From APIs to drug delivery solutions

**Exclusive Synthesis**
Proprietary advanced intermediates and APIs, from the clinical stage all the way to commercialization.

**Rexim® Amino Acids**
Amino-Acids for parenteral nutrition, as APIs or as versatile building blocks for chiral pharma syntheses.

**Formulation Services**
• Assist customers with formulation development

**Resomer® & Lakeshore Biomaterials™**
PLGA based polymers for controlled release depot injections and medical device applications

**Pharma Polymers for Depot & Medical Devices Applications**

**Pharma Polymers for Oral Dosage Forms**
Acrylic Drug Delivery excipients for oral solid dosage forms

**PRODUCT LINE PHARMA POLYMERS**

**BL Health Care**

Commercial APIs & intermediates
Portfolio of generic actives with global supply options
### History

<table>
<thead>
<tr>
<th>1970s</th>
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<th>1990s</th>
<th>2000s</th>
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<tbody>
<tr>
<td>Southern Research Institute establishes drug delivery group</td>
<td>Microencapsulated drug products on market</td>
<td>Microencapsulation patent portfolio (process, composition, application)</td>
<td>Acquisition of Alkermes ext. commercial Medisorb® polymer business (2004)</td>
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<td>First human clinical trial using biodegradable microsphere formulation</td>
<td>Polymer reactor built for Medisorb®</td>
<td>Corporate partnerships developed – new technologies &amp; manufacturing</td>
<td>Drug-delivery technologies and biomaterials alliances</td>
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<td>Formulation of peptides</td>
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<td>Atrix acquires Atrigel technology</td>
<td>Acquired by SurModics (2007)</td>
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<td>Acquired drug delivery assets from PR Pharmaceuticals (2008)</td>
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<td>Launched world class cGMP Lakeshore Parkway manufacturing facility</td>
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<td>(2010)</td>
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<td>Became part of Evonik, November (2011)</td>
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Cost of a New Ballpark

Target Field Opening
Day 4-12-2010

Cost of $545 Million
Cost of Developing a New Drug

Estimates from $800 million (deMasi 2001) to > $1 billion

Developing a new medicine takes an average of 10–15 years; the Congressional Budget Office reports that “relatively few drugs survive the clinical trial process”

Why drug delivery?
Why Drug Delivery?

- By avoiding peak and trough –
  - Better efficacy
  - Less side effects
- Assure compliance
- Less procedures (injections, capsules, physician visits)
- Lower cost
- Additional IP
- Allows for local delivery
- Enhanced utility of medical devices
Pfizer’s Procardia® was selling ~$400MM as a 4/day dose; converted to a once/day it became a $1.4B product over a 5-year period.

LHRH compounds for prostate cancer were selling $50M as a once/day injection; Lupron Depot® converted once a day to once every 1-6 month dosing---2011 sales of ~ $1.1 billion.

Verapamil is an effective treatment for angina; Pfizer’s Covera-HS ® approved in 1996; oral dose at bedtime provides peak blood levels in early morning.
Problem:

Fentanyl, a potent opioid, was too difficult to deliver via injection or pill
Value of drug delivery

Fentanyl solution #1

Encase drug in a long-acting patch to slow release and extend duration.

Duragesic ® patch designed for 3-day delivery.

Sold $2.083B in 2004.
Value of drug delivery

Fentanyl solution #2

Form drug into a “lollipop” that provides transmucosal delivery

Cephalon’s Actiq ® sold $412MM in 2005
The Nation's Health Dollar, Calendar Year 2009: Where it Went

- Hospital Care: 31%
- Physicians and Clinics: 20%
- Prescription Drugs: 10%
- Dental Services and Other Professionals: 7%
- Government Administration and Net Cost of Health Insurance: 7%
- Investment: 6%
- Nursing Care Facilities and Continuing Care Retirement Communities: 6%
- Other: 14%

1 Includes Research (2%) and Structures and Equipment (4%). Note: Sum of pieces may not equal 100% due to rounding.
“Every $1 spent on prescription drugs saves $4-7 in overall health care costs.”

---Peter B. Corr, Ph.D. Senior Vice President, Pfizer

National Bureau of Economic Research
http://www.nber.org/digest/oct01/w8147.html

It also found that the use of newer medicines reduced hospital and other non-drug costs, so that for each additional $1 spent on newer pharmaceuticals, over $6 are saved in total health care spending, and over 4 of those dollars come from savings in spending on hospital stays.

http://www.phrma.org/index.php?option=com_content&task=view&id=444&Itemid=119
Federal and Industry Roles in Research and Development

Government and biopharmaceutical industry research are complementary

Private Sector – $65.3B¹

NIH – $31.2B³

There is an ecosystem of science and biotechnology. Public organizations, patient organizations, universities, Congress, FDA, all of this is an ecosystem that is envied in the rest of the world.

– E. Zerhouni, Director of NIH

Some Trends

Biologicals growing, including biogenerics

* by 2016 7 of the top 10 drugs are expected to be biologics including the top 3—humira, avastin, rituxan.
* and 45% of the top 100 drug sales will be biologics (including vaccines)

Pharmacoeconomonics will grow in importance

* 1994 Australia first country to use pharmacoconomics in approval
* QoL

Globalization

* in the US market 40% of drugs are manufactured outside the US and 80% of APIs
* China is the #1 consumer of cars, luxury goods, cell phones; #2 in jewelry, electronics, internet usage----predicted to be #2 in pharmaceutical by 2015