BY DENISE MYSHKO

» DEVELOPMENT

THE CHANGING R&D BUSINESS MODEL

Companies throughout the industry are experimenting with new models designed to **TACKLE THE PIPELINE PRODUCTIVITY CHALLENGE**.

Pharmaceutical research and development is facing many pressures, from decreased productivity to the impact of the economy to changing technology to an increasingly global environment.

Companies are looking for solutions, but industry experts say the answer may lie in the R&D business model. A report by PricewaterhouseCoopers released earlier this year predicts that by 2020 the old business model — where companies employ a strategy of placing big bets on a few molecules — will no longer meet the market's needs.

The industry, PricewaterhouseCoopers' experts say, is undergoing a period of disruptive innovation.

Companies will need to join forces with a wide range of organizations, from academic institutions, hospitals, and technology providers to companies offering compliance programs, nutritional advice, stress management, physiotherapy, exercise facilities, health screening, and other such services.

In R&D development specifically, Carolyn Buck Luce, global pharmaceutical leader at Ernst & Young, says the current R&D business model has proven to be unsustainable.

"Companies are exploring models that involve smaller groups of researchers who feel a high degree of ownership," she says. "Increasingly, companies are engaging partners from outside their traditional R&D networks to collaborate, share risks, and share success."

A COLLABORATIVE MODEL

The entire enterprise of clinical research needs to become more efficient to allow the available resources to focus on the most important questions, says Glenn Gormley, M.D., Ph.D., president of Daiichi Sankyo Pharma Development.

Dr. Stephen Cutler
Kendle

"Information transfer technologies continue to change the way we do business. These technologies can significantly increase the speed, accuracy, and cost efficiency with which data changes hands while also providing version control across multivendor project teams."

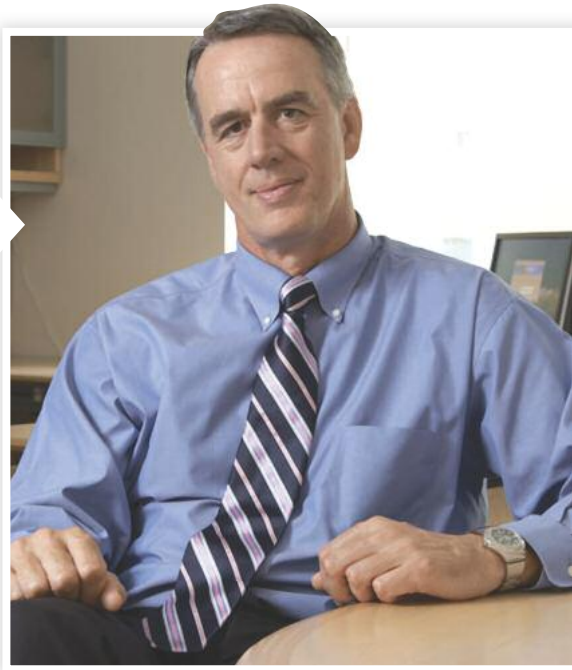
"We need to challenge the way we have operated in the past and remove low-value activities," he says. "One way to help with this is through collaboration, both with CROs and through alliances within the industry, to share knowledge and best practices."

Glen Giovannetti, global biotechnology leader at Ernst & Young, says the top issue facing life-sciences companies is how to increase the productivity of R&D efforts.

"Industry investment in R&D has increased steadily over the past two decades, while the number of new medicines introduced to the marketplace has fallen by about half since the mid-1990s," he says. "With the development costs for a new drug estimated at more than $1 billion, it is essential to reduce the cost, time, and risk of drug development."

Mr. Giovannetti says pharmaceutical companies are embracing new ways of meeting this challenge, including forming unprecedented alliances with peers in the precompetitive space, restructuring their own R&D efforts as a way to create smaller teams with a high degree of ownership over results, and by going virtual with parts of the value chain so they can focus on their true core competencies.

Robert Baltera, CEO of Amira Pharmaceuticals, says in the next year, and over the next five years, major drug developers will need to rely on an increased number of partnerships with small, innovative companies.



The U.S. CRO market generated more than $10.9 billion in revenue in 2009 and is expected to reach $22.87 billion in 2015.

FROST & SULLIVAN

"In addition, they will need to be more creative with these partnerships," he says. "The next generation of great discoveries will come from small, entrepreneur-led companies. These companies will partner with academic centers to drive great innovations."

Karen Ferrante, M.D., senior VP, clinical, at Millennium: The Takeda Oncology Company, says the collaborative model of pharma/biotech/academia remains a viable R&D

Robert Baltera
Amira Pharmaceuticals

"The current economic conditions are definitely impacting R&D by making it more difficult to identify sources of funding."

Dr. Karen Ferrante
Millennium: The Takeda Oncology Company

"The collaborative model of pharma/biotech/academia remains a viable R&D model and will continue to be expanded in the future. In general, there needs to be an enhanced openness with future collaborative effort and a transfer and sharing of IP."

Glen Giovannetti
Ernst & Young

"The industry must undergo a cultural shift that embraces open innovation and true collaboration throughout the innovation ecosystem, from traditional partners such as biotechs, academia, and CROs to important new partners such as IT, telecom, or medical technologies companies."

model and will continue to be expanded in the future.

"In general, there needs to be an enhanced openness with future collaborative efforts and a transfer and sharing of IP," she says.

Ms. Buck Luce points out that, at a time when the demand and opportunities for innovation — in both the product pipeline and the business model — have never been more urgent, companies may be underinvesting in the people and talent pipeline that will be essential to innovation.

"Under pressure to reduce costs, the pharmaceutical industry has undergone a wave of layoffs, creating a vacuum of know-how that will be difficult to fill as the business cycle recovers," she says. "This is compounded by the demographics of the changing work force, which are creating a talent shortage at a critical time. Companies need to dramatically reinvent the business processes and approach to the discovery, development, and life cycle management of people and talent to drive innovation, and rise to the challenge of serving new markets, customers, and stakeholders around the world."

James Weston, senior VP of Talaris Advisors, says in today's heightened resource-conscious business environment, it can be a challenge to identify and justify the allocation of significant resources for a project that has yet to achieve proof of concept.

"In mature businesses, full-time teams are often not required to expeditiously move a project forward," he says. "In cases where full-time teams are necessary, capacity constraints can lead to excess costs and delays. In start-ups, not all projects require the infrastructure of full companies. Because of this, I believe that the drug development model will come to rely more heavily on outsourcing to streamline these R&D processes, become more cost-efficient, and accelerate milestones."

TECHNOLOGICALLY DRIVEN

Dr. Gormley says for global development to be successful, the R&D process must evolve with technological changes, including the use of virtual models and adaptive clinical trials to increase efficiency.

"Modeling and simulation activities have made impressive contributions to the drug development process, allowing us to derive more data from a single experiment than ever before," he says. "Any new technology that can improve our understanding of the underlying biology of the human body and its diseases and allow researchers to better predict the effects of new drug candidates should be pursued."

Mr. Giovannetti says with major patent expirations looming, companies are exploring new approaches to R&D to improve productivity.

"These approaches include targeting new disease areas; using biomarkers to drive drug development and commercialization decisions; assessing the market need for product candidates at the earliest stages of development; and splitting up large, monolithic organizations into smaller, more autonomous units," he says. "This sort of transformational

OFFSHORING TRENDS

Pharma and biotech companies may be motivated to move offshore aspects of the R&D process for a variety of reasons beyond financial incentives. These include:

- Ability to leverage skills or technology hubs to move offshore countries through contract research.
- Access to skilled labor forces such as medical staff, analysts, and combinatorial chemists in offshore territories.
- Access to large treatment-naive patient pools and high patient recruitment rates.
- Cost savings and advantages in discovery, preclinical, and clinical trials.
- Establishment of IT/bioinformatics hubs to assist in data collation, analysis, and delivery throughout the world.
- Improvements in infrastructure within offshore countries.
- Increased regulatory burden at home, which makes offshore clinical trials more attractive to investors.
- Increased complexity of clinical trials and rising data requirements.
- Reduced product development time to market.
- Target bottlenecks in the R&D process, such as in vivo modeling and assay development, which may be uncompetitive within local markets.
- Tax incentives to encourage the relocation of R&D centers to offshore countries.
- The lifting of World Trade Organization restrictions.
- Tightening up of IP protections worldwide.

Source: Business Insights

Dr. Jason Hwang
Innosight Institute

"Precision diagnostics and therapeutics will render many traditional healthcare business models obsolete."

Dr. Glenn Gormley
Daiichi Sankyo Pharma Development

"The entire enterprise of clinical research needs to become more efficient to allow the available resources to focus on the most important questions. We need to challenge the way we have operated in the past and remove low-value activities."

By 2010 it is anticipated that only around two-thirds of contract R&D expenditure will remain in North America and Europe, and one-fifth will migrate offshore to the Asia-Pacific region.

BUSINESS INSIGHTS

change will require intense focus on execution to achieve the results desired in the time frame that is required."

Stephen Cutler, Ph.D., senior VP and chief operating officer at Kendle, says information transfer technologies continue to change the way business is being done.

"These technologies can significantly increase the speed, accuracy, and cost efficiency with which data change hands, while providing version control across multivendor project teams," he says. "But the trick is engaging people who know how and when to apply the right technologies and who understand the challenges and pitfalls of the plethora of systems that are available. Operationally experienced people who are open to change and new ways of working remain a key asset."

Jason Hwang, M.D., executive director, healthcare, at Innosight Institute, says precision diagnostics and therapeutics will render many of the traditional healthcare business models obsolete.

"The profit margins that have long favored therapeutics over diagnostics will begin to shift, as precision diagnostics enable new targeted therapies to emerge," he says. "The R&D business models that survive this transition will be those that have built processes and partnerships to develop therapeutics in conjunction with companion diagnostics."

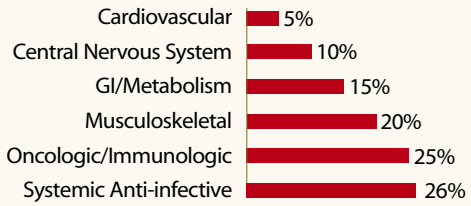
Process change is equally important in the move toward a more effective R&D model.

John Potthoff, Ph.D., chief operating officer at INC Research, says because of overall cost pressures, companies need to arrive at efficacy decision points earlier in development; most compounds that fail in Phase III do so for efficacy reasons, rather than safety.

"This requires established and standardized processes, along with an internal discipline to stop spending on unsuccessful compounds earlier," he says. "The biggest challenge is for companies to focus their R&D dollars on one goal: earlier determination of success or failure."

With many stakeholders, often money is spent well beyond the determination that a compound will not be successful, Dr. Potthoff says.

CLINICAL APPROVAL SUCCESS RATES BY THERAPEUTIC CLASS 1993-2004



- Systemic anti-infectives had the highest clinical approval success rate for self-originated new drugs, with more than one-quarter of those entering clinical testing during 1993-2004 receiving U.S. marketing approval.
- Less than 10% of cardiovascular and CNS drugs entering the clinical testing pipeline attained U.S. marketing approval during the same time.
- Clinical approval success rates for all therapeutic categories examined varied from 7% to 27%.

Source: Tufts Center for the Study of Drug Development

OUTSOURCING AS A STRATEGY

Analysts, consultants, and CEOs alike acknowledge that the development process needs to undergo major changes to reduce the time and costs associated with bringing new medicines to market. Companies are partnering more with CROs, which are continuing to refine and expand their services and become more expert in global development.

Mr. Weston of Talaris Advisors says most companies, large and small, will look to outsource some or all of their drug development activities.

"These outsourcing providers will become partners more so than contractors, as they will assume more of a stake in the outcome of the development," he says. "Best practices in drug development call for the use of the most experienced resources to get the job done. In these financially difficult times, this may not be feasible. Use of drug development management firms, CROs, or other outsourcing entities are becoming more and more the norm, which will allow more products to get to market sooner with more flexibility and cost efficiency."

John Hudak, president and founder of Criterium, says pharmaceutical companies have been less than sophisticated in their approach to partnering with CROs.

"Sponsors micromanage activities rather than direct the process," he says. "They manage their CRO partnerships without explain-

Carolyn Buck Luce
Ernst & Young

"The current R&D business model has been demonstrated to be unsustainable. Companies are exploring models that involve smaller groups of researchers who feel a high degree of ownership. Increasingly, companies are engaging partners from outside their traditional R&D networks to collaborate, share risks, and share success."

John Hudak
Criterium

"Virtual R&D can work with adequate training, a formalized process, and confidence that the team will get the job done."

ing their strategies for their drug/biotech projects."

Dr. Gormley says the best outcomes happen when companies develop long-term partnerships with CROs rather than one-off transactions.

"Developing strategic relationships with CROs leads to better coordination and alignment for functional collaboration and increased productivity," he says. "In my experience, CROs can be a lifeline for drug developers, and it's important to view them as an extension of our own organization, with shared goals and objectives."

Jan-Anders Karlsson, Ph.D., CEO of S*BIO, suggests selecting CROs and CMOs that have compatible business models and aligned business interests.

"These companies often may be medium-sized, agile, and industry leaders in their respective fields," he says.

Some best practices for working with

CROs include the standard practices of technically vetting vendors and creating competition among vetted vendors, says Steve Worland, president and CEO of Anadys Pharmaceuticals.

"A model that is truly fully virtualized suggests there's a market need for companies that only engage in planning, coordination, and marketing their ideas to providers of capital,"

Dr. Jan-Anders Karlsson
*S*BIO Pte Ltd.*

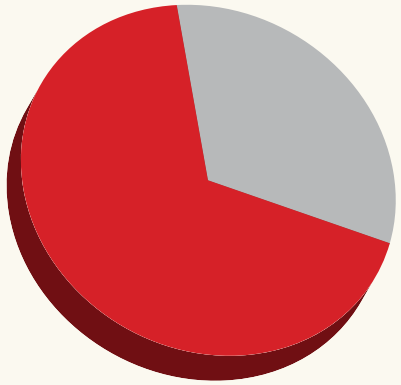
"Effective management of external resources has become a critical component of successful drug development."

he says. "That this, in and of itself, is a sustainable role to play in the market is questionable for two reasons: planning and coordination aren't really that scarce, and secondly these skills don't often reside in the same people who are most capable of promoting to sources of capital."

Mr. Worland says for a partnership to be sustainable, companies should develop a set of competencies that they then complement by outsourcing the many activities for which they aren't the ideal provider in the market.

"If their only skill is accessing capital, they should become bankers or fundraisers," he says. ✦

FDA RATINGS OF THERAPEUTIC SIGNIFICANCE FOR FOLLOW-ON DRUGS APPROVED IN THE U.S., 1960–2007



Priority (n=90)
Standard (n=192)

Source: Tufts Center for the Study of Drug Development

James Weston
Talaris Advisors

"In today's heightened resource-conscious business environment, it can be challenging to identify and justify the allocation of significant resources for a project that has yet to achieve proof of concept."

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

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STEPHEN CUTLER, PH.D. Senior VP and Chief Operating Officer, Kendle, a global clinical research organization providing a full range of early- to late-stage clinical development services. For more information, visit kendle.com.

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GLEN GIOVANNETTI. Global Biotechnology Leader, Ernst & Young, a global provider of assurance, tax, transaction, and advisory services. For more information, visit ey.com.

GLENN GORMLEY, M.D., PH.D. President, Daiichi Sankyo Pharma Development, the product development arm of Daiichi Sankyo Inc., which is engaged in clinical development, translational medicine and clinical pharmacology, regulatory affairs and risk management, informatics biostatistics and data operations, and development research. For more information, visit dsi.com/research/pharmadev.html.

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BY DENISE MYSHKO

» DEVELOPMENT

PARTNERSHIPS KEY TO IMPROVING GLOBAL R&D MODEL

Companies will need to **JOIN FORCES** with a wide range of organizations **TO ACHIEVE R&D SUCCESS** in the future.

According to Frost & Sullivan, the economic downturn and reduction in funding for early-stage projects is likely to result in a decline in growth rates across major therapeutic segments in the short-to-medium term. But because of this lack of funding, it is unlikely that pharmaceutical and biotechnology companies will invest in in-house capabilities to conduct clinical trials. This is set to benefit CROs in obtaining continued business from this segment.

Laurie Halloran, president and CEO of Halloran Consulting Group, says partners are the key to improving the R&D equation.

"Outsourcing partners will bridge the divide between pharma and technology since, theoretically at least, they can see both sides," she says. "The most successful partners will do the hard work of finding and analyzing the technology; sourcing the best-of-breed vendors; qualifying them; and managing the implementation and education so that adoption by the pharma company is as painless as possible."

John Potthoff, Ph.D., chief operating officer of INC Research, says his company is engaging in more strategic partnerships with pharma companies that are built around a set of value-based milestones: enrollment ready, enrollment complete, actionable data, and final deliverables.

Astrid Frank, general manager of Fisher Clinical Services' Basel, Switzerland, facility, says in the next five years companies need to partner with other companies that may offer pipeline potential or unique technologies.

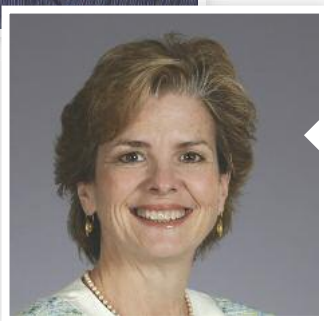
"We already see this model emerging, led by large pharma companies that are acquiring and often not fully absorbing the smaller companies, but allowing them to stay smaller and more nimble and apart

Astrid Frank
Fisher Clinical Services

"A growing percentage of companies will move to a sole supplier and a true preferred partner model."

Dr. Sanjay Parikh
Indegene

"Companies need to pursue a distributed innovation and development model to leverage a global talent pool."



Laurie Halloran
Halloran Consulting Group

"Outsourcing partners will bridge the divide between pharma and technology since, theoretically at least, they can see both sides."

HOW TO EVALUATE A CRO

When seeking a CRO, consider the following requirements:

- In-depth benchmarks and metrics: A CRO should employ comprehensive metrics to support its claims. Ask for discrete variables that track and measure specific sites, monitors, patients, IT, and data metrics that help to prove that the CRO's process can increase the efficiency of a clinical trial.
- Risk processes: Look for a company that can support its repeatable process and can identify and plan for risks to improve the probability of success. This should include alternative site selection and data management systems.
- On-demand experts: Seek a company that can immediately bring experts to the table to assist with project planning, metrics evaluation, and execution.
- Data management system-agnostic: The ideal CRO should be able to work with existing best-of-breed data management systems, eliminating the need to invest in new systems.
- Team quality: To determine if strong chemistry will exist between the CRO and the sponsor team, assess the proposed clinical trial team's experience in similar clinical studies.
- Communication systems: The best CROs employ the latest technology to streamline communication.
- Full range of services: Advanced CROs can scale to accommodate any biopharma need, including drafting protocols, designing studies, and performing regulatory activities and post-approval studies. The CRO should also provide the appropriate global reach to ensure ready access to targeted patient populations.
- Extensive experience: Look for a CRO that has at least a decade of proven trial experience and is dedicated to the therapeutic areas in need.
- Pediatrics expertise: Seek a CRO that has extensive experience with your unique regulatory requirements and understands how to address the challenges of working with pediatric patient populations and their caregivers.

Source: INC Research

STEPS FOR DEVELOPING PRODUCTIVE BIOPHARMA PARTNERSHIPS

- Start from a position of strength: Since one of the factors industry and academic researchers consider when they are looking for a partner is the product position of the company concerned, it makes sense for any large biopharmaceutical company to start building alliances in their strongest areas, and moving into others only when they have worked out strategies that help compensate for any weaknesses.
- Search for a win-win: Once a potential partner is identified, opportunities to "sweeten" the deal include not only financial considerations, but also development expertise and leveraging relationships. For example, biopharmaceutical companies more frequently take the career goals of industry executives and academic researchers into account.
- Look after the ABCs of managing alliances: Looking after three key areas — the internal alignment of a company's business strategy and functions with its research goals, the definition and management of its boundaries with other parties in the extended enterprise, and ongoing commitment to the alliance — is essential.
- Develop partnering skills throughout the extended enterprise: Successful alliances demand development of those skills required to engage different kinds of partnerships. While some companies try to force-fit all their alliances into one mold, those that succeed work beyond their own boundaries and tailor their approaches to a variety of partnering models identified in the survey.

Source: IBM Global Business Services

from the bureaucracy of the parent company," she says.

Ms. Frank predicts that there will continue to be a shift toward outsourcing, but a growing percentage of companies will move to a sole supplier and a true preferred partner model, as the infrastructure now needed to oversee one program at a time is cost and labor intensive.

Sanjay Parikh, Ph.D., director, Indegene, believes that to improve the R&D process, market insights — customer, regulator, payer, etc. — need to be incorporated very early into the development life cycle.

"R&D should not be treated as a stand-alone silo; it should enjoy a very clear line of sight to the market realities," Dr. Parikh says. "Companies need to pursue a distributed innovation and development model to leverage a global talent pool; before placing bets on select candidates, they need to learn from the successes and failures of the past, and they need to tap into a knowledge network of partner companies. There is a critical need for developing new knowledge bases, as well as tools to integrate key clinical, molecular, market, and payer information to enhance pipeline success rates." ✦

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

Sound Bites From The Field

ANALYSTS, EXPERTS, AND CEOS ALIKE ACKNOWLEDGE THAT THE DEVELOPMENT PROCESS NEEDS TO UNDERGO MAJOR CHANGES TO REDUCE THE TIME AND COSTS ASSOCIATED WITH BRINGING NEW MEDICINES TO MARKET. COMPANIES ARE PARTNERING MORE WITH CROS, WHICH ARE CONTINUING TO REFINE AND EXPAND THEIR SERVICES AND ARE BECOMING MORE EXPERT IN GLOBAL DEVELOPMENT. PHARMAVOICE ASKED INDUSTRY EXPERTS TO IDENTIFY BEST PRACTICES WHEN WORKING WITH CROS.

JESSE BOWDEN is President of Imaging Services at Biomedical Systems, a provider of innovative approaches to non-invasive diagnostic services, products, and supplies. For more information, visit biomedsys.com.

"To improve R&D efficiency, it's important that all stakeholders have excellent team communications; there are clear metrics in place; companies have real-time or near real-time data access; and there are comprehensive multiservice, global MSAs to reduce cost."

ALISTAIR MACDONALD is Executive VP, Global Services, at INC Research, a therapeutically focused global CRO. For more information, visit incresearch.com.

"We strongly believe that a CRO should employ process-driven clinical research methods. Proven and repeatable processes help achieve more predictable and actionable results. Of course, when done right, this approach can speed the R&D process while reducing trial risks.

Companies are no longer scared of going into Malaysia or Argentina to conduct a trial. We provide the guidance and expertise to help match protocols and therapeutic treatments with the most appropriate region or country."

JOSEPH PIERONI is President and CEO, Daiichi Sankyo Inc., the U.S. subsidiary of Tokyo-based Daiichi Sankyo Co., Ltd., whose focus is in cardiovascular disease, including dyslipidemia, hypertension, diabetes, and acute coronary syndrome. For more information, visit dsi.com.

"There is definitely a convergence of technologies and advances in each area that will lead to new developments in the healthcare industry. Collaboration with other companies that already have these technologies is the best way to bring outside expertise into an organization and drive innovation.

CROs can help cut costs and boost clinical trial efficiencies, particularly when there's a long-term partnership relationship rather than just a tactical one-off arrangement.

In those partnership relationships, companies begin to work together while they understand how to get trials up and running, and real efficiencies can be developed. What's most important is that we deliver these innovative products to patients as quickly as we can and with a high quality that will pass the regulatory reviews and the payer and provider reviews. Those are the qualities we look to optimize in a CRO relationship."

more >

Sound Bites From The Field (continued)

PHARMAVOICE ASKED INDUSTRY EXPERTS TO IDENTIFY THE TOP FACTORS THEY BELIEVE ARE CURRENTLY IMPACTING R&D.

CHRIS BODE, PH.D., is VP Corporate Development at Absorption Systems LP, a CRO that performs analyses that can predict the absorption, distribution, metabolism, and excretion (ADME) of small molecules. For more information, visit absorption.com or e-mail cbode@absorption.com.

"Instead of screening for the most potent and selective ligands for a particular molecular target, which leads to discovery of good research tools but not necessarily good drugs, companies need to start with phenotypic screens with live primary human cells for a beneficial functional effect and work out the specific absorption rates (SARs) later."

TONY CHANT is Managing Director of Eurocom Healthcare Communications, an international alliance of independent agencies offering global brand teams integrated communications solutions. For more information, visit ec-hc.net.

"In an environment where our industry is attempting to recover from a global economic crisis, the big pharma companies that are seeing their blockbuster drugs coming ever closer to end of patent life will look more aggressively to the many cash-starved biotech companies as acquisition targets to revive their own product pipelines and speed up the time to market entry with new compounds to offset the loss of income."

ROBERT DICKINSON is Client Service Officer of the Life Sciences Practice at Grail Research, a global strategic research and decision support firm. For more information, visit grailresearch.com.

"The most pressing factors impacting large pharma R&D include: less real innovation due to the industry's continued natural inclination to invest in low-risk projects; greater need to evaluate licensing/acquisition targets in the small and mid-sized biotech sector over doing basic research; and a steady decrease in R&D headcount due to decreasing performance."

SYLVIA MIRIYAM FINDLAY is Programme Leader, Pharmaceutical and Biotechnology, Healthcare, Europe, at Frost & Sullivan, which provides in-depth research coverage of various industries. For more information, visit frost.com.

"The pharma players have already invested in drug discovery technologies over the years and are reluctant to adopt certain novel and expensive alternate technologies. Hence the R&D business models are likely to change in the next few years, giving rise to partnerships with biotech companies, outsourcing to external research organizations, and forming symbiotic research networks."

MICHAEL J. HARTE is Founder and President of the Harte Group, an organization that represents and manages a suite of experienced functional service providers to provide a full-service CRO alternative. For more information, visit hartegroup.com.

"Companies will be more focused on sub-populations and using techniques, such as pharmacometrics, modeling, and simulation, to help establish solid development plans and target populations where their assets have a high likelihood of success. The growth of functional service provider models to support R&D will begin displacing the brick-and-mortar full-service models as they exist today."

A. SHABEER HUSSAIN is Programme Leader, Pharmaceutical and Biotechnology, Healthcare, EIA, at Frost & Sullivan, a consultancy that partners with clients to accelerate their growth. For more information, visit frost.com.

"To improve R&D, there lies a need to improve the business models: an increase in R&D outsourcing and off-shoring because of the consolidation wave among the top biopharmaceuticals companies and also a high focus on pharmacovigilance to cut after-cost for drug development."

JAN-ANDERS KARLSSON, PH.D., is CEO of S*BIO Pte Ltd, which is focused on the discovery and clinical development of novel targeted small-molecule drugs for the treatment of cancer. For more information, visit sbio.com.

"There is increasing regulatory uncertainty; FDA's focus is on safety rather than effectiveness or cost-benefit. The United States has historically been leading the trend of seeking to provide the 'right' balance between risk-benefit, but this has been changing in recent years and other countries are following suit.

Regulatory and reimbursement agencies have higher demands on new drugs to be able to demonstrate clinical/therapeutic superiority over existing therapies. This could tilt the balance in favor of the development of best-in-class over first-in-class compounds, further diminishing real innovation in mega pharma companies.

Diagnostics and biomarkers are becoming more important and facilitate the development of niche products in increasingly stratified patient populations. Human genomics and novel discoveries in disease genetics are driving the search for more personalized-like medicines."

NICHOLAS LANDEKIC is President and CEO of PolyMedix Inc., an emerging biotechnology company focused on the development of novel drugs and biomaterials for the treatment of infectious diseases and acute cardiovascular disorders. For more information, visit polymedix.com.

"The smartest thing big pharma companies could do right now is to buy some promising early- and mid-stage biotech companies. Rather than looking for a $60 billion mega-acquisition, they can

pay a fraction of that for several promising companies with solid, fundamental pipelines and use the money to actually develop the products. And in five years, they will have created real value instead of facing the same dry pipeline problem all over again. Unfortunately, this requires corporate compensation structures that provide rewards far beyond the current year, and few companies have that.

Companies also need to maintain a relentless discipline on the 'need to have' and not on the 'nice to have'. While drug development will always be the most expensive and difficult endeavor in commerce, it is amazing how much time and money can be saved if the company stays objective and focused on the critical path."

JOHN MACPHEE is President of Strativa Pharmaceuticals, the proprietary products division of Par Pharmaceutical Inc. For more information, visit strativapharma.com.

"Pharmaceutical companies can benefit by seeking to develop novel solutions that address clear unmet needs for an individualized approach, rather than pursue 'me-too' drugs that don't offer additional benefits.

Through collaboration, companies can also create value-added synergies and maximize resources in research, development, and commercialization. At Strativa, a key to our success has been the establishment of successful alliances with a number of healthcare partners to develop and commercialize new compounds.

Lastly, when introducing new treatments, pharmaceutical companies must do so in a way that is beneficial to patients, healthcare providers, and payers. Finding new ways to educate these stakeholders about their options will also continue to grow in importance."

KEN RIBOTSKY is President and CEO of The Core Nation Inc., a holding company created to

leverage strategic talent and resources across the three agencies: Core-Create, Alpha & Omega Worldwide, and Brandkarma. For more information visit, thecorenation.com.

"The need for greater investment in R&D that addresses global health concerns and crises is paramount. New vaccines and therapies are needed for disease states that originate in developing nations and subsequently cross into the developed world.

There will be a move toward a more patient-centric business model. Patient-centricity will generate demand for truly pioneering therapies that are not just innovative for innovation's sake, but that meet very real and immediate needs. To achieve this, third parties — patients, public and private payers, physicians, and other healthcare providers — will need to become involved much earlier in the R&D process to ensure that these new therapies fulfill actual, real-world needs.

R&D efforts will become much more targeted and will exist on a more-targeted scale than what we are typically used to. With a challenging economic environment, fewer FDA product approvals, and very public product recalls, companies are getting smarter with their investment into R&D, and clinical trials will be even more focused than before. This shift will be much more pronounced in the biotechnology industry and the development of biologics."

NAGARAJA SRIVATSAN is Head of Life Sciences, North America, at Cognizant Technology Solutions, a provider of information technology, consulting, and business process outsourcing services. For more information, visit cognizant.com.

"R&D organizations need to improve the throughput of their pipeline to get more submissions accepted by regulatory authorities. It is becoming important for R&D organizations to evaluate each of their processes and assess what is core versus non-core to them and look for collaboration and outsourcing models to reduce costs. The need to ensure that the outsourcing agreements are structured to deliver business outcomes so that R&D processes can be improved."

JASON STOWE is CEO of Cycle Computing, which provides turnkey solutions for computation and data management. For more information, visit cyclecomputing.com.

"On the high-performance computing side, we're observing the increasing importance of clinical trial simulation as part of the drug approval pipeline; an explosion in data, including next-generation sequencing data, compound databases, and mass spectrometer/proteomics data; and vast increases in the computation power required to analyze the data.

Providing cost-effective access to additional resources increases agility of discovery activities. Instead of dealing with a fixed-size cluster, these clusters can be provisioned dynamically to meet the needs of researchers. Lowering the costs of operating discovery and qualified high-performance computing environments, because the environments are virtualized, HPC clusters are provisioned on cloud resources at the same time they are created."

DANIEL ZURR, PH.D. is CEO and President, Quark Pharmaceuticals Inc., a development-stage company that discovers and develops novel RNA interference-based therapeutics. For more information, visit quarkpharma.com.

"Virtual R&D will probably become more common on the development side, but not for research in the majority of cases. Biological systems, diseases, and the human body are complex. Any virtual model or virtual patient would have to be based on very real data to be more than just a case of trial and error."

EXPERTS ON THIS TOPIC

ASTRID FRANK. General Manager, Fisher Clinical Services, Basel, Switzerland, facility, which offers services to support the continuum of supply chain needs within a clinical trial setting. For more information, visit fisherclinicalservices.com.

LAURIE HALLORAN. President and CEO of Halloran Consulting Group, a life-sciences consulting firm specializing in enhancing the development process for biopharmaceutical and medical-device companies. For more information, visit hallorancg.com.

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