

# An Unrelenting Focus On The Big Picture

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The business of bringing new therapeutic products to market is full of challenges. From high costs and long development trajectories to unanticipated side effects and questions of reimbursement, succeeding in the pharmaceutical industry requires intellectual, scientific, regulatory, and financial acumen. And even that may not be enough.

NPS Pharmaceuticals, a specialty pharma company now focused on developing novel therapies for rare disorders with substantial unmet medical need, has lived through the highs and lows that are frequent hallmarks of the standard industry business model. In the early 2000s, the company was developing its lead product as a potential blockbuster for the treatment of osteoporosis, a large market with substantial market opportunity. Unfortunately, the company received an approvable notice from the FDA that would have required the company to conduct an additional large trial, which would have been very costly and would have delayed the approval by years. Already carrying \$191 million in debt and with a stock price that dropped 37% the day the FDA's decision was announced, NPS was in a tenuous financial position. In view of the critical challenges with which the company was faced, it was a matter of survival to plan for a radical reorganization of the company's structure and focus.

Given the risks inherent to the drug discovery and development process, a need for drastic change is not an uncommon situation. Other companies faced with these challenges typically restructure, continue to focus on what they do best, and advance one or two of their lead programs. This approach has its advantages, but what if you excel at making square pegs and the best market for you is full of round holes? Rather than following the typical trajectory, NPS first looked at its portfolio of product candidates and their potential utility in therapeutic areas with few or no treatment options and limited competition. Then management transformed its business model to leverage its intrinsic expertise in areas that would optimize the

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company's potential for success in these indications. This led to a definition of operational excellence that is focused on identifying and retaining core and differentiating competencies and assets, and optimizing them for maximum productivity and value generation.

### **Find your focus**

Putting this definition of operational excellence to work requires management to identify those areas in which an organization can truly excel and aligning its financial and personnel investments accordingly. After a strategic review of the company's assets and programs, we determined that NPS' strongest value driver resided in the area of clinical development. The company jettisoned its in-house discovery research infrastructure which was deemed too expensive with a low probability of success. The company also transformed its business model to an outsourcing one, reducing the headcount by 80% and therefore relying on the operational expertise of outside companies on an as-needed basis. This approach allowed NPS to drastically reduce its overhead and cost footprint, and led to the consolidation of the company's operations in a single facility. Through outsourcing and the use of contractors, we have been able to meet operational needs "on demand" without the need to carry the costs of equipment, facilities and personnel that were underutilized.

With a focus on clinical development of therapies for rare diseases with high unmet medical needs, we partnered or out-licensed the assets that were considered non-core. This strategy had the dual benefit of reducing costs that were not essential for achieving the company's new objectives and generating capital that could be used to advance key programs and pay down the substantial debt burden.

### **Bring out the microscope**

With a new focus and business model in place, NPS sought to optimize every aspect of its operations for efficiency and productivity. First we determined which organizational structure and talent profile were required for our success. We retained key personnel and complemented them with additional resources that were more pertinent to the business model. The company then assessed the processes needed to operate smoothly and efficiently. This analysis identified five company-wide processes considered critical; these processes were dissected, streamlined and specific steps to simplification were implemented. SOP's had to be rewritten according to the revised processes and training followed. Last but certainly not least, the operational technologies had to be assessed given that many of the technologies had been acquired to serve a company 10 times larger and with a commercial twist, which was not the case anymore given the new orientation of the company as a development powerhouse. The technologies were retired, replaced or simplified. Throughout this process, the number one priority was to maintain compliance given the highly regulated aspects of drug development and the fact that NPS is a public company.

In order to ensure that the company maintains the highest level of efficiency, NPS established a mechanism for routine assessment of processes, personnel and

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productivity. These periodic assessments give the company the information that it needs to optimize efficiency and productivity and stay on track to achieving key objectives. More recently, we took the time and effort to assess the operational processes, and updated them based on what we had learned on the operational front and the evolution of the company. In addition, we hired Six Sigma experts to assist in simplifying and streamlining our processes even further.

### **Keep the big picture in mind**

Although excellence and efficiency within an organization are essential for success, it is important to recognize that a job done to perfection will still go unrecognized if the target audience fails to perceive its value. A beautifully formed square peg will find no place in the world of round holes. At NPS, this means that any given process or procedure is worthwhile only if it achieves the goals of creating value for patients and shareholders. Drug development companies must take a pragmatic view of their position within the pharmaceutical landscape and must identify factors that differentiate them from their competitors. Once they have established a business strategy, they must ensure that they have the right product and the adequate resources to compete with established players.

In establishing a business model that increases the likelihood for success, one could keep Darwin in mind. Companies should consider the overall environment for pharmaceutical products, and identify niches and areas of differentiation that are hospitable for their growth and evolution. From this perspective, the role of regulators and payers is becoming increasingly important. On one hand, regulators are more and more focused on product safety and positive risk-benefit ratios. The payers, on the other hand, are more and more reluctant to reimburse for drugs that may provide only modest benefits.

Recognizing that the pharmaceutical landscape is littered with the remnants of companies that were “good” at a lot of things, our mantra for true success has been to be “different, exceedingly well”. Rather than attempting to take on large pharmaceutical companies in highly competitive markets cluttered with multiple products, the company chose to build a business based on a differentiating culture, an innovative business model, and niche indications that could provide life-transforming value to patients with rare diseases, while creating value for our shareholders.

Today, NPS has two product candidates in Phase 3 registration programs for rare disorders, a healthy financial standing and strong investor interest. While focusing on clinical development of its lead programs, the company has leveraged multiple partnerships to reduce its clinical and commercial risk and increase its likelihood of success. By retaining commercial rights in North America, NPS has the opportunity to establish its own direct revenue streams while remaining eligible to earn substantial royalties on sales of products marketed by its partners across the globe.

### **Conclusions**

Building a business around the NPS model of operational excellence may enable

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other small- to mid-size pharmaceutical companies to navigate the challenges of their industry. Successfully filling one or more well-defined niches and capturing a majority stake of a small market are likely to create more value than can be achieved by competing for a small piece of a very large market.

Achieving operational excellence by looking for ways to excel at doing less rather than more runs counter to much of the conventional wisdom in the pharmaceutical industry. Yet the innovation gaps, product failures and shrinking margins within the industry suggest that a new perspective is needed. Reducing staff, eliminating or out-licensing programs in which substantial investments have already been made, and staying within a focus area can be difficult emotionally and operationally. If this were easy, everyone would be doing it. Companies should consider that the costs associated with these hard choices are well worth the price if they enable them to truly transform patients' lives. And that's the picture that matters most.

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