BY ELISABETH PENA

Delivering ON THE PROMISE

Drug delivery promises **FULLER PIPELINES**, **EXTENDED PRODUCT LIFE CYCLES**, and **IMPROVED PATIENT COMPLIANCE**.

AS THE PHARMACEUTICAL INDUSTRY FACES A FLOOD OF BLOCKBUSTER DRUG PATENT EXPIRATIONS, DRUG-DELIVERY COMPANIES WILL HAVE THE CHANCE TO PROVE THEMSELVES.

BY 2005, analysts predict that 20% of all pharmaceuticals will involve drug-delivery formulations. Frost & Sullivan estimated the drug-delivery market at $19 billion in 2001 with an estimated value in 2007 at $41 billion. Driving the market's growth are efforts to improve the safety and efficacy of a drug, as well as providing maximum patient convenience.

Drug-delivery technologies can be applied to existing marketed compounds, not only to improve safety and efficacy, but to extend a compound's half life.

Also, for drugs that are administered through invasive techniques, such as infusion or injection, drug-delivery technologies provide patients with less painful and more convenient alternatives, such as pulmonary, transdermal, nasal delivery, or oral administration. In addition, these technologies can open the door for chemical entities that cannot be delivered through traditional means.

"Some drug substances will not be able to get to the marketplace unless they have the appropriate drug-delivery system — they may be just laboratory curiosities unless they are delivered in a specific manner with a specific type of system," says Felix Theeuwes, D.Sc., chairman and chief scientific officer of Durect Corp. "There are certain cases where the compound is found to have great activity, works in a disease environment, and has a pharmacological response, but it may have too short a

half life, or it may not be stable, absorbed, or potent enough because it doesn't get to the site of action. In all of those situations drug-delivery technology may remedy that."

While drug-delivery technologies have been enhancing the profile of many drugs for decades, their role is expected to expand as the genomics field strives to bring improved therapeutics to patients. Furthermore, as the flow of blockbuster drugs begins to slow down and the patents of major products approach an end, pharmaceutical companies are looking to drug delivery to fill their pipelines and extend the product lives of their existing portfolios.

"We expect pharmaceutical companies to start incorporating more advanced drug-delivery technologies into their offerings," says Ashwin Singhania, analyst for strategic market reports at Front Line Strategic Consulting Inc. "One of the ways that a drug becomes a blockbuster is that it shows an improved efficiency and effectiveness over other drugs that are out there, and alternative drug-delivery systems are definitely a way to help promote the effectiveness of a drug.

"Pharma is hurting for new products and putting a compound that they have already discovered into an alternative drug-delivery system is a great way to reformulate the drug," Mr. Singhania continues. "Drug delivery is a very good way for pharma to stay profitable and look good to investors."

COMPANIES HAVE BEGUN TO APPLY DRUG-DELIVERY TECHNOLOGIES TO EXTEND THE PRODUCT LIVES OF THEIR LARGE-MOLECULE BLOCKBUSTER DRUGS.

Drug-delivery companies are confident that they can provide the pharmaceutical industry with what it needs to bring products to market.

"There is an enormous appetite for new products that R&D productivity in pharma has been unable to satiate," says C. Boyd Clarke, president and CEO of Neose Technologies Inc. "Drug-delivery companies offer the opportunity for improved products to fill the pipeline, thus providing a less risky way to get products approved and on the market."

Chris Searcy, VP of corporate development at Inhaled Therapeutic Systems Inc., concurs. "Lifecycle management is going to become more and more important to pharmaceutical companies because the research productivity in terms of output for dollar has gone down and is expected to get worse before it gets better," he says. "That means there needs to be more focus on both expanding the molecule franchises that companies currently have and trying to extend them from a patent perspective. Because companies are working with existing blockbusters, employing drug delivery in the future creates the opportunity for more blockbusters."

GIVING NEW LIFE TO LARGE MOLECULES

Experts say drug delivery can be broken into two categories: technologies that address the administration of small-molecule drugs and those for large-molecule drugs.

The small-molecule marketplace is where the vast majority of drug-delivery technologies have been used to date, which is hardly surprising since more than 75% of prescription drugs are small-molecule drugs, including most of the blockbuster products on the market. That does, however, mean that much of the traditional small-molecule market has been saturated.

"While some value can be added to the small-molecule drugs that are coming off patent through drug-delivery technologies, most of those products are already orally available, and have been picked through," says Peter Lanciano, president and CEO of Altus Biologics Inc. "In the small-molecule arena it is increasingly more difficult to improve a blockbuster through drug-delivery technology because developing a drug to be more patient friendly has been an integral part of small-molecule drug development for years."

Advances in genomic research and biotechnology have resulted in the development of new protein- and peptide-based compounds. Because these large molecules are deliverable mainly by injection, noninvasive and more patient-friendly alternatives increasingly are sought. In the large-molecule arena, however, patient-friendly delivery and convenience has been harder to build into the development process because of the delicate nature of the molecules. Large-molecule drugs include proteins such as insulin, human growth factor, and recombinant blood factors. Because of their size, they are difficult to formulate and are easily degraded in the gastrointestinal tract if they are administered orally.

While large molecules present a greater challenge to drug-delivery companies, that is the area of greatest growth potential. At least 40 large-molecule therapeutics are approved for marketing in the U.S., including drugs for treating diabetes, hepatitis, osteoporosis, multiple sclerosis, infertility, anemia, and growth deficiencies, and more than 100 other such drugs are in human clinical trials. Most are administered via an invasive route and require frequent administration.

"Most large-molecule drugs haven't been around for more than 10 or 15 years and most companies didn't focus heavily on large molecules until the segment began to prove itself," Mr. Lanciano says. "These drugs address some very substantial therapeutic areas, but they really haven't changed at all since the initial version. In the future, if there are going to be blockbusters that result from drug-delivery technology there is a better chance of that occurring in the large-molecule area as opposed to the small-molecule area."

Pharmaceutical companies have begun to apply drug-delivery technologies to extend the product lives of their large-molecule blockbuster products. For example, Amgen's Epogen (epoetin alfa), a recombinant version of a human protein that stimulates the production of red blood cells; Genentech's Activase, a recombinant DNA-derived version of naturally occurring tissue plasminogen activator; and Schering-Plough's Intron A (interferon alpha), each have been reformulated using drug-delivery technology to create second-generation drugs that require less frequent dosing. The reformulated versions, Aranesp (Epogen), TNKase (Activase), and Peg Intron (Intron A), have improved dosing profiles and increased half lives.

Additionally, the sequencing of the human genome has created a need for drug-delivery technologies to unlock the potential of large-molecule drug candidates arising out of the Human Genome Project and related proteomics efforts.

"The unveiling of the human genome will accelerate research that will result in the roll-out of a number of biological compounds in the upcoming years," says Colette Goderstad, program manager at 3M Drug Delivery Systems. "There will be a lot of new products, but almost all of these biotechnology products have to be delivered by injection, so drug-delivery companies are researching and developing less invasive routes of delivery for these drugs and I think alternative drug systems will be a boon to the pharma industry."

While drug-delivery technologies will expand the development possibilities for a drug, the benefits do not come without their own questions.

"Although there is not concern about bioavailability, half life, or gastrointestinal tract absorption of the drug, there are other issues associated with certain types of drug-delivery systems," says Rachel Loui, analyst for strategic

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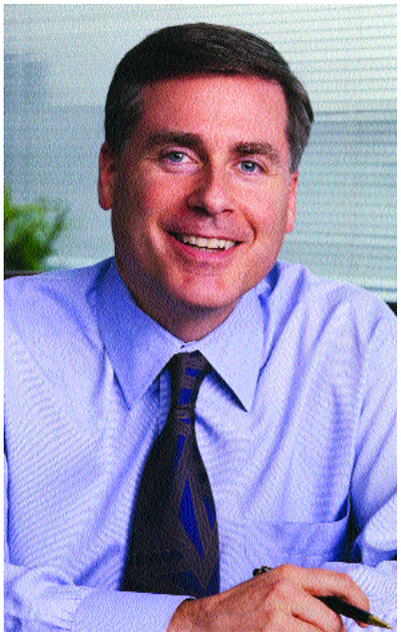
Molly Varnau, Rachel Loui, and Ashwin Singhania



▲ **A PARTNERSHIP BETWEEN A SUCCESSFUL PHARMA COMPANY AND A DRUG-DELIVERY COMPANY MAY HELP EXPAND A PHARMACEUTICAL COMPANY'S PRODUCT OFFERING AND EXTEND PRODUCT PATENTS.**

Andrew Purcell

▼ **A DIFFERENT FORM OF DRUG DELIVERY CAN GIVE A COMPOUND A BETTER CHANCE OF CLINICAL SUCCESS. A LOT OF PRODUCTS ARE ELIMINATED BECAUSE COMPANIES LOOK AT THEM THROUGH ONLY ONE ROUTE OF DELIVERY.**

Colette Goderstad

▲ **THE OFFICE OF COMBINATION PRODUCTS SHOULD HELP US DEMYSTIFY THE REGULATION OF COMBINATION PRODUCTS.**

Mark Kramer

▼ **THERE ARE MORE AND MORE DRUGS OUT THERE THAT DON'T WORK BY THE CONVENTIONAL ORAL ROUTE AND COMPANIES HAVE SAID THEY WON'T BE TURNED INTO A SUCCESSFUL PRODUCT — BUT IN SOME CASES, THAT IS NOT ACTUALLY THE CASE.**

Paul Atkins, Ph.D.

market reports at Front Line Strategic Consulting Inc. "The technology of delivering a drug into the body becomes a greater concern. For example, with transdermal administration there is the issue that polymers can make the drug more easily permeable through the skin or mucous system for delivery into the body."

THE BOTTOM LINE — PATIENTS

Traditionally, drug discovery begins with a compound, then finding out what the compound does. If a compound is thought to have a therapeutic use, it is applied to a target and, if effective, it enters the clinical-trial process.

"In some ways, the goal of chemists at the big companies is to develop molecules that don't need drug-delivery technology — they try to develop the perfect molecule," Mr. Searcy says. "The goal is to design a molecule that has perfect characteristics versus using an add-on technology, whether it be a formulation or modification of the molecule, to improve the compound after it's on the market."

However, as drug-delivery technologies advance, experts believe that the product teams will approach drug development from the patient's perspective as opposed to first developing the clinical effectiveness of a drug.

"The old model of drug development was really serendipity, it was hit or miss," says Donald E. Morel Jr., Ph.D., CEO and president of West Pharmaceutical Services Inc. "Today we are seeing more rational approaches to disease treatment, with product development being done by therapeutic teams, who increasingly are starting to work backward from the user perspective."

Experts say the most important benefit that drug-delivery technologies can bring is increased patient satisfaction.

"The success of drug-delivery technologies is a balance of cost and benefit of the product to the healthcare professional and consumer," says Andrew Purcell, VP of diabetes marketing at Novo Nordisk Pharmaceuticals Inc. "Products that demonstrate a therapeutic advantage for the patient will have a significant chance of succeeding. Healthcare professionals are looking for products that provide clinical improvement as well as being covered by managed care. Patients want the treatment options to be convenient and require minimal lifestyle change. Managed-care companies are looking for products that demonstrate a therapeutic advantage over other available options, and require that they be cost effective."

In cases where drug delivery can change a treatment regimen from a frequent or invasive procedure to a less frequent non-invasive procedure, the benefit to the patient is immeasurable.

"One of the key issues for the future of the industry is patient compliance," Dr. Morel says. "Whatever the industry can do to make it easier for patients to adhere to their dosage regimens will be critical to achieving healthier outcomes and lowering overall patient-care costs."

But, Mr. Searcy advises, while many drug-delivery technologies have been developed, there has been modest commercial success of those technologies.

"More commercial examples of success are necessary, so there is a confidence in the industry that delivery technologies can contribute to value in terms of attracting big partners," Mr. Searcy says.

ALL-AROUND BENEFITS

From improved efficacy and safety, to convenient, patient-friendly options, the drug-delivery industry's efforts are expected to improve treatment options for all patients.

"It is not just one particular indication that is expected to benefit most from drug-delivery

A Combination for Success

DRUG-DELIVERY TECHNOLOGIES ARE USED TO DELIVER MEDICINE TO A PATIENT WHEN CONVENTIONAL METHODS ARE NOT THE BEST OPTION. IN SOME INSTANCES, THE BEST OR ONLY WAY TO DELIVER A MEDICINE IS THROUGH THE COMBINATION OF A DRUG-DELIVERY METHOD AND A DEVICE.

BUT WHEN IT COMES TO REGULATORY APPROVAL, DRUG-DELIVERY/DEVICE COMBINATIONS HAVE CREATED A CONUNDRUM FOR THE INDUSTRY. THE COMBINATION OF A MEDICINE, DRUG-DELIVERY TECHNOLOGY, AND A DEVICE CAN RESULT IN CONFUSION FOR BOTH THE DEVELOPER AND THE FDA.

Until recently, the agency handled combination products through four inter-center agreements created in 1991. These entities are, Biologics/Devices, Drugs/Devices, Drugs/Biologics, and Drugs/Food. The agreements specify product characteristics or indications that require collaborative review by the centers and contain mechanisms for dispute resolution and guidance on the logistics of collaborative reviews, including the use of advisory committees.

"There has been an intercenter agreement for more than a decade between the centers on how to handle combination products that fall between the appropriate centers," says Robert Etheredge, Ph.D., a principal at Tiax LLC. "There can be inefficiencies and delays and there is a great amount of dialog. That is a disincentive to design combination products."

On October 25, 2002, as part of the Medical Device User Fee and Modernization Act (MDUFMA), the FDA announced the formation of the Office of Combination Products, which as this issue went to press was expected to begin operations in December. This office is expected to help reduce the confusion surrounding the assignment and regulation of these products.

The office is an outgrowth of the combination products program the agency formed in February 2002 to improve and clarify the way it regulates combination products. The combination products program was formed in part in response to industry concerns that combination products slip through the cracks and that the agency has not had clear policies on how it regulates combination products.

"The office was formed as required by the Medical Device User Fee and Modernization Act of 2002," says Mark Kramer, director of the Combination Products Program. "There is a great degree of flexibility in how the agency can regulate combination products, but that flexibility can lead to less predictability."

Experts agree that the regulatory authority's uncertainty in handling combination products has led to failures in oversight management.

"The FDA has had to rely on two or more centers to take ownership for the review of combination products," says David Fox, partner at Hogan & Hartson. "There has not been any oversight or management structure that stands above the centers to help coordinate the review of combination products. For the first time, the new office moves the oversight function out of the centers to the Office of the Commissioner."

The new office is expected to help manufacturers better understand and navigate the approval process.

"I ultimately hope to develop guidance in a number of areas that aren't always clear cut when dealing with combination products," Mr. Kramer says. "There are a variety of issues that we often need to consider each time a combination product comes before the agency, partly because these products are coming into different parts of the agency. The office will provide a coordinating function in terms of generating guidance with regard to combination products. Such guidance will help companies plan their development program and help them better understand how their product will be regulated."

"The Office of Combination Products, if implemented well, is going to bring order and greater predictability to the process, providing companies with a clearer vision of their path to market," Mr. Fox says.

One of the challenges for small companies with an innovative delivery system is the ability to outline for their investors what the regulatory

technologies," Mr. Singhania says. "We expect biological drugs and proteins to benefit from alternative delivery systems. One of the main limitations with proteins is that they can't be delivered orally because the stomach degrades them very quickly. Once they do enter into circulation, antibodies kill them right away, so alternative delivery systems would be a way around this."

Chronic conditions that require long-term, if not life-long treatment, are expected to be an area of focus for drug-delivery researchers.

"The systems that will be able to deliver medicine for chronic conditions will be most important," Dr. Theeuwes says. "There are certain classes of drugs that require attention from a drug-delivery point of view and those are the biotech agents, all of which need to be injected and often very frequently. Those agents specifically will be able take advantage of new drug-delivery technologies."

As many chronic conditions are related to old age, geriatric medicine is expected to benefit from advances in drug-delivery technology.

"Geriatric conditions are a big area for growth because of the forgetfulness factor," says Molly Varnau, director of strategic market reports at Front Line Strategic Consulting Inc. "With controlled patch or a sustained delivery product, countless pills don't have to be taken at different times during the day. Geriatrics is definitely one area that will benefit from drug-delivery technologies, as well as conditions that make it difficult for the patient to swallow pills, such as Parkinson's disease."

Dr. Theeuwes agrees that diseases of old age are an area that drug-delivery systems can definitely impact.

"Many chronic conditions are diseases of old age or failing organ systems," Dr. Theeuwes says. "For example, cardiovascular disease, where the heart needs support for a long time, or diseases of the brain and central nervous system, or cancer. Those are areas where drug delivery will play an important role."

In the near term, cancer is thought to be the therapeutic area that stands to benefit the most from advances in drug-delivery technology.

path looks like. According to Mr. Fox, companies that develop combination products face a multitude of issues. Does the product need approval by one or more centers? Is partnership with a pharma company a necessity for approval? And, how is the application managed by the center(s)?

The new office is intended to make the path to regulatory approval clearer for the developers and manufacturers of combination products.

"When companies encounter cost or time barriers, they risk losing their marketing window of opportunity," Dr. Etheredge says. "As efficiencies within the regulatory arena are increased there will be more incentive for companies to develop combination products. Over the next decade the industry will begin to fully exploit the profound nature of the combination product, which can be better than a drug, and better than a device, but right now these products sit in a land of uncertainty."

Going forward, Mr. Fox believes that regulators will need to develop processes that distinguish products that use traditional dosage form technologies and passive delivery systems from those that incorporate active delivery systems, such as intelligent implants using feedback mechanisms, implantable systems that can be activated through an external power supply or remote control, and systems that rely on nano technology.

"In those instances where the device issues are clearly predominant, we'll have to watch whether the FDA will map out an approval path that will allow those products to be reviewed in the Center for Devices and Radiological Health through a single PMA or 510(k)," Mr. Fox says.

Another concern with the formation of the office is a management issue. According to MDUFMA, the regulatory centers are responsible to the Office of Combination Products with respect to the timeliness of combination product reviews.

"In practice, what we plan to do is establish a method to make sure that the office can monitor the progress of combination products under review in the agency, particularly where two centers are involved and be as proactive as necessary to make sure that the centers are working together, providing the consulting reviews that are often needed on combination products, and that companies are hearing back in a timely way from the centers," Mr. Kramer says. "The new office will not conduct the actual product review, but facilitate and coordinate the review process."

The effectiveness of the new office is dependent upon authority that the office will have over the centers.

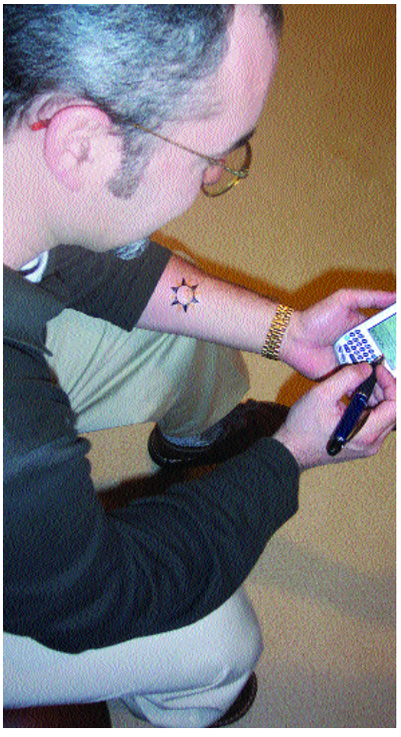
"The Office of Combination Products has responsibility without apparent authority," Mr. Fox says. "That is a difficult position to be in. If the office can overcome this obstacle, I think it will be a tremendous success."

BASIC FUNCTIONS OF THE OFFICE OF COMBINATION PRODUCTS:

- Transfer responsibility for the assignment of combination products from the Office of the Ombudsman to the Office of Combination Products
- Ensure the timely premarket review of combination products by facilitating and coordinating the way the regulatory centers work together on combination products
- Ensure consistent and appropriate post-market regulation
- Resolve disputes regarding the timeliness of reviews of combination products, and advise the Commissioner regarding disputes related to the substance of combination product reviews
- Review and update guidance, agreements, and practices regarding the assignment of combination products
- Report to congress

▶ THERE WILL BE A NATURAL PARTNERSHIP BETWEEN THOSE COMPANIES THAT SYNTHESIZE CHEMICAL ENTITIES AND DRUG DELIVERY, THE TWO ARE COMPLEMENTARY.

Dr. Felix Theeuwes

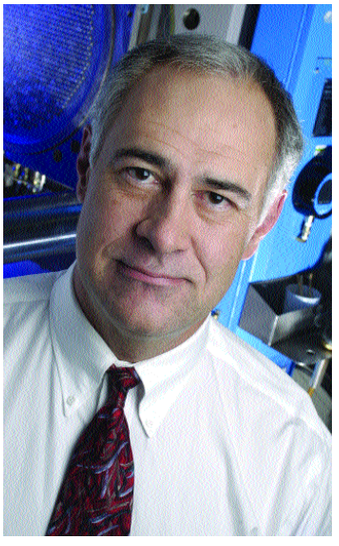


▲ WE HAVE A FUN TRANSDERMAL DELIVERY SYSTEM, A TEMPORARY TATTOO, THAT OFFERS A VISUAL INDICATION AS TO WHEN IT IS TIME FOR ITS NEXT APPLICATION. FOR THE RIGHT DRUGS THIS COULD BE THE PERFECT APPLICATION.

Chris Lipper

▼ THE FUTURE FOR DRUG DELIVERY IS TO ACTUALLY DELIVER ON THE PROMISE AND I THINK THAT WILL HAPPEN. SUCCESS BREEDS SUCCESS AND THAT WILL CREATE THE MOMENTUM FOR DRUG-DELIVERY TECHNOLOGY.

Chris Searcy



▲ SOME OF THE NEWER DRUG-DELIVERY TECHNOLOGIES WILL ALLOW VERY SPECIFIC TARGETING OF THE DRUG.

Dr. Donald E. Morel Jr.

▼ A LOT OF PHARMA COMPANIES DO NOT WANT TO TAKE THE RISK OF INVESTING IN NEW TECHNOLOGIES OF THEIR OWN, IT IS BETTER TO HAVE COMPANIES SUCH AS OURS DEVELOP THE TECHNOLOGY.

Charles Bramlage

"There is a lot of work to be done in the oncology field," Mr. Searcy says. "Those molecules historically have been very toxic and they are very insoluble, so they need drug delivery from a solubility and a targeting perspective. Many of the side effects of first-generation oncology drugs are not to the drug itself, but to the formulation required to get the drug into the body."

While a variety of drug-delivery methods are expected to be used successfully, oral drug-delivery will continue to be the preferred method.

"We assume that oral-controlled release will be the most successful because of the sheer number and caliber of drugs that are used in this system and the advantages of the system," Ms. Loui says. "Because most people take tablets, the idea of an oral-controlled release method isn't as foreign as a patch or nasal spray, it is easier to market an oral technology enhanced product."

However, as proteins and other molecules are discovered that cannot be delivered via the gastrointestinal tract, pulmonary delivery will experience significant growth.

"Drug-delivery technology is moving ahead and transforming, and the technologies that are shaping the market are the inhaled, transdermal, and oral," says Ajit Baid, research analyst for pharmaceuticals at Frost & Sullivan. "In the next couple of years perhaps the one drug-delivery system that is going to make a major impact in the market is pulmonary drug delivery."

LET'S MAKE A DEAL

Drug-delivery and pharmaceutical companies' missions complement each other. The

drug-delivery industry's main objective is to create technologies that improve the delivery of drugs to patients. Pharmaceutical companies develop drugs to meet therapeutic demands and market them to the appropriate patients. While there are some companies that can perform both functions, the majority cannot.

"The market is segmented into companies that develop and commercialize drugs and those companies that develop technologies or products to help the other segment with its role," Mr. Searcy says. "The barriers to entry for companies that develop and commercialize drugs are high, and in some ways getting higher. Deep pockets and lots of infrastructure are required to enter, and it's not easy in some of the primary-care indications for small companies to do that. Likewise big companies can't afford to invest in breakthrough technologies, so they will continue to in-license those."

In-licensing technology for drug delivery is a lower risk strategy for a pharmaceutical company when compared with the investment required to develop the technology itself.

"Many pharma companies do not want to take the risk of investing in new technologies of their own, so it is better to have companies such as ours to develop technologies," says Charles Bramlage, senior VP and general manager for specialty pharmaceuticals at BattellePharma. "This way pharma companies can tap into our innovations and use them without paying for the total development."

Intrinsically, partnerships between the industries would be the best way to achieve the goal of serving patients. However, the task of marrying a technology and a compound is not always that simple. Drug-delivery companies and pharmaceutical companies also have to watch for the best interests of their businesses.

"A key issue from the drug-delivery point of view is the ownership of the technology because if a company loses the ownership and cannot expand the capability, they have put themselves out of business," Dr. Theeuwes says.

Retaining ownership of a technology can be a problem for the drug-delivery company, which often is the underdog.

"One of the key issues is equitable rights and the need for big pharma to recognize that it is a true partnership, not a dictatorship, and that drug-delivery companies have a key role to play in the successful outcome," says Paul J. Atkins, Ph.D., CEO of Oriel Therapeutics Inc. "Equitable risk and reward must be taken in a partnership and they should not just involve the buying of a technology for a relatively small amount of money and then not being committed to developing it as a product."

A chief concern among drug-delivery companies is that a licensed technology could get shelved if the priorities of the pharmaceutical company change.

Pharmaceutical companies also have concerns when entering a partnership with a drug-delivery company.

Proof of concept is important in terms of licensing a drug-delivery technology; if the technology has not consistently been shown to be effective, the pharmaceutical company is taking on a larger risk.

"Pharmaceutical companies will be looking to partner with drug-delivery companies that have actually shown proof of concept," Ms. Varnau says. "There also is competition within the industry among large pharma companies that are trying to add value to products that face generic competition."

Pharmaceutical companies must also be alert to potential competition from the drug-delivery companies that have partnerships with other pharma companies, even if the technology is a good fit. In some cases, smaller, unaffiliated companies are more attractive to major pharmaceutical companies than drug-delivery operations that are closely tied to major pharmaceutical competitors.

"A drug-delivery company could have a lot of technology capabilities, but if it also is a player in the inhaled pharma business, for example, a pharmaceutical company with a similar therapeutic focus might refrain from engaging in a partnership for that particular technology," Dr. Atkins says.

BIG PHARMA COMPANIES CANNOT AFFORD TO INVEST IN BREAKTHROUGH TECHNOLOGIES, SO THEY WILL CONTINUE TO IN-LICENSE THOSE.

DELIVERY IN THE FUTURE

Scientific breakthroughs, such as the Human Genome Project, will continue to give researchers new compounds and molecules to work with. Drug-delivery technologies will need to continue to advance at a rapid pace to bring these discoveries to patients.

"The industry is headed toward innovative delivery systems," says Chris Lipper, principal, president, and founder of Lipper-Man Ltd. "Delivery is the key in many cases. If a company can develop a delivery device that gets its compound to where it needs to be, when it needs to be there, and stops working when it is supposed to, the chance of success is much higher."

The possibility of bringing otherwise abandoned compounds to market will propel companies with the right technologies to growth and success.

"The drug-delivery industry is going to continue to grow because it can differentiate in terms of speed to market and provides the capability and specialist expertise that often doesn't exist in large pharma," Dr. Atkins says. "If used properly, drug delivery can create a product that may not have existed before. Opportunities for growth are clearly available."

Analysts agree that drug-delivery companies are poised to take advantage of the opportunities the market presents.

"The drug-delivery market definitely has great potential," Mr. Baid says. "The market is in for a change; there is going to be a shift from injectables to non-invasive therapies — providing patients with better, and more convenient therapies. There will be fewer injections used and more inhalables."

However, with growth and success comes the possibility of failure. Industry analysts predict that as the industry grows, some companies will have to consolidate or go out of business.

"It is a really difficult time to turn a profit and investors are really looking for that," Ms. Varnau says. "There will be consolidation, there will be companies that just go away because the technologies can't support the company. And then there will be companies that emerge from consolidations as spin offs. There will be a churning of the market during the next 10 to 20 years."

Analysts also expect that as the industry grows, drug-delivery companies will begin to emerge as larger entities that will be able to sustain their own marketing programs and initiatives.

"In the long term, drug-delivery companies will take on a life of their own as they start to market their own products," Mr. Singhania says.

According to Mr. Singhania, companies that supplement drug-delivery technology development with other sources of revenue, such as generic drug manufacturing, may be able to distance themselves from partnerships with big pharma.

"Andrx is a good example of a company that started as a drug-delivery company and has formulated its own drugs," he says. "The company is involved in taking drugs such as Prilosec, that use oral-controlled release methods such as delayed release, and marketing

them as a generic. Prilosec makes about $6 billion a year, so even though the generic is going to sell for a lot less, it will still generate substantial revenue."

As the industry evolves, drug-delivery companies are expected to grow beyond simply being developers of technology.

"As drug-delivery companies continue to evolve, they are becoming more and more like pharma companies," says Pam Sobotka, director of the 7th Annual Drug Delivery Partnerships Conference for the Institute For International Research. "In some cases, certain companies are starting to develop their own drugs and as such are starting to serve the industry much like a traditional pharmaceutical company." ✦

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

Experts on this topic

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MARK KRAMER. Director, Combination Products Program, Food and Drug Administration, Rockville, Md.; The Office of Combination Products, which as this issue went to press was expected to begin operations in December 2002, was established to help reduce the confusion surrounding the assignment and regulation of combination products. For more information, visit fda.gov.

PETER L. LANCIANO. Chairman, president, and CEO, Altus Biologics Inc., Cambridge, Mass.; Altus Biologics is focused on using its proprietary and innovative protein crystallization technology to transform proteins into highly concentrated, stable, and pure crystalline products. For more information, visit altus.com.

CHRIS LIPPER. Principal, president, and founder, Lipper-Man Ltd., Morristown, N.J.; Lipper-Man is a limited partnership developed to license a transdermal drug-delivery system. For more information, visit lipperman.com.

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DONALD E. MOREL JR., PH.D. CEO and president, West Pharmaceutical Services Inc., Lionville, Pa.; West Pharmaceutical Services is a global pharmaceutical technology company that applies proprietary materials science, formulation research, and manufacturing innovation to advance the quality, therapeutic value, development speed, and rapid market availability of pharmaceuticals, biologics, vaccines, and consumer healthcare products. For more information, visit westpharma.com.

ANDREW PURCELL. VP, diabetes marketing, Novo Nordisk Pharmaceuticals Inc., Princeton, N.J.; Novo Nordisk Pharmaceuticals, the U.S. headquarters of Novo Nordisk AS, Bagsværd, Denmark, is a focused healthcare company and world leader in diabetes care. For global information, visit novonordisk.com, for U.S. information, visit novonordisk-us.com.

CHRIS SEARCY. VP, corporate development, Inhale Therapeutic Systems Inc., San Carlos, Calif.; Inhale Therapeutic Systems develops advanced drug-delivery solutions for the biopharmaceutical industry. For more information, visit inhale.com.

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PAM SOBOTKA. Director, 7th Annual Drug Delivery Partnerships, Institute For International Research, New York; IIR is the world's largest international conference company. For more information, visit iirusa.com.

FELIX THEEUWES, D.SC. Chairman and chief scientific officer, Durect Corp., Cupertino, Calif.; Durect is pioneering the development and commercialization of pharmaceutical systems for the treatment of chronic debilitating diseases and enabling biotechnology-based pharmaceutical products. For more information, visit durect.com.

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