

SPECIAL ISSUE

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# Pharma **VOICE**

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# Building a Culture of INNOVATION

Pharmaceutical R&D is under pressure to counter rising costs, depleted pipelines, and impending patent expiries. The industry is facing not only a productivity crisis, but also a crisis in innovation.

**I**ndustry analysts say many pharmaceutical and biopharma companies are turning their focus away from R&D and innovation, yet a recent survey by Quintiles and the Economist Intelligence Unit reveals that innovation is key to bringing new, more effective products to market to treat diseases.

The research also reports that while no single model works for all companies, the top innovators, those companies that are open to insights from many different sources, generated almost twice as many products and NMEs as their peers in the last three years.

The survey identified several barriers that prevent pharmaceutical companies from achieving or even pursuing innovation on a clinical front, including culture, which was identified as the primary obstacle. Culture was followed by high costs, complex regulations, and long development time scales.

Dr. Terri Cooper, principal at Deloitte Consulting LLP, and national leader of the life-sciences R&D practice, agrees that many companies often struggle with how to build innovation capabilities since the process encompasses a long-term strategy involving time and personnel resources as well as determination, with results measured in future value.

"Innovation can be at odds with, and sometimes overshadowed by, the immediate need to hit growth and profit targets," she says. "The need for different types of innovation is a factor as well — the radical, blockbuster big idea versus the more tactical, incremental and implementable idea, that yields smaller, but still valuable, results. In large companies, the search for the next big thing, such as a new pharmaceutical drug, technology, or device is often handled by creating a separate business unit devoted to the effort. But to generate smaller innovations, such as

## Fostering Innovation

Deloitte researchers suggest that a number of strategic levers influence organizational culture, and these can be oriented in a way that fosters innovation. Some things to consider:

- » **Leadership:** Incorporate innovation-focused competencies into the leadership profiles and emphasize the role of the leader to drive and support innovation at all levels of the organization.
- » **Processes and Technology:** Formalize processes to allow employees to solicit, share, develop, prioritize, evaluate, and monitor new ideas.
- » **Capabilities:** Define competencies and behaviors that support innovation, and incorporate innovation recognition into the goals, metrics, and rewards processes.
- » **Structure:** Ensure organizational structures enable collaboration, and design roles and responsibilities of executives, managers, and staff to include opportunities to discover, incubate, and accelerate innovation.

Source: Dr. Terri Cooper, Principal, Deloitte Consulting LLP, National Leader, Life Sciences R&D Practice. For more information, visit [deloitte.com](http://deloitte.com).

process or product improvements, or for smaller organizations without separate innovation functions, the goal is to cultivate and



“Information systems, in particular, will need to change radically to provide fast, easy, and secure access to data for colleagues and partners alike.”

JEN GOLDSMITH / Veeva Vault

harness the ideas of the collective employee group.”

## Innovation Through Partnerships

Several industry experts have identified the area around partnerships as being essential to increase innovation and create new opportunities.

Open innovation requires a flexible model where transformation comes from both internal



“An environment of more open scientific collaboration will provide increased focus around development, rather than a reinvention of the wheel.”

JOHN BLAKELEY / ERT

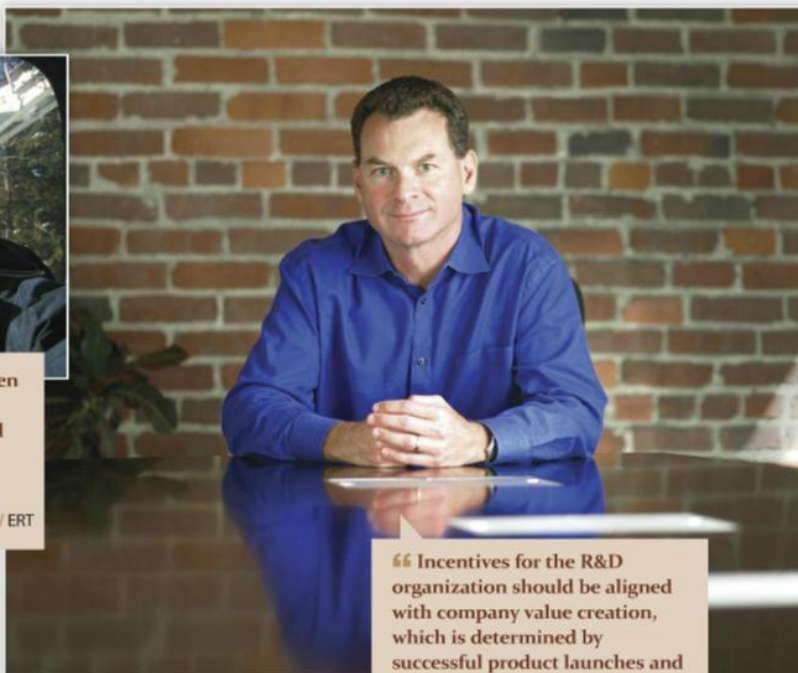
and external ideas and where intellectual property is shared as a way to create value. While a relatively new concept in pharmaceutical drug development, open-source collaboration first began in the computer software industry.

Experts say the benefits of open innovation for drug development include access to knowledge and high-quality and reliable networks of strategic partners who can bring talented individuals to the table.

“Every company is concerned about its intellectual property and downstream profits,” says John Blakeley, executive VP and chief commercial officer, ERT. “But an environment of open scientific collaboration can provide more focus around development rather than a reinvention of the wheel and speed success. The challenge of course is to work out how the downstream revenue can be managed in the appropriate manner.”

Subhro Mallik, associate VP with the life-sciences practice at Infosys Ltd., says pharmaceutical companies have spent billions of dollars in internal R&D investment, and yet there are very few that have been able to capitalize on their investment; therefore some companies may be willing to adopt open partnerships as a long-term strategy and be willing to take the risk.

“On the other hand, there may be a movement during which pharmaceutical and biopharma companies break up their internal research organizations into smaller, nimble teams,” he says.



“Incentives for the R&D organization should be aligned with company value creation, which is determined by successful product launches and a differentiated pipeline.”

DR. OLIVER FETZTER / Cerulean Pharma

Dr. Cooper says by moving to an open innovation model, Procter & Gamble now sources more than 50% of its new ideas from outside the company.

“There is no reason that this strategy cannot work for life-sciences companies,” she says. “By engaging in open partnerships, companies can find new sources for intellectual property and source highly specific capabilities to develop their pipelines. Life-sciences companies — especially those looking to accelerate innovation without having to make significant new investments in R&D infrastructure — are finally starting to seriously look into developing ways to better collaborate with both traditional partners, such as CROs and academic research centers, and nontraditional partners, such as crowd-sourcing forums and users of their proprietary innovation portals.”

Kiran Meekings, Ph.D., a consultant in the life-sciences consulting team at Thomson Reuters, says through the sharing of knowledge, resources, or experience, novel methods of collaboration can increase innovation, accelerate the drug discovery process, and capture new growth opportunities.

“Alliances with academic institutions can

aid with target validation, high-throughput screening, and the identification of repurposing opportunities,” she says. “Recent academic collaborative initiatives by Glaxo-SmithKline, Lilly, Pfizer, and Bayer are already starting to produce positive leads.”

The most recent company to pursue open innovation is Lilly, which in September announced the launch of a new open innovation platform designed to help build the company’s pipeline and identify molecules that may have application for treating multidrug-resistant tuberculosis (MDR-TB).

The new platform, titled Open Innovation Drug Discovery, is supported by a new website available at [openinnovation.lilly.com](http://openinnovation.lilly.com).

The program builds on the success of Lilly’s Phenotypic Drug Discovery Initiative (PD2), which was launched in 2009 to facilitate research on molecules around the world that have the potential to ultimately be developed into medicines.

Improving innovation is essential for future success, but Robert Nauman, principal of Bio-

Pharma Advisors, says the investment by the life-sciences industry in this area is not being made.

"Pharmaceutical companies are not engaging so much in an open innovation model, as

picking the right development horse that they hope will win the big race," he says. "We believe that in the not-too-distant future the cost to bring a fully developed product to market will be more than \$1 billion."

Mr. Nauman says this may mean that a lot of good compounds may never see the light of day because they may only generate \$250 million in revenue and cannot justify the research and development costs.

## SOUND BITES FROM THE FIELD ▶

### The Top Trends Impacting R&D



**JOHN ARROWSMITH, PH.D.**, is Science Director, Thomson Reuters, a source of intelligent information for businesses and professionals. For more information, visit [thomsonreuters.com](http://thomsonreuters.com).

1. Regulatory hurdles on safety continue to rise, and for chronic treatments the thought of having to do multi-year morbidity and mortality studies can dissuade companies from investing in some disease areas.
2. Having sufficient differentiated drugs ready to emerge from the R&D pipeline in order to offset the patent cliff is a challenge, particularly in cancer and CNS. Differentiation is linked to personalized medicine and the challenges of lining up the right patient with the right drug occupy the minds of R&D leaders.
3. In the early pipeline, PoC (proof of concept) is still proving to be very challenging when the R&D hurdle is best-in-class or first-in-class; this applies to large and small molecules. Differentiation trumps novelty of mechanism.



**BILL COONEY** is President and CEO of MedPoint Communications Digital Inc., which provides specialized digital services to the global biopharma industry. For more information, visit [medpt.com](http://medpt.com).

1. Finance: There is an immediate need to control costs of drug development. Runaway costs are unsustainable and reaching a tipping point.
2. Deconstruction: Biopharma companies will continue to outsource key functions, with clinical operations increasingly contracted out to more efficient providers on a strategic scale. Drug innovation will occur at small firms that are better suited for the high science of risk taking.
3. Globalization: Emerging countries will continue their ascent, both as markets for manufacturing and sales, and as regions for clinical research. The boom in clinical trials in emerging countries has slackened as industry has encountered many

nuanced challenges, but this pause will only be temporary, as drug developers will overcome the learning curve when operating in different cultures.



**FRANCES L. DEGRAZIO** is VP, Marketing and Strategic Business Development, West Pharmaceutical Services, a provider of solutions for injectable drug administration. For more information, visit [westpharma.com](http://westpharma.com).

1. There is a need for industry to consider regulatory and insurance reimbursement requirements early in the development process.
2. There is a need to develop "new" products, rather than developing products where an equivalent brand already meets the market need. Such me-too products have only a small incremental value.
3. It is important to meet regulatory, compliance, and quality challenges early in development, particularly with regard to suitability of packaging. Early partnerships with packaging manufacturers can help to establish suitability and meet quality challenges throughout the product's life cycle.



**DENISE (DEEDEE) DEMAN** is Founder, Chairman, and CEO of Bench International, a global, executive recruiting and consulting firm serving the life-sciences industry. For more information, visit [benchinternational.com](http://benchinternational.com).

1. Life-sciences companies are trending away from internal discovery stage investment, in favor of depending on the smaller, emerging companies to take the risk, in a form of "off balance sheet R&D."
2. At the end of the day, we will see thinner pipelines and significant pent-up demand for the return of scientific exploration on a broader scale. The smaller companies simply do not have enough to feed the demand.
3. There will be a deceleration in "R" and an increased dependence on "D," which will require companies to play catch-up for decades to come, if

the life-sciences sector is to remain the architect of innovative discovery.



**GLEN DEVRIES** is President of Medidata Solutions Worldwide, a global provider of SaaS-based clinical development solutions that enhance the efficiency of customers' clinical trials. For more information, visit [mdsol.com](http://mdsol.com).

1. Productivity, as defined by an organization's ability to produce evidence in support of labeling claims, will emerge as the highest-level key performance indicator for any life-sciences company.
2. The most successful companies will start using more modern techniques, including automation, more dynamic processes, and quality-enhancing risk-based approaches to run clinical trials at a lower overall price point per study.
3. Competitive dynamics between CROs competing for more prevalent outsourcing, as well as internal sponsor teams looking to differentiate their contributions to the development life cycle, will create an environment where process change and continuous improvement will become the norm, instead of a rare exception.



**DAVID FISHMAN** is President of Snowfish LLC, a marketing firm focused on the pharmaceutical, biotechnology, and medical device industries. For more information, visit [snowfish.net](http://snowfish.net).

1. Given the advances in genomics, the age of personalized medicine is fast approaching. Studies today that are not now set up based on genetic profile, will be in the future.
2. The increasing failure rate of Phase II and III products is forcing companies to look outside their traditional product development pipelines.
3. Mergers and acquisitions are having a greater importance in filling product pipelines.

**SEAN MCCARTHY, D. PHIL.**, is CEO of CytomX

## Challenges of Open Innovation

Dr. Cooper says the hurdles to open innovation are largely the same as for other forms of collaboration in that strong leadership, clear

governance processes, information security, and enabling technologies are needed to be successful.

"These challenges are magnified, however, by the sharing of intellectual property," she

says. "Pharmaceutical companies considering open innovation will need to make sure they have the proper agreements, standards, and committees in place to manage these collaborations and ensure they are adding value to



Therapeutics Inc., a privately held biotechnology company developing Probodyes, or proteolytically activated antibodies. For more information, visit [cytomx.com](http://cytomx.com).

- 1. Reclassification of disease and tailored therapy:** As molecular techniques, including next-generation sequencing and proteomic analysis, become more widely available, the molecular dissection of disease will continue to result in more efficient targeting of therapies to the places they will work best. Advances such as these mean that diseases that are pooled together today under outdated diagnostic classification systems, and therefore treated as single conditions, will be re-classified and their treatment will become dramatically more effective.
- 2. A drive to more efficient operating models:** Small groups have shown the ability to consistently outperform in metrics such as IND filings per year. The reasons for this are social (e.g. close teamwork), motivational (e.g. employee ownership), and practical (e.g. co-location). As such, pharma will continue to experiment with biotech organizational models in an attempt to capture these efficiencies enjoyed by smaller biotech companies.
- 3. Targeting of biologics:** With tens of antibodies, cytokines, and hormone therapies already FDA approved and several hundred in development, the golden age of biologics is upon us. But these classes of drugs are not immune to dose-limiting toxicities that either prohibit their fully effective clinical use or render their successful development impractical at best, and impossible at worst. Various targeting approaches are being developed, including antibody-drug conjugates, bi-specific antibody formats, and pro-biologics that become selectively activated at sites of disease.



**STUART W. PELTZ, PH.D.**, is President and CEO, PTC Therapeutics Inc., a biopharmaceutical company focused on the discovery, development, and commercialization of orally administered small-

molecule drugs that target post-transcriptional control processes. For more information, visit [ptcbio.com](http://ptcbio.com).

- 1. In the United States, the implications of national healthcare reform and the overall healthcare spend will be an important influence and will shape R&D budgets, priorities, and strategies moving forward.**
- 2. The degree to which the government continues to fund the NIH and other agencies that fund basic and applied research as well as clinical trials. Reductions in funding will impact innovation and reduce the nation's competitiveness in areas where we are currently a world leader.**
- 3. Upcoming patent expirations on blockbuster drugs will continue to affect how companies prioritize R&D and build their pipeline — both from within and through partnerships and acquisitions. The growing market opportunity in BRIC nations will provide a source of revenue growth, which could offset the pending patent cliff.**

**JOHN ROTHMAN, PH.D.**, is Executive VP, Science and Operations, at Advaxis Inc., a biotechnology company developing the next generation of immunotherapies for cancer and infectious diseases. For more information, visit [advaxis.com](http://advaxis.com).

- 1. The ability to use living bioengineered organisms as drugs is an opportunity to create new classes of therapeutic agents that may have greater safety and efficacy than current treatment modalities. For example, by using pathogens that have evolved to infect us, and to which we have evolved immune mechanisms to thwart infection, these agents enable us to access hardwired evolutionary immune mechanisms that we are born with to fight that specific pathogen, and redirect these responses to those Pathogen Associated Molecular Pattern or Danger Associated Molecular Patterns to cancer or other infectious disease. The immune response to living, metabolically and reproductively competent, bacteria is considerably more complex than the response to synthetic chemicals or**

**antibodies, and enables stimulation of diverse and integrated mechanisms not previously possible.**

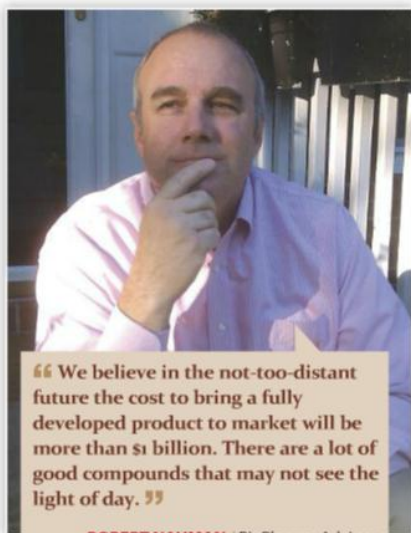
**KK RUMRILL** is Client Services Director at BBK Worldwide, a provider of patient recruitment services for clinical trials. For more information, visit [bbkworldwide.com](http://bbkworldwide.com).

- 1. Social media will be an ever-evolving component of patient recruitment for the foreseeable future. But with as many potential pitfalls as opportunities, it is vital for sponsors to stay informed and proceed, however cautiously, with an online strategy for connecting with patient audiences.**
- 2. Patients will share their opinions, including negative clinical trial experiences, and may even comment on adverse drug events in online forums whether you join them in the online environment or not. Before long, sponsors will not have a choice whether to participate in social media. Only decisions about how, when, and where to incorporate online programs will remain.**



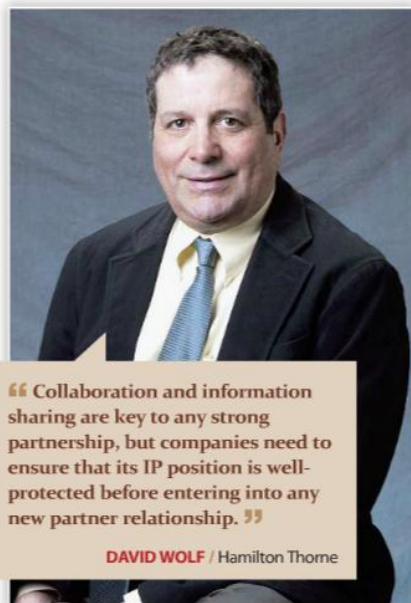
**LEE VALENTA** is President of OptumInsight Life Sciences, which specializes in technology, information, analytics, business, and consulting services. For more information, visit [optum.com](http://optum.com).

- 1. Many life-sciences companies need to alter how they develop their pipelines to leverage all the data and tools available to help them. This will enable a better review and understanding of what is needed to maximize chances for regulatory, reimbursement, and marketing success.**
- 2. By using evidence mapping, based on proven real-world evidence and data-based analyses and projections, products and protocols would be developed in a way that will resonate with regulators and payers.**
- 3. Looking at compounds based on the value they'll need to deliver enables companies to make smarter pipeline decisions earlier, getting ahead of more complex risk-benefit calculations.**



“We believe in the not-too-distant future the cost to bring a fully developed product to market will be more than \$1 billion. There are a lot of good compounds that may not see the light of day.”

ROBERT NAUMAN / BioPharma Advisors



“Collaboration and information sharing are key to any strong partnership, but companies need to ensure that its IP position is well-protected before entering into any new partner relationship.”

DAVID WOLF / Hamilton Thorne

their organizations. In addition, the engagement between partners will need to happen at the senior level to make sure both parties are providing value to the program and achieving their goals through the collaboration.”

Elliott Berger, VP, global marketing and strategy, at Catalent, says a collaboration model requires a new degree of flexibility in both R&D operations and legal terms to be able to cooperatively develop new products, manage IP issues, and accelerate speed to market.

“The traditional ‘all expertise inside the wall’ models that worked so well previously need significant adjustments both in terms of mindset and process,” he says.

Oliver Fetzer, Ph.D., president and CEO at Cerulean Pharma, agrees, stating that overcoming established large pharma traditions and ways of doing business is the biggest challenge.

“Companies need to change their mindsets, attitudes, goals, decision-making capabilities, and incentive structures if they are to engage in open innovation,” he says. “Clearly, this is not an easy transition. But it is encouraging to see that several large pharmaceutical companies are now openly acknowledging the need for this type of change and some are taking serious steps to make it happen.”

Dr. Fetzer says those at the top of an organization have to properly define innovation so that it is more than a buzzword.

“Innovation has to be grounded in a clear mission that is ‘lived’ in the way decisions are made,” he says. “Incentives for the R&D organization should be aligned with a company’s value creation, which is determined by successful product launches and a differentiated pipeline. An aligned incentive structure based on long-term value creation through innovation will serve companies far better than focusing too much on short-term candidate advancement goals.”

Neil MacAllister, chief business officer at INC Research and president of AVOS Consulting, says, however, there is a dynamic happening at the basic research level that is complicating open innovation.

“The drug industry is moving away from discovery in a big way; companies have cut scientific headcount and R&D budgets,” he says. “At the same time, more federal grants for academic research are requiring commercial endpoints. Academic institutions are under pressure to convert grants to patents with commercial propositions before handing them over to the drug industry. To some de-

gree, the tightening of basic research dollars is compromising the open innovation model. In response, academic industry collaboration is becoming more pronounced than ever before.”

Mr. MacAllister says the biggest issue with academic industry collaborations is the cultural divide between academia’s thirst for knowledge and a drug company’s thirst for commercial products.

“They do not speak the same language when discussing preclinical and clinical processes,” he says. “CROs are able to fill this gap and provide a translational function between institutions and drug developers as they understand and can articulate both the science and operational know-how; something they do as a normal course of business.”

### Partners in Innovation

Strategic partnerships are key to competitive advantage in the new model of open innovation, says Nagaraja Srivatsan, senior VP and head of life-sciences, North America, for Cognizant.

“Governance at all levels ensures the correct level of involvement of both executive and operational leaders, and by tracking and monitoring appropriate metrics, pharmaceutical companies can leverage a balanced scorecard that will ensure the realization of common goals of the partnership,” he says.

Kimberly Ramko, Americas life-sciences sector leader for advisory services, at Ernst & Young, says pharmaceutical companies that are willing to collaborate externally with partners such as other pharma, biopharma, or medical device companies, as well as academic medical centers, payers, and providers will benefit from a reduced time to market while sharing the risk and reward.

“Creating collaborative business models around a specific disease state with these partners as well as technology-based partners, such as wireless device companies, social media, and managed service providers, will enable life-sciences organizations to have more control of their product perception in the market, while also gaining more meaningful insights and opening up new avenues of market access,” she says.

David Wolf, CEO of Hamilton Thorne, says for companies to truly collaborate, there needs to be more information sharing between partners on not just the perceived advantages of the alliance, but also the potential or current technical hurdles that need to be

addressed throughout the development cycle.

“With a model of a more open partnership, both companies can speed up the development process and prevent fewer issues, while still protecting their IP position,” he says. “Collaboration and information sharing are key to any strong partnership, but companies need to ensure that their IP position is well-protected before entering into any new partner relationship.”

Jen Goldsmith, VP at Veeva Vault, agrees that an open innovation model requires information sharing across companies and around the globe.

“Incremental change is no longer enough,” she says. “Information systems, in particular, will need to change radically to provide fast, easy, and secure access to colleagues and partners alike. At the same time, application complexity must be reduced so that training for partners and vendors is a matter of minutes not hours or days.

“Academic institutions are under pressure to convert grants to patents with commercial propositions before handing them over to the drug industry.”

NEIL MACALLISTER / INC Research

“For years, life-sciences organizations have been generating data and documents across the business in support of specific research, development and other activities,” Ms. Goldsmith continues. “In many cases, this information was created, used, and archived in a way that made it inaccessible for future endeavors. Today, new information technologies make it easier than ever to unlock the potential of these underused information assets, a process that will prove critical to future innovation.”



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