful, highly valued employees stay focused on their jobs and resist many temptations that are offered them by other companies. We have one of the lowest attrition rates within the entire U.S. pharmaceutical industry. There also are increased challenges because of greater regulation, greater intensity of competition, and greater need to prove the company's worth to shareholders. But at the end of the day all of these challenges are well met by having the right people working at the company.



Dey LP

Big pharma will continue to be a source of product opportunity for specialty pharma. As the saying goes, "one person's trash is another person's treasure."

J. MELVILLE ENGLE

SMITH. I believe success in business starts with a company's people. Thus, attracting and retaining the right talent and experience is critical and is often a key challenge for a specialty pharma company depending upon factors such as available resources, the level of risk, commercial status, and business strategy for the future as well as the firm's ability to compete for talent with larger pharmaceutical companies. There often needs to be mutual interest and value between the candidate and company that is outside the typical recruiting thought process.

BITTERMAN. Securing quality scientists, regulatory, and medical people is a challenge. They are not inclined to go to small companies that don't have a reputation or where things are done on a wing and a prayer. Today, a company has to have an infrastructure in place — critical mass. The whole drug-development process is such a team effort that one person alone can't do it. Getting a drug through the FDA, regardless of whether a company is small pharma or big pharma, is not easy. In this day and age, a small company may not be able to afford to invest \$5 million to \$10 million with the hope of hiring all the right people just to bet on the possibility of a positive future outcome — and this doesn't even count the out-of-pocket development costs. Fortunately, we have had success in gaining the approval of five NDAs from 1997 through 2001. That was critical in fueling our growth.

SHACKNAI. There are challenges that are faced by all pharmaceutical companies beyond a certain size and dimension. Those involve an increasingly fiduciary spirit within the managed-care community and to some extent state and federal governments. There also is pressure for constant innovation. Specialty companies, in particular, can become victims of their own success. By definition, most specialty companies are smaller than the universe of general medicine and as a consequence the more a specialty company succeeds, the bigger the denominator of revenue is needed and the more pressure to achieve a rate of growth higher than expected by larger pharmaceutical companies. The areas that specialty pharma companies serve are not infinite in their revenue potential. There is more money in major disease areas, so there is pressure to keep a growth rate that is consistent with shareholder expectations.

FRIEDMAN. It is important to recognize that there is a competitive market for late-stage projects of quality. Like many other firms, we search for late-stage quality projects. This is one of our greatest challenges. It is especially challenging because there are companies that are making deals at multiples that would be beyond the economic feasibility of many companies such as ours. These are deals that don't

seem to work, and we don't know why some companies are entering into such transactions.

BITTERMAN. For a specialty company starting up, the biggest problem is to get critical mass and then grow beyond that. If a company chooses to acquire products already on the market, these will be fairly expensive, otherwise they will probably not have much value. Accordingly, a quality acquisition most likely will require a huge cash outlay. Some companies have tried to get a start by acquiring a line of generic dermatological products from which they hope to secure enough sales until they can find or develop something else. But to differentiate oneself in this segment, one should have products that have some type of intellectual property or regulatory protection.

PEACOCK. The challenge of in-licensing as an emerging specialty company is convincing prospective partners that we are their best choice. And, sometimes the opportunity is in an area of expertise where the company hasn't yet executed. For example, a specialty company may be in a situation where it is still building its pipeline and is trying to in-license more opportunities, but the licensor has concerns. How does the potential partner know the spe-

cialty company is going to build a sales and marketing capability? How does it know the specialty company will be able to manufacture its product at scale? Specialty companies need to have a good plan and be able to convince the licensor that they are capable of executing. More importantly the specialty company has to convince a potential partner that the project will have high visibility within a smaller organization. This commitment is critically important to licensors. As a specialty company, we need to assure our partners that their products won't be lost in the multitude of opportunities a larger company might have.

KAZIMI. Often products in the portfolio of a specialty company, particularly when its focus is on acquisition, are products that have been surpassed by newer products and also may have generic competition. The opportunity for a specialty company is through focused marketing, which can reinvigorate a product that may not be the newest medical advance, but still provides value to a number of patients.

PEACOCK. One of the initial challenges that specialty companies face is getting name recognition and identification. Coming out of the box, physicians may not be familiar with what

a company does. Specialty companies can gain name recognition through scientific publications and developing a presence at scientific meetings. But when a specialty pharmaceutical company is developing relationships with physicians from scratch it takes time to develop this recognition. The relationship between a physician and a sales representative is one that relies on a large degree of confidence and trust.

AMMON. Specialty companies, especially in the early days, need to build awareness around the company and build awareness around their brands. At Endo, from day one our job was to go out to the medical community to build an awareness that Endo is a pain-management focused company with important brands such

as Percocet and Percodan, and now Lidoderm. We had to find a way to differentiate ourselves from the big companies and from the other specialty companies. To do this, we leveraged the Endo name, which is from the 1920s, and was the original company that DuPont purchased to get into pharmaceuticals. Endo had a great reputation within the industry, the medical community, and the pharmacy community. We decided to take that name when we were building this company.

Show Them the Money

AMMON. Our goal from the beginning has been to develop internally as well as acquire

products to drive our revenue and build a sustainable company. Today, Endo has a strong market cap of about \$2 billion, a solid balance sheet, with nearly \$168.5 million in cash, and no debt as of June 30, 2003. In the first six months of 2003, we generated \$139 million in cash flow. We are well-positioned to self-finance our business development opportunities as they arise and borrow against our cash flow.

MCLAIN. At Nabi Biopharmaceuticals, we want to break the industry paradigm and we are setting a new business model. We are using the cash flow from our marketed products — acquired and organic — as the source of investment in new products in the pipeline. So we not only are looking at an acquisition strategy

Corporate Snapshots

aaiPharma Inc.

Public

2002 Revenue: \$230.5 million

Specialty Area: Pain management, gastroenterology, and critical care

■ aaiPharma is a science-based specialty pharmaceutical company focused on acquiring, improving, and marketing well-known, branded medicines in pain management, gastroenterology, and critical care. aaiPharma also offers comprehensive drug-development services to the pharmaceutical, biotechnology, generic, and device industries through its services division, AAI Development Services.

Adolor Corp.

Public

2002 Revenue: (\$60.5 million)

Specialty Area: Pain

■ Adolor is a late-stage biopharmaceutical company committed to the development and commercialization of novel products to relieve pain and reduce the side effects of currently marketed narcotics.

Alkermes Inc.

Public

2002 Revenue: (\$106.9 million) Fiscal year ended March 2003

Specialty Area: Controlled, sustained-release injectable drugs and inhaled formulations

■ Alkermes is an emerging pharmaceutical company developing products based on sophisticated drug-delivery technologies to enhance therapeutic outcomes.

Cumberland Pharmaceuticals Inc.

Private

2002 Revenue: NA

Specialty Area: Critical care, emergency medicine, gastroenterology, pulmonology, cardiology, and infectious disease

■ Cumberland Pharmaceuticals is a specialty pharmaceutical com-

pany with a mission to acquire rights to branded, prescription products and grow them through marketing to targeted physician segments.

Dermik Laboratories Inc.

Parent: Aventis

2002 Revenue: \$400 million

Specialty Area: Dermatological

■ Dermik provides product innovation to treat a wide range of skin problems, including acne, dermatitis, eczema, psoriasis, and rosacea.

Dey LP

Parent: Merck KGaA

2002 Revenue: NA

Specialty Area: Respiratory diseases and respiratory-related allergies

■ Dey is a specialty pharmaceutical company focused on the development, manufacturing, and marketing of prescription drug products for the treatment of respiratory diseases, such as chronic obstructive pulmonary disease and asthma, and respiratory related allergies, such as anaphylaxis.

Endo Pharmaceuticals Holdings Inc.

Public

2002 Revenue: \$399 million

Specialty Area: Pain

■ Endo is a specialty pharmaceutical company engaged in the research, development, sale, and marketing of prescription pharmaceuticals used primarily to treat and manage pain.

INO Therapeutics Inc.

Parent: AGA Linde Healthcare, a unit of Linde AG

2002 Revenue: 100 million euro

Specialty Area: Heart and lung function

■ INO Therapeutics is a global pharmaceutical company committed to developing treatments in the areas of heart and lung function. The com-

but also at the ability to develop new and innovative approaches as the way to position the company for long-term success. And we're going back to that old-fashioned business discipline of only investing the cash generated from the business, without counting on speculative investors or big dollars from corporate partnerships early in a product's development stage. The latter strategy does not optimize value for the shareholders.

TABBINER. It is a much more difficult financial environment today for smaller startup specialty companies looking to fund an IPO. We are in a unique position, because our organization has been around for 30 years. We made the decision to get into specialty pharma from

having a strong base of operations. We used this base to acquire products and we have a healthy business in terms of revenue growth and profitability growth. We continue to pay down our debts significantly. We have many different options as to how we can grow the company in the future, whether it's through equity infusions, additional product acquisitions through debt, or internal growth.

MCLAIN. Part of the challenge we have is developing investor understanding of the business and how the company is positioned to generate value and getting the investor recognition for that positioning. This is certainly true for any specialty company in the public space. A specialty pharmaceutical company is harder for an

investor to understand because of the nature of the products that we market and how they are positioned and developed. Specialty companies are unique and that makes it more difficult for the message to be understood by our investors, who are an important source of capital.

BULLION. The market for financing is changing at a critical time. A lot of companies are going to need capital. The next 12 months to 14 months are going to be very important in terms of building a capital base and allowing specialty companies to be proactive about their strategic direction.

HOWARD-TRIPP. Clearly the overall market conditions in the last 18 months to two years

pany is focused on making innovative therapies available to healthcare professionals and patients.

Ista Pharmaceuticals

Public

Specialty Area: Eye diseases and conditions

2002 Revenue: \$278,000

■ ISTA Pharmaceuticals is focused on saving and improving eyesight by developing proprietary products to treat serious diseases and conditions of the eye.

Kos Pharmaceuticals Inc.

Public

2002 Revenue: \$172.7 million

Specialty Area: Cardiovascular and metabolic diseases

■ Kos is a fully integrated specialty pharmaceutical company engaged in developing, commercializing, manufacturing, and marketing proprietary prescription products for the treatment of chronic diseases.

Labopharm Inc.

Public

2002 Revenue: (\$13.8 million)

Specialty Area: Oral controlled-release products

■ Labopharm is an international pharmaceutical company specializing in the development of drugs using the company's advanced controlled-release technology.

Medicis

Public

2002 Revenue: \$212.8 million; Fiscal year ended June 2002

Specialty Area: Dermatologic, pediatric, and podiatric conditions

■ Medicis is a leading independent specialty pharmaceutical company in the United States focusing primarily on the treatment of dermatologic, pediatric, and podiatric conditions. Medicis offers a broad range of pre-

scription products in a number of therapeutic categories, including acne, asthma, eczema, fungal infections, hyperpigmentation, photoaging, psoriasis, rosacea, seborrheic dermatitis, and skin and skin-structure infections.

Nabi Biopharmaceuticals

Public

2002 Revenue: \$2.1 million

Specialty Area: Infectious, autoimmune, and addictive diseases

■ Nabi Biopharmaceuticals discovers, develops, manufactures, and markets products that power the immune system to help people with serious, unmet medical needs.

Orphan Medical Inc.

Public

2002 Revenue: \$16.1 million

Specialty Area: Sleep and pain

■ Orphan Medical acquires, develops, and markets pharmaceuticals of high medical value for inadequately treated and uncommon diseases treated by specialist physicians. Driven by Xyrem, the only approved treatment for cataplexy associated with narcolepsy, the company intends to build a strong presence in the sleep and central nervous system markets.

Purdue Pharma LP

Private

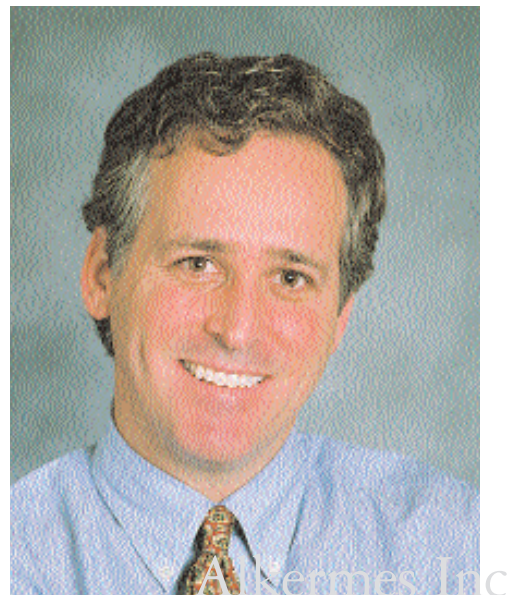
2002 Revenue: NA

Specialty Area: Pain

■ Purdue Pharma and its independent U.S. associated companies are known for their pioneering research on a principal cause of human suffering: persistent pain. These associated companies have also applied their expertise to other therapeutic areas such as respiratory diseases, oncology, and bacterial infections, and to a growing line of nonprescription products, including laxatives, microbicides, antibiotic ointments, and nutraceuticals.

Even if a CEO's interest is in science, marketing, business development, or management philosophy, all of these become incredibly dependent upon having enough capital to build the business. Many CEOs are surprised by how much time they spend focused on procuring the capital necessary to grow the business.

RICHARD POPS



have had a negative impact on how rapidly we were able to move forward in our corporate growth strategy. Companies that had a depressed share price found it a little more difficult to move, particularly on the M&A front.

FRIEDMAN. As a private company, we take a long-term view and are less interested in quarter-to-quarter earnings or multiples. We are interested in the overall long-term profitability and viability of our business. This is a fundamental difference between private companies and public companies, and it certainly is the case with Purdue.

SMITH. My company is not publicly traded so I do not have this challenge in the direct way that most publicly traded specialty firms face. But, I have had the experience of this issue in another way. For specialty pharma companies owned by a public nonpharma parent, unless the pharma portion makes up a large part of the parent's sales, it is difficult for the parent to gain the benefit of the higher multiples that often accompany pharma firms.

PEACOCK. With Adolor's business model, we can be successful with smaller specialty-physician focused, primarily chronic opportunities, whereas most of the larger companies need to field a salesforce that is working with a wide variety of physicians. These companies need a wide variety of products, and their hurdle rate is going to be higher than ours. Every company's model needs to generate positive cash flow and earnings for shareholders.

ENGLE. As a wholly owned subsidiary of a big pharmaceutical company we really don't get into issues of raising cash. Our business development — licensing/acquisition — approach is focused on near-term opportunities. We are not inclined to invest in Phase I or Phase II projects, as they take longer and are usually riskier. Instead, we lean more toward marketed products or products in very late Phase III.

FRIEDMAN. As a private company, we don't have the option of raising money through the public markets. So when public market funds aren't available, we don't really consider it a negative. We have substantial financial resources and are well positioned for the current business environment. A real advantage is that the company is immune to many of the investor relations issues that drive public companies.

POPS. We have a business model that is product oriented and based on advanced technologies that we have developed over time. As the financing markets ebb and flow, we have the flexibility to either rely on the public capital markets for additional funding or not. During the past few months, the market for financing has gotten much more permissive for companies of our size. That has been good; there is availability of capital now. During the previous year or two when there was very little capital available, we relied more on funding from partners to continue to advance our development.

Developing Partnerships

SMITH. To be an attractive buyer or other partner for specialty products, a company must be able to provide value. This usually means having an established franchise and strengths such as a proven track record and a recognized leadership position in focused research, regulatory approvals, salesforce/market presence, access to thought leaders, or all of these together. We apply a disciplined and focused approach to our search for new products that begins with our strategic planning process and includes first defining our mission and key strategies to achieve our mid- and longer-range goals. For us, the funding for acquisition of products is similar in some respects to the challenges of a biotechnology or start up company but fortunately we have our base business and track record working for us.

AMMON. Endo has become an attractive partner for a number of companies that are looking to do collaborations because the company is well-situated from a balance-sheet perspective. And Endo has become an attractive financing alternative for many development-stage companies. In addition, our success with Lidoderm shows we have the ability to commercialize a development product, and over the last year or so, we have strengthened our drug-development capability by adding management depth in our clinical and preclinical areas. So we believe we've become an attractive partner because of our marketing and R&D expertise as well.

FRIEDMAN. There are certainly quite a few large products on the market today being marketed by big pharma that were sourced from specialty pharma. We plan to partner more and more with big pharma, especially based on the capabilities of our sales organization. We also have products and technologies that may be of interest to big pharma, and we look forward to working with them.

ANIDO. Every time big pharmaceutical companies come together all of a sudden there is a divestment of product portfolios. Big pharmaceutical companies do this to not just simply get cash out of nonperforming assets, but if they get rid of enough of these products, they can actually take a big load off of their P&L. They have to offset the decline in revenue that the old products are putting on their top line.

BULLION. Big companies will continue to shed some smaller products. But they have wised up to what the value of these smaller products is and they are not selling them cheaply. They are selling them at going rates and a lot of companies may look at those products as cash cows with no need to sell them unless they get a top price. The special-



Ista Pharmaceuticals

There is a pretty good distinction between specialty pharmaceutical companies that are going after broad audiences and those that are going after truly niche businesses.

DR. VICENTE ANIDO JR.

ty companies that can afford to pay top price for those opportunities are companies that need a particular product for a strategic purpose. Specialty pharmaceutical companies have to be able to develop products internally and actively look for products that fit a strategic focus.

KAZIMI. The biggest difference between our company and a big pharmaceutical organization is that we execute our mission through a number of strategic alliances rather than through a wholly owned infrastructure. While we expect there will undoubtedly be some shift of resources from external to internal capabilities over time, we believe that a number of activities will continue to be external to our core organization into the foreseeable future.

Fielding the Force

SHACKNAI. I do all the final hiring of sales representatives. There is a collegial process, but I am the last stop on the train. We find in our system many talented sales representatives who are retreating from a major pharma because of a cap on economic opportunities or sheer frustration with the number of sales reps who are calling on general practitioners and family practitioners even within their own companies. Our sales representatives have nearly unfettered access to dermatologists and significant access to pediatricians and podiatrists. Dermatologists look forward to seeing

our sales representatives because each call adds value to their practices.

SMITH. As with other employee groups, we are competing with big pharma companies for talented and experienced sales reps. A company that is very focused, such as those having a single product or small customer universe, can encounter “product or customer fatigue” more easily so it can be a challenge to maintain enthusiasm and resilience in the salesforce. Resources in general may be an issue and the careful allocation of resources in a dynamic market requires very good management judgment. The broad geographic distribution of customers in a sales territory often can mean heavy travel and time use challenges.

MCLAIN. The products that we sell are highly specialized so when we hire people for sales and marketing, they have to be people who can develop a very deep understanding of how the products are used and they need to be individuals who can work with physicians on a consultative basis. Our sales reps need to be able to communicate the benefits that come from these specialized products and what they will truly do to make a difference in the lives of patients who need them. We develop and market biological products so the manufacturing and product development processes that surround them are more complex than traditional pharmaceutical products.

POPS. If a specialty pharmaceutical company has a good product it builds a salesforce around it. Good products attract good people to sell them. It is far more difficult to put together a salesforce to sell a basket of tired products with limited patent life that other companies have discarded. A key challenge is trying to understand where a company can create value on the sales and marketing side that hasn't already been created by one of the many companies already out there. CEOs need to ask themselves: Does the world need another salesforce, or is there an opportunity to use an existing set of capabilities by partnering with another company that would allow the company to achieve the same economic end result?

HOWARD-TRIPP. If a company is going to build a salesforce from scratch, as the CEO he or she has to appreciate that it is going to take a lot of time and a lot of risk. I firmly believe that a specialty company is better off working with an established salesforce.

ANIDO. The only challenge that we find in the sales and marketing area is whether we are going to build our own salesforce from scratch and put in an infrastructure or use a blended approach with a contract sales organization. In a niche market, such as ophthalmology, the audience is relatively small. There are only

about 10,000 physicians who we really have to worry about. So we can build a salesforce of about 50 to 100 sales reps to reach these physicians.

BULLION. The key challenge is making the upfront investment in a salesforce. The second challenge is finding an additional presence once a salesforce has been successful in marketing a particular product. Generally, sales representatives eventually need other products to sustain their presence in a specialty therapeutic area.

KAZIMI. The biggest challenge we face is the lack of recognition of our company name by our target audiences. Through the activities of our salesforce, we have been able to overcome this problem with our primary targets.

TABBINER. One of the things that we need to be able to do, like other pharma companies, is position our product vis-a-vis competition and be able to demonstrate to the physician the proper use of the product. On top of that, our salesforce has to be able to tie the innovative science to the product and how this creates benefits for the physician. It's a layering approach. The average tenure for our sales reps is about 10 years. We attribute the tenure of our salesforce to the fact that they are looking for smaller companies where they can make an impact. We are getting a lot of people coming from big pharmaceutical companies who were one of 8,000 or 10,000 who become one of 150 at our company. They like the appeal of a smaller company and they like the appeal of the strategy that we take — a much more sales-oriented approach to the marketplace.

BITTERMAN. When Dermik introduces a new product, our dermatologist customers usually will give us the benefit of the doubt because of the company's reputation. After that, it is our responsibility to deliver. The challenge for us as we get bigger is to seek out other physician specialties to help us enhance our growth, particularly in the face of managed-care gatekeepers. In doing that, we have to realize that different physician specialties have different paradigms regarding their patients and their needs, even in how our product might satisfy their patients' needs. Because market dynamics are changing, we have a challenge to seek out and service other physician specialties. As a company, we must be sensitive to these different customers and make sure we position our products fairly and balanced to satisfy their patients' needs. ♦

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmavoices.com.