Rovi

A Specialty Pharma Growth Story
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Overview
Multiple Pillars of Growth

Leading Spanish Specialty Pharma Company

- 2013 Revenue: €157 Mn '04-'13 CAGR: 18%

Exceptional Growth Drivers

- Differentiated specialty product portfolio
- Strong flagship product Bemiparin and unique expertise in LMWH
- Partner of choice in Spain
- Accelerating internationalization of Bemiparin
- World class pre-filled syringe and oral compounds toll manufacturing services
- Novel extended release injectable delivery technology with transformational potential

World Class Pre-filled Syringe and Oral Forms Toll Manufacturing

- 2013 Revenue: €60 Mn '04-'13 CAGR: 18%

Robust Research and Development and Broad Pipeline

- 2013 Operating revenues: €218Mn '04-'13 CAGR: 15%

Highly attractive risk / reward profile

- Fully invested infrastructure delivering strong operational leverage

2013 Revenue: €157 Mn

2013 Operating revenues: €218Mn

2013 Revenue: €60 Mn

2013 Operating revenues: €218Mn

2013 Revenue: €157 Mn

2013 Operating revenues: €218Mn

2013 Revenue: €60 Mn
Focused on Most Attractive Areas of the Spanish Pharmaceutical Market

**Diversified Specialty Pharmaceutical Business**

- 30 principal marketed products across 7 core franchises
  - not impacted by Spanish reference pricing regime
  - long patent protection portfolio
- 20 new products since October 2005
- Highly skilled and efficiently targeted > 250 person sales force

**Franchise Focused Business**

- **Cardiovascular**
  - Ameride®
- **Osteoarticular**
  - Calcio Vitamina D3 Rohi
  - Bertanel
- **Respiratory**
  - Hirobriz
- **Contrast Imaging**
- **Anaesthesia / Pain Relief**
  - EMLA®
  - Rhodogil®
- **Central Nervous System**
  - Thymanax®
  - Medikinet®
- **Primary Care**
  - Absorcol®
  - Vytorin®
Hibor: Differentiated 2nd Generation LMWH

Growing US $3.4 Bn Global LMWH market

Hibor Highlights

- Internally developed flagship product
- No. 2 market position in the ~€186Mn Spanish market with ~26% market share
- The only 2nd generation LMWH
  - clinically differentiated
  - applicable in a wider therapeutic window
- Sales in Spain of €43.8 Mn in 2013
- Patent protected until 2019
- Potential growth opportunity following Lovenox

Hibor Sales

Hibor Sales

Differentiated Product

Mean molecular weight (in Daltons)

<table>
<thead>
<tr>
<th>Tinzaparin</th>
<th>Dalteparin</th>
<th>Enoxaparin</th>
<th>Reviparin</th>
<th>Nadroparin</th>
<th>Beniparin</th>
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<tbody>
<tr>
<td>6,500</td>
<td>6,000</td>
<td>4,500</td>
<td>4,400</td>
<td>4,300</td>
<td>3,800</td>
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Anti-Xa: Anti-IIa Ratio

<table>
<thead>
<tr>
<th>Beniparin</th>
<th>Enoxaparin</th>
<th>Reviparin</th>
<th>Nadroparin</th>
<th>Dalteparin</th>
<th>Tinzaparin</th>
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<tbody>
<tr>
<td>8,0</td>
<td>5,3</td>
<td>4,4</td>
<td>4,0</td>
<td>3,2</td>
<td>2,5</td>
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Half-life (in hours)

<table>
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<tr>
<th>Beniparin</th>
<th>Enoxaparin</th>
<th>Reviparin</th>
<th>Nadroparin</th>
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</thead>
<tbody>
<tr>
<td>5,4</td>
<td>4,4</td>
<td>4,3</td>
<td>3,7</td>
<td>3,0</td>
<td>2,8</td>
</tr>
</tbody>
</table>

Source: Expert Opin. Pharmacotherapy (2003); 4: 1551-61
Bemiparin International presence

Highly efficient international strategy of partnering with leading local players

Rovi Group

52 countries with products launched through strategic alliances

59 countries with approved registration

15 countries with registration on-hold

14 countries with registration pending

Established International Network


(€Mn)

5,7 4,7 8,7 9,8 12,8 15,1 19,1 22,9 17,6 18,6

+22% +6%
Partner of Choice in Spain: Leading Specialty Sales Force

>250 member leading sales force: 11 products in-licensed in last 9 years and active pipeline of attractive new opportunities.

✓ 4 new in-license products to be launch until March 2020 under the MSD agreement.
In 2013, ROVI reinforced its product portfolio both through buying new products and signing new license agreements.

In June 2013, ROVI exercised the Purchase Option held over Rhodogil in Spain, which was owned by Sanofi. Under the new agreement, Rhodogil (an antibacterial drug used against infections of the oral cavity) is directly marketed by ROVI in Spain.

In November 2013, ROVI signed two important in-license agreements:

- **Agreement with Novartis** for co-marketing Hirobriz Breezehaler (indacaterol maleate) and Ulunar Breezhaler (indacaterol + glycopyrronium), being both products inhaled bronchodilators for patients with COPD. The combination of indacaterol and glycopyrronium delivered through the Breezhaler® device is the first once-daily dual bronchodilator (LABA-LAMA) for the maintenance treatment of COPD to be approved both in Europe and in Japan, and will marketed by ROVI in the last quarter of 2014.

- **Agreement with MEDICE** to market in Spain, on exclusivity basis, both Medicebran and Medikinet, pychostimulant drugs aimed for the treatment of ADHD in children and teenagers. These products are already marketed in Spain with annual sales c. €9Mn and a 20% market share.

These operations will significantly contribute to revenue growth.
Pre-filled Syringe Toll Manufacturing: High Value Added Business Model

A Global Leader in Pre-filled Syringes

- Differentiated capabilities
  - Highly flexible and responsive to our customers’ needs
  - Annual capacity of 180 Mn pre-filled syringe units
  - Can deliver pre-filled syringes in 4 weeks
- GMP, FDA approved for filling syringes that are prefilled with Water for Injection.
- Highly profitable contracts
- Limited competition and significant barriers to entry

“Customer-for-life” Business Model

Strong Revenue Visibility

- Numerous late stage conversations with multinationals
- Revenues: +15% CAGR 2010-2013.
Oral Compounds Toll Manufacturing: High Value Added Business Model

Frosst Ibérica

- Long tradition of formulation excellence in pharmaceutical products
- GMP, FDA approved for formulation and packaging of solid compounds
- Exports to more than 40 countries
- State of the art technology – Roller compaction
- Manufacturing capabilities of 3 billion of tablets and 100 million of boxes

Customers

Customers include:

- Formulation and packaging activities for Maxalt and Maxalt-MLT until March 2020
- Packaging activities until March 2017 for products sold in Spain and March 2015 for products sold abroad
- In conversations with potential new customers

Strong Revenue Visibility

- Formulation and packaging activities for Maxalt and Maxalt-MLT until March 2020
- Packaging activities until March 2017 for products sold in Spain and March 2015 for products sold abroad
- In conversations with potential new customers
A Productive R&D Engine with a Higher Probability of Success

Full spectrum of in-house R&D capabilities with a **market-driven** approach focusing on chronic diseases with large, unmet medical needs

**Efficient R&D Model**

- ~5% of sales dedicated to R&D
- Broad pipeline
- Focused on approved compounds with proven safety and efficacy
- Pursuing new indications and product enhancements
- Smaller clinical trials expected
- R&D effort enhanced through extensive partnerships
- Strong IP protection of product portfolio
Spanish pharmaceutical market
In the last four years (2010-2013), pharmaceutical expenditure decreased by 27%.

19% of reduction in the monthly pharmaceutical expenditure since the introduction of the copayment (July 2012) to December 2013.

ROVI’s prescription products sales increased by 50% in 2010-2013, beating the market by 77pp.

Slight rise of 1% and 2% reduction in pharma expenditure expected for ‘14 and ‘15 respectively.

(*) Source: Farmaindustria (Spanish Pharmaceutical Association)

http://www.farmaindustria.es/web/indicadores/mercado-farmaceutico/
## Reduction of pharmaceutical spending in Spain

<table>
<thead>
<tr>
<th>When?</th>
<th>Savings</th>
<th>Impact for ROVI</th>
</tr>
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<tr>
<td>July 2010</td>
<td>€1,500m</td>
<td>Minimal</td>
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<td>June 2010</td>
<td>€1,300m</td>
<td>€3.5m on ‘10 sales and €8m on ‘11 sales</td>
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<tr>
<td>Mar 2011</td>
<td>€1,033m</td>
<td>Minimal</td>
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<td>€2,400m</td>
<td>$&lt; 1.0m</td>
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<td>Apr 2012</td>
<td>€650m</td>
<td>Minimal</td>
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<td>July 2012</td>
<td>€7,000m</td>
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<tr>
<td>Sept 2014</td>
<td>€580m</td>
<td>Minimal</td>
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**March 2010**  
- Reform of the Reference Price System (RPS). The reference price calculated taking the lowest price in the market.

**May 2010**  
- Mandatory discount of 7.5% on the sales of medicines excluded from the reference prices system.

**March 2011**  
- Reference prices update.

**August 2011**  
- Prescription per active principle, except for drugs belonging to a group of a drug and its licenses at the same price.

**Dec 2011**  
- Co-payment on medicines based on income levels. A max of €8 or €18/month is set for pensioners. Active workers will rise to 50-60%.

**April 2012**  
- Incorporation to the RPS of medicines authorized for >10 years, without generic, as long as there is another medicine with the same AP.

**March 2014**  
- Single health card and health service portfolio.
- Restriction of health tourism.
- Joint purchasing centre.

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**Impact for ROVI**  
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Business growth strategy
Our main strategic pillars to lead growth

**Specialty pharma**
- Bemiparin
- Recent launches such as Vytorin, Absorcol and Medikinet
- Existing portfolio (Corlentor, contrast imaging agents...)
- New in-licensed products to be launched (Hirobriz, Ulunar)
- 4 additional MSD products

**Toll manufacturing**
- Spare capacity both in the injectable plant and in the oral compounds plant
- New customers to be acquired in both plants

**R&D**
- ISM Platform
  - Risperidone
  - Paliperidone
  - Letrozole
- Glycomics
## Focus on Drug Release Platform & Glycomics

<table>
<thead>
<tr>
<th>Platform</th>
<th>Product</th>
<th>Potential indication</th>
<th>Current situation</th>
<th>Expected milestones</th>
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<tr>
<td>ISM</td>
<td>Risperidone, monthly</td>
<td>Schizophrenia</td>
<td>Pre-Clinical</td>
<td>• Phase I results disclosed</td>
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<tr>
<td>ISM</td>
<td>Paliperidone, monthly</td>
<td>Schizophrenia</td>
<td>II</td>
<td>• Phase II ongoing</td>
</tr>
<tr>
<td>ISM</td>
<td>Letrozole, quarterly</td>
<td>Breast Cancer</td>
<td>III</td>
<td>• Phase III starts 2H 2015</td>
</tr>
<tr>
<td>Glycomics</td>
<td>Bemiparin (LMWH)</td>
<td>Small Cell Lung Cancer (*)</td>
<td></td>
<td>• Phase I starts 1H 2015</td>
</tr>
</tbody>
</table>

ISM: *in situ* microparticles; LMWH: low molecular weight heparin;  
* Currently looking for a strategic partner to go on further clinical development
ISM®: innovative technology for the prolonged release of substances

**Administration technology**

- Separated syringes containing:
  - The drug and polymer (solid state)
  - The solvent (liquid state)

**Combination of syringes**

1. **Reconstitution**
2. **Carrier strengthening**
3. **Drug released in body fluids**

*The ISM technology aims to combine the advantages of micro-particles and pre-formed implants*
Risperidone ISM®. First Phase I study ("proof of concept")

- Phase I, open label, single dose escalation, single centre, on 17 healthy volunteers
- "Proof of concept": kinetics, safety, and tolerability
- Results disclosed in July 2011

ClinicalTrials.gov # NCT 01320410
9M 2014 financial results - Highlights

- **Operating revenue** increased by 8% to €173.3Mn, mainly driven by the strength of the prescription-based pharmaceutical business, where sales rose 9%, clearly outperforming the market, and by the toll manufacturing business which grew by 6%. Total revenue increased by 8% to 175.5 million euros in the nine-month period ended 30 September 2014.

- For 2015, ROVI expects a mid-to-high single digit growth rate for the operating revenue.

- **Outstanding performance of Bemiparin**: +8% growth to €53.0Mn, representing 31% of total operating revenue.

- **Excellent performance of Absorcol & Vytorin**: sales increase of 19%.

- **Excellent performance of Corlentor**: sales increase of 19%.

- **Sales of Medicebran and Medikinet**, both products launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, reached €5.1Mn.

- **EBITDA increased by 14%** to €28.9Mn, reflecting a **0.9pp EBITDA margin rise** vs 9M 2013.

- **Net profit** (€19.9Mn) growth of 6%.

- In July, ROVI paid a gross dividend of **€0.1612/share** on 2013 earnings, +18% vs last dividend.
Growth driven by the specialty pharmaceutical business strength…

Operating revenue increased by 8% in 9M 2014, up to €173.3Mn, driven by the strength of:

- the specialty pharmaceutical business, where sales rose 9%; and
- the toll manufacturing business, where sales increased by 6%.

ROVI forecasts to continue growing despite the difficult situation that the Spanish pharmaceutical industry is going through:

- 1% rise expected by Farmaindustria¹ for 2014;
- 2% reduction expected by Farmaindustria¹ for 2015; and
- continued decreases in the pharmacy retail market at least until 2017 according to IMS Health².

¹ http://www.farmaindustria.es/web/indicadores/mercado-farmaceutico/
² http://www.farmaindustria.es/web/documentos/boletines (boletín nº 108, April 2014)
Gross margin impacted by the increase of customers being invoiced for materials in the injectables plant

- Gross margin decreased by 1.4 pp in 9M 2014 vs 9M 2013 mainly due to:
  - the increase in volumes manufactured for clients being invoiced for materials in the injectables plant, contributing with lower margins.
  - The decrease of the Bemiparin raw material cost impacted positively in 9M 2014 gross margin.

- Gross profit increased by 5% to €105.7Mn in 9M 2014.
EBITDA increased by 14% to €28.9Mn in 9M 2014, reflecting a 0.9 pp rise in the EBITDA margin to 16.7% in 9M 2014 up from 15.8% in 9M 2013. This increase has been achieved on higher sales and operating leverage of the business.

Depreciation and amortization expenses increased by 31% in 9M 2014, up to €6.5Mn, as a result of the new PP&E and intangible assets purchases made during the last twelve months.

EBIT increased by 10% to €22.4Mn in 9M 2014, reflecting a 0.2 pp rise in the EBIT margin to 12.9% up from 12.7% in 9M 2013.
Net profit increased by 6% to €19.9Mn in 9M 2014.

Effective tax rate of 5.2% in 9M 2014 vs 4.1% in 9M 2013. This favourable effective tax rate is due to:

- deduction of existing R&D expenses; and
- capitalisation of existing negative tax bases from Frosst Ibérica.

As of December 2013, Frosst Ibérica had €57.5Mn of negative tax bases, of which €7.4Mn were used in the 2013 income tax and €6.2Mn to be used in 9M 2014.

On 20 June 2014, the Spanish Government announced a deep tax reform, to be introduced from January 2015.

These suggested tax measures would positively affect ROVI income statement and income tax payable rate. ROVI expects to maintain an effective tax rate from mid to high single digit for the following years.

The tax reform content is still pending to be approved. Among the suggested tax measures that would affect corporate income tax, it should be noted that:

- the tax rate is reduced from 30% to 28% in 2015 and to 25% from 2016;
- tax losses may offset positive taxable income faster and without time limit from 2016; and
- R&D tax credit schedule is maintained.
Debt with public administration represented 44% of total debt, with 0% interest rate.

New banking debt of €20Mn, of which €12Mn came from European Investment bank funds (through banking institutions) with very good conditions.

- despite the new banking debt (€20Mn) obtained in 9M 2014, total debt increased only by €6.3Mn as of 30 September 2014 compared to total debt as of 31 December 2013.

Gross cash position of €36.1Mn as of 30 September 2014 vs €36.7Mn as of 31 December 2013.

Net cash position of -€1.2Mn as of 30 September 2014 vs €5.8Mn as of 31 December 2013 mainly as a result of a 6.3 million euros total debt increase.

On July 3, ROVI paid a dividend of €0.1612 per share on 2013 earnings. This dividend meant an increase of 18% compared to the dividend on 2012 earnings.
Guidance 2014 and 2015

Operating revenue 2013
€217.6Mn

Operating revenue 2014
mid single digit – high single digit

Operating revenue 2015
mid single digit – high single digit

Our main strategic pillars to lead growth

Specialty pharma
• Bemiparin
• Recent launches such as Vytorin, Absorcol, Medikinet…
• Existing portfolio (Corlentor, contrast imaging agents…)
• New in-licensed products to be launched (Hirobriz and Ulunar)

Toll manufacturing
• Spare capacity both in the injectable plant and in the oral compounds plant
• New customers to be acquired in both plants
News-flow 2014/2015

- **Specialty pharma**
  - Additional new in-licensing products to be launched

- **Toll manufacturing**
  - New contracts to be announced

- **R&D**
  - Results of ISM-Risperidone® Phase I to be released in Q4 2014
  - Results of ISM-Risperidone® Phase II to be released in Q3 2015
  - Start of ISM-Risperidone® Phase III
Multiple Pillars of Growth

**High Growth**
- Specialty focus
- Bemiparin, Ulunar, Vytorin, Absorcol,
- Corlentor, Hirobriz, Medikinet ...
- Partner of choice
- Internationalisation
- MSD marketing agreement
- New secured products

**Low Risk**
- Long patent life
- Not affected by reference pricing

**Specialty Pharma**

**Toll Manufacturing**
- Fast growing market
- Unique capabilities
- Trusted partner
- Targeting diluents
- FDA approval
- MSD manufacturing and packaging agreement

**Research & Development**
- Novel extended release injectable technology (ISM)
  - Risperidone
  - Paliperidone
  - Letrozole
- Glycomics
  - Bemiparin in Small Cell Lung Cancer

- Customer for life
- Strong revenue visibility
- High barriers to entry

- Proven compounds
- Efficient approach
- Market-driven strategy