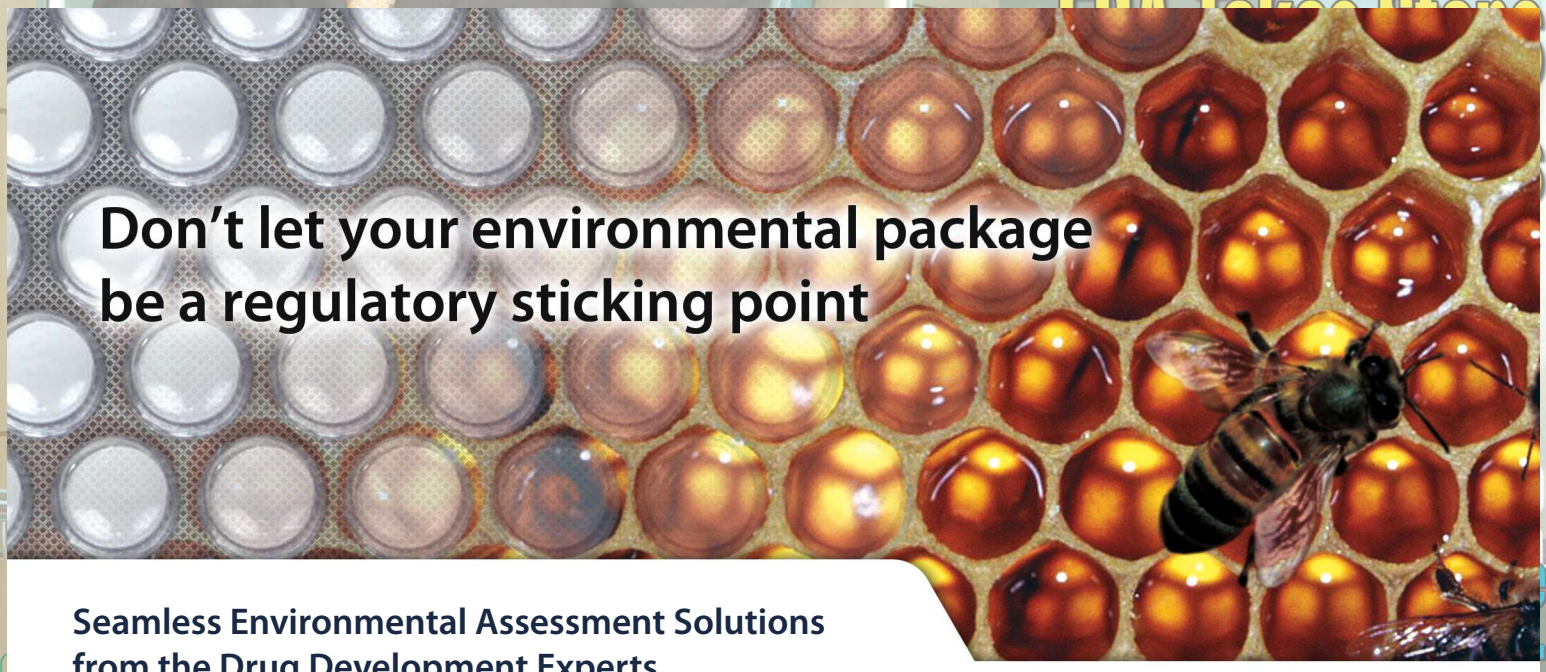
Life Science Leader
The Industry's Essential Business Source
APRIL 2012
LifeScienceLeader.com

Serialization: Back On Again?

PART ONE OF A FOUR-PART SPECIAL SERIES p. 38

SHARED EXPECTATIONS



Life Science Leader
The Industry's Essential Business Source
APRIL 2012
LifeScienceLeader.com

Serialization: Back On Again?

PART ONE OF A FOUR-PART SPECIAL SERIES p. 38

SHARED EXPECTATIONS

FDA Takes Steps To Align With Industry Goals

Jeff Baker, Ph.D., deputy director, office of biotechnology products at the FDA's CDER p. 16

Corporate Espionage:

Pharma Industry At Risk p. 42

Mistakes To Avoid On The Path To Commercialization

p. 22

Leading the way in early drug and device development.

Your responsive CRO partner, delivering customized solutions and adaptability to changing needs.

MPI Research is the CRO that defines responsiveness, moving your development program forward with customized solutions for all your preclinical research and early clinical support needs. From discovery services to safety evaluation, including analytical and bioanalytical support, you can count on MPI Research for quick quotes, frequent updates, rapid turnaround, and scientific rigor. At every stage, and on every level, we adapt to your most exacting needs.

Explore the breadth of capabilities that make us your responsive CRO at www.MPIResearch.com.

MPI RESEARCH

Customized. Responsive. On-Time.®

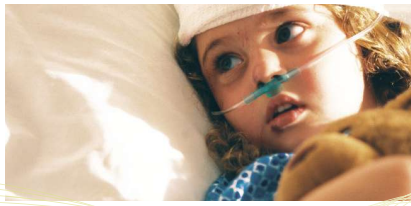
DDN
A Dohmen Company

Propelling Life Science™

THE DIAGNOSIS: A LIFE THREATENING ILLNESS.

THE PRESCRIPTION: YOUR MIRACLE DRUG.

THE CHALLENGE: DELIVERY WITHIN 8 HOURS.



DDN Urgent Access™

The industry's first 8-hour-or-less delivery solution.

When extreme medical emergencies arise, lives may literally be at stake. That's why DDN has created a unique, configurable solution that can deliver emergency medications anywhere in the continental U.S. within 8 hours. Safely. Efficiently. Like clockwork.

If your patients need treatment at a moment's notice, call us at 1-888-374-8873.
Or visit www.ddnnet.com/urgentaccess

Solutions | cold chain • same day delivery • company launch • product launch • international markets • specialty products

Services | financial services • customer call center • IT services & reporting • logistics • reverse logistics • contract management • medical affairs

Life Science Leader

16 FEATURE: FDA

"We need a shared vocabulary between the FDA and industry in order to have mutually successful shared outcomes," explains Jeffrey Baker, deputy director, office of biotechnology products at the FDA's Center for Drug Evaluation and Research (CDER).

April 2012

DEPARTMENTS

Welcome to *Life Science Leader*

Follow *LSL* on:

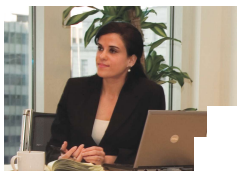
twitter

at twitter.com/LifeSciLeader

and

LinkedIn

CONTENTS



4 WAYS LOGISTICS CAN IMPROVE YOUR HEALTH.

The health of your supply chain, that is. UPS surveyed healthcare executives and found that their key concerns were compliance, expanding globally and managing costs. UPS understands the challenges of your industry. And has the resources to help you.

1) ENSURING RELIABILITY UPS runs the best integrated logistics network—freight and package—on the planet. As one of the world's largest air freight forwarders, we have the flexibility to help ensure a consistent and compliant supply of healthcare products.

2) GAIN GLOBAL ACCESS UPS serves over 220 countries and territories, and has 30 dedicated healthcare distribution facilities worldwide.

3) KEEPING YOU COMPLIANT The movement of medical products triggers costly compliance issues. UPS's team of experts maintains hundreds of geographically specific regulatory licenses and registrations that can help keep your supply chain cost efficient and compliant.

4) PROTECTING TEMPERATURE-SENSITIVE PRODUCTS Many healthcare products require special handling. That's why UPS Temperature True® provides proactive global monitoring to help keep your shipments within strict temperature ranges and prevent costly excursions.

For healthcare industry insights, go to **thenewlogistics.com/healthcare** or snap the QR code.

UPS®

WE ♡ LOGISTICS™

thenewlogistics.com/healthcare

Life Science Leader

APRIL 2012

Life Science Leader
2591 Wexford-Bayne Rd. Bldg. II, Level 3, Ste. 305
Sewickley, PA 15143-8676
Telephone: (724) 940-7557 ● Fax: (724) 940-4035

LIFE SCIENCE LEADER (ISSN: 21610800) Vol. 4, No. 4 is published monthly by VertMarkets at Knowledge Park, 5340 Fryling Road, Suite 300, Erie, PA 16510-4672. Phone (814) 897-9000, Fax (814) 899-5580. Periodical postage paid at Erie, PA 16510 and additional mailing offices.
SUBSCRIPTION RATES for qualified readers in the US $0. For non-qualified readers in the US and all other countries $97 for one year. If your mailing address is outside the US or Canada, you can receive the magazine digitally if you provide a valid email address. POSTMASTER: Send address corrections (Form 3579) to Life Science Leader, Knowledge Park, 5340 Fryling Road, Suite 300, Erie, PA 16510-4672.

Serenity Now

The past month was a very busy one for all of us here at *Life Science Leader*. For me personally, in addition to writing two articles for this month's magazine, I had the opportunity to attend five different meetings around the country.

The first event I attended, Partnerships In Clinical Trials, was held in Orlando, FL, March 4 to 7. Prior to the show, I had the opportunity to interview one of the conference cochairpersons, Deirdre BeVard, VP development operations with Endo Pharmaceuticals. Creating an innovative culture — something most pharma and biotech companies are claiming they have done — is no hoax at Endo. Watch for my article in next month's issue for how Endo accomplished this feat and some tips you can use at your company. One of my favorite talks was given by Dr. Ram Charan, author of *The Game Changer.* His talk was on innovation and used just three hand-drawn slides placed on an old-school overhead projector. As you might guess, the first question asked by a member of the audience sought an explanation for how someone could speak on innovation using such dated technology. Charan responded by explaining that to be innovative does not mean you have to use the latest gadget. One of the first keys to innovation is developing a laser focus. According to Charan, this is difficult to do when you have a 50-slide PowerPoint presentation. He advocates a less-is-more mentality and suggests most presentations can be conducted in seven slides or fewer.

The second show I attended was held in San Francisco, March 11 to 15, where the Society of Toxicology (SOT) held its Annual Meeting and ToxExpo. Across the United States in New York City, DCAT (Drug, Chemical & Associated Technologies Association) Week was taking place at the same time. So as soon as I wrapped up at SOT, I caught a flight to NYC so I could attend the 86th DCAT annual dinner, featuring the 43rd President of the United States, George W. Bush, as the keynote speaker. Then I was off to the invite-only R&D Leadership Summit in Aventura, FL. This C-level event took place March 19 to 20 and was put on by The Conference Forum. From there I went directly to the Women In Bio (WIB) 2012 Annual Gala Dinner in Washington, D.C. Here I had the opportunity to meet a number of executives including keynote Laura Shawver, Ph.D., who is the CEO of Cleave Biosciences. Shawver's success story at Cleave was detailed in an article in our February 2012 issue called "From Concept To Biotech Start-Up." After reading about how her company's bank account went from $0 to $44 million overnight, I had to meet her. I wanted to know more about how she survived her company's meteoric rise financially.

In the coming months, I look forward to sharing some of the stories uncovered during my travels, but until then I seek, as Frank Costanza once uttered on *Seinfeld*, "serenity now."

Rob Wright
rob.wright@lifescienceconnect.com
@RFWrightLSL

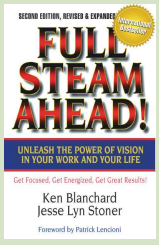
The one thing we can provide to a well-oiled machine.

Your drug development program has many moving parts. To ensure everything runs smoothly, Charles River provides flexible insourcing of research services from discovery to safety assessment. Through our innovative partnering model, you can maximize the productivity and efficiency of your programs, streamline operations, and save up to 20%, while leveraging 65 years worth of technical and operational expertise. **For more information, visit www.criver.com/info/insourcing**.

charles river | insourcing solutions

1.877.CRIVER.1
www.criver.com

WIN THIS BOOK!



Ask the Board wants to hear from you. Have a question that you would like to pose to our editorial advisory board of experts? Send it to atb@lifescienceconnect.com.

If we select your question for publication, we will provide you with a complimentary copy of a business book, such as *Full Steam Ahead!* by Ken Blanchard and Jesse Lyn Stoner.

MORE ONLINE CONTENT

LIFE SCIENCE connect
CONNECTING BUYERS & SUPPLIERS

Find more original content (and submit your own) on any of the other Life Science Connect websites, such as Bioresearchonline.com, ClinicalLeader.com, and PharmaceuticalOnline.com.

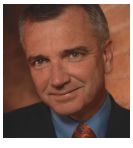
Clinical Leader · Bioresearch Online · Pharmaceutical Online

ASK THE BOARD

Have a response to our experts' answers? Send us an email to atb@lifescienceconnect.com.

Q: Why has there not been a push for more awareness and a new guidance regarding the concept that kinase inhibitors cause other nontargeted organ damage when used repeatedly?

I thought it best to reach out to a toxicologist, Grace Furman, Ph.D., who had this to say: "ICH [International Conference on Harmonization] safety guidelines typically will not provide guidance specific to certain molecular targets or drug classes. Since the specific molecular targets (and thus the biological effects) of tyrosine kinase inhibitors (TKIs) vary widely across members of this 'class,' it's misleading to consider cardiovascular or other safety issues associated with TKIs as class effects. Drug developers should seek to understand each TKI on a case-by-case basis, focusing on the specific kinase(s) inhibited and what is known from the basic science literature which might raise concerns regarding safety."



Jeff Evans
Jeff Evans, Ph.D., founder and CEO of Oncoholdings, previously served as president of Rondaxe, a leading pharmaceutical consultancy which he cofounded in 2003, and as director of worldwide development sourcing and planning for Bristol-Myers Squibb.

Q: Where do you see the next breakthrough in drug discovery?

The greatest challenge facing the world in terms of healthcare is in the area of Alzheimer's disease (AD). Today there are 5.4 million Americans with AD. By 2050, that number will triple. The Alzheimer's Association estimates that the cost of care of AD patients is over $180 billion annually.

The biopharmaceutical industry has been working for over 20 years trying to understand AD pathogenesis and develop medicines for it. Great work has been done in understanding the multiple mechanisms on how plaques form and then coming up with molecules that can stop disease progression, if not reverse it. Companies like Lilly, Pfizer, and J&J have advanced experimental medicines into the clinic and key compounds are in late-stage trials. However, the challenge in AD studies is that halting or reversing plaque progression doesn't occur overnight. Thus, clinical trials are long, and it is not until you finish Phase 3 that you know if your drug worked.

John LaMattina, Ph.D.
Dr. John L. LaMattina is the former senior VP at Pfizer Inc. and president, Pfizer Global Research and Development. In this role, he oversaw the drug discovery and development efforts of over 12,000 colleagues in the United States, Europe, and Asia.

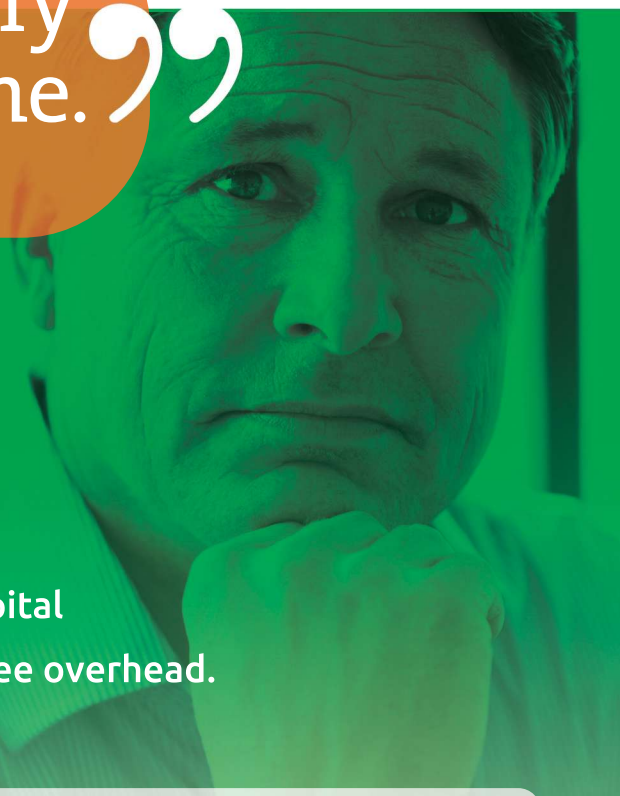
Q: Aside from layoffs, what are pharma companies doing to restructure their business models to be successful in the next 5 to 10 years?

Our 9th annual report of biomanufacturing shows that budgets for hiring operations staff are increasing among 29% of global facilities by 1% to 10%. The numbers are slightly rosier for hiring of new scientific staff. In fact, only 17% of companies are reducing their staffing budgets. Where companies put their budgets are an indication of short- and long-term solutions. Training for existing staff is playing a major role in the restructuring strategy, with 51% of manufacturers increasing training budgets this year. Thus, restructuring during the next 10 years is likely to include 1) hiring in the right areas, 2) laying off where core competencies are not valued, and 3) retraining of existing staff to do the critical, future work and attending various national training conferences to continuously educate on better training methods, technologies, and approaches.

Eric Langer
Langer is president and managing partner at BioPlan Associates, Inc. He has more than 20 years experience in biotechnology and life sciences international marketing, management, market assessment, and publishing.

"We *need* an automated visual inspection system.

We simply can't justify the capital to buy one."



At Visionspect, contract visual inspection is all we do. Our service offers all the advantages of automated visual inspection without the capital outlay or employee overhead.

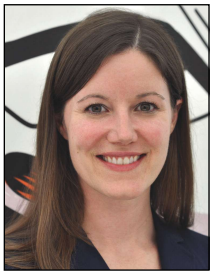
We furnish your site with Viswill (formerly Kanebo) vision systems, the industry's premier visual inspection technology. Our skilled operators and technicians run, maintain, and service the equipment, freeing you to focus on what you do best.

With Visionspect, you have the flexibility of pricing by batch, by unit, or by volume…*and all our inspection results are guaranteed.*

Contact us today to schedule a free verification batch test. Call 630-776-2459 or email us at info@visionspect.com.

visionspect
contract visual inspection

630-776-2459 | info@visionspect.com



OUTSOURCING INSIGHTS

Focusing On Innovation

By Kate Hammeke, research manager, Nice Insight

In 2011, innovation was a major topic among the various players in the drug development industry. Feedback from clients and sponsor-side industry personnel prompted a change in the outsourcing drivers included in the Nice Insight Pharmaceutical and Biotechnology Outsourcing survey, such that innovation — or the ability to improve in-house capabilities with customized solutions — replaced accessibility for the 2012 research cycle. The results from the Q1, 2012 survey indicated that while important, innovation ranked sixth after quality, reliability, productivity, regulatory track record, and affordability with respect to partner selection.

Five of the CMOs in Nice Insight's study received "excellent" scores — 80% and above — in the innovation category. The top-scoring businesses included Cangene bioPharma, Legacy Pharmaceuticals, Norwich Pharmaceuticals, Sandoz, and UPM Pharmaceuticals. Interestingly, each of these companies received a score of 81% in innovation, and their results averaged eight percentage points higher than the industry mean of 73%.

Quality and productivity tend to link closely to innovation. These outsourcing drivers are indicative of enabling the sponsor organization to focus on core competencies while trusting that its project is receiving the necessary attention to be successful. Nice Insight compared how the top-scoring companies for innovation fared on these two measures. Among innovation leaders, the average productivity score was three percentage points higher than the CMO benchmark (77% vs. 74%). This difference was present but less pronounced (at one percentage point) when comparing the quality score of innovation leaders to the CMO benchmark for quality.

As a matter of fact, innovation leaders averaged higher ratings across each of the outsourcing drivers when compared to the CMO benchmarks. These businesses also averaged ratings four percentage points higher with respect to regulatory track record and three points higher in terms of affordability. The one exception was reliability, where the innovators' average and industry benchmark were both 73%.

Next, Nice Insight reviewed how innovation leaders fared with respect to market share when compared to the custom manufacturing, analytical testing and regulatory support benchmarks. For all of these services, the innovation leaders averaged a greater percentage of market share than the overall benchmarks for each service. Both the customer perception ratings and market share data indicated these businesses would make solid partners for specialized projects, where customized solutions may be necessary.

Innovation can come in the form of breakthrough science, inventive business practices, or more broadly, changes in an industry's way of thinking or approach to problem solving. CROs and CMOs often look to advances in technologies and focus on the breakthrough science segment of innovation. Sponsors have also looked to business practices as a means to innovate — in part by engaging CROs and CMOs with the hopes of bolstering their competitive advantage — enabling sponsors to focus on core strengths and at the same time decrease fixed costs. As the drug development industry moves toward partnerships based on shared risk, rather than the more transactional relationships of years past, the business climate is becoming more open to alternative forms of innovation.

Evolving from a closed process to one of "Open Innovation"* — with collaborative intelligence across multiple sponsors and contract organizations — may initially cause challenges with respect to regulatory requirements and IP ownership. But a major overhaul in status quo problem solving is likely a necessary component of any plan to maintain profitability while bringing less expensive medication to the people who need it. It is very likely that the topic of innovation will continue to resurface not just as it relates to the problem-solving process and frequently converts to dollars — whether saved or earned.

**"Open Innovation" is a term coined by Henry Chesbrough, director of the Center for Open Innovation at the Haas School of Business, University of California.*

Quality for Life®

Quality
Reliability
Traceability
Sustainability

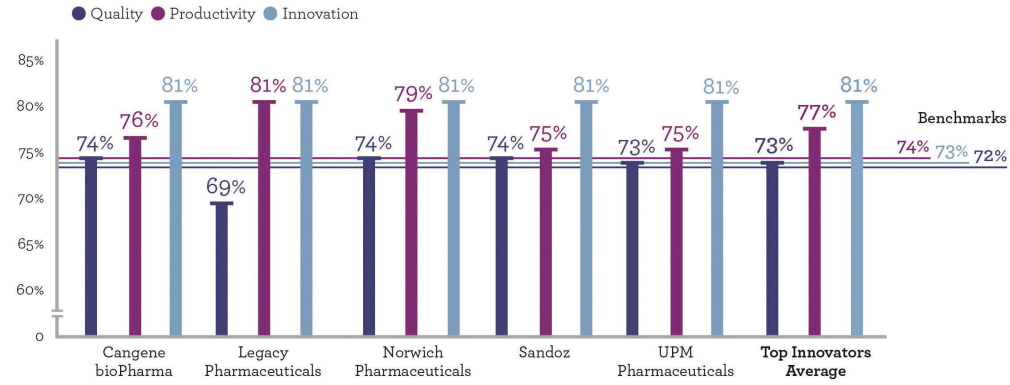
Sustainability

At DSM, our purpose is to create brighter lives for people today and generations to come. This mission is supported by sustainability as a core value and one of four pillars in our Quality for Life™ commitment. Its philosophies and metrics are evident in everything we do, highlighted by a top ranking in the Dow Jones Sustainability Index in the global chemical industry for 10 consecutive years. Sustainability is also an increasingly valued criterion for vendor selection, so it's not only a responsible approach, but a strategic business driver.

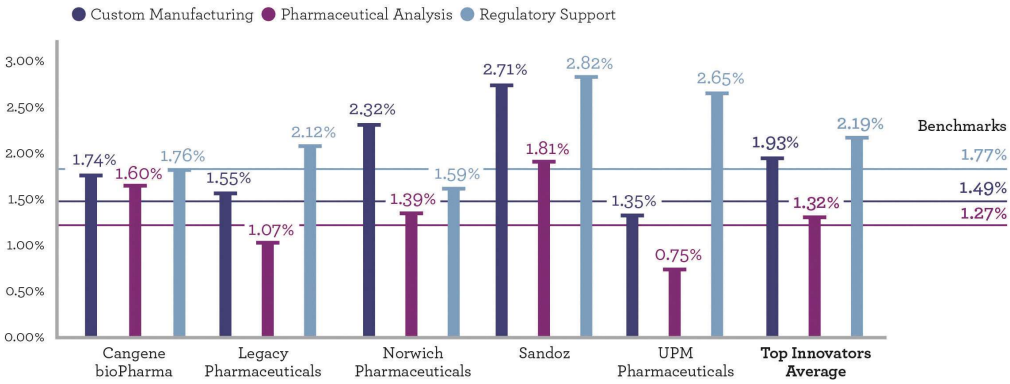
DSM Pharmaceutical Products
45 Waterview Boulevard, Parsippany, NJ 07054-1298 USA
Tel: +1 973 257 8011
www.dsmpharmaceuticalproducts.com
www.dsm.com

DSM
BRIGHT SCIENCE. BRIGHTER LIVING.

NI Customer Perception Measures



NI Estimated Market Share



Survey Methodology: The Nice Insight Pharmaceutical and Biotechnology Survey is deployed to 40,000 outsourcing-facing pharmaceutical and biotechnology executives on a quarterly basis [Q4 2011 sample size 2,619]. The survey is composed of 1,000+ questions and randomly presents ~30 questions to each respondent in order to collect baseline information with respect to customer awareness and customer perceptions of 300 companies that service the drug development cycle. More than 1,200 marketing communications, including branding, websites, print advertisements, corporate literature, and trade show booths are reviewed by our panel of respondents. Five levels of awareness from "I've never heard of them" to "I've worked with them" factor into the overall customer awareness score. The customer perception score is based on six drivers in outsourcing: Quality, Accessibility, Regulatory Compliance, Pricing, Productivity, and Reliability, which are ranked by our respondents to determine the weighting applied to the overall score.

If you want to learn more about the report or how to participate, please contact Victor Coker, director of business intelligence at Nice Insight, by sending an email to niceinsight.survey@thatsnice.com.

ropack.com

ROPACK®

35 CELEBRATING YEARS OF SUCCESS

Ropack is positioned to meet your packaging needs, including some you may not have considered.

Ropack's ample available capacity brings efficiency to a wide range of options for the packaging of solid oral dosage. In nearly 250,000 sq. ft., Ropack operates 27 Class 100000 Clean Rooms in modular systems that allow for scalable growth and rapid expansion for packaging in blister, bottle, stick and sachet formats.

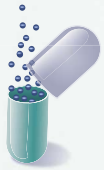
Our Montreal location has the flexibility to provide efficiencies you may not have considered:

Unique Efficiencies for the U.S. and Canadian markets

- We can run products on custom lines designed for shorter runs and quick changeovers for smaller Canadian market volumes.

- Savings and simplified customs processing occur when clients ship bulk product to us and we purchase materials locally, store and distribute product in-country.

Powder Blending



Encapsulation

Clinical Distribution

For more information contact: **Paul Dupont**
Director, Business Development **513.846.0921** **paul.dupont@ropack.com**

BIO DATA POINTS

Biomanufacturers Increasing Budgets For New Technologies

By Eric Langer, president and managing partner, BioPlan Associates, Inc.

Nearly 65% of biomanufacturers are planning to increase their budgets for new technologies to improve efficiencies and costs for downstream production, and three out of every five are increasing funding for new upstream production technologies. All of these statistics come from data from our newly released 9th Annual Report and Survey of Biopharmaceutical Manufacturers. These are not incremental changes, either: Almost 1 in 10 biomanufacturers will be making large increases (of 20% or more) in these areas, while 1 of every 5 plan an increase of 10% to 20%.

Budget increases are not limited to technologies that can improve efficiencies and cut costs, though. Biomanufacturers are looking to up the ante on big ticket items, too. On a note sure to inspire optimism, 15% of respondents are planning an increase of more than 20% in new facility construction. This is a greater proportion than are planning any level of decrease in funding for new facility projects, at 12.8%. A clear sign of industry segment growth, new capital equipment, is a focus, too, with 12.3% planning large increases and 46% planning a small-to-moderate increase. Again, this compares with fewer than 1 in 10 who forecast a decrease in funding for capital equipment. Compared with the past few years, these increases are substantial.

The vast majority of CMOs are increasing their level of spending in new capital equipment.

INCREASED FUNDING

With Big Pharma layoffs getting attention in the news, it is also encouraging to see that biomanufacturers are planning to increase their budgets for a variety of staffing-related causes. Roughly half of the 325 biomanufacturers we surveyed forecast an increase in funding to hire new operations staff and new scientific staff. Fifty-three percent are also upping their budgets for operations staff training, including 23% who plan to increase funding by at least 10%.

Comparing biotherapeutic developers and CMOs, we find that both are in relative agreement regarding areas most are tapping for increased funding. The vast majority of CMOs are increasing their level of spending in new capital equipment, with new downstream and upstream technologies not far behind. The area for which most are projecting a more than 20% increase is in new facility construction (33.3%).

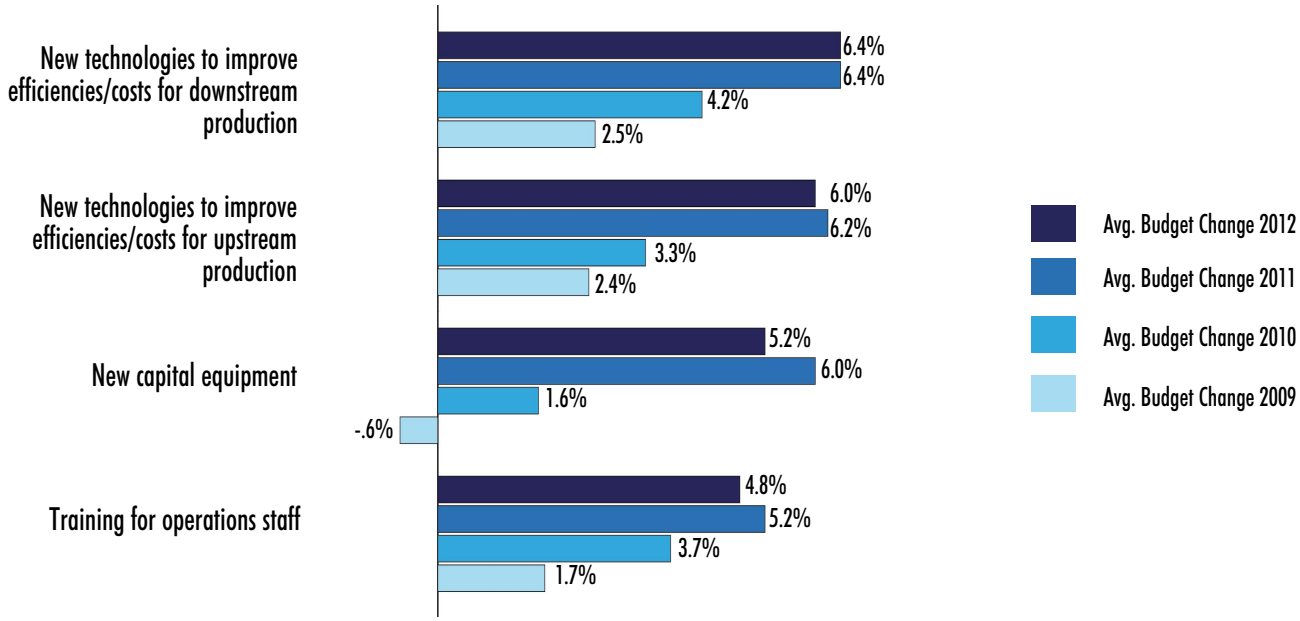
Among biotherapeutic developers (in comparison to CMOs), about three in five (61.9%) are scheduling a budget increase in new downstream technologies, followed closely by the proportion increasing their funding for new upstream technologies (58.1%) and new capital equipment (54.4%). As with CMOs, new facility construction sees the largest proportion, expecting a more than 20% increase in budget levels over the next 12 months (11.9%).

Not all areas are slated for a loosening of the reins, though. Just ¼ of respondents (biotherapeutic developers and CMOs combined) said they would be increasing their funding for outsourced biopharmaceutical manufacturing, and only 4 in 10 would be increasing their general budgets for in-house biopharmaceutical manufacturing or basic R&D for new therapeutic products. Even so, it is difficult not to get the sense that the industry is on a spending upswing: 4 out of 5 respondents will be either maintaining current spending levels or increasing them by some level for each of the areas we surveyed. This is certainly reason for optimism.

When we average out the planned increases and decreases across respondents, we find that biomanufacturers are reserving their largest budget increases for new technologies for downstream (6.4%) and upstream production (6.0%), much the same as they were last year. What this means is that the emergence from the economic perils that started over the past couple years has continued on into this year.

Healthcare segments historically have been relatively insulated from adverse economic situations, and this year we continue to see evidence that the economy within this segment has leveled out, witnessed by the uptick in budget allocations, especially in areas that improve performance for manufacturing activities and areas involving productivity. Budgets are favoring spending on productivity, which includes internal new technology investments (both upstream and downstream), and process development and optimization.

Selected Budget Change Comparisons: 2009-2012 Biomanufacturers And CMOs



	CMOs Only			Biomanufacturers (Drug Innovators) Only		
	Large (>20%) or Moderate increase (10-20%)	Small increase (1-10%)	No change	Large (>20%) or Moderate increase (10-20%)	Small increase (1-10%)	No change
New downstream technologies to improve efficiencies/costs	48%	29.6%	18.5%	26%	36.3%	25.6%
New upstream technologies to improve efficiencies/costs	45%	29.6%	22.2%	27%	31.3%	31.3%
New capital equipment	45%	37%	14.8%	29%	25%	26.9%
New facility construction	48%	18.5%	25.9%	23%	20.6%	40.6%
Hiring new operations staff	37%	22.2%	18.5%	21%	28.8%	32.5%

Survey Methodology: This ninth in the series of annual evaluations by BioPlan Associates, Inc. yields a composite view and trend analysis from 352 individuals at biopharmaceutical manufacturers and CMOs from 31 countries. The methodology also encompassed an additional 186 direct suppliers (vendors) of materials, services, and equipment to this industry. This year's survey covers such issues as current capacity, future capacity constraints, expansions, use of disposables, trends and budgets in disposables, trends in downstream purification, quality management and control, hiring, employment, and training. The quantitative trend analysis provides details and comparisons by both biotherapeutic developers and CMOs. It also evaluates trends over time and assesses differences in the world's major markets.

If you want to learn more about the report, please go to bioplanassociates.com.

Jeffrey Baker, Ph.D., deputy director, office of biotechnology products, FDA Center for Drug Evaluation and Research (CDER)

Photos By Pete Gool

Connecting The FDA And Industry

By Rob Wright

Even with more than 8,800 employees and an annual budget of around $3.2 billion, the FDA's task of protecting the public health seems daunting, considering the complexity of products being developed by industry. Factor in other issues such as counterfeiting, terrorism, drug reimportation, and the globalization of drug discovery, development, and manufacturing, and you soon realize that working at the FDA is indeed quite a challenge.

Jeffrey Baker, Ph.D., is learning how true that statement is. Baker, who was hired in 2011, is the deputy director, office of biotechnology products at the FDA's Center for Drug Evaluation and Research (CDER). His hiring is an example of how the FDA, in an effort to learn more about the industry it governs, brought in someone with extensive industry experience.

Having spent 20 years working for the likes of Eli Lilly and MedImmune, Baker arrived at the FDA with what he describes as his "industry toolbox," which includes a Lean Six Sigma Black Belt — indicating significant competency with a variety of tools and techniques that represent the best practices for quality in process improvement. Perhaps more importantly, he brought a willingness to learn. "I am trying to share my relevant experiences and be an active listener, a student of folks who have been doing this for years." With that mindset, Baker's goal is to help develop a shared vocabulary and shared expectations between the FDA and industry, thereby making it not just a governing body, but an enabling body.

DEVELOPING A SHARED VOCABULARY

When Baker first joined FDA, one of the first things he wanted to do was to meet as many people as he could to gain a greater understanding of the organization. "I would introduce myself, and they would tell me who they were, followed by an alphabet soup of acronyms," he explains. "I would then ask if they could tell me what their deliverables were, as I was new to the organization." He says people would often respond with something like, "This is the department that I am in, and here is what I work on." He quickly realized that the people were not specifically focused on providing deliverables, a common business term which encompasses task completion, metrics, and timely delivery of products. The FDA, on the other hand, generally views its mission as ongoing and part of a continuum to provide public-health solutions. "We have to be able to manage progression within that continuum, but we also have to complete tasks in a timely and high quality way," says Baker. To help accomplish that goal, he began the process of developing a shared vocabulary. To his colleagues, he asked questions he was used to asking while working in the pharma industry,

questions such as, "What are our goals? What are the value adds of certain activities?" For some people, the reaction was, "We are not a business." But, the majority of people didn't take that attitude and instead saw the benefit of taking a different approach to their jobs. "We need a shared vocabulary between the FDA and industry in order to have mutually successful shared outcomes," Baker explains.

During another interaction with a colleague, Baker was listening to someone explain the hiring and onboarding process for a new FDA employee. To gain a better understanding of the process being described, he drew a workflow diagram. Other members of the FDA saw the drawing sitting on his desk and found it helped improve their own understanding of the process. Even though there was no new information in what he created, his approach of looking at the problem differently proved fruitful and was recently discussed at a director's meeting as a means of teaching the hiring and onboarding process.

THE IMPORTANCE OF SHARED EXPECTATIONS

Both industry and the FDA are in the business of ensuring a reliable supply of safe, high-quality medicines which produce high-quality outcomes. To achieve this has historically involved long wait times. "When I was in the industry, we would have to explain to people that we cannot snap our fingers and have a building appear," analogizes Baker. "It is a long lead-time item. Similarly with the FDA, navigating public policy and providing sound guidance are long lead-time items. But both industry and the FDA recognize that the pace of change is rapid, and the needs of the public are immediate." For the FDA to successfully partner with industry and vice versa, in addition to having shared language, Baker believes in a shared set of expectations. One way the FDA partners with industry in developing shared expectations is the draft guidance process. This process also facilitates a level of open communication and helps the FDA to be a learning organization. When the FDA creates draft guidance, it is an iterative process involving a series of refinements. Through a synthesis of internal and external discussions between industry and the FDA, guidance is refined before becoming policy. A recent high-profile example involved the development of draft guidances on biosimilars. It included an attached Q&A sheet of commonly asked questions regarding the FDA's initial interpretation of certain statutory terms and requirements of biosimilar development. By taking a proactive

CAPACITY MANAGEMENT AND OUTSOURCING DECISIONS

"Executives who make sourcing decisions really need to fully assess the total manufacturing capability of that outsourcing opportunity," says Baker. By capability, he is not referring to statistical capability or Cpk (process capability index, a measure of how close a facility is to its targeted goal along with how consistent it is with average performance), but rather to systemic ability to deliver. He believes executives making the outsourcing decision need to see the process as not about buying grams of material from another shop, but more of a means of delegating the manufacturing responsibilities of one organization to another. "I think there is a disproportionate amount of attention paid to whether a process can be executed in a physical plant as opposed to whether a reliable high-quality product is going to be released in a timely way," he states. When due diligence is done and when those decisions are made, Baker advises executives to look at the whole picture. Manufacturing capability assessments should include the quality and depth of local technical support, integrity and transparency of quality systems, and the ability to allow people to make high quality risk-based decisions quickly.

"I think there is a disproportionate amount of attention paid to whether a process can be executed in a physical plant as opposed to whether a reliable high-quality product is going to be released in a timely way."

Understanding manufacturing capability is critical to making a successful outsourcing decision. "Very rarely does a capacity-based failure arise because we try to put 3,000 liters in a 2,000 liter tank," he states. According to Baker, capacity problems arise because there is a poor understanding of queue time, switch-over time, and the time associated with transactional or review processes within the supply chain or quality system. "All of these things can cut the actual practical capacity to a fraction of the theoretical capacity," he relates. "Capacity is not what a plant can deliver per unit time, but what a plant is very likely to deliver over time."

As outsourcing has increased in popularity, so has the enthusiastic marketing of manufacturers touting capacity. Unfortunately, Baker believes this has resulted in an increase in pain of failure to both clients and the public, especially in multiproduct or multisponsor plants. Baker's message to executives — approach capacity management systemically and use dynamic and stochastic modeling tools to be very data-driven in understanding capacity and probable outcomes.

Baker believes that to gain a better understanding of capacity management when making an outsourcing decision, start by developing a team with a diversity of disciplines and backgrounds, including individuals who are experienced in manufacturing and system engineering. Also, seek team members with experience in statistical outcomes and decisions sciences. Baker also suggested the use of a variety of statistical analysis programs such as JMP or Mathcad. Baker concludes that companies must see outsourcing of manufacturing not as a cost center, but a value center. When deciding to outsource, Dr. Baker advises companies to thoroughly understand why they are choosing to outsource. "If you are outsourcing to gain additional capacity, to defer capital investment, to manage a value-add tax situation, or to manage headcount of a specific core discipline, the value proposition of why you are outsourcing needs to be assessed in that light," he states. Baker believes we will see a continuing increase in strategic partnering. He sees this as being quite different from outsourcing. "In strategic partnering, there is shared pain and shared gain," he says. "You succeed and fail together. I think folks sometimes mistakenly think that's not the case with outsourcing." Baker puts it this way, "You can contract out activities, but you cannot contract out responsibilities."

Focus on your patients.

Focus on you.

With a focus on improving patient outcomes via product development and commercial manufacturing, you can depend on Norwich — a reliable partner for all stages of your product's lifecycle. Our proven processes ensure no surprises. Your customers rely on you, and our 125-year history of quality and compliance provides a foundation for that trust.

FOCUSING ON
CUSTOMER CARE
SINCE 1887

Contact us to help you focus on your patients at www.norwichpharma.com

NORWICH
CELEBRATING 125 YEARS

approach to addressing questions that could arise in early stages of biosimilar product development, the FDA aims to improve interpretation of the draft guidance, thereby enabling companies to effectively implement and provide commentary on the draft guidance. Some examples included how to request meetings with the FDA, what differences there are in formulation from the reference product, and how to request exclusivity. As to why the recently issued guidance is only considered to be a draft and not policy, Baker explains, "It is draft guidance because it is important that we give industry and the public a chance to respond and a chance to provide their input prior to finalizing. By the same token, the FDA needs to put it out there because biosimilars are being developed now. Industry and the FDA need to have shared expectations now."

Another example Baker cites as a means for developing shared expectations is having members of the FDA attend and speak at industry conferences. For example, this past January, Vicki Seyfert-Margolis, senior advisor for science innovation and policy, spoke at the Conference Forum's New Paradigms to Fund & Move Drug Development Conference in San Francisco, providing insight on how biotechs can better navigate the regulatory system. Baker recently participated in a roundtable at MIT and is scheduled as one of the keynote speakers at this year's Interphex conference. Not only does this type of FDA involvement at industry events help foster a shared language and shared expectations, it assists in carrying out the transparency initiative set forth in 2009 by FDA Commissioner Margaret Hamburg, M.D.

"We need a shared vocabulary between the FDA and industry in order to have mutually successful shared outcomes," says Jeffrey Baker, Ph.D.

Recently, the FDA gained full membership in the Pharmaceutical Inspection Convention Scheme (PIC/S). This is another example of how the FDA is working to develop shared expectations with industry. "This is a big deal," states Baker. "When I was in industry, the FDA was not a full member. There were 36 other countries that were. I think it really shows the agency's commitment in aligning with and projecting influence on the global standards."

QUALITY BY DESIGN IS JUST GOOD BUSINESS

QbD is a concept first outlined by quality expert Joseph Juran who believed that quality could be planned. QbD principles were adopted by the FDA as a vehicle for the transformation of how drugs are discovered, developed, and manufactured. Baker sees QbD as a reiteration of developing shared expectations, not as a ticket to regulatory relief or a shortcut. "QbD is about providing a very high level of assurance that we have control of process and product," he states. Utilization of QbD by companies enhances the FDA's decision making, which uses a risk-based decision-making (RBDM) approach. RBDM is defined as a process that organizes information about the possibility for one or more unwanted outcomes to occur into a broad, orderly structure that helps decision makers make more informed management choices. Since the sponsors are the technical experts and the ones who know the most about the products being developed, it is their responsibility to demonstrate and explain processing controls to the FDA. Baker sees QbD as good business because it emphasizes reproducibility in meeting expectations and demonstrates product control. "A process that is in control is a process that itself reproducibly meets expectations. If a company cannot crisply articulate the expectations of a manufacturing process from beginning to end and the measures by which it is going to demonstrate control, then it is very difficult to say the process is in control and therefore consistently reproducible," Baker states. His advice for industry to demonstrate QbD — be transparent with the FDA. Further, he believes industry can benefit from using a variety of statistical and decision-science tools currently available in identifying and implementing a reproducible control strategy. "The organizations that are able to pull upon the disciplines of statistical process controls, measurement systems analysis and component of variance analysis and use them in a facile and efficient way are coming out with very solid data-driven decisions," he affirms.

Baker sees the heart of QbD as not being very different from the principles of process validation, which include define, demonstrate, document, and maintain. By define, he says you need to identify and justify the measures that assure a process or product will meet expectations. With regard to demonstrate, Baker asks, "What does the process look like when it runs correctly?" Companies need to demonstrate they can actually perform in the defined envelope. By document, quite simply, Baker says to write it down. As for maintain, companies need to provide some reasonable level of assurance as to how they intend to operate in the prescribed manner. Define, demonstrate, document and maintain is something Baker developed at Eli Lilly. By bringing this concept from industry to the FDA, Baker exemplifies how the FDA is developing both shared vocabulary and shared expectations to serve as a governing and enabling body.

INTELLECT
INNOVATION
INVALUABLE

IT HAPPENS AT
INTERPHEX
ARE YOU IN?

SCAN TO LEARN MORE
ABOUT INTERPHEX 2012

MAY 1-3, 2012 | JAVITS CENTER | NEW YORK, NEW YORK

REGISTER TO ATTEND AT WWW.INTERPHEX.COM/AD2

If you are interested in exhibiting at INTERPHEX 2012 please contact
Pete Zezima for more information at 203-840-5447

INNOVATION + INTELLIGENCE + PASSION

INTERPHEX™ 2012

CORPORATE SPONSORS:

Baxter FedEx DSM BRIGHT SCIENCE. BRIGHTER LIVING.

BRINGING TOGETHER KEY PHARMA AND BIOTECH PROFESSIONALS
WITH SUPPLIERS TO CREATE INNOVATIVE SOLUTIONS.

AD2

"They thought they had developed the product. They didn't realize there was such a long road remaining," explains Brian O'Callaghan of Sangart as he describes the company's internal team and external investors after he joined as president and CEO.

Getting A Biotech Back On The Path Toward Commercialization

By Rob Wright

There has been much debate as to how much it costs to get a new drug from discovery to market — anywhere from Light and Waburton's 2011 estimate of R&D costs being in the neighborhood of $59.4 million to PhRMA's mind-numbing figure of $1.32 billion. R&D costs aside, what cannot be debated is the time it takes to get a drug approved, which is, in a nutshell, a long time.

Drug discovery and development is measured in years, often taking more than a decade to get from the laboratory onto pharmacy shelves. For some unfortunate few, the process can be even longer. Sangart, a biopharmaceutical company based in San Diego, recently passed the 14-year mark without a successful commercial drug launch of its oxygen therapeutic agent (OTA).

Founded by Dr. Robert Winslow in 1998, Sangart created a new model for thinking about the mechanisms of oxygen transport and delivery in the body. In short, the Sangart team had created a means to enhance how red blood cells work to optimize how gases can be delivered to tissues. For example, improving oxygen delivery has a therapeutic benefit for patients experiencing trauma-related oxygen deprivation by rapidly providing oxygen to where it is needed most. The trauma compound in development is referred to as MP4OX. Discoveries from Sangart's research looked so promising that they were granted patents and widely published in numerous scientific articles. It seemed the company was doing everything right, and yet no commercially viable product had made it to market. In 2008, Sangart took a very bold initiative, replacing its founder and CEO, who also served as chief science officer, chief regulatory officer, and chief medical officer, with a nonscientist. Brian O'Callaghan, Sangart president and CEO, arrived with extensive commercialization experience and one objective — to be the first company to successfully launch an OTA. But, first he had to address past strategic errors which, in his opinion, had placed the company at a drug discovery dead end. O'Callaghan's two-pronged approach of first assessing the product and then assessing the management team has placed Sangart back on the path toward commercialization.

ASSESSING THE PRODUCT REQUIRES TOUGH DISCUSSIONS

When O'Callaghan arrived at Sangart, one of the first issues he had to overcome was the company's focus on developing a blood substitute and the perception this had created with the medical community and regulatory agencies. Not being a scientist (he had started his career in the industry as a field sales representative in Ireland for Pfizer), he approached the problem from a different and rather simplistic perspective. O'Callaghan looked at the product in development, keeping in mind all of the properties blood possesses, and asked Sangart' scientists, external experts, and consultants a very simple question, "Are we truly saying, that if somebody loses vast quantities of blood, we're going to inject them with milliliters of this fluid and it's going to be a blood substitute and do everything that blood does?" The consensus was a resounding "no." With that he then asked, "So what do we have then? What does this product actually do?" The only things the company could realistically claim were that the product has some oncotic properties, i.e. drawing fluid back into capillaries and restoring pressure, and is very effective at delivering oxygen to ischemic tissue. "Why shouldn't we develop this as an oxygen-delivery agent?" O'Callaghan inquired. By asking simple questions, O'Callaghan was working with the team to help each other understand where the company was and where it needed to go. It also prepared them for the next difficult message he had to convey.

O'Callaghan had the unenviable task of informing Sangart stakeholders (i.e. the internal team and the external investors) that the company had failed to implement a build-it-to-label commercialization strategy (the process of creating a drug with appropriate labeling geared toward eventual commercialization). "They thought they had developed the product," he states. "They didn't realize there was such a long road remaining."

As the bearer of bad news, he attempted to soften the blow by reminding them of the significance of their achievement in terms of what it might mean to patients and science in general. But, the reality was, unless the product achieved commercialization, their efforts would only serve as a manual for how *not* to commercialize an OTA. In order to keep the team motivated, as well as to prevent a mass exodus of investors looking to cut their loses, O'Callaghan believed the company needed a different business strategy which involved having more than one potential commercially viable product in its portfolio. Sangart scientists had conducted some preliminary research on the possibility of enhancing the delivery of low doses of carbon monoxide (CO). The benefit of delivering CO in low doses is that it acts as a messenger to cells and reduces both inflammation and oxygen requirements while preventing programmed cell death (apoptosis). Sangart began development of MP4CO, which may prove useful in treating sickle cell anemia. O'Callaghan thought the company had the opportunity to restrategize on one product, MP4OX, and properly strategize from the beginning with MP4CO. "To get MP4OX successfully licensed and on the market," he says, "we needed to go way back in the process and restrategize, because previous management hadn't considered the regulatory implications." He explained to the team that it would be a three-to-four-year process just to get back to where the employees already thought they were — on the verge of launching MP4OX. O'Callaghan admits that in all areas of the company, people were simply not prepared for receiving this message. He dusted off his selling skills and began the process of convincing the entire organization, as well as the investors, on a new vision for Sangart — "developing life-saving medicines specifically designed to enhance the perfusion and oxygenation of ischemic tissue through targeted oxygen delivery, not trying to claim MP4OX was God's gift as a blood substitute," he states. The new strategy was going to involve proof-of-concept studies going all the way back to phase 2A for MP4OX. "We were going to have to negotiate with the regulatory authorities a brand-new pivotal path

for MP4OX, i.e. identify an actual and meaningful indication that not only served an unmet clinical need but had some commercial viability as well," says O'Callaghan. In addition to getting MP4OX relabeled as an OTA as opposed to a blood substitute, the company began the initiation of phase 1B studies for MP4CO and the pursuit of U.S. Orphan Drug Designation, which they received in November 2010.

Sangart began the MP4OX relabeling process by putting together clinical and regulatory advisory boards, as well as reaching out to the medical community to gain additional perspective. "From all angles, the regulatory perspective was much easier to manage as an oxygen therapeutic agent, not as a blood substitute," states O'Callaghan. "We had to stop using the term blood substitute and convince regulatory authorities that this wasn't just a cosmetic exercise of relabeling our product," he clarifies. "To truly understand our product better, it had to be characterized much more accurately." O'Callaghan describes this as "a big wake-up factor for Sangart to truly realize who and what we are." With this new focus, investigators are now focused on developing an oxygen-delivery agent, and regulatory authorities are regulating it as such. In addition to the error of pursuing the commercialization of a blood substitute as opposed to a drug, there were other strategic errors made by the company — some of which turned out to be blessings in disguise.

STRATEGIC ERRORS ON THE PATH TO COMMERCIALIZATION

According to O'Callaghan, for many of the scientists working at Sangart, this was their first experience with developing a drug through to commercialization. "It was not a lack of intelligence or education or drug-development experience," he elaborates. "But, in terms of drug-development experience with a regulatory pivotal path attached to it, they thought that the build-it-and-they-will-come strategy was enough, but it wasn't." In addition to inexperienced management, O'Callaghan identified a number of other strategic errors.

For example, none of the development work was being done in the United States. This was intentional and not intended to snub the United States. "You can generate data in Europe and use it in the United States," states O'Callaghan. "But it's usually advisable to have at least some of your data being generated in the United States if you want to create a meaningful dialogue with the FDA." If you intend to launch a drug in the United States, it is better to have results from a pivotal clinical trial conducted in the United States when approaching the FDA for approval.

Another strategic error was the company's decision to move very quickly through the clinical trial phases. O'Callaghan recounts, "There was very little Phase 2 work actually done. So, there were a lot of unknowns about this drug when they were going into what were

two very large Phase 3 studies — one for the prevention of hypotension in hip surgery. This was taking us down a dead end because we were talking about developing an oxygen therapeutic agent." OTAs and hemoglobin-based oxygen carriers (HBOCs) are products being used for patients experiencing hemorrhagic shock and severe bleeding with the goal of restoring oxygen delivery to ischemic tissue and organs. In any Phase 3 study, there are several objectives, such as demonstrating a safety profile with recognized adverse events and having an indication which meets an actual unmet medical need. These were not achieved because of another strategic error — not having a real indication for the Phase 3 study — as evidenced by the study being conducted in a very low-risk patient population.

The strategic error of not conducting any clinical trials in the United States and the premature implementation of the two large phase 3 trials turned out to be blessings in disguise. First, early on in OTA/HBOC development, Sangart had several U.S. competitors. As a result of initial findings by former competitors, the FDA questioned the safety of HBOC development and put a hold on all U.S.-based clinical trials. Since Sangart was conducting studies overseas, the company was able to continue conducting research. Second, the results from the large phase 3 studies were very promising in the areas of safety. Instead of considering these as Phase 3's, Sangart approached the FDA with the data positioning them as really being phase 2 trials. This proved very important when beginning to renegotiate the *relabeling* of MP4OX with the FDA as an OTA and not a blood substitute — a key component in attempting to get Sangart back on the pivotal path.

O'Callaghan identified some other strategic errors as well. For example, the company had chosen Voluven as a comparison product, which worked very well in the treatment and prevention of hypertension and hip surgery. "It's nearly impossible for an OTA to demonstrate true benefit and overcome safety concerns in that patient population," says O'Callaghan. "You will demonstrate certain end-points regarding safety, but you're certainly not going to demonstrate a benefit over Voluven, especially when it comes to pharmacoeconomics, which weren't even built into this study." Pharmacoeconomics refers to the scientific discipline that compares the value of one pharmaceutical drug or drug therapy to another. Not considering pharmacoeconomics as an integral component of the study was yet another strategic error. In Europe, where the studies were being conducted and where Sangart was anticipating the initial submission and launch, reimbursement is critical and pharmacoeconomic end-points are as important as chemical end-points. The company would not be able to prove pharmacoeconomic superiority over Voluven because it was less expensive compared to Sangart's product, which was anticipated to cost between $1,000 and $2,000 a bag.

Failing to plan for commercialization was yet another strategic error. "They were running a fine facility," O'Callaghan explains. "But being a pilot plant, it was not capable of producing peak projective commer-

sartorius stedim biotech

SINGLE-USE TECHNOLOGY

New sterile filters Sartopore® 2 XLG and XLI
A quantum leap in flow rate and throughput

With their unique hydrophilic, heterogeneous, double-layer polyethersulfone membranes, new Sartopore® XLG and XLI provide broad chemical compatibility, high-thermal resistance and significantly higher throughput and flow-rate than any other sterilizing grade filters.

Typical applications include sterilizing grade filtration of:

- Buffer
- Media
- Biologics (intermediate & terminal)
- SVPs and LVPs
- Ophthalmics
- Antibiotics
- APIs

www.sartorius-stedim.com/sartopore2
turning science into solutions

Sartorius Stedim Biotech
USA +1.800.368.7178
Europe +49.551.308.0

cial quantity. There was no planning for either expanding this facility or creating a new facility elsewhere." In effect, Sangart had no chemistry, manufacturing, and control (CMC) section for the drug submission process. "If by some miracle the Phase 3 studies were actually suitable for submission, not having a CMC section would have prevented approval," he states. "It would have taken, at best, 18 months, but more than likely two years to produce at that stage."

ASSESSING AN ACQUIRED LEADERSHIP TEAM

After a thorough review of the product, O'Callaghan began assessing the Sangart leadership team he had inherited. He would advise those coming into a similar situation to first begin with an objective mindset. "Unfortunately," says O'Callaghan, "there are too many general managers or CEOs who believe they have to come in and clear the decks, automatically assuming that because the strategy is wrong or because something has not worked out, that management is incompetent, is not experienced enough, and needs to be replaced." In his experience, this is usually not the case.

Over the years O'Callaghan has found two consistent problems with management teams — they lack core competencies and/or experience. This was the case with Sangart. For example, the CEO he was replacing was serving in too many capacities. "By default, we did not have core competency from a regulatory or clinical perspective," he explains. "A good chief scientific officer does not necessarily make a good CEO, CMO, or head of regulatory. These are very distinct and different core competencies."

Regarding lack of experience, O'Callaghan describes it as executives lacking *executiveness*. Clarifying, he says, "You have people in management who may not actually be executives. They have found themselves in these positions by default, because they were very early recruits to the company who initially did everything from washing the dishes to developing the drugs. They have inherited titles that they wouldn't have if they were at Pfizer or any established biotech company." O'Callaghan had to effectively right-size people, a conversation and process not achieved in just one day. "You have to build a sense of trust over time, and the first part of that is the chemistry between you and these people and how you communicate," he states. Communicating the type of competencies necessary to build a c-level leadership team and bringing in people with those competencies to serve as mentors to those being right-sized builds trust among employees. Rather than pass out a bunch of pink slips, O'Callaghan took the approach of creating a leadership team for the former c-level executives he had to right-size. "Now, the leadership team," he explains, "is very important because they're responsible for the execution aspect of the company, making sure all project management is effectively conducted and all project teams are effectively managed and ensuring that our overall corporate strategy is followed and all milestones are met." Communicating that every decision being made is to benefit the company, not the individual, is key. "That is where trust builds up and people begin to see how they will benefit," he concludes.

Being right-sized can be tough to take. But had this step not been taken, these execs would most likely have been out looking for jobs for which they weren't qualified because Sangart would have gone out of business. By retaining most of the team and taking a mentoring approach, O'Callaghan believes these former executives are now capable of stepping up to the VP titles they previously held. Some have left the company in order to do so, which he sees as a good thing for growth and development. "They need to get experience throughout the industry that they won't get at Sangart," he asserts. By conducting a thorough product assessment and retaining top talent with an active mentoring approach to those who required right-sizing, O'Callaghan believes he and his team have now positioned Sangart back on the pivotal path toward commercialization — developing an OTA (not a blood substitute), having more than one product in the pipeline, gaining U.S. orphan drug designation for MP4CO, and having a recently signed cooperative R&D agreement with the U.S. military in developing MP4OX.

As of this writing, Sangart has negotiated itself back on a pivitol path with 15 regulatory authorities around the world. The company is in negotiations with the FDA and officially still on clinical hold in the United States.

UPM Pharmaceuticals®
Formulating Your Future™

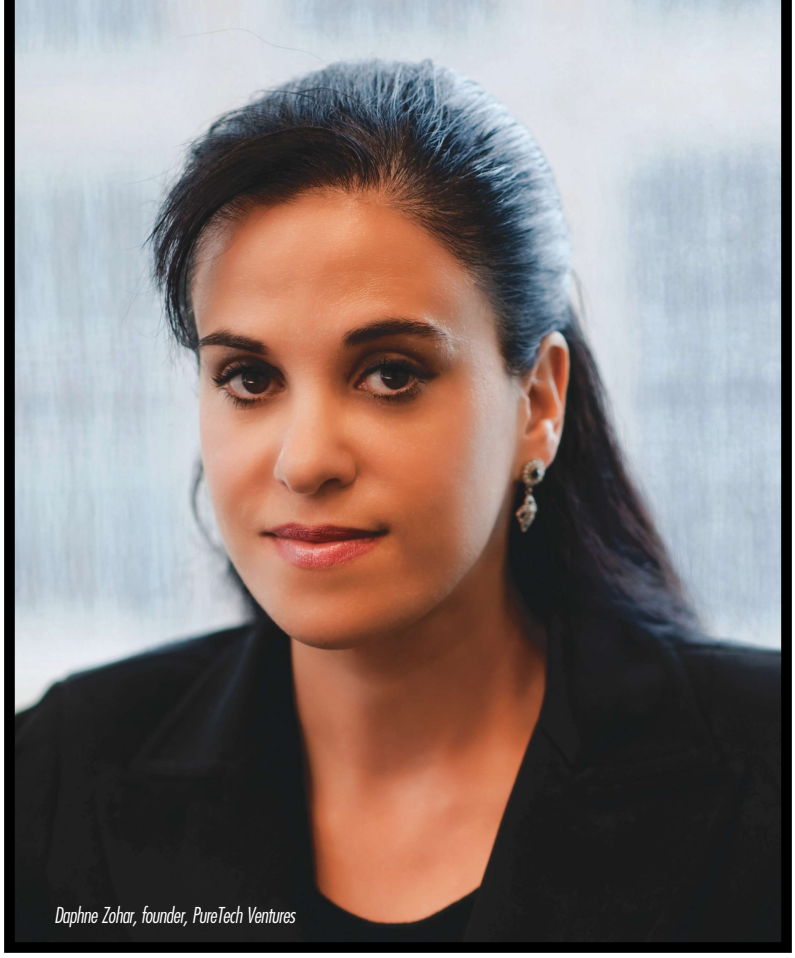
UPM's Flexibility. Your Success.

UPM Pharmaceuticals has the flexibility to consistently meet your solid dose needs. We are a partner committed to optimizing your process and combining expertise to ensure you meet strategic and time-sensitive goals.

FORMULATION DEVELOPMENT
CLINICAL MATERIALS SUPPLY
ANALYTICAL SERVICES
COMMERCIAL MANUFACTURING
COMPLEX FORMULATIONS

Visit us at booth #1104 during Interphex 2012 in New York.

TO LEARN MORE, VISIT **www.upm-inc.com** CALL **+1 410 843 3738**



Daphne Zohar, founder, PureTech Ventures

The Evolution Of Biotech VC Funding

BY SUZANNE ELVIDGE, CONTRIBUTING EDITOR

PureTech Ventures Founder Daphne Zohar is one of the growing group of women entrepreneurs in a world that is still male-dominated. But, that's not the only thing that makes PureTech Ventures different. In these cash-strapped times, when VC funding is hard to find, especially for companies with unproven research, the PureTech Ventures model focuses on creating and providing seed funding in very early-stage companies, often even before the initial business plan is written.

ONE 2 ONE™

Parenteral Contract Manufacturing Service of Hospira

Our comfort zone is global parenteral manufacturing

- **Biologics**
- Highly Potent Drugs
- Cytotoxics
- Betalactams
- Controlled Substances
- Sterile Compounding
- Single-Use Technology
- Lyophilization
- Global Regulatory Services
- QP Release

COME SEE US AT:
INTERPHEX 2012
Level 3,
Booth #1211

Discover your comfort zone at one2onecmo.com

Get your custom report online or contact One 2 One.
Call +1-224-212-2267 or +44 (0) 1926 835 554 or e-mail one2one@hospira.com

ONE 2 ONE™

Parenteral Contract Manufacturing Service of Hospira

Your Parenteral Comfort Zone

P11-3517A-Mar., 12

Zohar's career as an entrepreneur started at 16 with her first start-up company and continued through graduate school where she created two companies. One, with a classmate who later became her business partner and husband, manufactured and sold olive oil and other health-promoting foods and managed to take a large percentage of the Israeli market. After graduation, she created an equine veterinary care company, EQ. Through PureTech, which was launched in 2004, she has been involved in founding 16 start-ups that are now at varying states of maturity, and she is currently on the boards of Enlight Biosciences, Follica Inc., Vedanta Bioscience, Mandara Sciences, Karuna Pharmaceuticals, Tal Medical, and Satori Pharmaceuticals. This catalog of experience has given Zohar an almost unique perspective on the entrepreneurial process, from both the side of the entrepreneur and that of the investor.

THE CURRENT ROLE OF VC FUNDING

According to PriceWaterhouseCoopers, in the first three quarters of 2011, life sciences (biotechnology and medical devices) saw declines related to the dollar value of venture capital investments and the number of deals, as well as a shift from early-stage and seed deals toward later-stage deals.

"The VC industry has been going through tremendous change and attrition over the past few years. While there are still funds with capital, assuming a fund has cash available is no longer a given, as many venture funds have not raised a new fund since 2008 or before and are therefore primarily in the position to support their existing companies," says Zohar.

This leaves a funding gap for all biotech companies, particularly for the very early-stage companies. PureTech Ventures aims to provide funding and support in order to fill this gap, at least to some degree.

"The VC model is changing, and there seems to be a movement to a closer relationship with strategic partners, with flexible models for new companies, and more capital-efficient approaches to building companies. This is the polar opposite of the perspective of the VC industry a few years ago and is all very much aligned with our model — we have been thinking this way from the beginning," says Zohar.

A DIFFERENT TYPE OF VC MODEL

Rather than just providing funding to already-established companies, PureTech Ventures works with scientists to create companies from the ground up: from establishing a leadership team through to creating syndicates for later-stage financing rounds. The company's portfolio includes companies in the preclinical to early clinical space developing devices, drugs, and diagnostics, as well as research technologies, with a focus on major unmet medical needs. One example is Gelesis, which focuses on obesity and other related comorbidities.

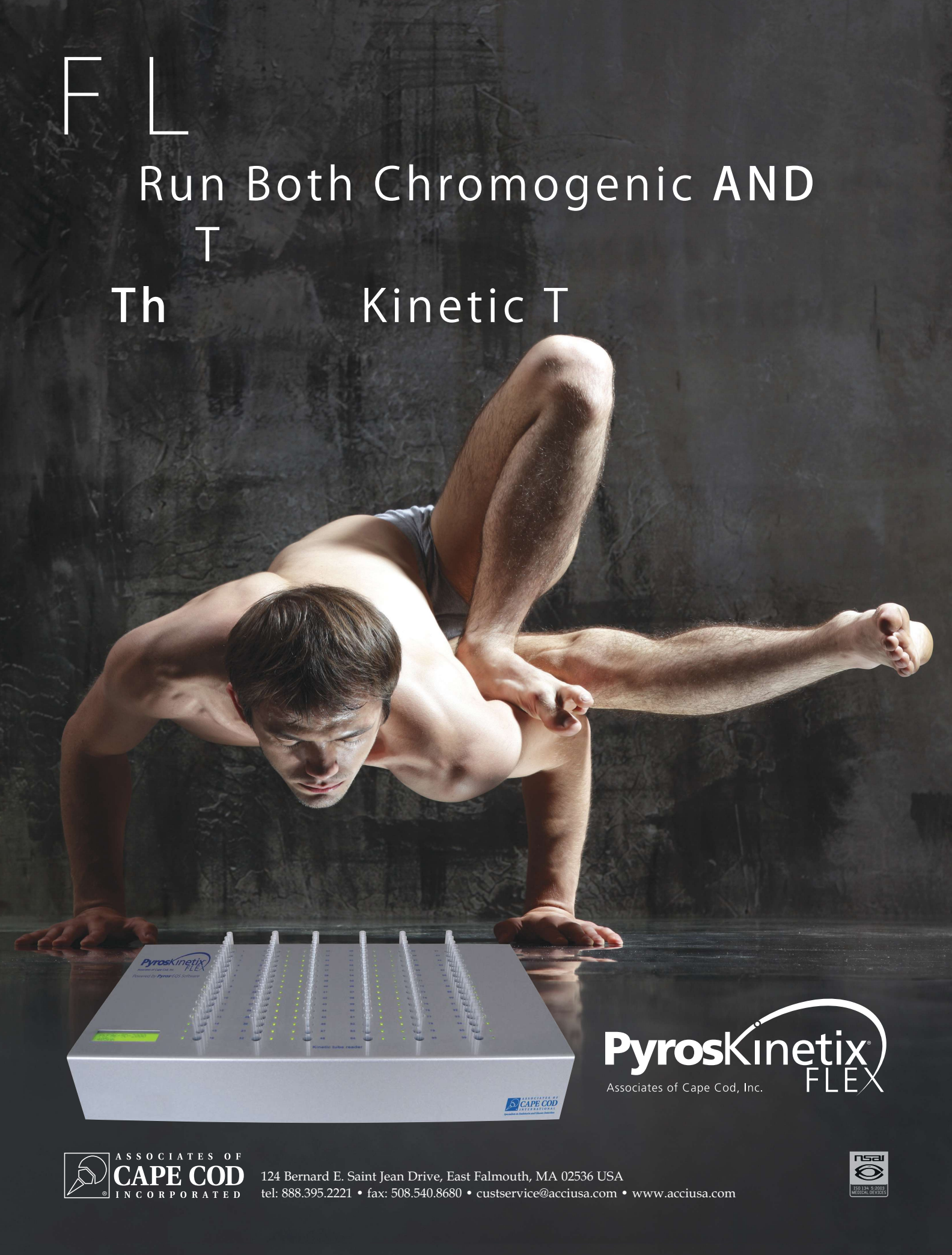
"I believe our approach is unique because we proactively form companies with scientific leaders where most VCs primarily invest in companies that someone else (an entrepreneur) has already formed. We are therefore more of an 'institutional founder' or entrepreneur, where a VC is more of an 'institutional funder' of companies."

There are other players that are involved in supporting early-stage new companies, such as incubators and accelerators, university technology transfer offices, seed and early-stage venture funds, and corporate incubators. But, Zohar sees PureTech Ventures' approach as rather different — as being the entrepreneur, rather than just supporting an entrepreneurial individual. "What we are doing more closely mirrors what an individual entrepreneur does but with the benefit of the breadth and scale of an organization," says Zohar.

THE ROLE OF TRANSLATIONAL MEDICINE

Translational medicine is the transfer between academic research and the clinic, often described as moving research from bench to bedside, but it is traditionally difficult to fund, particularly from VCs. The gap between the concept and the market is where many technologies face obstacles and ideas fail, often known as the "valley of death."

"Traditional VCs generally prefer to be part of a syndicate investing tens of millions and backing an entrepreneur/management team that they know and trust. VCs are primarily structured to invest capital and provide some guidance and mentorship, but they are not set up to found and manage newly formed companies, particularly if those new companies require only a small amount of money initially. This step requires a significant amount of human resources.



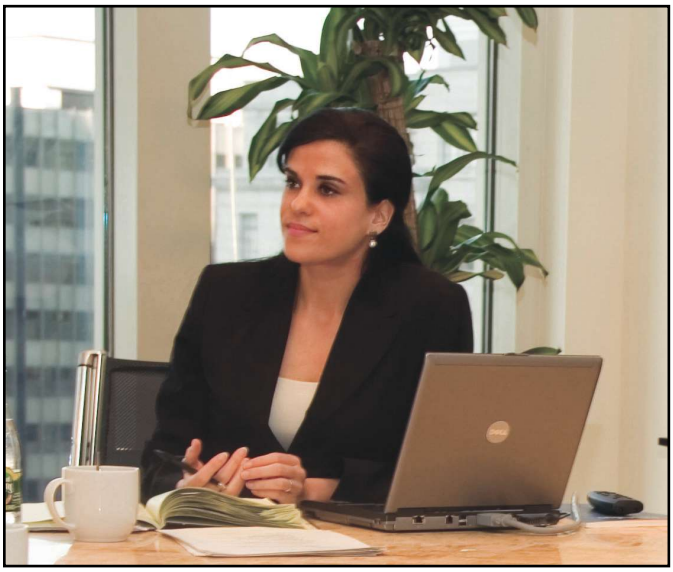
ASSOCIATES OF
CAPE COD
INCORPORATED

124 Bernard E. Saint Jean Drive, East Falmouth, MA 02536 USA
tel: 888.395.2221 • fax: 508.540.8680 • custservice@acciusa.com • www.acciusa.com

In contrast, we are not confined by the same restrictions," says Zohar.

Filling the "valley of death" gap allows PureTech Ventures the opportunity to invest in new research.

"We are doing a lot in areas that some VCs have written off due to past failures, such as obesity and metabolic disease, which are both areas of major unmet need and are growing markets and a focus



"Venture capital is now just one component of a funding ecosystem necessary to get a company to its key inflection points," says Daphne Zohar, founder, PureTech Ventures.

for interesting, breakthrough science. We also tend to do things where several technology areas converge. Some examples include the interface between the immune system and the microbiome, and noninvasive devices and new media influencing cognition and CNS disorders," says Zohar.

Though she does not have an academic science background, as the daughter of a researcher at Massachusetts General Hospital, medical laboratories have always been a familiar place for her, and she has built a team of top-tier scientists and advisers at the company, vital for the transition between bench science and the market. "While my background focuses on business and entrepreneurship, most of the team that we have built at PureTech Ventures have strong scientific training. When we form a new company, we also make sure that we work closely with the leading experts in the relevant field," says Zohar.

HOW DOES IT WORK?

Within the area of translational medicine, the PureTech Ventures team, along with a group of leading experts in that field, proactively identifies a problem and then scans technologies across a wide range of scientific disciplines that might address the specific problem identified by the scientific experts that have cofounded the company. When scanning through the technologies, PureTech applies a sort of due diligence "shopping list" — looking for novelty, significant unmet need, protectability, and scientific credibility. In order to attract investment and support from PureTech Ventures, the ideas must fulfill these points:

Novelty: Research must be cutting-edge, and technologies must have the potential to yield products that are clearly differentiated from others on the market.

Significant unmet need: Technologies must address clearly defined gaps in the market. This means they must be a "need to have" not just a "nice to have" for the end users, the physicians, and the patients.

Protectability: Technologies must be patented or patentable, and PureTech Ventures is able to get involved even before patents have been filed.

Scientific credibility: PureTech Ventures' scientific team members and advisers must be confident of the scientific credibility of the scientists and the technologies, and they will review reproducible data, peer-reviewed papers, grants, and even the history of the lab from which the technology originates.

These concepts are then formed into virtual companies, and they are kept virtual for as long as possible, because this increases flexibility and reduces costs. Once the idea is shown to be practical, PureTech Ventures team members act as an interim management team, and employees are hired and advisory boards are put into place.

FINDING THE FUNDING

Venture funding isn't always the answer (or at least the only answer) in the long term, because it puts enormous pressure on a company to produce a financial return and can lead to VC control of company boards, causing a potential conflict of interest between the return on investment for the VC fund investors and what's best for the start-up and its other (non-VC) investors. The VC board members also don't always have the specific experience and expertise needed on a technology-based start-up board, where the new company needs both scientific as well as business advice.

"Entrepreneurs need to take a really thoughtful approach to the funding process and not assume that the past approach of raising subsequent series of financing is still relevant to everyone. Venture capital is now just one component of a funding ecosystem necessary to get a company to its key inflection points," says Zohar.

PureTech Ventures finds its portfolio company funding from a variety of sources, such as grants from nonprofit organizations, investments from angel investors, industry partnerships, as well as from traditional VCs. An example of PureTech Ventures' partnerships is Enlight Biosciences, founded in 2008, which allows a syndicate of seven leading global pharmaceutical companies to work together (precompetitively) to support new platform technologies from academics and innovators through founding and managing new technology startups. Exits — whether through acquisition and IPO or partnerships — are also tailored to the company. An example of this is Mersana Therapeutics, which signed a deal with Teva Pharmaceuticals worth up to $334 million.

Get Flexible Staffing Solutions at...

Your Place *or Ours.*

Professional Scientific Staffing SM (PSS)

Managing our scientists at your site, committed to the success of your projects, Lancaster Labs' PSS program:

- Eliminates headcount, co-employment and project management worries.
- Costs you less than your own full-time employees.
- Avoids Temp turnover rate.
- Provides a 50-year history of regulatory-compliant technical expertise in your lab.

Full-Time Equivalent (FTE)

With a dedicated team of analysts working on your projects within our GMP-compliant facilities, our FTE staffing program:

- Can save up to 35 percent off testing costs.
- Manages your projects with your systems/SOPs and utilizes the same level of QC and regulatory expertise as our fee-for-service program.
- Provides extensive and meaningful productivity metrics to maximize team utilization rates.

Partner and prosper with Lancaster Laboratories' scientific staffing solutions.

eurofins | Lancaster Laboratories

www.LancasterLabsPharm.com

SOME ADVICE ABOUT YOUR PITCH

Through her career, Zohar has heard her share of excellent pitches, as seen by the company's current portfolio. "The best pitch is one that happens as a result of us proactively reaching out to a scientist or innovator and where they tell us about their work and ideas. For us, the best of these involve a high level of novelty coupled with deep knowledge of a given field. For example, one scientist we are working with has an entirely new perspective on how the immune system functions that could fundamentally alter the field," says Zohar.

However, with the good comes the bad, and she has seen pitches that clearly have not been very well thought through. "The worst pitch is one that feels generic and is targeted very broadly and is clearly being sent to many people at once. This can result in us being approached by an entrepreneur who clearly has no idea where we are focused. We work in venture creation and seed investments, so when someone comes to us proposing a large Series D round, that signals that they haven't taken the time to look at what we actually do and that they haven't really thought through their funding strategy and prospects. These mistakes could reflect on other decisions that they have made or will make in the future. Another thing that can reflect negatively is if someone comes to a venture firm and mentions other venture firms they are talking to by name. For us that is a surefire way to make us lose interest fast, because we pride ourselves on being ahead of other firms. You can also lose a competitive dynamic by telling one venture firm about others you are talking to."

Throughout this process, she has learned lessons, too — for instance, how much credence to put on gut feelings. "Opportunity analysis is a balance between feeling in your gut that something is a great idea and then validating that gut feeling independently. If you only follow that 'gut' excitement, there is a risk of devoting yourself to a project that has flaws. On the other hand, if you are too aggressive in looking for a reason to kill a project, pretty much every project (even great ones) can be snuffed out. Finding that optimal balance is a career-long endeavor," says Zohar.

Overall, Zohar advises those seeking VC funding to be innovative, to learn to balance gut feelings and validation, to think through the strategy, to do research when creating a pitch, to consider a number of routes for funding, and to keep certain things confidential. Actually, these are probably a wise set of rules by which to run any business, whether start-up or established.

To a courier, this is just another box.

To Marken, this is a fragile drug in your Phase III clinical trial.

When a study depends on the integrity of the drug being administered, any excursions can compromise the entire clinical trial. At Marken we understand this better than anyone because Life Science is our business. Marken is led by experts from the pharma industry with deep knowledge of worldwide logistics and pharma regulations. Our global Pharmaceutical Service Network is purpose-built for the secure storage and distribution of your valuable IMPs and medical devices, while our temperature-controlled depots offer a host of services, from pick-and-pack to return and destruction.

When it's out of your hands, it's in ours.

MARKEN®

Global Life Science Supply Chain Solutions

Call (800) MARKEN1 to speak with a Marken drug distribution specialist today.

marken.com

The Long Road To Serialization

By Gail Dutton, contributing editor

The on-again, off-again efforts of the United States to implement serialization are on again, with a one-year phase-in scheduled to begin Jan. 1, 2015. At that point, California's regulations become the de facto standard for the country. While large pharmaceutical companies are developing plans and piloting projects, smaller companies are maintaining a wait-and-see attitude.

Such hesitation is logical, given serialization's regulatory history. Serialization and track-and-trace concerns began with the Prescription Drug Marketing Act of 1987. The 21CFR Part 203 section of that act was intended to provide guidance for the FDA and the life sciences industry regarding enforcement efforts related to ePedigree requirements. Although 21CFR Part 203 was published in 1999 for implementation in 2000, implementation was delayed repeatedly until an agreement on definitions was reached in 2006. In the meantime, California, Florida, Texas, and New York developed their own ePedigree laws.

Because manufacturers don't segment the California market, its regulation, which takes effect Jan. 1, 2015, effectively sets the standard for the United States. According to California Board of Pharmacy documents, "The goal is for any owner/possessor of a prescription drug located at a licensed wholesaler, repackager, reverse distributor, or pharmacy in California, upon request, to have and keep electronic records that show the lineage of the drug from the manufacturer through to the current point in the drug distribution channel (wholesaler, repackager, pharmacy)." More specifically, it calls for an ePedigree, interoperability, and serialization at the unit level and includes repackaging and returns. Implementation will be staggered, with completion mandated by the end of 2015.

SERIALIZATION DRIVERS

"The California Board of Pharmacy was concerned about counterfeiting and patient safety," recalls Greg Cathcart, CEO of Excellis Health LLC. It worked with the California state legislature to pass anticounterfeiting and antidiversion legislation (SB 1307) in 2004 that mandated an ePedigree for drug distribution, according to the California Board of Pharmacy. Portions of that legislation were enacted in 2005 and 2006. At about that time, Katherine Eban's book, *Dangerous Doses: A True Story of Cops, Counterfeiters, and the Contamination of America's Drug Supply*, was published, underscoring the need to secure the pharmaceutical supply chain. Then, in 2006, the California Board of Pharmacy sponsored legislation that clarified the ePedigree requirement and moved implementation of that component of the law to 2009.

While California was developing serialization guidelines, the pharmaceutical industry was going global. Manufacturing began moving overseas, with pharma companies working with CMOs internationally and by establishing their own manufacturing facilities. Many of these facilities were in emerging nations that lacked a strong pharmaceutical industry and regulatory framework. Because regulations often were weak, it was easy for organized crime to become involved, building a business that was considered less risky than smuggling narcotics, but equally lucrative. A stretched, fragmented supply chain made counterfeiting relatively easy.

Against that backdrop, patient safety is a primary driver, but there are additional concerns. "European nations back serialization as a reporting mechanism for healthcare providers to receive reimbursement from their government health programs for medications they dispense," Cathcart says. In emerging nations, protecting the brand image is a potent driver to serialization. In India, the law requires manufacturers to serialize only drugs manufactured for export and to report the serialization to the government. If the drugs are for India's domestic market, serialization is unnecessary. "India realized it had a counterfeiting problem and wanted to protect its image as a good place for pharma manufacturing," he adds.

INDUSTRY PREPARATION

For the pharmaceutical industry, the challenges of preparing for serialization have been noteworthy. As Natalie Lotier, VP of strategic supply chain operations and planning for Bristol-Myers Squibb (BMS), recalls, "Within the industry, there was uncertainty surrounding the guidance for the protocol." Technology to implement serialization and track and trace was still emerging — and continues to emerge.

In the time since the first serialization laws

were passed, the industry has rightly sensed that guidelines could continue to evolve. In fact, the permissible technologies are still being determined. For example, this past February (2012), the FDA closed its comment period regarding the use of RFID as a technology to enable track and trace. According to CBER (Center for Biologics Evaluation and Research) spokesman Benjamin Chacko, "The comments will be reviewed, but no date has been set for a decision." Even in late 2011, the California Board of Pharmacy continued to work on the regulations.

As the serialization and track-and-trace guidelines were being developed and then delayed, pharmaceutical companies had several questions to address. Tracking the regulations and their evolving requirements necessitated the involvement of multiple departments, causing leaders to question where the project fit into the organizational structure. Regulatory affairs, information technology, manufacturing, and supply chain were all involved at a foundational level.

At BMS, IT was involved early in the process and collaborated closely with other business units. "Industrywide, IT departments struggled to understand the standard and to select partners with the right capabilities," says Terry Young, director of enterprise data operations at BMS.

When the standards were first introduced, the pharmaceutical industry had little involvement. In the intervening years, when implementation was pushed back from 2009 to 2011 and then again to 2015, many companies shuttered their programs, waiting for certainty. According to Lotier, during those times BMS focused on strategic awareness and development as it continued to track international serialization efforts. BMS also established its supply chain integrity council to provide global visibility into the international supply chain, including serialization and track-and-trace issues. With insights gained from its global supply chain council, BMS has been putting together its global plans.

Like other industry leaders, BMS is working proactively, providing input to standards and regulatory bodies and serving on GS1 committees. "We have people who are dedicated full time to understanding the regulations and responses," Lotier notes.

Additionally, Young says, "We have developed formal and informal networks within the

industry to help us appropriately interpret the regulations. When a new regulation is published or a change occurs, it's sometimes subject to interpretation. In some mature markets, the regulations are self-explanatory. But in emerging markets, the regulations aren't necessarily as clear. Therefore, discussions with regulatory authorities are required." Collaborative networks within the pharmaceutical industry help keep the companies up to date on changes in regulations that sometimes are evolving monthly, as well as to develop consistent interpretations of the requirements so the industry speaks to regulators with one voice.

> "We have people who are dedicated full time to understanding the regulations and responses."
>
> Natalie Lotier, VP of strategic supply chain operations and planning, Bristol-Myers Squibb

INTERNATIONAL MOMENTUM FOR SERIALIZATION

While serialization regulations are pending in the United States, Canada, and the EU, they are already implemented in several other nations. Regulations are in place today in Turkey, India, China, Brazil, Argentina, and South Korea. Brazil launched a three-year rollout of track-and-trace requirements in 2009, culminating at the prescription level in January 2012. "Because the final requirements were changed at the last moment without industry consultation or time for adjustment, few, if any, pharmaceutical companies operating there are in compliance," Cathcart speculates.

In Asia, India's regulations went into effect July 1, 2011, three months after the industry comment period closed. The country mandates a bar code on every pharmaceutical exported from India, in an effort to thwart counterfeiting. China, in 2010, mandated that a "drug electronic supervision code" be printed on the smallest sales package by March 31, 2011. If the package is too small, it may be printed on the larger packaging.

In Europe, several individual countries have their own guidelines, in addition to those pending with the EU. French manufacturers must meet the EU requirements as well as slightly different national requirements mandating that lot, serial number, and expiration date must be readable by humans. That human-readable requirement poses obvious challenges for small packages. In contrast, Belgium's requirement for sequential codes for medicines was published in December 2003 and implemented July 1, 2004. It calls for a 16-digit sequential code, structured as a product identification number, sequential number, and check digit. Unlike the EU requirement, it does not mandate a batch number or expiration date as part of the code.

Despite such differences, each nation's regulations tend to be built around GS1 standards and are sufficiently similar so that pharmas, generally, can develop one program that meets all the global requirements. "The pending EU and California regulations, for example, only differ at the data transmission level," Cathcart explains.

Although the GS1 format is the favored standard, ISO, IETF (Internet Engineering Task Force), and other competing standards also may apply to serialization. GS1, for example, has multiple standards that could be applied, including the GS1 Drug Pedigree Messaging Standard (DPMS) that governs track and trace. Additionally, Dirk Rogers, owner and sole contributor to the blog RX Trace, points out, "There is some confusion in the industry about how to link the National Drug Code [NDC] and serial number of the repackaged drugs with the original manufacturer's NDC and serial number on the source drug packages. This linkage cannot be done within an RFID tag or a bar code. That's because these data carriers are not the pedigree." Companies, consequently, are confused about which standard to use.

ePEDIGREE IS ANOTHER SEPARATE CHALLENGE

Serialization is just one part of the challenge. The ePedigree is the other part. "The Network Centric ePedigree (NCeP) work group of the GS1 Healthcare Traceability group recognized that the current California pedigree law, as written, leads you down a path that only ends up at a document-based approach to compliance," Rogers points out. "In the United States, the thinking is a new federal pedigree law may define a network-centric approach to pedigree that aligns with one of the models defined by the NCeP group, and — most importantly — that it will preempt the California pedigree law so the industry can veer away from document-based compliance before the deadline.

"If Congress does not enact a new law that can be met by 2015 using a network-centric approach, then companies will need to invest in DPMS-based systems. Those systems would almost certainly also make use of the EPCIS (Electronic Product Code Information Service) standard to capture and hold serial number events, but those events would be encapsulated in DPMS pedigree documents for exchange," Rogers concludes. Given the frequency of the delays in implementing a U.S. serialization strategy and the still-evolving changes in the regulations, it's no wonder that pharmaceutical manufacturers are cautious.

Editor's Note: This is the first of a four-part series examining serialization strategies in the United States. Part two will look at strategies pharma manufacturers are using to meet the requirements for item-level serialization.

Racking Your Brain Trying to Find the Right Drug Safety Solution?

Let Sentrx help.

Sentrx is the <u>one</u> place for all of your drug safety needs.

Your One-Stop-Shop:

- ✔ Hosted Oracle Argus Safety Database
- ✔ Hosted Oracle Argus Interchange for Electronic Case Submission
- ✔ Proprietary Technologies for Post-Marketing Safety (Medical Inquiries, Product Complaints and Adverse Event Intake)
- ✔ Proprietary Technologies for Case Management and Compliance
- ✔ Proprietary Technologies for REMS Registry Needs
- ✔ Variable Case Pricing Based Upon Level of Effort
- ✔ Technology Services Desk
- ✔ Medical Affairs Call Center for Medical Inquiries, Product Complaints and Adverse Event Intake
- ✔ REMS Assistance and Customized Workflows
- ✔ DSUR and Other Safety Reporting
- ✔ Audit Ready (Clients and Health Authorities)
- ✔ Quality Tracking and Reporting
- ✔ Training Provided through Sentrx University and Kaplan EduNeering
- ✔ Enormous Pool of Health Care Professionals within Sentrx Patient Safety Nation

sentrx safety solutions

Overlook at Great Notch
150 Clove Rd, 2nd Floor
Little Falls, NJ 07424
www.sentrx.com
888-399-8032

Corporate Espionage Is Real — Even In The Pharma Industry

By Jonathan Snyder

Imagine you spent the past 15 years of your life passionate about finding a cure for Alzheimer's. You stayed up nights struggling to continue your research, yet you were running out of funding. Knowing your competitors were years behind your research, you finally found your angel investor who provided the seed capital you needed — but with the time-sensitive precondition that you must provide a return on investment within two years or they would pull your financing.

A year later, your team made incredible headway into your research. Passionate about his work, one of your most seasoned research scientists innocently had taken his research home on his laptop. While he was traveling home for the weekend via the airlines, he logged on to the free airport Wi-Fi to check his emails. Sounds innocent enough, right? Six months later, though, a competitor that the industry previously discounted as unworthy of concern, starts to announce eerily familiar breakthroughs in Alzheimer's research. You scratch your head, wondering how they could have made the same advancements as you in such record speed. In six more months, they received a patent for the drug and went public with the cure for Alzheimer's, not to mention reaping recognition and profit for the work your team created. Fifteen years of your life's work is in someone else's hands, and your company's investors and employees bail. Now what? This story may sound far-fetched to you, but it is much closer to the truth than you know.

A RISK THAT CAN AFFECT ANY SIZED COMPANY

Espionage is as prevalent today as the flow of the ocean tides 1,000 years ago. The FBI estimates from $2 billion to $400 billion in technologies, inventions, and intellectual property are stolen every year through an invisible network of corporate espionage by a multitude of actors that come in every shape and size and from various geographic regions and economic capabilities.

Corporate espionage is real, with real players and real impact on the future of any company and, in some cases, the domestic product of countries. When there is major investment at stake that will change the tides of economic prosperity, political capacity, military prowess, or a competitor's reputation, you can surely bet that an organization will be targeted by illicit eyes.

Some of the greatest and most recent examples of espionage have brought together industry behemoths into a web of deceit, betrayal, and major competitive loss.

In 2009, Starwood Hotels accused Hilton Hotels of corporate espionage. Hilton baited 10 Starwood executives and managers to steal the intellectual property of a new brand idea of Starwood Hotels and then bring the truckload of competitive documents to their new employer at Hilton. After a well-planned infiltration hiring process, the former Starwood executives began secretly transferring competitive information back to Hilton headquarters. The espionage was so well-played and detrimental to Starwood's business that Hilton was ordered to pay Starwood millions and also forbidden from developing a competitive brand until 2013. In further recognition of their intentional espionage, federal regulators were assigned to monitor the business activities of Hilton's empire.

THE PHARMA INDUSTRY IS AT RISK

The formidable espionage challenges facing the pharma industry have become a growing concern internationally. The issue has become so mainstream, global insurance underwriters such as Lloyds of London and Heath Lambert and Samian have created an entire pharma-related department dedicated to protecting their clients against corporate espionage. With the targeting of intellectual property and corporate secrets and the industry's growing reliance on outsourcing, pharma has earned its place in the spotlight of espionage.

In 1997, Bristol-Myers Squibb (BMS) got to experience espionage firsthand when Hsu Kai-Lo and Chester Ho were arrested and pleaded guilty to stealing certain plant cell culture technology specific to the drug Taxol (pacilitaxel), a product of BMS.

In the last decade, technology has been a game changer in the espionage realm,

DR. REDDY'S

More Than Meets The Eye

API & Intermediates
Development

cGMP/FDA Approved
Manufacturing Facilities

PEGs

Chirals

HPAI, Steroids,
Prostaglandins & Complex
Carbohydrate Chemistry

Formulation Development, Customised Solutions
& Manufacturing

Dr. Reddy's Laboratories Ltd,
Custom Pharmaceutical Services
US: +1 908 203 4932
EU: +44 1223 728010
India: +91 40 4465 8888
www.drreddys-cps.com
cps@drreddys.com

CPS
MORE THAN MEETS THE EYE

which has dramatically increased the pharma industry's loss of secrets — and revenue. The use of technology by corporate spies is so effective that pharma has earned second position to financial institutions in cyber theft incidents.

The pharma industry has many reasons to be concerned about espionage. Based on the industry's need to conduct research and clinical trials on exploratory drugs, there is the issue of animal testing, which has exposed the industry to alternative espionage threats, such as physical threats that include catastrophic violence from subversive wings of animal activist groups.

In 2001, Unilever was targeted by Proctor & Gamble. P&G described the situation as an "unfortunate incident," yet admitted no wrongdoing. P&G did agree to abstain from using the information in its future product development and eventually settled the case out of court to avoid possible criminal consequences to its executives. The incident went on record as one of the most obvious cases of espionage in recent corporate history. The blatant arrogance and complicity of their staff was revealed during an examination by investigators of their facility trash bins. While going through the discarded material, multiple letters were identified wherein P&G executives put in writing what they had done and how their plan would crush Unilever forever.

A GLOBAL THREAT

In modern times, China is the number-one perpetrator of corporate espionage from both a commercialized and military perspective. With a historically turbulent political system and an economy based on unfair governmental practices, currency manipulation, and abuse of the labor force, China has somehow still been able to gain substantial ground-breaking advancements in the scientific and technological industries — mostly in part due to their insidious appetite to steal the research and technologies of others.

What makes the outright theft and production of pharmaceutical breakthroughs attractive to China? The Chinese have a major problem — almost 1.4 billion people, and of those, 167 million are considered part of the aged population. With a lack of medical capacity and the high costs of pharma, China has taken to stealing the very technology their manufacturing facilities benefit from. In addition to China, countries such as Russia, Iran, Israel, and certain South American countries all are in the running to identify game-changing data and technology that will give their country competitive superiority.

Even worse than the thought of a major transnational conspiracy involving state-sponsored espionage is number-one culprit of corporate espionage — the threat from "insiders." It is true that espionage actually sounds sexier and more intriguing when you think that some country such as Russia has its eyes set on you, but the reality is that employees at all levels of the corporate structure are the main perpetrators of malicious threats, which cost corporations billions of dollars annually.

STEPS TO TAKE TO PREVENT CORPORATE ESPIONAGE

Rather than focus on the myriad of potential corporate espionage dangers, the bioscientific community should be more concerned with learning how to stop — or at least significantly mitigate — the threat or action of stolen commodities and ideas that are the lifeblood of their organizations. There are ways to make it more difficult for corporate espionage to succeed within the walls of your company, but it takes serious planning and a strong commitment to the concept and implementation of threat mitigation/counter-intelligence tactics to keep your company ahead of the curve. Companies first need to understand that if what they do, create, or sell has admirable value, then someone, somewhere, will consider how to obtain it illegally for their own benefit — whether based on a financial, political, or military need. Denial or complacency is the first stepping stone to placing your organization on the easy-target list.

Second, understanding corporate espionage and the tricks of the trade are not learned skills which every security director, risk manager, or general counsel may have knowledge of in depth. I have witnessed very smart executives who believe their internal general counsel can protect them from espionage, as well as the belief that their security director, who has been a police officer for 20 years, would be the right candidate to protect their secrets. The practice of this philosophy is shortsighted and naïve.

Giving proper kudos to those professionals who may bring significant experience in other disciplines to the corporate table, it still bears the billion-dollar question, "How can you keep your secrets just that — secret — especially in this world of data expediency and information overload, where there is a plethora of 'trained' professionals who make their living in the low-profile, high-risk, high-reward world of corporate espionage?"

In reality, corporate espionage is a relevant fact of commercial activities which must be dealt with in a proactive manner. There is a circulating quote in the industry that states: "It took 20 years to develop and only 15 minutes to steal." This has never been truer than it is today.

With the goal of eye-popping profiteering as the main catalyst to corporate espionage, the problem will not just go away. It is not unusual for pharmaceutical companies to introduce a single drug to the market which generates billions in profits. This is more than a motivator for all types of espionage-laden activities.

As a key decision maker who is charged with generating profits and protecting the umbrella of people and investment that is the lifeblood of your company, it is imperative you give proper consideration and attention to the real world of corporate espionage and how it may affect your organization — before it is too late.

About the Author

Jonathan Snyder, CGC, CHS, is a 20-year veteran of the security and intelligence community and serves as the president & CEO of Argus International Risk Services, Inc., a global provider of security, intelligence/counter-intelligence, specialized training and risk management solutions to the Fortune 500, federal agencies, and the Department of Defense.

GLOBAL ADVANTAGE

LabCorp Clinical Trials is focused on being the leading global provider of laboratory testing services for clinical trials – that's our entire focus and mission.

We offer clients one of the largest and most comprehensive test menus at our wholly owned central labs and regional specialty labs in Asia, Europe and North America.

LabCorp Clinical Trials provides an unprecedented level of expertise with over 30 years experience working on thousands of studies across all major therapeutic areas. From large global safety studies to the most sophisticated esoteric tests – we have the people, resources and capabilities to exceed expectations.

No matter the scientific question, our goal is to be there with the optimal solution as your one global lab partner.

LabCorp
CLINICAL TRIALS

For more information, please visit
labcorp.com/clinicaltrials

5 Strategies To Accelerate The Transformation Of The Pharmaceutical Industry

By Ed Giniat, David Blumberg, and Chris Stirling

The pharmaceutical industry has performed disappointingly over the last 10 years, relative to other industries, and is facing a future with lower growth prospects than in the past. In fact, IMS forecasts global spending on medicines will reach $1.1 trillion by 2015, but the revenue growth rate will slow from 6% between 2005 and 2010 to 3% to 6% between 2010 and 2015.

Additionally, research and design productivity is declining — returns have nearly halved over the last 10 years, according to research — and scientific, political, legal, and personnel risks are all rising. In the United States, the number of pharmaceutical industry settlements with state and federal government has risen dramatically over the past decade.

However, the situation can and is changing as pharmaceutical companies alter the way they are organized and operate, set prices, incorporate more efficient development spending, and have a more dynamic approach to risk reporting with greater disclosure of potential and actual risks. In fact, during the next 10 years, the pharmaceutical industry could deliver growth in line with real GDP (3% to 5%).

To accomplish this, the industry needs to redefine itself in the minds of shareholders, stakeholders, consumers, and governments. Companies need to demonstrate the value of their products (and services), and returns need to be more predictable. Companies can do this by reassessing their product strategy, investing in their marketing and sales infrastructure, acquiring more talent and experience from other industries, using internal rates of return to prioritize and rationalize the R&D portfolio, and reviewing and revising their governance standards.

REASSESS PRODUCT STRATEGY

Products must take into account the needs of consumers in emerging markets. The recent volume increases reported by some companies for products for which prices have been substantially reduced indicate a path the industry must pursue. Emerging markets offer largely blank slates. Using an adapted "Old Western" model of the drug industry will miss a significant opportunity to redraw how the industry interacts with patients and governments. Today, pharmaceutical leaders should focus their business strategies on delivering high-value modern medicines to emerging markets at much lower prices than have been accepted in Western markets. Doing so would underpin a root-and-branch reassessment of the costs of bringing these medicines to market, the marketing and sales support required, and the risk of counterfeiting and parallel trade. Taking this approach also should drive strategies regarding clinical development, location of trials, marketing plans, sales infrastructure, and manufacturing investment. The opportunity for biologic therapies for cancer, for instance, is very large, providing the right pricing strategy can be developed.

Emerging market governments are moving rapidly to increase medical consumer spending. As generics become more commoditized, the use of "established generic" growth routes in emerging markets could run out of steam. That's why every possible opportunity to drive consumer/OTC business in these markets should be explored, in addition to a focus on speed to market and lowering the costs of development and efficient delivery of appropriate, differentiated, quality prescription products.

INVEST IN MARKETING AND SALES INFRASTRUCTURE

Pharmaceutical companies must accelerate the modernization of selling and marketing in mature markets. The key to doing this is mapping the new technology opportunity with the business in a sustainable and updatable way. For instance, investment in technologies such as using QR bar codes to transmit information to physicians might mean improved efficiency to a pharmaceutical company's sales force.

print, verify and weigh

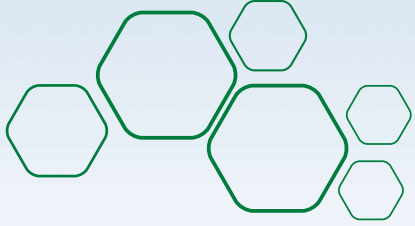
The new track and trace standards for the pharmaceutical industry are on its way. Thermo Fisher Scientific can help you prepare for these changing regulations by providing solutions that work for new and existing packaging lines. One solution is the new Thermo Scientific Versa RxV, which provides printing, verification, and checkweighing in a single platform.

Thermo Scientific Versa RxV
Combines marking, verification and weighing functions into one system

integrated track and trace solutions

Thermo SCIENTIFIC

- Learn more about the Versa RxV by calling 1-800-227-8891 or at **www.thermoscientific.com/productinspection.**



Business leaders in key emerging markets need to develop investment plans that support new marketing and sales strategies and operating models that reflect what these emerging markets will become, not those that they are today. Merely adding more sales professionals on the ground in a traditional model does not seem an appropriate strategy for the future. A traditional model may be of help initially in building a presence, but plans should be regularly reviewed and realigned.

Finally, companies should accelerate development and integration of social media. Being prepared to use social media might be a key competitive advantage in many markets. For instance, social media use is higher in emerging markets as compared to Western markets, with more than 70% of the population of the Philippines and Malaysia, for example, as active users of social media.

ACQUIRE MORE TALENT AND EXPERIENCE FROM OTHER INDUSTRIES

Within the last five years, in aggregate, less than 20% of executive team members within the pharmaceutical industry have come from outside the industry, according to our research. CFO is the most common role now filled by individuals with industrial experience from outside the pharmaceutical sector. Their fresh thinking has improved the scale and speed of efficiency programs at several companies.

To be sure, some companies have recruited new talent in the areas of manufacturing, administration, and R&D, but there is more to do. Indeed, fresh approaches to key account management in marketing and sales may be the areas of greatest need, given the shifting nature of both traditional Western and emerging markets. In particular, regional and country management would benefit from having experience from other sectors. With the old "sales rep calling on doctor" model now fading away, the industry should look to import key account management techniques from other sectors.

USE INTERNAL RATE OF RETURN TO PRIORITIZE AND RATIONALIZE THE R&D PORTFOLIO

All companies should have a standardized approach to show the internal rate of return (IRR) on past investments and an internal perspective on what the range of returns is forecast from the current investments, as well as the assumptions used in these projections. Such analyses should also include off-balance-sheet funding through partnerships and minority investment in third-party companies (typically development-stage biotechnology companies). This type of IRR-based information could transform the investment decisions recommended by senior management in the industry and signed off by boards of directors.

Additionally, companies should reevaluate the value proposition of all Phase 2, Phase 3, and registration assets on an IRR basis. This review should include a detailed review of the assumptions that supported development of these assets. Consideration could be given to whether the forecast returns could be improved by partnerships or comarketing arrangements.

> The industry needs to redefine itself in the minds of shareholders, stakeholders, consumers, and governments.

R&D finance is also key to reducing operational obstacles that slow the progress of product candidates to market. Companies should conduct a timely analysis and financial review through the introduction of early warning indicators and go/no-go checkpoints based on financial analysis and evaluation.

REVIEW AND REVISE GOVERNANCE STANDARDS

Companies need to conduct a root-and-branch review of governance and enterprise risk management across the entire value chain, from early research and development, through late-stage development, and from manufacturing to sales and marketing. Such a review will help leaders appreciate the impact from speed of change and the increasing pressures on each link of the chain.

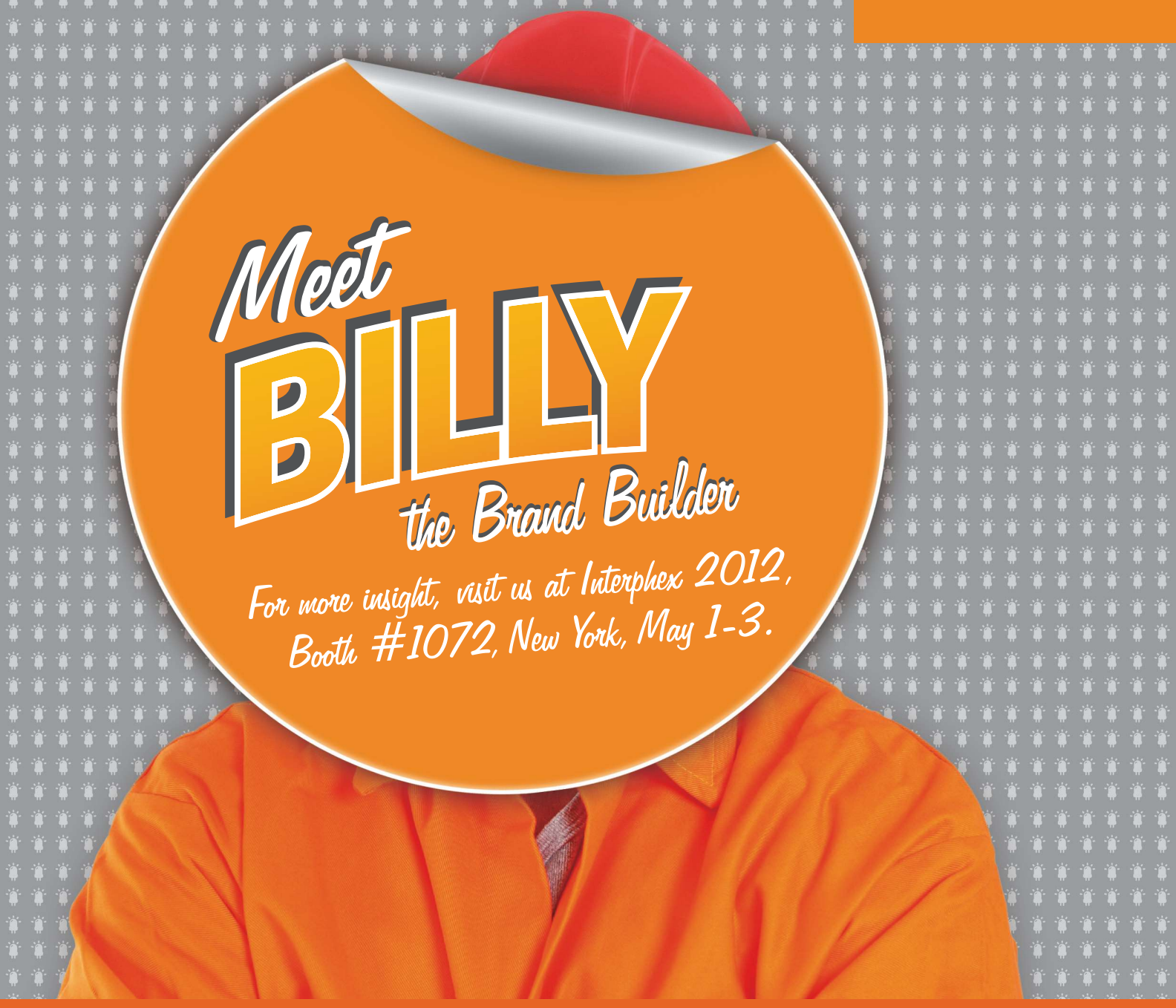
To deal with the new risks, companies should implement internal independent checks and balances where people review each stage and have a reporting line outside of that area's direct access to C-suite executives. Additionally, power and credence should be given to internal audit groups and their outputs. Finally, companies should use independent and external experts who are allied with ethics, risk, and governance as a final check and balance for each element of the value chain.

About the Authors

Ed Giniat is a partner and global chair, David Blumberg is a principal and global advisory leader, and Chris Stirling is a partner and European sector leader, all with KPMG's pharmaceutical practice.

This commentary represents the views of the authors only and does not necessarily represent the views or professional advice of KPMG LLP.

thatsnice



Ready to Build

That's Nice is a full-service strategic marketing agency with 17 years of experience in branding and marketing for global science-based companies. Nice Insight is our subsidiary that provides quarterly intelligence driven by primary research among 3,500+ outsourcing executives, offering a more informed basis for strategic decision making.

Call us at **+1 212-366-4455** or visit **www.thatsnice.com** for more information.

niceinsight
Quarterly Intelligence

nicexhibit
Turnkey Exhibit Design & Fabrication

niceshort
CGI Animation Studios

NiceGift
Gift & Premium Distributor

Creating A Start-Up: Private Or Public?

You're prepared to launch your start-up company, but now you're faced with a difficult decision: private or public?

First, ask yourself, why go public? Is it for investor returns, exit for founders, access to capital, M&A, or something else? The only companies achieving and benefiting from IPOs have actual revenue or are very close to revenue. They receive analyst coverage and media attention and, if successful, reap the rewards. Most others will be penalized by public markets for not hitting targets, needing to raise further cash, low trading volumes, product failures, down-markets, or recessionary influences. If a nonrevenue-generating company has market support in the form of investors and analysts, it is much more likely to continue to have its valuations supported.

On the other hand, private companies are somewhat immune to down-markets if they do not need to raise further financing. It is only when financing is to occur that they need to deal with valuation concerns.

A key driver for the decision to go public is the availability of funding sources and management's experience and relationships. The VC model for funding is relevant for those companies that have the luxury of longer timelines, have a limited operating history, or have not yet reached a point where the fundamentals of the company allow for the best economics and intrinsic valuation to be realized.

A DECISION BASED ON MULTIPLE FACTORS

Many successful companies were formed from angel investors, seed funding, and strong VC backing. We have all seen IPOs for strange products and public companies that have failed, yet there are hidden gems that continue to fly under the radar of the public markets, become larger, and build shareholder value — but in a private company setting until forced to go public for regulatory reasons. With an experienced management team familiar with the capital markets, seeking a public listing through an IPO or reverse merger is beneficial for broader visibility and the ability to reach potential investors. Small companies that choose to go public need strong banking endorsement from a firm interested in the company's needs and cannot be motivated solely by the economics of a megamillion-dollar IPO that leaves clients hanging with no post-IPO support. If the base is not there, it is a steep and risky hill to climb — in which case, staying private with strong investor backing is needed until the company is ready to go public. Public companies are subjected to many complexities such as absolute transparency, more shareholders to deal with, more compliance and regulatory guidance, more costs, and more scrutiny. You better be ready to compete with different stakes and more eyes watching every move.

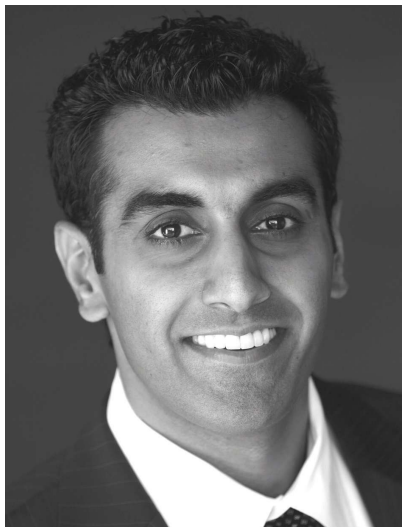
A company should not go public if it has no viable reason to do so: Investor and founder liquidity should not be the sole reason. It either needs revenue or very good market support, or it will suffer.

Before going public, a company needs a clear business strategy and exit opportunity, whether it is product commercialization, M&A, or out-licensing. Then it needs to be adaptable to market-driven conditions. If a company does not have these figured out, it will have a tough time being public because it is not adequately prepared for the expectations of a broader base of shareholders.

Despite these caveats, hundreds of companies will go public with an early-stage clinical development plan, including outliers. The underlying technology and product will drive this decision, while the board of directors and management team must ensure the successful execution of the business plan.

Another consideration is that IPOs spur job creation and are thus good for the country. Unfortunately, the extensive attention to new regulations for public companies has thwarted the public company market, from more than 8,500 companies in 1999 to a little over 5,000 companies in 2011. Meanwhile, foreign markets have now surpassed the United States in the number of public companies. There are many macroeconomic issues here, but the bottom line is that when answering the tough question of "where can stimulation of growth begin?" I believe the public sector will play a fundamental role for economic recovery in the U.S. market, since it is one of the largest in the world.

In summary, the decision of private vs. public for your start-up depends on factors that will vary widely from case to case. A serious appraisal of how your product will be valued by shareholders today is necessary before deciding to go the latter route.



Punit Dhillon

Punit Dhillon is president and CEO of OncoSec Medical Inc., a biotechnology company developing advanced-stage Oncology Medical System ElectroOncology therapies to treat skin cancer and other solid tumor cancers.

what's your BIO?

For business leaders, it's a marketplace of INNOVATIONS to keep you on the cutting edge.

Explore innovative solutions from 1,800 companies in the BIO Exhibition. Meet with innovators—potential partners from 4,000 companies looking to advance their objectives. BIO connects you with thousands of opportunities to innovate through the new technologies, connections and ideas you'll find here.

Bio International Convention

The Global Event for Biotechnology

June 18–21, 2012 ■ Boston, MA

CONNECT. PARTNER. INNOVATE.

Register today for Full Convention Access & Partnering at convention.bio.org

Follow us:

A SERVICE OF: Bio BIOTECHNOLOGY INDUSTRY ORGANIZATION

Companion Diagnostics:

Improving Drug Development And Medical Practice

Companion diagnostics (CDx), which identify and detect biomarkers to predict whether a drug works or causes adverse effect in patients, has emerged as an exciting new field. With the cost and hurdles for new drug approval getting increasingly higher, pharmaceutical companies have begun to explore companion tests in order to develop safer, more effective drugs. The value of CDx tests has already been demonstrated by a number of marketed products, such as HercepTest for Herceptin and K-RAS mutation tests for Erbitux and Vectibix.

Oncology is the most developed segment of this market with products and tests representing more than 48% of the CDx development market. Recently, the FDA approved two drugs and their accompanying tests. Pfizer's Xalkori for lung cancer, which was approved in record time, has had great results for roughly the 5% of nonsmall-cell lung cancer patients that carry the ALK/EML4 fusion gene as determined by a test from Abbott Laboratories. The other drug, Zelboraf from Roche and Plexxikon, also has produced remarkable improvements but only for roughly half of melanoma patients whose tumors have a bRAFV600 mutation. The FDA approved a test from Roche's diagnostics division to detect the mutation.

THE CDx DEVELOPMENT PROCESS

CDx development can be divided into four steps:

1. Biomarker discovery includes identifying disease-relevant biomarkers and developing a test to measure each biomarker.
2. Analytical validation ensures that the performance of the test meets regulatory requirements.
3. Clinical utility and validity test, the most important and costliest part of development, has to prove that information generated has value in guiding clinical practice for patient management as required by the payers.
4. Data analysis and regulatory submission determines CDx performance by correlating the test's analytical data with clinical outcome information and then submitting the data package for regulatory approval.

COORDINATION OF CLINICAL TRIALS IN CDx DEVELOPMENT

Despite these proven successes and ever-increasing awareness of companion diagnostics, pharmaceutical companies are still moving slowly to adopt the new paradigm of codeveloping companion tests along with new drugs. The regulatory hurdles, physician and patient acceptance, insurance coverage, IP strategies, and other barriers remain unsettled for this young field. A well-coordinated plan of clinical trials can overcome some of these issues.

It is important to leverage both drug development and diagnostics expertise in trial design and execution. In order to prevent a slowdown of drug development due to the diagnostics timeline, you can use retrospective samples or samples from pilot trials to validate the biomarker before launching clinical trials. A preanalytical characterization of samples can help to define optimal tissue requirements. Also, address regulatory hurdles early on by scheduling pre-IDE (investigational device exemption) meetings and negotiating labeling of drug and diagnostics before approval. Regional differences in CDx product review and approval need to be considered.

Hua Gong

Hua Gong, M.D., Ph.D., is the executive director of medical diagnostics at Premier Research. Dr. Gong has more than 12 years of experience including both R&D and clinical expertise in the development of diagnostics.

IMPROVEMENT OF DRUG DEVELOPMENT

Many business models have been adopted for CDx development: Dx/Rx in one entity (Roche and Genentech), Rx/Dx partnership (Pfizer/Abbott), Rx acquire Dx (Novartis/Genoptix model). Regardless of which model one takes, early planning between the pharma and diagnostics companies will likely increase the chance of success in the development. Coordination of development timelines is essential in CDx development.

The recent success of Xalkori and Zelboraf serves as a testimony why companion diagnostics should be part of a drug development strategy. Pharma companies are more interested in stratifying patients for their clinical trials so that their drug will more likely demonstrate efficacy in the selected patients, leading to regulatory approval. Budget-conscious policymakers and payers like the idea of paying to treat only the patients who will benefit from the treatment, and physicians and patients are also keen as treatments are more likely to work for the patients. Innovation in technologies is expected to play a pivotal role. This also presents a great business opportunity; the global CDx market generated sales of $1.30B in 2010 and is predicted to be worth $3.45B by 2015.

Congratulations to Carolyn Buck Luce

2012 Healthcare Businesswomen's Association Woman of the Year

Ms. Buck Luce's accomplished career includes over 20 years at Ernst & Young, where she is the Global Pharmaceutical Leader for life science clients. The HBA community recognizes Ms. Buck Luce for her decades-long leadership in healthcare and life sciences as well as her tireless efforts for the advancement of women in the industry.

Please join us in celebrating her special achievement at the annual HBA Woman of the Year luncheon.

The Hilton New York | Thursday, May 3, 2012

- Reception: 10:30 AM
- Luncheon: 11:45 AM

HBA will also honor:

Mike Kaufmann, 2012 HBA Honorable Mentor
CEO, Pharmaceutical Segment, Cardinal Health

Nancy Larsen, 2012 HBA STAR
CEO, PROmedica Communications, Inc.

Registration Deadline

April 17, 2012

Grand Ballroom

- Member: $220
- Nonmember: $250
- Table: $2,350 (seats 10)

WOTY

HBAnet.org

HBA HEALTHCARE BUSINESSWOMEN'S ASSOCIATION

The Secret To Shifting Reality To Your Vision

Jesse Lyn Stoner

Has your team created a shared vision? Before you start setting goals and determining actions, assess your current situation. If you are only guided by a vision, you are in danger of setting unrealistic goals that cannot be accomplished.

As a team, have an honest and open discussion about what supports achieving your vision and what impedes you — what's working and what's not. It can be helpful to collect some data for this discussion to ensure your assessment is accurate.

This step anchors your vision and clarifies the gap so you can determine the best strategies, goals, and action steps.

But be forewarned — this is not as much fun as creating the vision. When you hold the picture of what you want and also take a serious look at your current reality, tension is generated. In an effort to reduce the tension, we are tempted to let go of our vision, thinking, "It's not what I really wanted after all" or "It's not practical" or "It's too hard."

Holding on to your vision while being realistic about your current situation at the same time generates tension. Robert Fritz, in his book *The Path of Least Resistance*, calls this "creative tension" because the tension helps create the future you desire.

It is a law of nature that tension seeks resolution.

When you accept the tension as inevitable and are willing to live with it … and
when you continue to hold an honest picture of your current situation … and
when you keep your vision front and center …
current reality will begin to shift in favor of your vision.

Use Tension To Your Advantage Rather Than Expending Energy Avoiding It

Have you ever gone fishing? Consider the difference between the fish that got caught and "one that got away." When hooked on a line, the fish that gets caught pulls against the tension of the line until it is worn out. Then it is easily reeled in. The smart fish swims toward the pole, keeping the tension loose until it finds a way to get off the hook.

The point is that it's important to recognize your current reality but not be overcome by the tension. Use the tension to your advantage. Don't let go of your vision.

When you are only focused on your vision, you see where you're going, but you are not grounded. When you are only focused on current reality, you start looking down at your feet, instead of where you're going, and your feet get stuck in the mud. When you hold a view of both your vision and your current reality, and when you accept the tension you experience as a result, you will be able to move forward with your feet solidly on the ground and with your sights on your vision.

Jesse Lyn Stoner is coauthor with Ken Blanchard of *Full Steam Ahead: Unleash the Power of Vision*, an international bestseller translated into 22 languages. A founding partner of the consulting firm Seapoint Center, her personal blog can be found at www.jessestoner.com. Follow her on Twitter @jesselynstoner.

To comment on this article, send an email to rob.wright@lifescienceconnect.com.

That's been one of my mantras - Focus and Simplicity.

We used to dream about this stuff. Now we get to build it. It's pretty great. – Jobs, 2004

As we celebrate our 200th single-use turn-key bioreactor system shipment, we continue to build on the foundation of our installed base, yet never cease in our quest for technical innovation.

We're gambling on our vision, and we would rather do that than make "me too" products. Let some other companies do that. For us, it's always the next dream. – Jobs, 1984

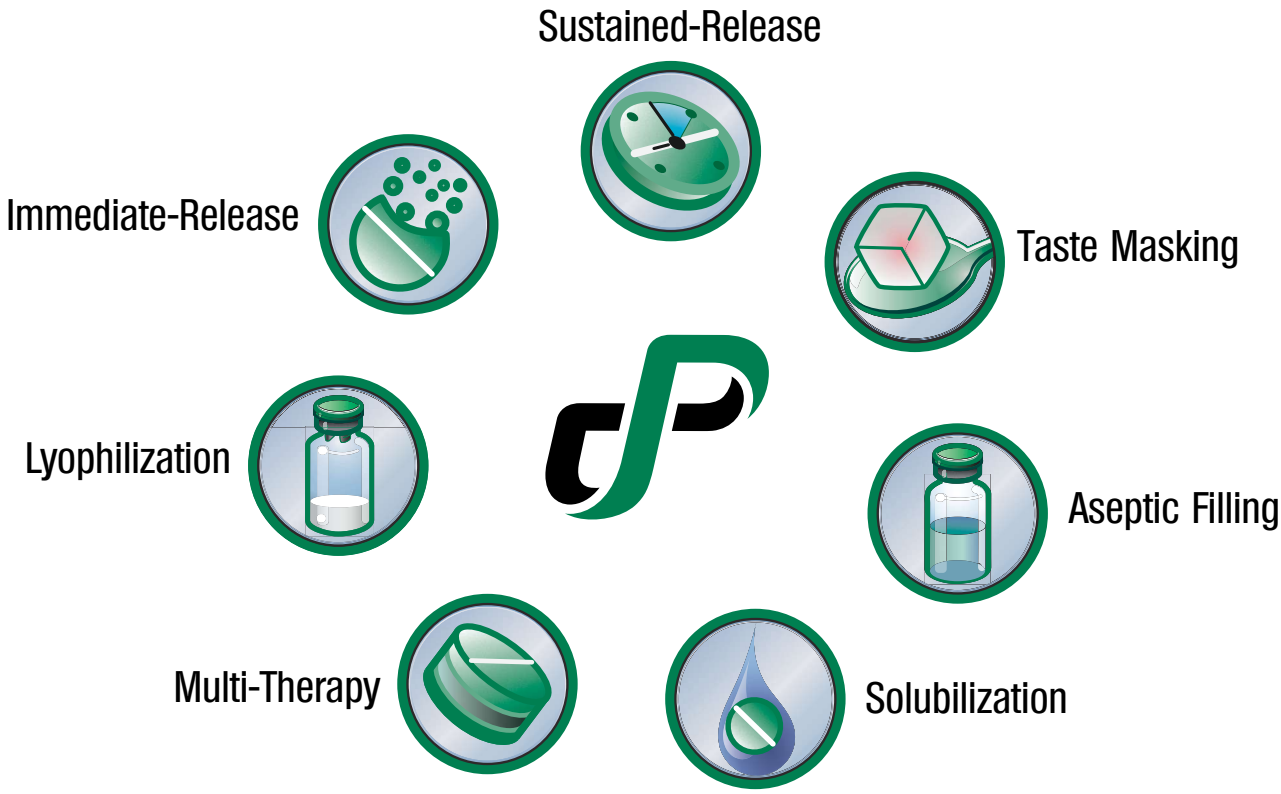
At Finesse, we will always take great pride in creating novel bio-process measurement and automation products that will enable our customers to develop and manufacture truly revolutionary solutions for life.

800-598-9515
finesse.com

In Europe, call: +41 81 641 20 00

Finesse

Choose Choice.



No other partner gives you more formulation options – royalty free.

Get access to the industry's widest range of complex formulation technologies for small molecules and biologics, and benefit from expertise forged over thousands of projects.

At Patheon, we're not tied to any technology. That means science alone drives the development of an optimal formulation, and you'll never pay us a royalty. Our commitment is to your success.

Choose choice – choose Patheon.

Visit Patheon at
INNOVATION + INTELLIGENCE + PASSION
INTERPHEX™ 2012
Booth 1418

Call +1 866-PATHEON (+1 866-728-4366) or email doingbusiness@patheon.com

US Headquarters

Patheon Inc.
4721 Emperor Blvd, Suite 200
Durham, NC 27703-8580
USA
P: +1 919 226 3200
F: +1 919 474 2269
www.patheon.com

European Headquarters

Patheon UK Ltd.
Kingfisher Drive
Covingham, Swindon
Wiltshire SN3 5BZ
UK
P: +44 1793 524411
F: +44 1793 487053
www.patheon.com

Published 2/12 PATH0236R0

Patheon™
Performance the World Over