

The Convergence of Innovative Devices with Therapeutic Drugs

Stephen Allan
Vice-President of Marketing
Unilife Corporation

About Unilife

Design, develop and supply of innovative safety medical devices

- Proprietary portfolio of safety syringes with best-in-class features
- Established in Australia in 2002
- Listed on NASDAQ and ASX
- FDA-registered facility in Central PA
- 175 staff, world-class team
- Strong relationships with pharmaceutical industry leaders
- Building operational capabilities to meet projected customer demands



Investing in Pennsylvania

State-of-the art device production facility



- Meeting pharmaceutical standards for primary drug containers
- 165,000 sqf facility and global headquarters in York, PA

Investing in Pennsylvania

Commenced clearance and construction in December 2009



Designed to manufacture up to 400mm syringes annually



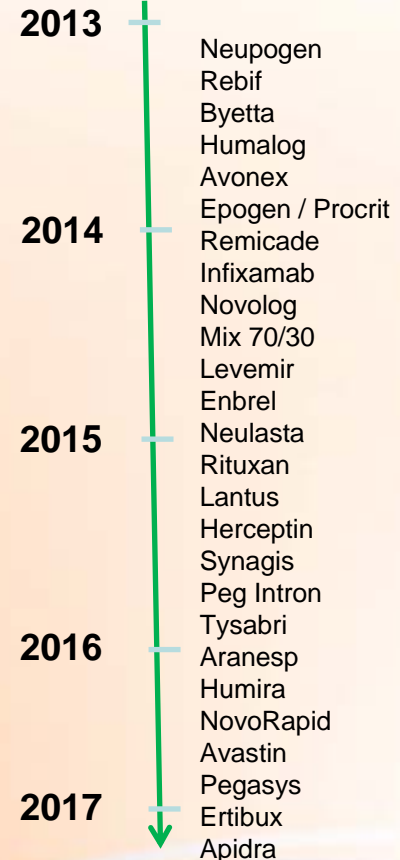
Ready for operations late-2010



The Convergence of Drugs and Devices

- Therapeutic markets becoming crowded and price-sensitive
 - \$80 b in drug revenues approaching patent cliff
 - Laws favoring generics / biosimilars
 - Pipeline portfolios being trimmed
- Two questions now driving Lifecycle Management (LCM)
 - How can we secure powerful brand differentiation for our drug product?
 - How can we optimize, and ideally extend, the lifecycle of our drug?
- Drug delivery devices at a key pillar of LCM strategies

Biotech Patent Cliff



How Devices Can Deliver Brand Differentiation

- Pharmaceutical companies seek devices that combine:
 - Ease of Use
 - Elegance
 - Performance
 - Safety
 - Strong IP
- Other influential factors include:
 - Streamline industrial costs
 - Enhance regulatory claims
 - Increase operating margins

“The fewer other differentiators there are, the more important the role of injectable drug delivery may be. In some therapeutic areas, we see a lot of competitive activities focusing on devices rather than the drugs themselves.”

Mathias Romacker
Principal Business Analyst
Amgen

American Pharmaceutical Review. 2009

Main Pharmaceutical Options for Accessing an Innovative Device

Which commercial path matches your business model?

- **Commercial Supply Agreement**

- **Acquisition of Company or IP**

- Roche buys semi-disposable insulin patch pump company Medingo for \$165m to expand market position for insulin delivery systems

- **Licensing**

- Intelliject enters \$230m licensing agreement with sanofi-aventis for U.S. / Canada rights to novel epinephrine auto-injector

- **Exclusivity**

- Sanofi-aventis commits \$40m in exclusivity fees & industrialization payments for right to negotiate purchase of Unifill prefilled syringe

Unilife's Relationship with sanofi-aventis

- Nov 2003 Sanofi-aventis approaches Unilife (10 staff at time)

Unilife begins work on the Unifill prefilled syringe

- Dec 2006 Initial 12 month exclusivity agreement - \$500k
- 2007-08 Full IP review, pilot production, validation tests
- Jul 2008 EU\$10m (\$16m) Exclusivity Agreement

Industrialization program commenced

- Jun 2009 EU\$17m (24m) Industrialization agreement
- Mar 2010 Parties agree to exclusivity list
- Jun 2014 End of current exclusivity period

(1) €10mm converted using exchange rate of \$1.57 to €1.00

(2) €17mm converted using exchange rate of \$1.39 to €1.00

The Unifill Ready-to-Fill (Prefilled) Syringe

- Primary drug container with safety integrated into glass barrel
 - Automatic, controlled retraction
- USP compliant materials
- Integration into fill-finish systems
- Optimal protection from harm
- Compact handling, intuitive use
- Strong patent position to 2028
- Commences production in 2011

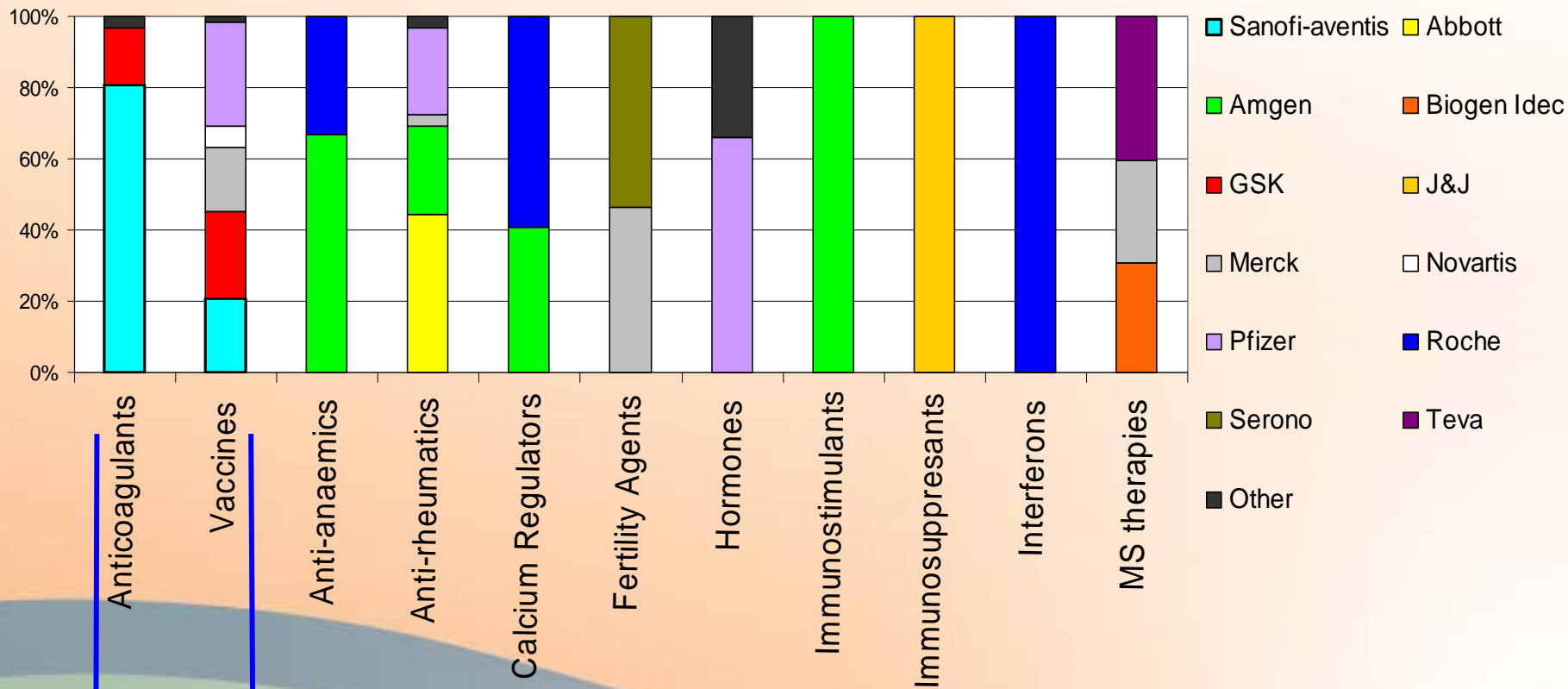


Key Benefits of Partnership for Unilife

- Relationship with world's largest prefilled syringe purchaser
- Internal access to proprietary pharmaceutical information
- Provided funding to help complete device industrialization
- Raised investor confidence in our company and its future
- Retained right to supply product to other interested parties

Prefilled Use by Therapeutic Drug Class

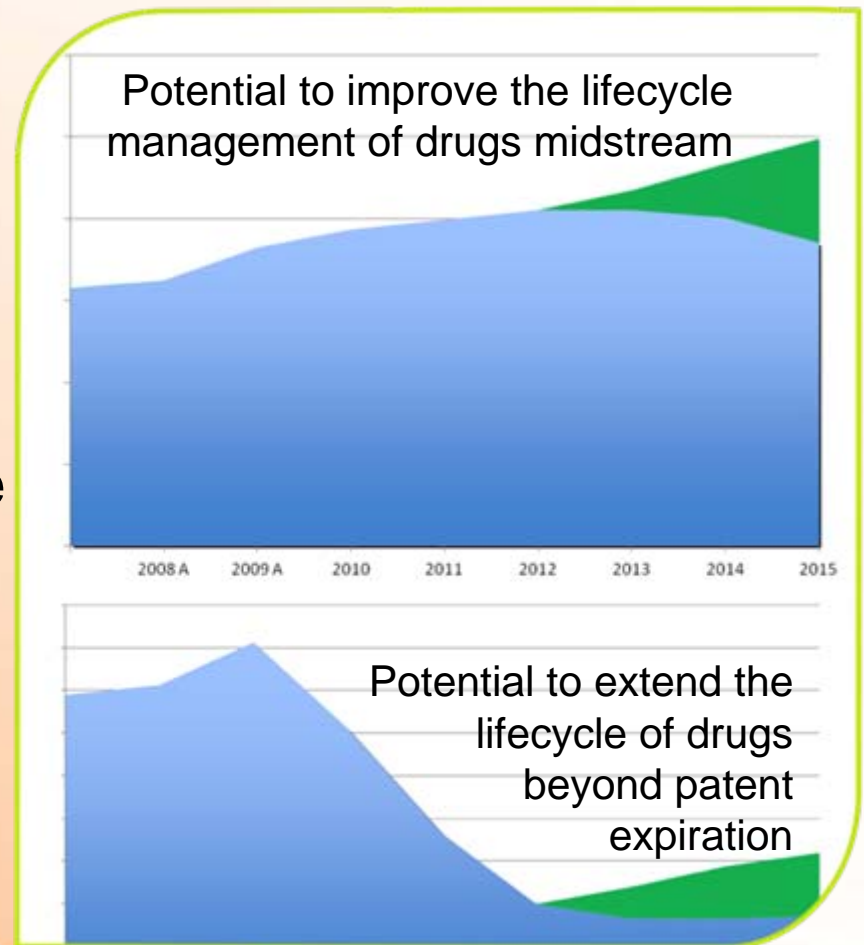
Indicative guide based on disclosed revenues for approved drugs available in pre-filled format



Exclusive to sanofi-aventis

The USP for the Unifill Syringe

- Use by clinicians or patients
- Optimal protection from harm
- Unique device: not commodity
- Powerful brand differentiation
- Can help optimize or extend the lifecycle of drugs
- Favors premium brand strategy
 - Potential for higher margins
- Potential to improve claims for drug device combination
 - May obstruct entry of biosimilars or generics



Key Lessons for Building Pharmaceutical Relationships

- Differentiate your device – make it special to the customer & patient
- Have a model that balances customer buy-in and retaining control
 - Have a strong patent position
 - Demonstrate your industrial capability to be a trusted supplier
 - Build a world-class team with the expertise to deliver
- Harness your USP via the drug-device combination product
 - How can it deliver powerful brand differentiation?
 - How can it optimize lifecycle management (or extension)
- Don't be a commodity item – offer something only you can!