Existing and emerging technologies/markets for Nasal, Pulmonary & Ophthalmic Drug Delivery

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Dedicated to proprietary innovative drug delivery solutions for biotechnology, healthcare and pharmaceutical applications

- Drug delivery solutions product portfolio for:
  - Allergic Rhinitis Asthma & C.O.P.D.
  - Pain Vaccines
  - C.N.S. and a variety of other Rx Applications

Strongly focused on innovation

Publicly traded on NYSE (ATR)

Manufacturing sites @ 6 locations:

- Argentina
- China
- France
- Germany
- Switzerland
- U.S.A.

2009 KEY FIGURES
Net sales: 430 M$
Number of employees: 2,280
Some factors affecting the dynamics of the pharmaceutical market

- Severe pressure on health care costs
- Increasing generics sector
- Fast growing emerging markets sector
- Drugs coming off patent → differentiation & life cycle management
- Increased and ageing population
- Unmet medical needs
- More emphasis on patient compliance and convenience
Nasal spray pumps

- Have been around for >40yrs, growing market
- Main applications are for nasal congestion, allergic rhinitis (350M sufferers worldwide)
- More recently systemic treatments introduced, pain management (incl. controlled subs), migraine
- Large OTC market for nasal salines etc
- One strong driver for change – increasing regulatory standards, e.g. FDA, EMA guidance docs
  - Increased levels of control for CQA (critical quality attributes) e.g. spray performances
- Two recent introductions in nasal spray pumps addressing these issues are:
  - Equadel ®
  - CPS
Nasal spray pumps

**Equadel®**

- pre-compression
- Minimal patient influence on dosing, user independent spray performance
- Improved spray plume & quality

**CPS**

- pre-compression
- Improved spray plume & quality
- No metal contact parts in drug path
- Tip seal mechanism
- Preservative free system
Nasal spray pumps

- Other drivers for change - Emerging markets, low cost, & effective, ease & simplicity of use…
  - e.g. unit dose systems for influenza,
    - Nasovac ®
  - e.g. pain management products, ease of use & fast onset of action
    - Instanyl ®, Nycomed
    - PecFent ®, Archemedes Pharma
Devices for pulmonary aerosol delivery

- Have been around for >50yrs (pMDI), growing market
- Main applications are for asthma & COPD (chronic obstructive pulmonary disease), 600M devices sold worldwide
- Devices include pMDIs (metered dose inhalers), DPIs (dry powder inhalers) and nebulisers
- More recently anti-viral treatments introduced (influenza)
- DPIs are gaining market share
- Drivers for change – improved product features
  - Convenience, multi-dose (30 or 60) devices
  - Dose counting (also a regulatory requirement in the US)
  - Intuitive, easy to use (hand lung coordination), portable
A recent development addressing these issues is Prohaler ® DPI

- 30 doses
- Dose counter
- Breath triggering opening system
- Easy to use
- Developed with clinical input to optimize patient use
  - Patient acceptance
  - Breath triggering levels
  - Air flow
  - Powder delivery performance
Eye care is a large and growing market (~340M people have impaired vision worldwide).

Increasing due to age-related visual impairment (aging population).

For chronic treatment, multi-dose containers used, cost effective.

Most require preservatives to guarantee microbial stability and sterility.

Common non-preserved alternative, blow fill seal unit dose.

Drivers for change – improved product features:
- Preservative free multi-dose alternatives.
- More cost effective than unit-dose.
- Opportunities for LCM.
A recent development addressing these issues is the OSD (ophthalmic squeeze dispenser)

- Multi-dose
- Preservative free due to
  - Spring loaded tip-seal technology
  - Sterile filtration of the venting air
- Metal free fluid path
- Cost effective (per dose)
- Life cycle management opportunity by differentiation
Improving patient compliance & convenience

- Pressure on health care costs – improved patient compliance can reduce these costs
- Lack of patient compliance (i.e. hospitalizations etc) wastes ~$100 billion /yr

Drivers for change – improved product features
- Device that are convenient and easy to use can improve compliance, user centric designs
- Devices that improve compliance can significantly reduce healthcare costs
- Opportunities for LCM
Recent developments addressing these issues are:

**Latitude®**
- Can improve compliance due to
  - Improved ergonomics
  - Handling comfort, hygiene
  - Ease of actuation
- Developed using direct input from patient acceptance studies
- Provides LCM opportunities

**E-solutions**
- E-counters
  - Dose counting, improved compliance, timely prescription refills
- E-lockout systems
  - Allow self dosing, e.g., breakthrough pain, healthcare professional supervision unnecessary
  - Eliminates risk of overdosing
- E-data monitoring
  - Telemedicine, part of integrated e-healthcare system
Many new & innovative developments emerging in the nasal, pulmonary and ophthalmic drug device delivery area

They aim to meet the evolving needs of the market:
- Healthcare costs, generics sector, emerging markets, differentiation & life cycle management, more emphasis on patient compliance and convenience
- Patients as well as health care costs should benefit from these advances

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