BY KIM RIBBINK

Prioritizing the Pipeline

THE CRITICAL ROLE OF

Increased pressures on the pharmaceutical industry — SHRINKING PIPELINES, RISING COSTS, REIMBURSEMENT ISSUES, REGULATORY PRESSURES, AND CONSUMER DEMANDS — mean companies have to find ways to focus on the projects that will meet corporate goals. AN OPTIMAL WAY TO DO THAT IS THROUGH PORTFOLIO MANAGEMENT.

THERE IS A TREND TOWARD MOVING PORTFOLIO MANAGEMENT EARLIER INTO R&D. There's a recognition that product research is not just serendipity. Quality management and well-designed strategies also are important to successful programs.

MARK NOGUCHI
ROCHE

PORTFOLIO PERSPECTIVE

PHIL BECCUE. Director, strategic portfolio management, Baxter Bioscience, a division of Baxter International Inc., Deerfield, Ill.; Baxter Bioscience provides biopharmaceuticals derived from human plasma or recombinant technology to treat hemophilia, immune deficiencies, and other blood-related disorders as well as vaccines for the prevention and treatment of certain infectious diseases, as well as biosurgery products. For more information, visit baxter.com.

JERRY CACCIOTTI. Managing director, life sciences, Strategic Decisions Group, Menlo Park, Calif.; Strategic Decisions Group is a strategic consulting firm that applies decision theory to uncover opportunities for creating shareholder value. For more information, visit sdg.com.

MICHAEL CHANG. Executive director, portfolio and project management, CV Therapeutics Inc., Palo Alto, Calif.; CV Therapeutics is a biopharmaceutical company focused on applying molecular cardiology to the discovery, development, and commercialization of small, novel molecule drugs for the treatment of cardiovascular diseases. For more information, visit cvt.com.

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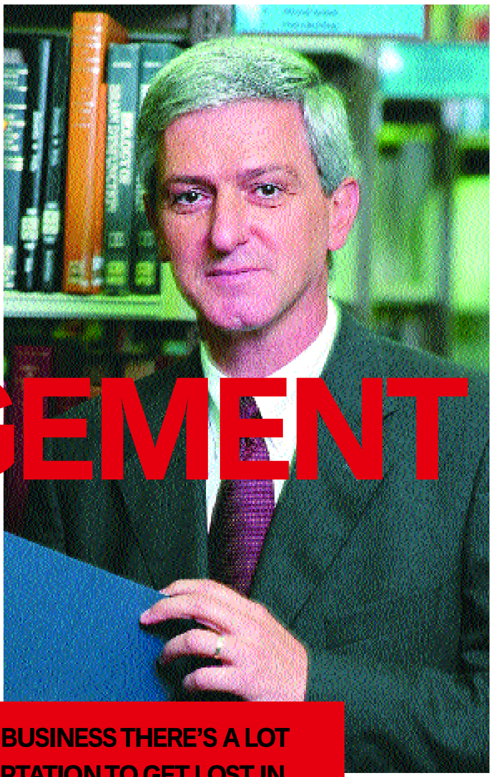

PORTFOLIO MANAGEMENT

From research and development through to marketed products there are numerous challenges pharmaceutical company executives face in managing a complex business strategy.

Since the amount of time, staff, and money a company can allocate to each project is finite, it must find ways to assess the value of each project to the corporation as a whole — not just from a financial perspective but also in terms of strategic fit, market perception, and balance within and across therapeutic areas.

Portfolio management, which Datamonitor describes as a framework for facilitating the implementation and development of corporate strategy, is the one function within an organization that is equipped to provide an analytical assessment of each project in the context of corporate goals and strategies.

The cost of bringing a drug to market combined with a slew of market pressures, including shrinking pipelines, a tougher regulatory climate, pricing concerns, reimbursement issues, and growing consumer demands, intensifies the need for good portfolio analysis. And yet, according to Datamonitor, fewer than 50% of executives surveyed indicated that portfolio management plays a role in implementing changes in corporate strategy, and only 30.3% said it plays a role in developing corporate strategy (for more information, see box on page 16). Companies will need to ask themselves if can they afford to forego rigorous portfolio management in today's market.

IN THIS BUSINESS THERE'S A LOT OF TEMPTATION TO GET LOST IN THE DETAILS AND RUN THE RISK OF NOT FOCUSING ON THE REALLY IMPORTANT, HIGH-PRIORITY PROJECTS. That's why I believe that portfolio management has an important role to play.

DR. JOERG REINHARDT
NOVARTIS

automotive, consumer markets, energy, financial services, healthcare, and technology sectors. For more information, visit datamonitor.com.

MICHAEL MENARD. President, North American operations, The GenSight Group, Doylestown, Pa.; The GenSight Group is an international firm specializing in project portfolio management, business portfolio management, and resource allocation for companies in complex, rapidly changing business environments. For more information, visit gensight.com.

MARK T. NOGUCHI. VP, strategic portfolio management, Roche, Palo Alto, Calif.; Roche, with global headquarters in Basel, Switzerland, is a leading healthcare company active in the discovery, development, manufacture, and marketing of novel healthcare solutions that address prevention, diagnosis, and treatment of diseases. For more information, visit roche.com.

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PAUL SAATSOGLOU. Practice leader, global resource/portfolio optimization, IMS Consulting, Plymouth Meeting, Pa.; IMS Consulting is a global source for information solutions to the pharmaceutical and healthcare industries, providing critical information, analysis, and services that drive decisions and shape strategies. For more information, visit imshealth.com.

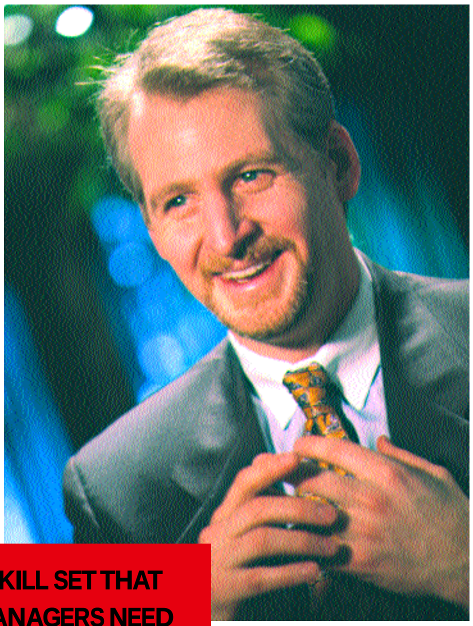
CHARLES SALDARINI. Vice chairman and CEO, PDI Inc., Upper Saddle River, N.J.; PDI is a healthcare sales and marketing company that provides strategic alternatives to the portfolio challenges of biopharmaceutical and medical-device and diagnostic manufacturers through two core businesses: sales and marketing services and product commercialization. For more information, visit pdi-inc.com.

EDWARD C. SALTZMAN. President, Defined Health, Millburn, N.J.; Defined Health is a strategic consulting company that provides opportunity assessments, therapeutic area growth strategies, and identification and evaluation of partnering opportunities. For more information, visit definedhealth.com.

KEITH VADAS. VP and general manager, pharmaceutical solutions, ProModel Solutions, Orem, Utah; ProModel Solutions delivers services and innovative technology solutions that help pharmaceutical, healthcare, and manufacturing companies maximize throughput, decrease cycle time, increase productivity, and manage costs. For more information, visit promodel.com.

DAVID J. WINIGRAD. President, The Hal Lewis Group, Philadelphia; Hal Lewis is a privately held healthcare marketing communications agency. For more information, visit hlg.com.

DEEANN YABUSAKI. Associate director, portfolio planning, Genentech Inc., South San Francisco, Calif.; Genentech is a biotech company, with 12 protein-based products on the market and 20 projects in the pipeline. For more information, visit gene.com.



Value Proposition

CACCIOTTI. Success in the industry these days is about innovation — finding innovative projects, bringing them forward quickly, and managing them well. There is no way a company can succeed without a rigorous, deliberate portfolio framework to manage R&D.

YABUSAKI. Portfolio management is about making the right decisions that optimize our resources and dollars, which allows us to invest in the pipeline and meet corporate objectives. Effective portfolio management allows us to identify those opportunities that advance our mission, and that is to deliver products that have the potential to improve and extend patients' lives. It also helps frame the requirement for a consistent management focus and creates a disciplined approach to investment decisions. That might mean saying no or stopping development when other opportunities create more value.

SALDARINI. Portfolio management is critical because companies now have to begin shifting their focus to start maximizing profits as opposed to optimizing profits. The industry has been very adept at adjusting resources to optimize the margin of any given product contribution. But to sustain the growth that investors are expecting, we believe they have to find ways to maximize every product in the portfolio.

THE QUESTION IS, WHAT DEFINES A BALANCED PORTFOLIO? We make decisions within the context of our mission statement, and we balance risk, value, and return on investment for our shareholders.

DEEANN YABUSAKI ● **GENENTECH**

GASPERS. Portfolio management should work hand in hand with the strategic-planning department and upper management to determine where the company wants to head and set the overall corporate strategy.

NOGUCHI. Portfolio management to me, at its core, is resource management, which is an important clarification of the term. It's an investment decision process. In that regard it's extremely important to a pharma company to appropriately invest resources for the promise of optimal return. But first a company needs to understand where it wants to go and what the company's vision is. That vision can be very broad or fairly specific. It can identify the general direction for the company or identify a customer base. Regardless, the vision sets where we want to go as a company, and then portfolio strategies should facilitate reaching that vision. There's a danger of portfolio management becoming a buzz term, like empowerment, which in the 1980s was a key term but meant something different to each person. Portfolio management can mean something different to everyone as well. What we've tried to do is clearly define what we mean by managing and designing the portfolio.

THE BIGGEST SKILL SET THAT PORTFOLIO MANAGERS NEED IS AN ABILITY TO ANTICIPATE CHANGES IN ANY GIVEN MARKET and make course corrections to their portfolio to keep pace with those changes.

CHARLES SALDARINI ● **PDI**

MENARD. Portfolio management is really the essence of the decision-making architecture of the corporation. The reason it's so important now is that resources are more constrained and the stakes are higher. The pharmaceutical industry is experiencing profound fundamental change, including advances in technology, pressure on pricing and profit, and high expectations from the financial community. The pressure is on and it's all about where a company allocates its resources to bring the greatest return. Portfolio management should be about decision making, not about looking at the current portfolio.

SALDARINI. The biggest skill set that portfolio managers need is an ability to anticipate changes in any given market and make course corrections to their portfolio to keep pace with those changes. Those course corrections might involve development activities, formulation extensions, or new clinical programs to provide data in support of new indications. Or adjustments might need to be made to sales and marketing strategies or manufacturing strategies, which will allow managers to better adjust their costs and focus in relation to changes in the market or changes to the competitive set when they can't change the profile of the product.

WINIGRAD. Companies can no longer rely on their pipelines to ensure revenue growth. There are just too few new products and too many setbacks. So maximizing the commercial potential of their existing brands is imperative to their sustained success. The companies succeeding are the ones that place a high value on their existing brands, viewing them as stepping stones to new and better compounds, line extensions, and other lifecycle management opportunities. The companies that are struggling have placed all of their bets on new products, particularly new blockbusters. Companies that have not invested in their existing portfolios will have trouble, particularly when new products fail in development.

JONES. While the role that portfolio management can play in developing corporate strategy has been explored more extensively in strategic literature in recent years, there has been far less investigation of the practicalities of linking the two processes. Therefore, while many executives have acknowledged the potential of portfolio management as part of strategic development, due to the lack of tried and tested tools or models few companies are actually linking the two.

SALTZMAN. The classic portfolio-management process involves looking at the risk-adjusted rate of return on investing in a series of individual projects. Companies are starting to become a little more sophisticated. They are beginning to look at the return from an overall collection of products as well as how a development-phase product will contribute to the return on an integrated basket of projects or products within a current commercial franchise or a contemplated commercial franchise. We're moving more and more toward a return on franchise investment perspective as opposed to valuation of a particular product.

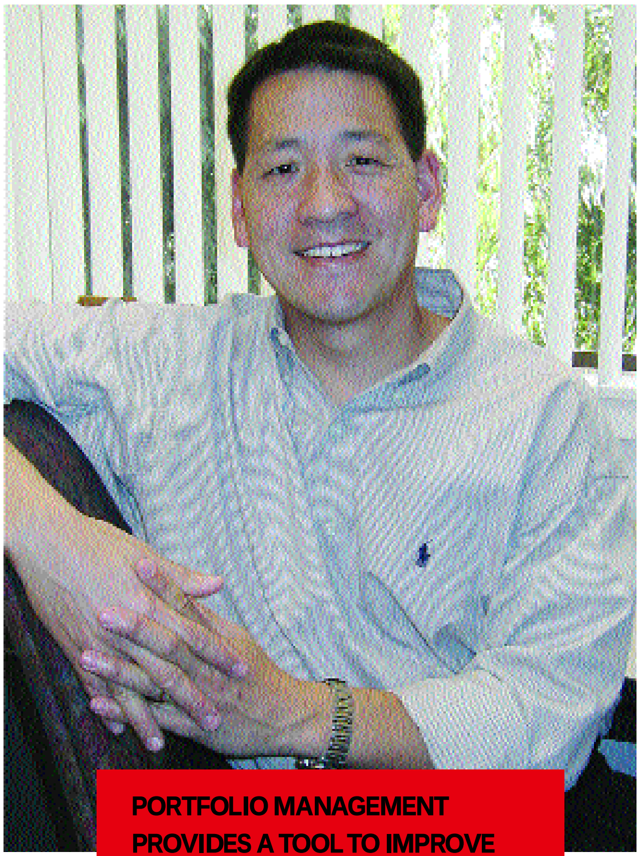
PORTFOLIO MANAGERS NEED TO GET INPUT FROM A LOT OF DIFFERENT FUNCTIONAL AREAS WITHIN THE COMPANY TO FIND OUT WHAT THEIR NEEDS ARE. Portfolio managers also need to work closely with senior management to understand what the board's imperatives are.

BRETT V. GASPERS
● **OBJECTIVE INSIGHTS**

Tools of the Trade

CHANG. The Monte Carlo simulation introduces a more sophisticated modeling technique that in some ways has replaced the discrete choice decision trees because what it does is provide continuous distributions of all the possible outcomes. There are also the classical business parameters, such as the net present value (NPV), though my personal experience is that NPV is much more relevant to large pharma companies that have massive portfolios. At smaller companies, such as CV Therapeutics, with a smaller portfolio where it is possible to know more about the individual project issues and risks, a more helpful tool is the Kepner-Tregoe rational process model of decision making, because it allows us to evaluate a portfolio based on a multitude of criteria and to assign a weighting system to the different criteria. These might be strength of intellectual property, time to next decision point, cost to next decision point, and probability of technical and regulatory success. With a smaller portfolio, we have the luxury of drilling down another level than would be possible at a large pharma company.

BECCUE. I believe that decision analysis provides a solid foundation for rigorous portfolio management. This is a quantitative approach that distinguishes between choices and information, accounts for uncertainty explicitly, and puts numbers on measures of shareholder value, such as NPV of cash flows, time to market, and revenue forecasts. Numbers are used to help quantify uncertainty, so instead of saying high risk, medium risk, low risk, we actually determine the probability distribution around NPV or are able to make statements such as "the chance of having positive NPV is 75%." Decision analysis helps an organization to drill down, and the more we drill down the more defensible and transparent the project information is. By doing this consistently across projects, we can produce a prioritized list based on any number of different metrics. This provides a great deal of insight as to where the gaps are, what the value of the portfolio is, and what areas we need to improve on. The other tremendous benefit is that by participating in the decision analysis process, project teams discover the link between cost, risk, and value for their particular situation, which helps them do a better job of bringing their product to market.



PORTFOLIO MANAGEMENT PROVIDES A TOOL TO IMPROVE PRODUCTIVITY and to maximize return on investment, because ultimately that's what it's all about.

MICHAEL CHANG
● **CV THERAPEUTICS**

NOGUCHI. A tool is just a tool. It's embedding concepts within the organization that is important. We view portfolio management in three stages: portfolio assembly, portfolio management, and portfolio design. Each is very different and requires a different type of investment in the activity. Portfolio assembly means gathering all of the information we may need to manage the portfolio. It means getting consistency so we can compare apples with apples. It's speaking the same language and using the same terms. At Roche, we now have four research centers; we used to have six. In the early 1990s each center used its own terminology and decision-making processes, based on certain criteria that were different, to advance compounds. Different criteria are fine, but different decision-making processes and terminology can lead to real trouble. Assembling the portfolio means getting clarity on what we have in the portfolio so when I talk with the research site head in

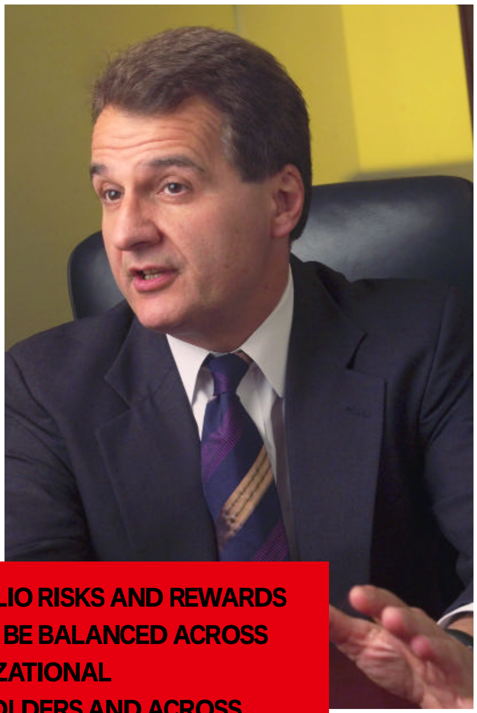
Penzberg, Germany, about a lead optimization program, we're talking about the same thing as when I talk with our head of Swiss research. Assembly means we're striving for consistency in terminology and decision making. Then we can manage the portfolio and make decisions on what we have; that's active portfolio management. From there, we can be confident in the data we have and can move to the third stage, which is what we call portfolio design and that is defining a portfolio prospectively of what we want and actively managing the portfolio to get there.

WINIGRAD. The most important tool a company can use in portfolio management is market research. The company that knows the market needs and the customer best has the competitive advantage. Unfortunately, this customer-based approach is often subordinate to the internal needs of the company. For example, if a company has two products in the same category that compete, often the question becomes: how do we protect the share of both products? The better question might be: which product will better satisfy customers' needs five years from now? That answer may give companies better insight into the decisions they make today.

Calculating Pipeline Success

SAATSOGLOU. The aim of R&D pipeline portfolio analysis is to prioritize areas with the greatest potential in terms of the market and competition and make more informed decisions through, firstly, assessing probability of success and analysis of individual projects, secondly, maximizing expected ROI, and, thirdly, reducing the chance of making unprofitable decisions. In reality, the payoffs have been difficult to quantify. Agreement of metrics is key. The biggest hurdle is to align the organization with the vision that it is better to have consistent metrics and portfolio-evaluation methods than not have any at all and depend solely on subjective evaluations. Regular and rapid re-assessment using these techniques is equally critical as the competitive pace continues to accelerate.

NOGUCHI. From an opportunity standpoint, the further we get into development the more detail we want on the opportunity. When assessing a Phase III program, the commercial assessment is highly detailed and refined. At the research stage, we work with something called a target product profile, which is a description — sometimes in words, sometimes quantitative — of the product and how we



PORTFOLIO RISKS AND REWARDS SHOULD BE BALANCED ACROSS ORGANIZATIONAL STAKEHOLDERS AND ACROSS TIME. This is difficult to achieve but essential for success.

PAUL SAATSOGLOU
● IMS CONSULTING

Portfolio Management Activities Often Overlooked by Pharma

FOR MOST PHARMACEUTICAL COMPANIES, A WIDE ARRAY OF PRODUCTS ACROSS THERAPIES MEANS A MULTITUDE OF PROJECTS TO OVERSEE. THESE PROJECTS VARY FROM THE R&D PIPELINE TO MARKETED PRODUCTS. THE CHALLENGE FOR COMPANIES IS TO DETERMINE IN WHICH PROJECTS THEY SHOULD INVEST. PORTFOLIO MANAGEMENT PROVIDES A WAY FOR COMPANIES TO PRIORITIZE THE PIPELINE.

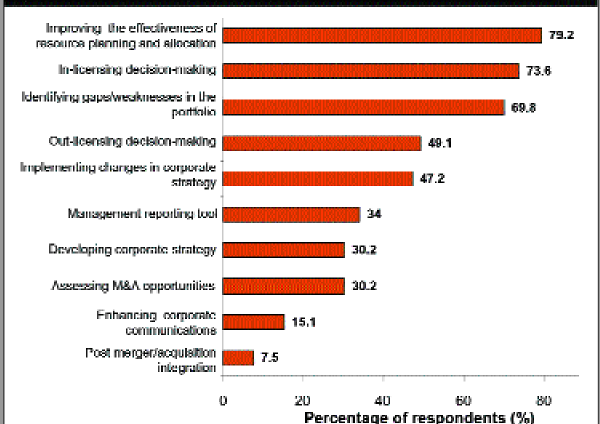
Research from Datamonitor reveals that while portfolio management can play a central role in achieving corporate success, a significant proportion of pharmaceutical companies are failing to optimize their portfolio-management activities.

Datamonitor analysts believe that to meet today's business challenges, executives must implement robust portfolio-management practices that are supported by novel strategies. But more than 40% of executives surveyed by Datamonitor believe their companies are failing to commit adequate time and resources to portfolio management. Futhermore, 25% believe their organizations have little ability to implement and execute portfolio management effectively. Deficiencies are particularly notable in the specialty and midtier sectors, according to Datamonitor.

The most important barriers to effective portfolio management are not technical deficits, according to Datamonitor research, but relate more to company culture and operational capabilities, namely lack of buy-in to the portfolio management process. Organizational structure, poor management, and inadequate or poor infrastructure are some of the top barriers to portfolio management, according to executives surveyed by Datamonitor. Other findings include:

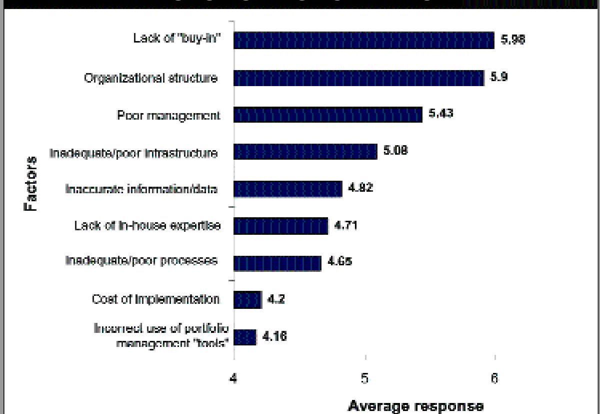
- **67%** of executives from specialty pharmaceutical companies and 47% from midtier companies believe too little time and resources are committed in their organizations to portfolio management.
- **47.2%** of executives indicated that portfolio management plays a role in implementing changes in corporate strategy, but only 30.2% stated that it plays a role in developing corporate strategy within their company.
- **41%** of specialty pharma executives believe their organizations have less than adequate (very little or no) ability to implement and execute portfolio management effectively. Deficits also are apparent among midtier companies, with 47% of executives indicating less than adequate ability.
- Executives rated lack of buy-in as the most important barrier to portfolio management. Moreover, while 31.9% indicated that buy-in was adequate at all levels within their organization, 36.2% said it was less than adequate at either the project-team or senior-management level.

ROLES OF PORTFOLIO MANAGEMENT*



* Percentages of respondents who identified the roles played by portfolio management within their organizations.

BARRIERS TO PORTFOLIO MANAGEMENT*



*Executives were asked to rate each factor on a scale of 1 to 10 where 1 indicates that the factor does not represent a barrier and 10 indicates that the factor represents a significant barrier.

Source: Datamonitor, London, Pharmaceutical Portfolio Management: Strategies to Deliver Corporate Success. For more information, visit datamonitor.com.

believe it will succeed in the market. That target product profile describes the opportunity, the efficacy required, the safety required, the convenience required, the dosing regimen, and so on, for a successful commercial product. And then we offer a general ballpark estimate of the value of a product that addresses the target product profile. We will not start a research program unless there is a target product profile in place. As a product candidate is identified and moves in the clinic, that general description becomes more specific and the quantification of the commercial opportunity becomes more specific.

WINIGRAD. One strategy that works is to create an ideal product profile for the given disease or therapeutic category. This profile must be market derived. It's the customer's view of what the ideal product would be. Once this profile has been developed, then it can be valued and used to assess product candidates from within and from outside the company. Of course, the ideal product doesn't exist, therefore optimal portfolio management consists of compounds or line extensions, copromotion deals, and in-licensing, all of which put together as an aggregate, come closest to the ideal.

VADAS. Portfolio managers need to understand, based upon where their organization stands today with the compounds or candidates in its portfolio, what the potential is for the future. The only way to do this is to have some idea of the probability for success of these compounds making it to market, which means assessing success at key milestones. These executives have a broad idea based on their project plans, historical information, and benchmarking what the approximate cycle times are for products to achieve key milestones, such as Phase I and Phase II. From there they need to project out — 8 years to 14 years — what the potential is for bringing those products to market and then assess what the projected value is for those products. By looking at key resource costs or overall costs based on reaching key milestones, they have a baseline view of the portfolio and can look at what it will cost to bring those products to market. They then can start to calculate net present value of the portfolio and from there start to strategize on what compounds they should or shouldn't have in the portfolio, as well as those appropriate for licensing strategies.

WINIGRAD. Portfolio managers need to develop the art of the long view. They need to be people who are not overwhelmed by the day-to-day demands of product management. They have to be insulated from those considerations so they can look across brands, look across markets, and truly focus on the future. Their focus should be two, three, and five years out.

BECCUE. Within any organization, there are many approaches to managing a portfolio. My personal bias is to drill down, to quantify data, and to produce very transparent outcomes to support decision making. For example, I want to know what the risks versus returns versus investments are for each product and compare this information on a consistent basis.

THIS IS AN INDUSTRY ENAMORED WITH SEXY NEW SCIENCE, PRODUCT LAUNCHES, AND BLOCKBUSTERS. This is where the energy and excitement is. Unfortunately, the hard work of optimizing portfolios is not so glamorous, requiring day-in day-out work to squeeze new revenue from the brands.

DAVID WINIGRAD
● THE HAL LEWIS GROUP

REINHARDT. To do portfolio management properly, it is important to look at the different parameters, such as network values, risk levels, likelihood of success, timing of projects in terms of launch schedules, as well as such issues as the balance between new molecular entities and life-cycle management activities and the balance between general products and specialist products. There is an aspect of strategic risk within franchise management. So if a company is strong in a certain franchise, it might make sense to have additional projects that may not have dramatic NPV, but still make important contributions to the existing franchise.

YABUSAKI. For us, portfolio management is about managing the information and ensuring that the right information is in front of our decision makers. To do that we balance our analyses by looking at multiple value metrics that address the specific investment decision and tie the decision to corporate performance. We don't anchor to one specific metric that might turn a decision. There is a balance and a consideration across the basic drivers of the decision — risk, value trade-offs, and so on.

Balancing Act

JONES. Executives must ask two key questions when determining whether a portfolio will meet strategic objectives: is the portfolio balanced across the types of projects defined in the strategy and are resources being deployed in alignment with strategic objectives? Companies must ensure that all projects within a portfolio are "on-strategy" and that spending across the portfolio mirrors strategic priorities. There are a number of models that have been developed to achieve such strategic alignment. Scoring approaches rate projects against each strategic dimension thereby enabling project prioritization by channeling resources to those projects that have the greatest overall "strategic fit." While this approach ensures that all projects within a portfolio are strategically aligned, scoring models fail to ensure that budget allocation across the portfolio is balanced across key priorities. An alternative is the strategic bucket approach. Once a corporate strategy has been developed, management determines a set of distinct priorities or strategic dimensions along which it needs to commit resources. Funding decisions are then made, and different levels of investment are assigned to each strategic priority. Projects within the portfolio are grouped together into strategic buckets according to

WE RECOMMEND THAT COMPANIES FIRST IDENTIFY THEIR KEY STRATEGIES — which direction is the company going in, which therapeutic areas will it focus on, and so forth — and then develop opportunities, which include pipeline, in-license opportunities, even out license and acquisition opportunities.

MICHAEL MENARD
● GENSIGHT

their fit with each distinct funding priority. Projects can then be prioritized within each bucket using maximization approaches such as scoring models and financial analysis, which take into account a range of additional parameters, such as project value and associated risk and resource requirements. But it is often difficult to divide resources across buckets without first considering the quality of the projects and opportunities that are available within each bucket. Senior management should therefore attempt to determine the attractiveness of projects before committing resources.

HALL. Companies need to get back to basics and understand where their therapeutic and scientific strengths lie and find ways to diversify within those strengths. Should an oncology company be reinvesting and rounding out its oncology portfolio or getting into other areas that are similar in terms of types of diseases? A cardiovascular company could go into diabetes and a lot of other diseases that build off its core competency. A risky portfolio strategy is when a company buys into a totally different therapeutic disease area. An automobile and an airplane are both transportation vehicles but building one is very different from building another. In the same way, while developing drugs is similar, developing a cardiovascular drug is vastly different from developing an oncology or central nervous system drug.

SALTZMAN. Companies are increasingly apt to enter new therapeutic areas by acquiring an existing business or commercial presence, acquiring a product, licensing in development-stage opportunities, or partnering for those opportunities. My experience tells me that certain companies have cultural impediments to understanding complex, specialized therapeutic areas.

NOGUCHI. Roche has chosen to be active in certain therapeutic areas and less so or not at all in others. That's our strategic portfolio plan and we align our research and development strategies around those decisions. The goals differ from one therapeutic area to another. So our goals in oncology, for example, are very different from our goals in dermatology. We have determined that we want to be a major player in oncology and our strategy is in line with that. And we're a minor player in dermatology research, and our goals are in line with that decision.

REINHARDT. Our two main therapeutic areas are oncology, which is a specialist area, and cardiovascular, which is a generalist area. We want to maintain a balance and not fully focus either on the general practitioner or specialist areas. Within those therapeutic areas we want to ensure a balance between the more risky, but novel products and others that may be less risky that have a better known mechanism of action. So in oncology we have a broad array of products, not only signal transduction inhibitors, but also some conventional cytotoxics. We recognize that to treat cancer now and in the future, there is a need for a combination of approaches; no single product alone will do the trick. To be successful in oncology we believe it is important to have a broad range of products.

CHANG. Throughout marketing research development, management needs to align portfolios and resources with the corporate strategy. Companies in general need to make balanced investments across projects — different therapy areas, different development stages — subject to the risk and return profiles. The way to integrate decision making and maintain balance is to have a continuous cycle of guidance and feedback and to include all of the relevant functions, including the head of research, the head of marketing, and key development executives.

BECCUE. We assess cost, risk, and value for each opportunity, whether it's internal or external. We use that information to come up with a set of metrics that can add insight to help determine the right product mix for the company. Those metrics include NPV of cash flows and a productivity ratio that measures the expected cash flows given success versus the cost to get to market. We can then plot these results on a productivity curve to compare disparate projects with each other. Another metric would be the expected number of products launched each year. This can help highlight gaps and help determine in-licensing strategies that might fill those gaps. Peak sales is another important metric. This offers a sense of the market size, as well as the cost to market a product. And finally, the metric to communicate a project's riskiness is the probability of technical and regulatory success or, the chance it will reach the market. It can be helpful to look at metrics in two dimensions and compare, for example,

SOMEONE ON THE TEAM HAS TO HAVE A POWERFUL VOICE TO SAY WE'VE GOT TO DO THIS, AND WE HAVE TO DO IT CORRECTLY. Without a champion, it's probably not efficient for an organization to even attempt portfolio management.

PHIL BECCUE
● BAXTER BIOSCIENCE

THE GOAL OF PORTFOLIIO MANAGEMENT is to maintain commercial relevance and/or increase commercial strength in defined therapeutic areas.

EDWARD SALTZMAN ● DEFINED HEALTH

expected NPV versus probability of success. We try to come up with different ways to look at all these quantitative metrics so management can glean insight into what's going on and really understand what trade-offs need to be made. This helps assess future opportunities in a way that meets corporate goals.

SALDARINI. Portfolio management is not a new theory. Our pharmaceutical clients have been very adroit at optimizing products, whether they have been part of a franchise or a single entity. Over time, the very large companies that have grown up over the last several years will bring increased focus to maximizing a portfolio within a franchise.

Inside and Out

HALL. When big pharma licenses in products from biotech or smaller pharma, these companies are licensing niche products. By definition they are helping themselves by reducing the risk. These products are less expensive to develop and to market, and they balance the portfolio. For many big pharma companies, they are gap fillers and because of the cost and duration of developing a chemical entity, many companies have some pretty big gaps in their pipeline.

REINHARDT. When we assess an external opportunity, it has to go through the same rigorous assessment as our internal projects. We then classify the external opportunity in the context of our internal existing portfolio and whether it fits the upper segment of attractiveness, the middle segment, or the lower segment. And only then do we make the decision to invest in that product. It has to be better than a number of our internal existing products to make the cut for in-licensing.

WINIGRAD. Industry trends necessitate that portfolio management and life-cycle management be front and center. The existing products in the portfolio should be seen with a new appreciation as precious assets for the corporation.

CHANG. The evaluation techniques of in-licensing must reflect the key differences of external versus internal opportunities. Some of the considerations that are important for in-licensing are the financial aspects as well as the risk involved in the agreement, such as cancellation issues. There also needs to be consideration if an ongoing relationship with an external partner could generate additional opportunities.

SALTZMAN. In the future, there will be very few single-product franchises; companies will have multiple product franchises governed by a mixed, integrated offering. For instance, in diabetes, most companies will have more than one type of drug or treatment mechanism. In addition, to maintain the relevance of the franchise, companies will need to have an important position in standard-of-care drugs. If a company has these products in the pipeline that's wonderful, otherwise it needs to be not only aware of what's available externally and where to find opportunities but also to have a solid strategic perspective from which to evaluate the potential for the opportunity.

REINHARDT. It is not always possible to have a blockbuster every second year in the cardiovascular arena, for example. So it's important to have other GP areas that can fill gaps. That's why we believe it is healthy to be in seven or eight therapeutic areas as long as we can afford to have the right talent on board and can afford to have a highly experienced workforce in research and development to cover all these areas. We don't want to be active in a therapeutic area where we would be a second-tier player or where we would not have the quality or quantity of the critical mass to get to a leading position. Whatever area we enter, we want to be a leader. For example, we decided some time ago that we wanted to invest in the infectious diseases area. We understood that it would be difficult for us to have a jump start based on our in-house resources. That's why we forged a deal with Idenix and acquired a pipeline with a Phase III product in hepatitis B and an option to a Phase II product in hepatitis C.

CACCIOTTI. When it comes to licensing opportunities, too often companies react to the assets that are in play. In other words, a small biotech is looking for a partner or a midsize European company is looking for an American major to be its marketing partner. The big pharma companies then rush to make themselves seem like the most attractive partner or sweeten the deal. This is fundamentally a reactive process. In the future, companies will need to look at what is inside their portfolios, identify assets that may be better outside, and then think about win-win business models that are going to allow them to access those opportunities in a better way.

SAATSOGLOU. The licensing environment is becoming increasingly competitive. This is forcing companies to look at earlier stage projects, including those in preclinical. To identify attractive licensing candidates, companies need to involve teams of individuals from a mix of disciplines, including research and development, marketing, and business development. An in-licensing portfolio strategy entails comprehensive product and therapeutic area benchmarking; modeling business performance of an individual product as a function of individual unit therapeutic area level characteristics; scoring/profiling current, or near launch, products; and selecting the one with the best prediction for incremental growth based on the model.

WINIGRAD. In-licensing decisions start with strategic life-cycle management. Companies must understand the trends and where the opportunities lie in the future. They need to evaluate what enhancements to their current portfolio will make them more competitive. This might be a combination product or a new delivery system. Ultimately the market's unmet needs best inform the decisions regarding in-licensing and clinical development.

GASPERS. The focus in pharma has been much more on in-licensing than out-licensing. Yet, biotech companies might be a potential gold mine in terms of out-licensing sidelined products to them and getting a good royalty stream without having to make a major investment to move the products along in development.

REINHARDT. We have a number of examples where we've out-licensed products from our pipeline that didn't make the cut. This is an opportunity, but obviously not our primary objective. In the future, we would like to cut projects that are not attractive much earlier to avoid significant expenditures. While those products might not be attractive enough for us, they may still have a good biological effect and may be good candidates for out-licensing.

SALDARINI. We believe companies need to continue to focus on outsourcing solutions to deliver the product maximization goal that we think is critical to achieving investor expectations. As the dynamics in the industry continue to change, pharmaceutical companies will need a greater range of strategic alternatives to provide them with both cost and flexibility advantages without compromising the effectiveness they are used to from their own internal capabilities.

A Wide-Angle View

MENARD. The unfortunate fact is that different parts of the company are vying for resources, so they're almost competing against each other. Marketing is trying to get money for advertising, and R&D is trying to get money for drug development. There's a constant battle. And each business unit uses different decision models and different tools. When senior management puts emphasis on portfolio management the dialogue changes, and the game changes. The primary goal of portfolio executives must be enterprise portfolio management. This requires one database to capture industry and competitive information, R&D pipeline information, and in-licensing data so that it becomes possible to model the total opportunity. Today, those functions are in separate silos.

CHANG. At CV Therapeutics, portfolio management begins very early. We look at new target selections and evaluate those against more advanced research projects. We do an analysis of our exploratory portfolio and examine key issues, such as scientific risk assessment, commercial risk assessment, and competitive assessment. We then resource the programs based on the insights that we've gained from going through these processes. But the key to any analysis is management buy-in.

CACCIOTTI. Silos are a reality. The R&D organization won't be managing the marketing portfolio. What the industry needs to tackle is how can it elevate cooperation across the pipeline and along the pipeline to balance cross-corporation views and tradeoffs. A company doesn't want to manage its preclinical portfolio alongside its Phase IV marketing investments in support of in-line products. What it wants to do is build a framework that optimizes a given set of investments at one stage of the pipeline and another set of investments further on, and whether the relative rates of return are comparable.

WINIGRAD. Within pharma companies there is a need to create multidisciplinary teams that are aligned around a central strategy. But even more crucial, there needs to be leadership — executives who are empowered and who have final decision-making authority for portfolio management. Too often, though, the power, resources, and money are consolidated in the brand teams. Sometimes, this is the missing piece.

JONES. At any given time, a company has finite resources, therefore, to maximize shareholder value, portfolio management must aim to distribute investment resources optimally across all projects within the enterprise. Accordingly, because there is competition for the same resources, the management of R&D portfolios and marketed product portfolios should not be separate processes, because the performance of both impacts the company's market capitalization. Portfolio management must therefore be seen as a decision-making process that extends across the entire enterprise, encompassing not only the clinical R&D pipeline portfolio but also preclinical research and discovery projects and the marketed product offering.

NOGUCHI. We manage hundreds of programs in the Roche research portfolio, leading to the delivery of clinical candidates in early development. In research portfolio management, the scientists are the experts on the mechanisms and targets being addressed. This expertise must absolutely be used in portfolio decision making. My challenge is to use the right information for decision making. Because we have hundreds of programs, the scientific expertise lies with many people. To facilitate the decision-making process, we have chosen to structure our research sites as performance units, or centers of productivity. Our four research units are the primary operational units for portfolio management and each unit manages its portfolio. This way we're able to incorporate the detailed expertise of our scientists from each site into a smaller unit. The authority and program decision making resides in the local sites, and the global portfolio-management group provides guidance on the global goals, strategies, and direction. The sites are expected to be aligned with the global vision and strategies.

How a company manages attrition — **THE GO/NO-GO DECISIONS FOR COMPOUNDS** — is probably the biggest issue in portfolio management.

JAMES HALL
● WOOD MACKENZIE

THE GOAL IS TO LOOK AT THE RISK AND REWARD OF EACH INDIVIDUAL CANDIDATE compound and mix them together in a portfolio and then take into account the resources that are available.

KEITH VADAS
● PROMODEL SOLUTIONS

YABUSAKI. Priorities are established and identified through our decision-making body, which is the Portfolio Planning Committee (PPC). The PPC is a senior-management level decision-making body, cochaired by our chief operating officer, Myrtle Potter, and the head of the development organization, Sue Hellmann. Both women also belong to the executive committee, which establishes the therapeutic focus areas, and having them cochair the decision making body for the portfolio lends alignment to the decision-making process. This allows for very effective discussions and decisions at the PPC level and enables us to talk about trade offs within our portfolio and identify portfolio priorities.

VADAS. Within every organization, especially large pharma, there is a disconnect between the strategic and tactical planners. The project teams think their project is going to be successful and they are typically very optimistic about how long it will take to get their product to market. Then there are more site-based or functional-group teams that look at milestone goals. And those goals might not align with the project team or strategic planner's goals. To come up with an optimal portfolio all of these groups should have a common methodology based on common data and assumptions that shows the long-term impact of decisions across the entire development process.

HALL. Until a few years ago, most portfolio decisions were made based purely on science. That was the classic R&D view. Do we have good science? Do we have good scientific programs? Are we managing those programs effectively? About five to eight years ago, most companies injected a heavy dose of marketing assessment. Now decisions are not only based on the science but both on the science and whether there is a market for the product. What started to emerge a couple of years ago, and not many pharma companies are doing this yet, is a sense of competitive assessment. As markets get tighter and fewer novel drugs come to market, it's important in terms of managing risk to know when the drug is launched what else will be on the market.

IT WILL BECOME INCREASINGLY IMPORTANT FOR DECISION MAKERS TO BE ABLE TO IDENTIFY THE PORTFOLIOS THAT OFFER BOTH THE HIGHEST EXPECTED RETURNS FOR A PARTICULAR BUDGET as well as the highest expected returns for the amount of risk that their organization is willing to take.

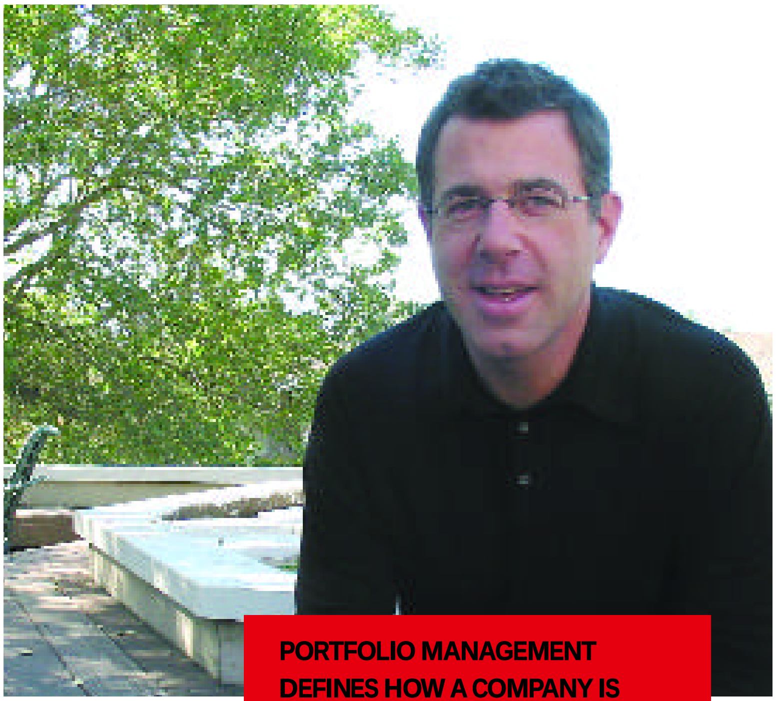
ANDREW JONES
● DATAMONITOR

BECCUE. Baxter Bioscience has a broad array of products, from vaccines to medical products to therapies to manufacturing. Baxter recognizes the need for rigorous portfolio management. The challenges are in comparing apples with apples and having a consistent way of making trade-offs between diverse sets of activities, whether it's a manufacturing initiative or investing in a Phase III study that could help solve a pressing unmet medical need in the next couple of years, or pursuing a set of discovery projects that require 10 or more years of development before coming to market.

HALL. There's going to be a lot of pressure from the market and sooner or later from regulators on pricing, which will force pharma companies to take a look at what's appropriate to spend to develop a drug and what's the appropriate price for a drug. This will force companies to think in terms of what is the potential of the drug. It's going to force companies to know what's the right indication, what's the right set of patients, and how they are targeting sales, rather than just going for the mass market.

REINHARDT. The time for "nice to have" portfolios is gone. Companies will have to focus much more on products that add medical benefit and add value for the customers. Portfolio management helps companies to better focus on these issues.

WINIGRAD. From an in-line product point of view, we see more emphasis on long-term branding that accommodates opportunities down the road. With a sound life-cycle management strategy, it is critical to be mindful of what the brand represents today so that it can continue to represent what the market needs in the future even if it emerges as a different iteration. Branding is how the product exists within the mind of the customer, so if a company is to capitalize on that, it needs to be very deliberate in its use of branding early on.



PORTFOLIO MANAGEMENT DEFINES HOW A COMPANY IS DOING. It poses questions about how the company can get the success it wants from its assets. Is the company having the success in therapeutic areas that it anticipated, and are these areas growing fast enough to drive value in the future? And if not, what can the company do to fill those gaps?

JERRY CACCIOTTI
● STRATEGIC DECISIONS

SALDARINI. The biggest trend impacting portfolio management is an increasing focus on whether sales resources have been cost adjusted to their current effectiveness. As salesforces have increased in size and companies have gone to portfolio equivalency within those sales organizations, people are starting to question whether that same profile is needed across the entire sales organization or if it would be better to focus on a tiered profile, where there might be a higher-end specialty organization wrapped around a primary care salesforce, which might be wrapped by a service salesforce. ✦

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