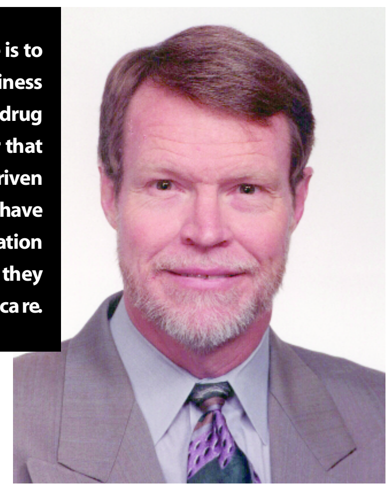
> **Today, alliances between small biotech companies and large pharmaceutical companies are helping to balance the risks of drug discovery and provide biotech companies with the resources as well as the expertise needed to advance projects aggressively.**

NIGEL SHEAIL
Roche

> **The biggest challenge is to reexamine the current business model guiding most mature drug manufacturers and evaluate whether that model can survive in a consumer-driven healthcare system where patients have access to huge amounts of information and are more cost-conscious than they have ever been with regard to healthcare.**

DR. MERRILL MATTHEWS
Institute for Policy Innovation



> The culture of the pharmaceutical industry, along with the technology industry, is one of the last great frontiers of the sales-driven culture. It is slowly changing to be both more customer-centric and marketing-centric, but cultures change slowly.

MARK PERLOTTO
Adair-Greene Healthcare Communications

BUSINESS MODELS

TURETT. The pharmaceutical industry needs to resolve multiple bipolarities: being a business and being a public utility; being doctor-focused and being consumer-focused; and being about medical innovation and being about marketing. The industry has begun a process of self-reinvention that in 2005 will lead to a period of further self-discovery where the industry will be concerned with what the world expects and needs from pharmaceutical companies and not just pharmaceutical products. Additionally, in 2005 there will likely be more collaboration with companies in other parts of the industry, as well as with both governmental and nongovernmental organizations. One or two companies will take bold moves by creating some truly different models for marketing and selling their products.

BARRETT. The next generation of blockbusters is diminishing. Patent expirations are looming. For 10% revenue growth, a major pharma company must bring three new drugs to market each year. Because of these issues, along with the move toward more targeted

ANGEL BIAGGI. VP, Marketing, STADA Pharmaceuticals Inc., Cranbury, N.J.; STADA Pharmaceuticals, a wholly owned subsidiary of STADA Arzneimittel AG, is a pharmaceutical company specializing in the marketing of generic and branded pharmaceutical products for the U.S. market. For more information, visit stadausa.com. (Note: The views expressed in this forum by Mr. Biaggi are his and do not necessarily represent the views of STADA Pharmaceuticals or its affiliates.)

JEFFREY O. BOILY. President and CEO, Rogers Medical Intelligence Solutions, New York; Rogers Medical Intelligence Solutions provides trusted information and insights on the latest medical and clinical research worldwide. For more information, visit rogersmis.com.

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drugs against specific medical issues, the No. 1 issue for pharma will be the pressure on R&D to produce new drugs to bring to market to meet the revenue growth expected by investors. This will require more clinical trials and a need for increased efficiency of the process. An efficient clinical-trials process is where the fundamental roadblock lies, so solutions that increase standardization, automation, and visibility will be hot topics in the coming year.

S. LEVY. 2005 will be the year that the industry begins to reconsider the merits of blockbusters and behemoth companies. Conglomerates will need to show shareholders why the creation of behemoth companies is a benefit to profitability. Merger activity may slow dramatically as stakeholders reconsider if bigger is necessarily better. Blockbusters, though attractive for their ability to generate billions of dollars in sales, may be a dangerous addiction in the long run. In the merger/blockbuster market, many investors look down at drugs that sell in the hundreds of millions, because consolidated pharma companies need billions in cash to reinvest in R&D and marketing. Companies and, more importantly, their investors, will take a hard look at the risks involved in depending on big revenue and big overheads.

FRESHLEY. Many have written about the death of the blockbuster, but that may be too simplistic. Perhaps we need to be more innovative in how blockbusters are created, developed, and marketed. The industry needs to get more creative in how it views the potential marketability of a drug. It kills any drug that does not

LEADERSHIP WILL MAKE OR BREAK PHARMA COMPANIES IN 2005

NEED FOR POSITIVE PUBLIC PERSONA IDENTIFIED

Concerns such as rising healthcare costs, parallel trade, and product withdrawals will put drug company CEOs in the spotlight more than ever — and market pressures will demand that they rise to the occasion, sccording to a report from Wood Mackenzie.

A key issue is the role of leadership in determining success or failure in the pharmaceutical industry, according to Wood Mackenzie's Executive's Guide. According to the findings, senior-level leaders of major pharmaceutical companies must define a new set of ideals to create success in the coming year.

"Our analysis suggests that in the coming year, pressures such as patent expirations and pipeline strength will be matched by a need to improve the image of an industry whose lifeblood is public health," says James Featherstone, European head of consulting for Wood Mackenzie Life Sciences. "Those CEOs who build value in the minds of both investors and the general public will stand out as leaders in 2005."

Source: Wood Mackenzie, Boston.
For more information, visit woodmackenzie.com.

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RICHARD CHAMBERLAIN. President, Chamberlain Communications Group Inc., New York; Chamberlain Communications is a full-service public-relations agency. For more information, visit chamberlainpr.com.

PAUL D. COTTONE. Chairman, President, and CEO, Odyssey Pharmaceuticals Inc., East Hanover, N.J.; Odyssey Pharmaceuticals is a specialty pharmaceutical company, and a wholly owned subsidiary of PLIVA Inc., focused on key therapeutic categories, including urology, respiratory, and metabolic disorders. For more information, visit odysseypharm.com. (Note: As this issue went to press, Mr. Cottone is no longer with Odyssey Pharmaceuticals; Wayne Yetter has assumed the titles of president and CEO.)

GREGG DEARHAMMER. Director, Biometrics, Kendle International Inc., Cincinnati; Kendle is a global CRO delivering clinical-development solutions to help the world's biopharmaceutical companies maximize product life cycles and grow market share. For more information, visit kendle.com.

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EDWARD L. ERICKSON. Chairman, President, and CEO, Immunicon Corp., Huntingdon Valley, Pa.; Immunicon has developed a ▶

INDUSTRY TRENDS TO WATCH

1 THE GROWTH OF THE U.S. PHARMACEUTICAL MARKET IS FORECAST TO RETURN A COMPOUND ANNUAL GROWTH RATE (CAGR) OF 9.7% FROM 2003 TO 2008, DROPPING BELOW 10% FOR THE FIRST TIME IN RECENT HISTORY. **WOOD MACKENZIE.**

2 FOR 10% REVENUE GROWTH, A MAJOR PHARMA COMPANY MUST BRING THREE NEW DRUGS TO MARKET EACH YEAR. **PAT BARRETT.**

3 THE U.S. IS TRANSITIONING FROM A DOCTOR-DIRECTED HEALTHCARE SYSTEM TO A PATIENT-DIRECTED HEALTHCARE SYSTEM. **DR. MERRILL MATTHEWS.**

4 LARGE PHARMA COMPANIES WILL MIGRATE INTO CHANNEL MARKETING ORGANIZATIONS. **MICHAEL MUYOT.**

5 28% OF INTERNET USERS HAVE PARTICIPATED IN ONLINE OR OFFLINE BEHAVIOR-MODIFICATION PROGRAMS. **FORRESTER RESEARCH INC.**

6 ONLY THREE OF EVERY 10 MARKETED DRUGS WILL PRODUCE AFTER-TAX REVENUE. **MICHAEL MUYOT.**

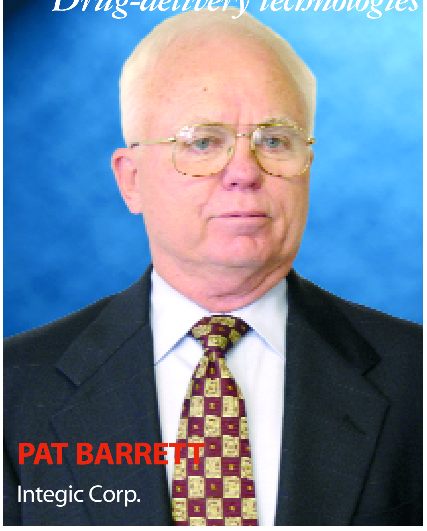
7 DRUG DEVELOPMENT TAKES BETWEEN 10 YEARS AND 15 YEARS AND COSTS UPWARD OF $800 MILLION PER DRUG, YET ONLY 8% OF ALL DRUGS IN DEVELOPMENT RECEIVE FDA APPROVAL. **FDA.**

8 THE FULLY LOADED COST OF A FULL-TIME EQUIVALENT (FTE) IS ABOUT $100,000 PER YEAR LESS IN SMALL PHARMA COMPANIES COMPARED WITH BIG PHARMA. **DR. GEERT CAUWENBERGH**

9 EACH NEW NCE COSTS FROM $500 MILLION TO MORE THAN $1 BILLION TO BRING TO MARKET. **BRUCE PEACOCK.**

10 DEMAND SOON WILL OUTSTRIP THE CAPACITY OF THE CURRENT TRIAL INFRASTRUCTURE, SUPPORTED BY LESS THAN 5% OF PHYSICIANS (AS INVESTIGATORS) AND FEWER THAN 1% OF PATIENTS (AS TRIAL PARTICIPANTS). **LAURA CARABELLO.**

Drug-delivery technologies are allowing generic companies to penetrate the branded field more quickly and aggressively at a lower cost of development. The line between branded and generic pharma is quickly blurring.



PAT BARRETT
Integic Corp.

Developing a drug is like walking on a tightrope blindfolded. New financial models will be required to share the significant costs and associated risks involved in bringing new drugs to market.

JEFFREY BOILY
Rogers Medical Intelligence Solutions

SCOTT FREEDMAN
MonitorForHire.com

Innovative companies, the ones with superior ROIs, seem to be more receptive and willing to adopt new ideas and methodologies to make R&D more efficient and productive.

JOHN FRESHLEY
Genetics Squared Inc.

The industry needs to get more creative in how it views the potential marketability of a drug. It kills any drug that does not meet the traditional measure of blockbuster. Maybe instead of killing so many drugs, we could look at these drugs in new ways with new tools that are rapidly being developed, such as pharmacogenomics and personalized medicine.

MICHAEL MUYOT
Tracer Analytics

We believe that the large pharmaceutical companies will migrate into channel marketing organizations. They cannot sustain the high cost and high risk of R&D. Rather they will become the commercialization and marketing channel for promising technologies developed by others.

meet the traditional measure of a blockbuster. Instead of killing so many drugs, maybe the industry could look at these drugs in new ways with new tools that are rapidly being developed, such as pharmacogenomics and personalized medicine. The specialty pharma companies and biotechs have led the way in this area. A basket of targeted oncology drugs may be able to generate similar revenue to a blockbuster,

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platform focusing on cell-based and molecular diagnostic products for monitoring cancer. For more information, visit immunicon.com.

SCOTT FREEDMAN. President, MonitorForHire.com, Conshohocken, Pa.; MonitorForHire.com is a leading Web-enabled resource management company providing qualified, regional independent clinical monitors to the pharmaceutical, biotechnology, medical-device, and contract research industries. For more information, visit monitorforhire.com.

PAUL E. FREIMAN. President and CEO, Neurobiological Technologies Inc., Richmond, Calif.; Neurobiological Technologies is a biotechnology company engaged in the business of acquiring and developing central nervous system-related drug candidates. For more information, visit ntii.com.

JOHN FRESHLEY. President and CEO, Genetics Squared Inc., Ann Arbor, Mich.; Genetics Squared is an emerging biotechnology company whose mission is to advance the clinical development of therapeutics and to rescue failed drugs by discovering novel diagnostics that predict disease progression and patient response. For more information, visit genetics2.com.

AARON GRAHAM. VP and Chief Security Officer, Purdue Pharma L.P., 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.

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PAUL HAMELIN. President and Chief Operating Officer, AlgoRx Pharmaceuticals Inc., Secaucus, N.J.; AlgoRx is a privately held, emerging pharmaceutical company focused on the development and commercialization of products to treat pain. For more information, visit algorx.com.

THE PHARMACEUTICAL INDUSTRY IS NO LONGER A GROWTH INDUSTRY

The next generation of industry leaders must innovate, elevate, and grow. This will require a paradigm shift from pharmaceuticals to life sciences, much in the same way that the banking industry transformed itself into the financial services industry.

The blockbuster-centric branded, small-molecule pharmaceutical business model experienced tremendous success in the last decade. The industry experienced more than a 500% increase in market capitalization from 1990 to 2000. Industry consolidation propelled pharmaceutical companies into megacap status with the likes of Pfizer, GlaxoSmithKline, Aventis, and Novartis. The market capitalization of Tracer's LSI (Life Science Industry) Pharmaceutical Index exceeds $1.3 trillion, making up more than 70% of the total LSI 100 Index. This leaves a lot of room for growth in the other four sectors: medical devices, biotechnology, specialty pharma, and drug delivery.

Wall Street continues to expect double-digit growth despite recent market challenges. The pharmaceutical industry faces big challenges in its attempt to maintain shareholder value.

A majority of the pharmaceutical drugs go after the low-hanging fruit within healthcare. There is still a lot of room for new market segments within oncology, cardiovascular, CNS, hormone therapy, organ transplants, tissue regeneration, and so on.

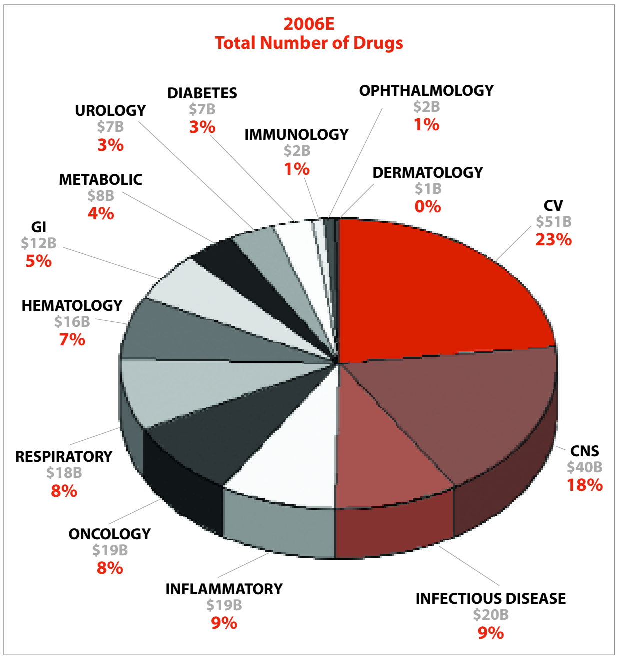
With the pharmaceutical industry considered to be a value play at best, there has to be a major transformation to a more expanded business model that incorporates other growth sectors. When institutional investors and portfolio managers look at their pharma holdings they are searching for more than just a decent EPS; they are looking three to five years out and how the portfolios score from a quality vs. momentum perspective. They are looking at the key growth drivers to determine where to extend and contract their positions.

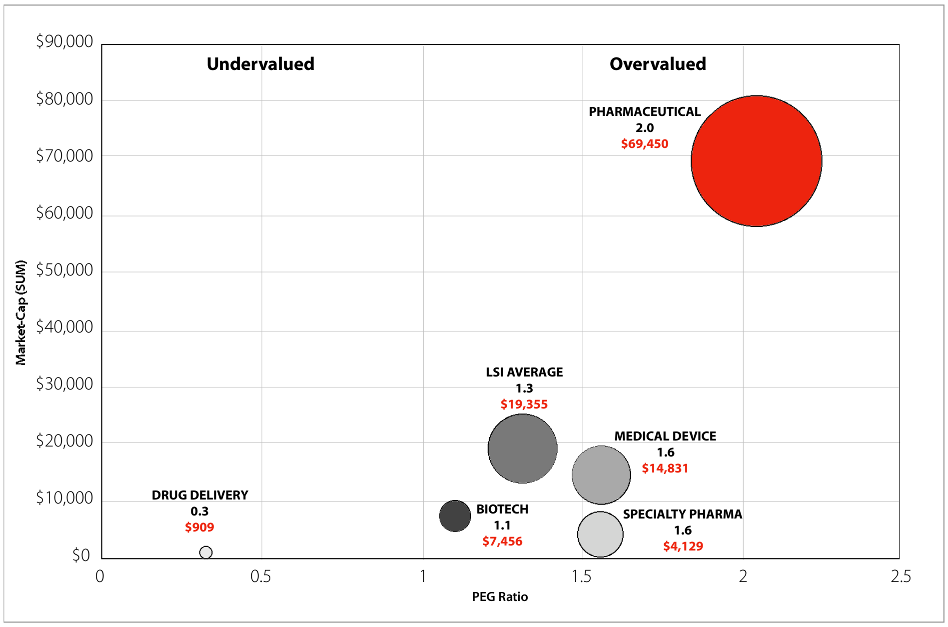
One of the ways to return to double-digit growth is for pharmaceutical companies to invest in other sectors such as biotechnology, medical devices, specialty pharma, and drug delivery. This is where a majority of the new innovation will come from in the form of better diagnostics, biological treatments, and combination devices, such as drug-eluting stents and pain specific drug-delivery mechanisms.

It doesn't take double-digit revenue to generate double-digit investor return when a company operates in the specialty markets; that's how these companies built their foundations several decades ago.

In a climate of investment uncertainty, it is more important than ever to get the right messaging out to the investment community. One of the keys to success is to clearly understand how Wall Street investment analysts perceive a given company relative to the rest of the market segment, sector, or even the industry as a whole.

Whether it is an institutional investor, portfolio fund manager, or hedge fund, a favorable rating goes to the company that clearly portrays its own strengths relative to its peer group. In turn, by presenting the long-term financial viability to Wall Street it will expand its coverage of the company, products, and market segment. Increased exposure will increase investment awareness. When the Street perceives financial reward opportunities that are quantifiable, a particular sector will tend to grow faster in terms of market capitalization.





Source: Tracer Analytics, New York.
For more information, visit traceranalytics.com.

and with their targeted nature they may be able to justify a higher reimbursement and incur lower marketing costs than a traditional blockbuster product.

MATTHEWS. The most significant business challenge facing industry leaders is to develop a vision for how the pharmaceutical industry fits and survives in an evolving healthcare model. The United States is transitioning from a doctor-directed healthcare system to a patient-directed healthcare system. This is in large part because patients have so much access to information that they never had before. But also because in a patient-directed healthcare system — also referred to as a consumer-driven healthcare system — patients control more of the healthcare dollars (through mechanisms such as health savings accounts) and want value for their money. Insurers and employers recognize this transition and are embracing it. Large insurers that focused entirely on managed care are buying small insurers that have been at the forefront of the consumer-driven changes to stake out a place in the new model. While drug company marketing departments have recognized the transformation — hence the growing trend toward advertising directly to consumers — industry leadership hasn't. The biggest business challenge is to reexamine the current business model guiding most mature drug manufacturers and evaluate whether that model can survive in a consumer-driven healthcare system, where patients have access to huge amounts of information and are more cost conscious than they have ever been with regard to healthcare.

W. LEVY. With costs for developing and marketing drugs continuing to escalate and increased public demand to reduce the price of drugs to match levels in other countries, companies must develop a new coordinated strategy to address these issues. The largest companies are depending too heavily on developing new products with peak sales potential in excess of $1 billion, limiting their new product candidates. The larger pharmaceutical companies in the near term must increase in-licensing budgets in a focused manner, especially in areas that address unmet pharmaceutical needs or in products that are lower risk, such as new formulations of existing products that will increase patient compliance. In the longer term, they need to increase R&D budgets in those same areas to generate new product candidates with appropriate patent protection to delay generic competition. Additionally, they need to decrease direct selling costs, which in many cases over-emphasize time to peak year sales or inefficient detailing.

NASH-WONG. Pharma will be anything but "business as usual" for the next few years until recently renewed industry focus on R&D

PHARMACEUTICAL INDUSTRY SUCCESS DEPENDENT ON BETTER PRODUCT LIFE-CYCLE MANAGEMENT

Product life-cycle management, a holistic approach that addresses integrated operations such as marketing and sales, is one of the most important priorities for the pharmaceutical industry today, according to the fourth annual Vision & Reality report from Capgemini.

More than 90% of senior executives believe that product life-cycle management is important for their future prosperity, with 60% saying its importance will increase significantly in their organizations over the next five years.

This increased focus stems from concern over the failure of research and development activities to maintain a steady stream of new blockbuster drugs.

This leaves pharmaceutical organizations facing a dangerous combination of high costs and falling revenue as drugs lose patent protection.

Capgemini analysis reveals that about 150 NMEs will be required in the United States alone by 2007 to plug the drug pipeline shortfall.

This situation is unlikely to be resolved in the short term. Many industry observers believe the only way pharmaceutical companies will survive and prosper will be through a more sophisticated approach to life-cycle management that maximizes profitability throughout the product's life span.

"The importance of this issue should not be underestimated," says Paul Nannetti, global life sciences leader at Capgemini. "The pharmaceutical industry's success to date has been built on a consistent flow of high-earning, innovative products. But, as the industry faces the challenge of weaker R&D pipelines and likely reduced returns from new products, there is an imperative to drive greater value from existing portfolios. It is therefore not surprising that this year's research reveals that product life-cycle management is an important, if not the single most important, priority for the industry."

In addition to declining R&D productivity, pharmaceutical companies face increasing competition from other branded products and from generics. For some drugs, market exclusivity is less than one year with "fast followers" often entering the market to capture a greater share of sales.

In 2003, the global generics market was estimated to be worth $27 billion. This may seem modest compared with the total pharmaceuticals market estimated at more than $400 billion, but because of price differentials the generics market share in prescription terms is much greater than the value comparison suggests. In countries such as the United Kingdom

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DENNIS HURLEY. VP, Latin America, Kendle International Inc., Cincinnati; Kendle International is a global CRO delivering clinical-development solutions to help the world's biopharmaceutical companies maximize product life cycles and grow market share. For more information, visit kendle.com.

BOB KARCZEWSKI. Executive VP, Director of Client Services, HealthSTAR Communications Inc., Woodbridge, N.J.; HealthSTAR is a healthcare marketing services network. For more information, visit healthstarcom.com.

THOMAS KEMPISTY. Senior VP, Strategic Business Development, HealthEd, Clark, N.J.; HealthEd is an agency devoted to creating and implementing integrated patient-begins to replenish depleted pipelines and make up for patent expirations. Innovation will be critical as brand teams have to learn to do more with less. And, marketing will become more sophisticated and integrated, with the focus squarely on the patient instead of the product. Manufacturers talk a lot about acquisition and retention but the reality is that the industry more typically focuses on quarterly NRx sales, which puts all the energy into acquisition and short-term ROI. This approach fails to meet the retention side of the equation. Retention efforts have to address the long-term needs of consumers, such as continuing and progressive disease management, strategies to manage treatment barriers, and proactive side-effect management to name a few. New outcome measures are needed that can demonstrate shareholder value by tracking consumers through the life cycle of a product. With smart and sophisticated customer-relationship initiatives, lifetime value doesn't have to pertain just to one product, it can be extended throughout the entire portfolio as well as to new products as they emerge from the pipeline.

MUYOT. The large pharmaceutical companies will migrate into channel marketing organizations. They cannot sustain the high cost and high risk of R&D. Rather they will become the commercialization and marketing channel for promising technologies developed by others. There will be a significant shift toward acquisitions, licensing, and joint-venture models focused on drug delivery, specialty pharma, biotech, and medical devices. There is declining productivity and the cost of drug development has gone up significantly. Only three out of every 10 marketed drugs will produce after-tax revenue.

KOVAC. A company's IT investment is an important factor to shareholders. With IT investment comes challenges, so, to maintain shareholder value, most companies will have

and the Netherlands, generics account for more than 50% of pharmaceutical prescriptions.

But despite the recognition of the importance of product life-cycle management now and in the future, only 19% of executives believe their companies are currently doing an excellent job in successfully implementing life-cycle management strategies; 35% of respondents believe their companies' efforts rate no better than average; and more than 15% believe they do a poor or very poor job.

Major challenges include the fact that life-cycle strategies often are developed from functional perspectives rather than across the organization as a whole and that overall responsibility is not clear. The development of appropriate metrics also is a hurdle with many companies having no specific measures or key performance indicators in place for life-cycle management.

Looking to the future, indication expansion will continue to be an important factor, but executives expect in-licensing and alliances to become the leading strategies, with 45% stressing their increasing importance.

Strategies also are often adopted too late with imminent patent expirations acting as the trigger for action.

In terms of strategies for life-cycle management, indication expansion has been clearly favored in the recent past with 63% of executives citing it as having had a strong impact on profitability for their companies. Looking to the future, indication expansion will continue to be an important factor (with 31% of executives stating they expect it to become increasingly important), but executives expect in-licensing and alliances to become the leading strategies, with 45% stressing their increasing importance.

Such strategies seek to bolster pipelines and also contribute to the creation of therapeutic franchises and establishment of market leadership positions in key areas.

The research also looked at strategies that were falling from favor; 40% of respondents believed that Rx-to-OTC switching would become less important in years to come, suggesting disenchantment with OTC switching, following costly exercises that have delivered low returns.

As part of the survey, Capgemini also canvassed the opinions of more than 8,000 physicians across the globe about their views on the pharmaceutical industry's approach to product life-cycle management. A key finding of this research was that a significant majority of physicians were keen to become more involved in the development of the industry's life-cycle management strategies. Of the life-cycle management practices that physicians most preferred, indication expansion was identified as the most favored practice.

But the physicians surveyed were unhappy with strategies such as comarketing and Rx-to-OTC switching.

"A rigorous and focused approach to life-cycle management is in its infancy in the pharmaceutical industry and there is much to learn from more consumer-oriented industries," says Terry Hisey, Capgemini's U.S. leader for life sciences. "To move forward, companies need to take a more integrated approach to life-cycle management that has a strategic view across the organization, rather than taking a tactical view from individual business units, such as R&D and marketing."

Alasdair Mackintosh, VP in the life sciences practice, says companies need to establish clear ownership for life-cycle management with small powerful teams that ideally report directly to the board.

"Planning ahead and starting early also are crucial to move life-cycle management to become proactive rather than a last-stage attempt to fend off generic competition," he adds. "Such changes are not easy and require a different way of thinking and a different way of working across the organization. Companies that choose to address these challenges will create opportunities for competitive advantage by producing products capable of enjoying longer more profitable lives."

Source: Capgemini, New York.
For more information, visit capgemini.com.

GREGG DEARHAMMER

Kendle International Inc.

Kendle is embracing the new standard format in a variety of ways. Most importantly, we are using CDISC standards as our programming defaults and have trained all relevant programming, statistical, and clinical data management associates on the CDISC standards.

KATHRYN ROY

Phase Forward

We are committed to promoting standards and incorporating CDISC data interchange models into the functionality of our product suite.

to manage multiple product types and will need to adopt a new business model that requires changes at every stage in the value chain. This model will not only affect their critical operations but it will also entail new ways of performing daily activities, such as accounting, human resources, and IT.

SHANAHAN. The industry should take lessons learned from other science-based industries, such as the semiconductor, automotive, and aerospace industries. Those science-based industries have adopted formal, modeling software applications, and the result has been a dramatic increase in collaboration, automated analytics, and more informed planning. The pharmaceutical industry still depends on paper notebooks, passive pictures of systems biology, and verbal communication of research goals and results. The complexity of the research problems and the development of new automated platforms will demand a revolution in scientific methodology.

SHEAIL. Roche has learned that a key to successful alliance management is to help our partners develop as entrepreneurial, independent companies. Today, biotech companies expect and deserve more of a role in the management of alliances. We encourage our partners to get involved at every stage of the alliance, from early development through clinical trials to the marketplace. By transforming our partnerships into true strategic alliances, we will continue to expand deals with existing and new partners ultimately bringing new drugs to market. Today, alliances between small biotech companies and large pharmaceutical companies are helping to balance the risks of drug discovery and are providing biotech companies with the resources as well as the expertise they need to advance projects aggressively.

CDISC STUDY DATA TABULATION MODEL

B. THOMPSON. We are carefully reviewing the new Study Data Tabulation Model (SDTM) to ensure that our company is doing everything possible to streamline submissions of data to the agency. It should be a goal of companies and the agency to find and implement greater efficiencies to shorten the time to market for important new therapeutics.

DEARHAMMER. Kendle is embracing the new standard format in a variety of ways to ensure the highest quality data management

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centered marketing campaigns that focus on driving consumer behavior through educationally relevant strategies and tactics. For more information, visit healthed.com.

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CAROL KOVAC. General Manager, IBM Healthcare and Life Sciences, Somers, N.Y.; IBM Healthcare and Life Sciences brings together IBM resources, including IT, deep industry insights, and research expertise to help clients develop and deliver safer, more affordable, and more effective diagnostics, drugs, and medical care. For more information, visit ibm.com/industries/healthcare.

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