

DRUG DELIVERY

A Pipeline of Research and Market Opportunities

**DELIVERY TECHNOLOGIES WILL PLAY
AN INCREASINGLY IMPORTANT ROLE
IN THE DRUG-DEVELOPMENT PROCESS**
AS A MEANS TO IMPROVE THE EFFICACY OF A DRUG;
MAKE A DRUG SAFER, MORE EFFECTIVE, OR
CONVENIENT; EXTEND ITS PATENT LIFE; OR
DIFFERENTIATE IT IN THE MARKETPLACE.

In recent years, there have been a number of exciting advances in drug delivery. There's been the development of nicotine patches, implants that deliver birth control, small disks that deliver anti-cancer drugs directly to the site of brain tumors, and a variety of inhalation technologies.

The field of drug delivery has progressed from what was a little-known art to an important part of the global pharmaceutical industry. The sector is estimated by some analysts to be valued at \$40 billion worldwide in terms of the technology alone, according to Kalorama Information.

The primary goal of drug-delivery technology companies is to replace the use of needles, to offer advanced oral and other administration modes to improve patient convenience and compliance, to provide more effective use of therapeutic drugs, and to allow for the use of compounds that might otherwise not be possible.

Some sources estimate that revenue of pharmaceutical products that use drug-delivery systems accounted for 22% of total pharmaceutical sales, or \$23 billion, in the United States in 2005. Researchers at Kalorama, however, question the validity of these estimates, noting there is a problem of market definition. The researchers go on to forecast that by 2014 the market is expected to be \$76.6 billion.



IF THE LEARNINGS OF DRUG DELIVERY COULD BE APPLIED MUCH EARLIER IN THE DRUG-DEVELOPMENT PROCESS, the cost of drug discovery and development would be reduced, as well as, hopefully, the time to market.

- **DR. RAVI KIRON**
- Alza

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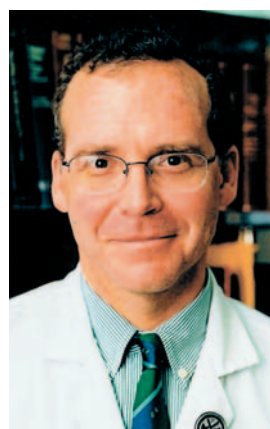
From a healthcare cost-containment standpoint, **THERE IS A GREAT DEAL OF INTEREST IN PULMONARY DELIVERY OR INHALED DRUG DELIVERY** for chronic diseases so that patients have the ability to self administer a drug.

LESLIE WILLIAMS ●
Ventaira Pharmaceuticals ●



A NOVEL DRUG-DELIVERY SYSTEM IS DEVELOPED TO ACHIEVE ONE OF SEVERAL GOALS: to improve the efficacy of a drug; to lessen the toxicity of a drug; or to allow for a more convenient way to deliver the drug to the patient.

DR. GREGORY BERK ●
Hana Biosciences ●



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● **DR. JOHN FARA**
● Depomed

“We expect companies that specialize in drug delivery will play an increasingly important role in the life-sciences value chain; and in fact, both figuratively and literally, their stocks are going to rise,” says Terry Hisey, U.S. deputy managing principal for Life Sciences and Health Care at Deloitte Consulting LLP.

Kalorama researchers say one factor driving the development of new delivery technologies is the large number of pharmaceuticals that are coming off patent. Many of these drugs are insoluble in water or have limited efficacy through their traditional routes of administration. These same drugs, however, have the potential to be very valuable when they are delivered through a more appropriate system.

“Today, pharmaceutical companies’ pipelines are between 40% and 65% class 2 and class 3 molecules, and these molecules are essentially not soluble or bioavailable,” says Ravi Kiron, Ph.D., executive director of new technology assessment and planning at Alza Corp. “There is no easy way to deliver those compounds to the body. There are innovative technologies being developed for delivery through the eye, the ear, the buccal cavity in

the mouth, the vagina, and through the skin.”

Dale Robinson, a consultant in the product and process engineering practice at PA Consulting Group, says drug-delivery devices can give companies an edge.

“Pharmaceutical companies can improve preferences for their products through unique devices that may make the drugs easier to administer and, in some cases, more effective to administer,” he says.

Collaborations between a drug delivery company and a pharmaceutical company are part of life-cycle management efforts, says Michael M. Goldberg, CEO of Emisphere Technologies Inc.

“It’s about taking an old, but well-performing, drug that is effective and safe, but is about to lose patent protection, and reformatting it in terms of drug delivery to create a life-cycle extension,” he says.

Another factor driving the development of drug-delivery technologies, according to Kalorama researchers, is the growing number of biotechnology products coming to market,

many of which are for diseases that have been untreatable. These therapeutics may be too large on a molecular level or too unstable to be delivered in any way other than by intravenous infusion or frequent injection.

Even as administration is made easier, Dr. Kiron says new delivery technologies could mean that development timelines may become longer, especially if delivered through a novel mechanism.

“Companies have to apply the value of drug delivery earlier on in the game of drug discovery and earlier on in the development of the R&D pipeline,” he says. “They have to think about the molecule that is, ultimately, to come, how they are going to deliver it, and how they are going to maximize its activity. If the learnings of drug delivery are applied much earlier in the drug development process, the cost of drug discovery and development — and hopefully the time to market — would be reduced.”

Plants Disks Inhalers Nasal Spray Patches

NEW TECHNOLOGIES

for **NASAL**

Pulmonary devices have matured significantly from the basic inhalers. The development of new technologies has enabled the

delivery of a wide range of therapeutics through the pulmonary system.

Experts believe the best is yet to come. One product of interest is a nasal insulin for diabetic patients being jointly developed by Pfizer Inc. and sanofi-aventis. In September 2005,

a FDA advisory committee recommended the approval of Exubera, an inhalable, dry-powder insulin for the treatment of Type 1 and Type 2 diabetes in adults.

Exubera uses a proprietary inhalation device and powdered insulin formulation developed by Nektar Therapeutics. Exubera closely mimics the normal physiological insulin response to meals by quickly being absorbed into the bloodstream to reduce meal-related spikes in glucose levels in people with diabetes.

“The recent news from Pfizer, sanofi-aventis, and Nektar is the start of an exciting time for companies in the pulmonary drug-delivery space,” says Leslie J. Williams, president and

CEO of Ventaira Pharmaceuticals Inc. “The FDA advisory committee’s decision is encouraging. The final outcome will open the door for other large molecules to be delivered systemically.”

Ventaira is developing pharmaceutical products using its novel proprietary electrohydrodynamic (EHD) aerosolization and formulation technologies to improve the profile of new or existing drugs.

“We are developing a new pulmonary delivery system that will allow us to efficiently and more effectively deliver drugs to treat local lung and systemic diseases,” Ms. Williams says. “For pharmaceutical companies developing new chemical

entities, we can provide an alternative mode of delivery using our devices with EHD technology to deliver their compound efficiently to, or through, the lung, potentially allowing for more rapid uptake.”

Another company working on nasal delivery technologies is Javelin Pharmaceuticals Inc., which is conducting Phase II trials in both the United States and Europe for an intranasal version of morphine called Rylomine.

Oral formulations of morphine do not provide rapid relief of pain in many patients. Oral morphine also demonstrates considerable patient-to-patient variability in absorption. Javelin’s intranasal form uses a proprietary

THE DRUG-DELIVERY MARKET

The field of drug-delivery technology is filled with opportunities to satisfy unmet needs, with more technologies emerging as time goes by and new types and classes of therapeutics being discovered and introduced. **THE GROWING NUMBER OF OPPORTUNITIES HAS SPAWNED A MARKET THAT IS ESTIMATED BETWEEN \$2 BILLION AND \$3 BILLION FOR THE TECHNOLOGY ALONE.**

The field of drug-delivery technology will be addressed primarily by young companies seeking to peddle the technology themselves and, in some cases, use it for entry into the generic drug markets.

INNOVATION WILL COME FROM START UPS AND NOT NECESSARILY ESTABLISHED COMPANIES. This will put a damper on any urgency for the big pharma companies to get involved in the technologies themselves. They will be primarily supporters and reapers of new technologies from smaller companies.

SMALL, MIDSIZED, AND BIG PHARMA COMPANIES PERCEIVE THE FIELD OF DRUG DELIVERY DIFFERENTLY. Smaller companies will focus on the technology itself and its application to existing pharmaceuticals and biopharmaceuticals. Midsized companies, mostly biopharmaceutical firms, will anxiously scan the new technologies for the means to bring new products to market that have been problematic in delivery. Big pharma companies will dip into drug delivery, primarily as a means to extend the product life cycle for products coming off patent.

A DRUG-DELIVERY TECHNOLOGY WILL BE THE MOST LIKELY CONTRIBUTOR TO THE PROBABILITY OF A FUTURE BLOCKBUSTER.

The field of drug delivery will affect the nature of the generics market, potentially reducing expected savings from off-patent formulations. Companies with drug-delivery technology backgrounds are moving to add value to off-patent drugs by providing their own delayed dosage, depot, and other time-release formulations. **GENERIC DRUG COMPANIES ARE NOW BRANDING THEIR NEW DRUG DELIVERY-MODIFIED PRODUCTS.**

Source: Kalorama Information, New York. For more information, visit kaloramainformation.com.

ESTIMATED U.S. MARKET POTENTIAL FOR DELIVERY-MODIFIED THERAPEUTICS 2004 TO 2014

YEAR	TOTAL MARKET POTENTIAL MODIFIED (IN BILLIONS)	MARKET POTENTIAL FOR DRUG DELIVERY (IN BILLIONS)
2004	\$101.9	\$20.5
2005	107.5	23.3
2006	113.9	26.4
2007	121.4	30.2
2008	129.8	34.6
2009	138.3	39.8
2010	147.7	46.0
2011	157.6	53.5
2012	168.3	61.3
2013	179.6	69.1
2014	191.7	76.6
AAGR 2004-2009	7.1%	18.8%
AAGR 2009-2014	7.7%	18.5%

Source: Kalorama Information, New York. For more information, visit kaloramainformation.com.

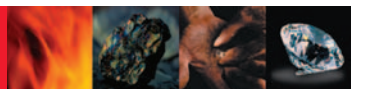
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technology, ChiSys, a carbohydrate polymer that, while pharmaceutically inert by itself, enhances the absorption of compounds across mucosal membranes.

“The ChiSys substance is generally recognized as safe,” says Michael T. Sheckler, VP of business development at Javelin. “ChiSys is based on the use of chitosan, a cationic polysaccharide obtained from partial deacetylation of chitin, which originates from the shells of crustaceans (e.g., crabs and prawns). It has been used extensively in the healthcare and consumer fields. A nonpharmaceutical grade of chitosan can be picked up at a health-food store. Chitosan acts as a mucoadhesive that permits a longer residence time of the drug in the nose. By using this with morphine, it allows the product to adhere to the mucosa for a longer period of time. This allows for better uptake or absorption of the drug.”

Company officials say Rylomine represents an alternative formulation that provides patient convenience, ease of use, and cost-effectiveness with the rapid onset of pain relief.

Javelin also is working on an intranasal form of ketamine, which is in Phase II trials for the treatment of acute moderate-to-severe pain. Ketamine, a nonopioid, is a N-methyl-D-aspartate (NMDA) receptor antagonist that has been in clinical use for more than 30 years as a general anesthetic.

Mr. Sheckler points out that the company is positioning both of these products to be dispensed rather than prescribed.

“These products will be dispensed in a medically supervised healthcare setting, which dictates a focus on the hospital market, as well as home hospices or home healthcare, nursing homes, ambulatory-care clinics, free-standing clinics, and even in the ambulance,” he says.

Mr. Sheckler says despite its advantages, nasal drug delivery still poses a few challenges,

COMPANIES THAT SPECIALIZE IN DRUG DELIVERY WILL PLAY AN INCREASINGLY IMPORTANT ROLE IN THE LIFE-SCIENCES VALUE CHAIN, and in fact, both figuratively and literally, their stocks are going to rise.

TERRY HISEY ●

Deloitte Consulting ●



PHARMACEUTICAL NASAL DEVICES ARE BECOMING MORE TECHNOLOGICALLY SAVVY.

The enabling technologies and new pumps and devices are allowing companies to develop such things as immunomodulators, gene-vector therapies, anti-infectives, vitamins, vaccines, and new pain medications that can be delivered via the nose.

MICHAEL SHECKLER ●

Javelin Pharmaceuticals ●

such as how large a molecule can be delivered, what the bioavailability of the product will be, and whether it can be delivered by a unit-dose or a multidose device.

NEW TECHNOLOGIES FOR ORAL DELIVERY

Companies are working to orally deliver products that previously weren't able to be put into a tablet.

Emisphere, for example, is working on oral insulin, which is in Phase II trials, and oral heparin, which is in Phase III trials. Both

products are being developed using the company's oral drug-delivery platform, eligen technology. The platform is based on the use of proprietary, synthetic chemical compounds that facilitate or enable the transport of therapeutic macromolecules across biological membranes, such as those of the gastrointestinal tract. Emisphere's technology makes it possible to orally deliver a therapeutic molecule without altering its chemical form or biological integrity.

“We believe that oral insulin can mimic the physiologic secretion of insulin from the pancreas,” Mr. Goldberg says. “An oral product will improve patients' quality of life by replacing the multiple injections that are needed per day, make insulin more effective and safer, and reduce the risk of overdosing.”

Mr. Goldberg believes that an oral heparin product could expand the market.

“We believe the injection mode of administration is what's holding back broader use,” he says. “We think we can expand the market by increasing the duration of dosing once a patient is on the drug and by making the drug available to more patients who are at risk.”

The company also is working with Novartis Pharma AG to develop a tablet form of salmon calcitonin, which is in Phase II trials for the treatment of osteoporosis. Novartis also will be pursuing an osteoarthritis indication. Novartis markets injection and nasal spray forms under the brand name Miacalcin.

Depomed Inc., another company working to advance oral delivery through extended release, uses its proprietary AcuForm drug-delivery technology. Many drugs are best absorbed in the stomach and upper reaches of the small intestine. AcuForm tablets deliver the drug to these upper GI sites. The AcuForm tablets sit safely and neutrally in the stomach for six, eight, or even more hours, and the drug is delivered at the desired rate and at the desired time.

The company has received U.S. approval for two products: Glumetza, a once-daily,

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● **PAUL PERREULT**

● ZLB Behring

soluble small-molecule compounds, peptides, proteins, and oligonucleotides,” Dr. Fara says.

He says to date Depomed has been focusing on partnering with other pharmaceutical companies for sales and marketing of its developed products.

“With two approved products, several more in the pipeline, and a candidate list for development of many more, we are beginning to evaluate when and how we can commercialize our products on our own,” he says. “As we continue to become a revenue-driven company, it will be important for us to look at niche markets where a small salesforce can be effective.”

NEW TECHNOLOGY
for **MOUTH SPRAYS**

Hana Biosciences Inc. is developing a mouth spray formulation for the anti-emetic ondansetron, which is available now as a tablet and marketed as Zofran by GlaxoSmithKline. Hana is conducting pivotal bioequivalence trials of this oral spray, which the company has branded as Zensana.

Company executives say they plan to file a new drug application in the spring of 2006 under section 505(b)2, a registration pathway that relies on data from previously approved NDAs and published literature. The company expects to launch the product in 2007.

Supportive care is a huge area of cancer management. In terms of the dollars spent in the global cancer market, supportive-care products account for a significant percentage of these expenditures. The worldwide anti-emetic market alone is currently a \$1.8 billion market, says Gregory I. Berk, M.D., senior VP and chief medical officer of Hana.

“Chemotherapy patients have trouble swallowing pills when they’re nauseated and vomiting,” he says. “This is a common problem that can be addressed with a different formulation.”

Hana acquired the rights to market the oral spray formulation in the United States and

Canada from NovaDel Pharma Inc. The spray delivers ondansetron to the oral mucosa, which avoids degradation in the gastrointestinal tract and metabolism by liver enzymes, the so-called first-pass effect.

“This delivery method allows for fast absorption, and the drug enters the blood stream directly through the buccal mucosa,” Dr. Berk says. “We have preliminary data that demonstrate detectable drug levels earlier than the standard oral tablet. Zensana is packaged in a multidose vial, which will add to patient convenience.”

Dr. Berk says the company’s product is not likely to be viewed by oncologists as a new product but rather as an improved way to deliver a well-established and efficacious drug.

Hana’s initial marketing strategy will be to adhere to its labeled indication of chemotherapy-induced nausea and vomiting and to target patients receiving emetogenic chemotherapy that requires a 5HT₃ anti-emetic, he says.

Postmarketing, Hana intends to perform additional clinical trials to expand the label to other indications, including radiation therapy and post-operative nausea and vomiting.

NEW TECHNOLOGIES
for **BIOLOGICS**

Companies are also working to develop new forms of biological products, which are generally given by injection or intravenously.

ZLB Behring LLC, for example, received FDA approval in January for Vivaglobin, a subcutaneous form of immunoglobulin (Ig) for primary immunodeficiency disorder (PID). Ig provides the antibodies needed to bolster patients’ immune systems and fend off infections in those with PID.

“IV administration is certainly a safe, effective method for delivering immunoglobulin to the body,” says Paul Perreault, senior executive VP, worldwide commercial operations, at ZLB Behring. “Yet, some patients have veins that are difficult to access. Some patients

extended-release formulation of metformin for the treatment of Type II diabetes, and Proquin XR (ciprofloxacin) for the treatment of uncomplicated urinary tract infection.

The company also is developing Gabapentin GR, which recently achieved statistically significant safety and efficacy benefits in a Phase II clinical trial to treat patients with postherpetic neuralgia, a long-lasting pain condition associated with nerve damage from herpes zoster, or shingles, infection.

According to John W. Fara, Ph.D., president, CEO, and chairman of Depomed, one of the company’s challenges is selecting appropriate drug candidates for development in the dosage form that meets the company’s criteria.

“These criteria include the potential market size opportunity, patent status — present/future generic competition — and whether and to what extent can we bring more value to a newly reformulated product, particularly improvements in dosage and dosing administration, as well as an improved side-effect profile for the new formulation,” he says.

But, he adds, once the company has identified an appropriate candidate, the formulation and development processes are straightforward.

“We have yet to identify a compound that cannot be formulated in tablet form with our technology, including very soluble and non-

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can't get to the infusion site because of where they live. There also some patients who experience intolerable side effects from IV."

Vivagloblin delivers Ig directly under the skin, offering a safe and effective alternative to intravenous infusions of immunoglobulin.

"Patients will be able to use a small portable pump to self-administer the Ig treatment," Mr. Perreault says. "Using this pump,

NEW DRUG-DELIVERY FORMS CAN INCREASE PATIENT COMPLIANCE

DR. MORRIS S. WHITCUP



NONCOMPLIANT PATIENTS RECOGNIZE THEY HAVE A SIGNIFICANT PROBLEM,

and they are seeking ways to overcome their difficulties.

A FIND/SVP Inc. online study asked more than 1,000 consumers in November 2005

questions about acceptability of new medication forms and compliance issues. The study found that noncompliant individuals are substantially more interested than the self-reported compliant individuals in several long-lasting medication forms, such as weekly tablets, long-lasting injections, patches, and, to a lesser extent, implants.

New delivery forms that are more effective are appealing to **73%** of consumers, outranking those that cost less (**68%**) or are less painful (**37%**).

"Lack of compliance with recommended medication dosing has a significant impact on the health of the U.S. population and the revenue of pharmaceutical companies," says Morris S. Whitcup, Ph.D., coauthor of the report and president and founder of Advanced Analytics Inc., a division of FIND/SVP. "The direct and indirect costs of noncompliance are at least \$100 billion per year and account for 11% of hospitalizations of elderly

patients."

Source: FIND/SVP Inc., New York. For more information, visit findsvp.com.

CONSUMER INTEREST IN MEDICATION DELIVERY METHODS

Weekly tablets	62%
Strips that dissolve in mouth	47%
Quick-dissolve tablets	46%
Chewable tablets	38%
Long-lasting injections	36%
Patches	31%
Needle-free, self-administered injections	30%
Chewing gum	24%
Inhalers	22%
Sprinkles to put on food	21%
Effervescent tablets	20%
Implants	18%

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Drug companies look toward drug-delivery devices as a way to differentiate their products. **THE FACT THAT A PRODUCT IS EASIER TO USE BECOMES A MARKETING TOOL FOR PHARMA COMPANIES.**

DALE ROBINSON ●
PA Consulting ●



the Ig is delivered directly under the skin so patients don't have to find any veins, and they can administer it when it's convenient for them."

ZLB Behring also provides Ig treatment via IV (referred to as IVIg) under the brand name Carimune.

Mr. Perreault says the marketing of the subcutaneous Ig will rely heavily on education.

"This is the first time a drug of this type will be administered subcutaneously, so we will focus on educating physicians about which patients are appropriate for this therapy," he says. "We will offer patient education around

administration, how the pump works, and dosing levels. We will also educate the providers who deliver these therapies to patients." ♦

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

Experts on this topic

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