The creation of a new niche specialty pharmaceutical company focused on rare diseases – with strong cash flow generation and growth potential

Biovitrum and Swedish Orphan will be combined forming Swedish Orphan Biovitrum with pro forma revenues 2009 of approximately SEK 2 billion and an EBITDA margin of 15 percent. Biovitrum will pay an upfront consideration of SEK 3.5 billion (on a cash and debt free basis), to be financed by a fully guaranteed rights issue, an issue in kind and bank financing. The Transaction will be instantly accretive to earnings per share for Biovitrum’s shareholders.


- **Shared mission.** Biovitrum AB (publ) (“Biovitrum”) and Swedish Orphan International AB (“Swedish Orphan”) will be combined forming Swedish Orphan Biovitrum (“SO-Bi”) (the “Transaction”). Biovitrum and Swedish Orphan share the same mission and business philosophy of developing and making available orphan drugs and niche specialty pharmaceuticals for patients with rare diseases and patients with high unmet medical needs.

- **Complementary capabilities.** Swedish Orphan brings recognized and successful business development capabilities, strong expertise in distribution, marketing, regulatory affairs, medical and customer support, along with its pan-European presence. This is highly complementary to Biovitrum’s strong product development expertise and manufacturing skills. More specifically, Swedish Orphan brings two proprietary orphan and niche specialty drugs as well as a diverse in-licensing portfolio of approximately 50 orphan and niche specialty drugs with significant growth potential to the combined group. Biovitrum contributes with its strong hemophilia franchise, manufacturing capability, several marketed niche specialty products, of which three are proprietary, as well as a late stage clinical development pipeline within rare diseases.

- **Strong platform for growth and profitability.** The combination of the two companies is expected to be instantly accretive to earnings per share for Biovitrum’s shareholders. The combined group will generate sales from approximately 60 orphan/niche specialty products plus a pipeline of two phase III and five phase II clinical product candidates to drive future growth. The combination will allow the new group to realize annual operating cost synergies and cost avoidance in excess of SEK 100 million with full effect from 2011. In addition, Swedish Orphan’s established European sales and marketing infrastructure is expected to accelerate the growth of Biovitrum’s current products as well as future pipeline products. The pro forma revenues for 2009 are estimated to reach SEK 2 billion with an EBITDA margin of about 15 per cent. The new group has a target to reach sales exceeding SEK 5 billion with an EBIT margin exceeding 30 per cent in 2015, based on its current product portfolio and pipeline.

- **Shareholder support.** Shareholders in Biovitrum, including Investor AB, representing 67 per cent of the capital and votes in Biovitrum in aggregate, have expressed their support for the Transaction and the industrial logic in the combination. The major shareholders in Biovitrum, Investor AB and MPM Capital, will propose Dr Bo Jesper Hansen, CEO of Swedish Orphan, to become Executive Vice Chairman in the new SO-Bi group. After the Transaction he will own 3 per cent of the shares in SO-Bi. Martin Nicklasson, current CEO of Biovitrum AB, will become CEO of SO-Bi.

"The two companies fit like a hand in a glove. By joining forces with Swedish Orphan, Biovitrum takes another important step in the transformation set out in the strategy adopted two years ago. In one giant leap, we form a company with a leading position within rare diseases and a solid platform for future growth and profitability," says Biovitrum’s CEO Martin Nicklasson.

"Swedish Orphan has undergone a tremendous development from a business primarily focused on the Nordic region to a broad pan-European business with both proprietary and in-licensed products. Along with Biovitrum’s product portfolio and late stage pipeline, we can further leverage Swedish Orphan’s strong platform in a value creating manner while continuing both companies’ commitment to rare disease patients and patients with unmet medical needs. This is a truly complimentary and winning combination,” says Swedish Orphan’s CEO Bo Jesper Hansen.
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About Biovitrum

Biovitrum is an international pharmaceutical company that markets specialist pharmaceuticals in several regions. Using its expertise and experience Biovitrum takes scientific innovation to patients with significant unmet medical need. Research expertise and capabilities are focused on development and production of biotechnology therapeutics within our prioritized areas of hemophilia, inflammation/autoimmune diseases, cancer supportive care and malabsorption. Biovitrum has revenues of approximately SEK 1.2 billion and approximately 400 employees (prior to the Transaction). Biovitrum’s head office is located in Sweden and the share is listed on the NASDAQ OMX Stockholm. For more information please visit www.biovitrum.com.

The above information has been made public in accordance with the Securities Market Act and/or the Financial Instruments Trading Act. The information was published at 09:30 CET on November 5, 2009.
Appendix

Background to Swedish Orphan

Swedish Orphan was founded in Stockholm, Sweden in 1988, with an initial focus on the marketing, sales and distribution of products for the treatment of rare diseases in the Nordic region. Swedish Orphan was a forerunner in the orphan drug space being founded 12 years prior to the enactment of orphan drug regulation in Europe in 2000. In 2004, Investor and Priveq, together with certain members of the Swedish Orphan management team, acquired the company. Following the change in ownership, Swedish Orphan accelerated its geographic expansion, successfully executing its strategy to establish a fully owned pan-European infrastructure. Through Swedish Orphan’s 11 regional offices, the company supports the marketing, sales and distribution of its products to all countries in Europe. Swedish Orphan has been able to finance its expansion efforts to date solely through cash-flow generated from its own operations.

The market for orphan drugs and niche specialty products differs significantly from the traditional pharmaceutical market. Due to the specialist nature of the products, the small patient populations served and the limited number of highly specialized, prescribing physicians, the orphan drug and niche specialty markets require highly scientifically skilled and well-educated personnel, as well as a strong local presence and knowledge of key local issues, including regulation, distribution, marketing, pricing and reimbursement of these products.

Today, Swedish Orphan is a partner of choice for the marketing, sales and distribution of orphan drugs and niche specialty products for the treatment of rare diseases on a pan-European basis. Swedish Orphan’s track record, full service offering and pan-European presence positions Swedish Orphan as a leader in the European orphan drug market. Swedish Orphan today has over 20 established partnership relationships, including some of the world’s leading pharmaceutical companies, including Cephalon, LFB, Ovation Pharmaceuticals (Lundbeck), PharmaMar and Shire. Swedish Orphan currently markets two proprietary products, Orfadin® (hereditary tyrosinemia type 1) and Multiferon® (malignant melanoma, as well as second line treatment to recombinant interferon, regardless of underlying condition), as well as over 50 contracted products including Yondelis® (soft tissue sarcoma), Wilfactin® / Wilfact® (von Willebrand disease) and Ammonaps® and Ammonul® (urea cycle disorders), among others.

Swedish Orphan’s increased geographic footprint and enhanced service offering has allowed the company to capture an increasing portion of the economics in the products it makes available. As part of this transition, Swedish Orphan has also successfully migrated from regional distribution agreements to pan-European licensing agreements benefiting from the higher margins associated with these agreements. As a result, gross margins have increased from 42.3 per cent in FY2005 (fiscal year end April) to 61.6 per cent in FY2009.

Financial track record

During the last five years, Swedish Orphan has grown net sales at a CAGR of 18 per cent, despite the expiration of a distribution contract with Gilead Sciences Ltd. in 2008 which reduced sales by approximately SEK 200 million on an annual basis. The CAGR in net sales amounts to 27 per cent adjusted for the Gilead products. During the same period Swedish Orphan’s operating profit (EBIT), as reported, has grown at a CAGR of 45 per cent, to a large extent driven by increased share of revenues from proprietary products.

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<thead>
<tr>
<th></th>
<th>3 months ended July 31st</th>
<th>Full year ended 30 April</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2008</td>
<td>2009</td>
</tr>
<tr>
<td>Net sales</td>
<td>200,294</td>
<td>200,871</td>
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<tr>
<td>Growth</td>
<td>-5.3%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Gross profit</td>
<td>112,526</td>
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<tr>
<td>Gross margin</td>
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<tr>
<td>EBIT(3)</td>
<td>61,898</td>
<td>60,736</td>
</tr>
<tr>
<td>EBIT margin(3)</td>
<td>30.9%</td>
<td>30.2%</td>
</tr>
</tbody>
</table>

1) Prepared in accordance with Swedish GAAP
2) Swedish Orphan adopted IFRS on May 1, 2006
3) Adjusted for non-recurring events
Products

In addition to Swedish Orphan’s two proprietary products, Orfadin and Multiferon, the company has successfully expanded its product portfolio through ongoing business development efforts. Swedish Orphan has added on average 2-3 new products per year since its founding and has today assembled an extensive portfolio of over 50 specialty products targeting orphan drug indications and rare diseases, which generally have a clear unmet medical need. Swedish Orphan currently carries 12 officially orphan drug designated and/or approved orphan drugs in its portfolio. Additionally, many of Swedish Orphan’s other products qualify as orphan drugs, but were approved prior to the implementation of the EU orphan drug legislation in 2000.

Though Swedish Orphan’s products address a broad spectrum of diseases, the company has established a strong level of expertise in several therapeutic areas including metabolic disorders, oncology, haematology, infectious disease, nephrology and emergency medicine. Swedish Orphan’s key products are detailed below.

Sales split 2008/09 for proprietary and contracted products

Orfadin®

Swedish Orphan’s proprietary orphan drug, Orfadin (nitisinone), is a multi-award-winning drug that has saved the lives of hundreds of rare disease patients worldwide since its initial launch in 2002 in the US, though the product was available prior to 2002 on a Named Patient basis. Orfadin is the clear standard of care and only available pharmaceutical treatment for the lethal inborn error of metabolism called hereditary tyrosinemia type 1 (“HT-1”). HT-1 is caused by a block in the degradation of the amino acid tyrosine, resulting in the formation and accumulation of harmful substances in the body. Based on a hypothesis developed in the early 1990s by two Swedish researchers, Swedish Orphan developed Orfadin, which is now approved as an orphan drug in both the EU and US. To date, Orfadin has been provided to over 700 patients in more than 50 countries across the world.

Multiferon®

Multiferon is Swedish Orphan’s second proprietary product, a human multi-subtype interferon alpha, that was initially approved in Sweden in 1994 for a second line indication for the treatment of patients who are intolerant to or do not respond to treatment with recombinant alpha-2 interferon, regardless of underlying disease. In 2006, Multiferon was further approved in Sweden for the adjuvant treatment of high-risk patients with malignant melanoma, stages IIb-III, after initial cycles of dacarbazine (DTIC). Based on these approvals in Sweden, Swedish Orphan initiated an MRP for Multiferon in 2008 which was completed in March 2009, at which time Swedish Orphan was granted the marketing authorization in an additional 14 European countries, including the Nordic countries, the Baltic states and certain Central and Eastern European countries. Swedish Orphan has obtained pricing and reimbursement approval in three Nordic countries and has recently launched Multiferon in two Nordic countries and intends to launch Multiferon during late 2009 and early 2010 in the 13 other countries in Europe where the product was approved. Swedish Orphan plans to follow the first round of approvals for Multiferon with a second round of MRP to be initiated in early 2012 addressing the remaining 14 European countries, including the two largest markets in Europe, France and Germany. In support of the planned second round of MRP, Swedish Orphan is currently planning two Phase III study clinical studies studying the safety and efficacy of Multiferon in the second line treatment of Hepatitis C. Multiferon has limited sales today.

Ammonaps® and Ammonul®

Ammonaps and Ammonul (sodium phenylbutyrate) were contracted from the US-based company Ucyclyd in 2004. Approved in 2000, Ammonaps is marketed by Swedish Orphan within Europe and is provided on a Named Patient basis in countries outside of Europe including Turkey, Middle East and North Africa. Ammonaps is indicated for the treatment of urea cycle disorders, a disorder caused by complete or partial deficiency of a liver enzyme that is needed to break down protein, which leads to the accumulation of ammonia (nitrogen) in the patient’s urea cycle. Ammonia is highly toxic to the brain and vital organs and at high levels rapidly leads to severe brain damage and eventual death. Ammonaps is a long-term oral treatment that improves the patient’s chance of survival by bypassing the lacking enzyme, thus reducing the increased levels of ammonium in the blood.

Yondelis®

Yondelis (trabectedin) is a leading novel oncology product in-licensed from PharmaMar in 2007. Yondelis was designated by the EMEA as an orphan drug in 2007 and is currently approved for second/third line treatment of soft tissue sarcoma. It is used when treatment with anthracyclines and ifosfamide have failed, or in patients who are not candidates for those treatments. Administered intravenously, Yondelis has proven it will prolong life even in a second/third line setting. For individual patients there can be a significant extension of life expectancy by stopping or decreasing tumour growth. In September 2009, the EMEA’s Committee for Medicinal Products for Human Use issued a positive opinion recommending the granting of marketing
authorization for Yondelis in combination with Caelyx® (pegylated liposomal doxorubicin) for the treatment of relapsed platinum-sensitive ovarian cancer patients in the EU.

**Wilfact®**

Wilfact is a product for the treatment of von Willebrand disease contracted in 2009 from LFB S.A., a French company, which specializes in plasma fractionation. Wilfact was approved in France in September 2003 under the trade name Wilfactin® and the product was approved in Germany in May 2009. Based on this recent approval, an MRP is planned to be initiated in early 2010. Von Willebrand disease is a hereditary bleeding disorder that is believed to affect one to two per cent of the general population and is caused by lack, deficiency, or malfunction of an important haemostatic protein called von Willebrand factor.

**Nascobal®**

Nascobal (Cyanocobalamin, USP) is a once weekly nasal application of essential vitamin B12, indicated for the maintenance of normal hematologic status in pernicious anaemia patients. B12 deficiency is a common side effect from many diseases, such as Crohn’s disease, Ulcerative Colitis and Multiple Sclerosis. For many of these patients, oral substitution is not possible and the patients today need to take regular injections. As the first available nasal B12 substitution, Nascobal offers an effective alternative to intra-muscular injections, minimising hassle and discomfort for the patients.