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Laboratorios Farmacéuticos ROVI

Initiation of coverage

Ace of Spain

Pharma & biotech

ROVI, a profitable, speciality healthcare company, markets ~30 proprietary and in-licensed products across nine core franchises mainly in its domestic Spanish market. ROVI is at a major inflection point; its internally developed biosimilar enoxaparin could be first to launch in key European markets (launch expected end 2017), transforming the sales growth and operating margins of the business. ROVI has a strong presence in the Spanish heparin market (and select international markets through partners), where it has been manufacturing and marketing its flagship product Hibor (second-generation LMWH) since 1998. Other top-line drivers include further product in-licensing and the potential launch (2021) of Risperidone-ISM (schizophrenia). We value ROVI at €1.0bn (€20.1/share).

Year end	Operating revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/15	246.0	22.9	0.44	0.14	35.0	0.9
12/16	265.2	30.3	0.58	0.18	26.5	1.2
12/17e	277.3	19.6	0.37	0.11	41.6	0.7
12/18e	305.4	31.1	0.58	0.18	26.5	1.2

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Biosimilar enoxaparin key near-term growth driver

ROVI could be first to launch a biosimilar enoxaparin (low molecular weight heparin [LMWH] for anti-coagulant indications) into major European markets. Originator Sanofi reported €1.03bn enoxaparin (Lovenox/Clexane) sales in Europe in 2016. ROVI's strengths lie in its long-established expertise and technical proficiency in developing, marketing and manufacturing the LMWH bemiparin (Hibor). Its operations are fully vertically integrated lending to operational efficiencies from start to finish. We anticipate operating margin expansion for the group in the longer term (beyond 2019) as enoxaparin sales ramp up and forecast a 2019 operating margin of 12.0% from 10.7% in 2016.

Portfolio of drugs growing ahead of the market

Spain accounted for 71% of net revenues in FY16, which were generated from Hibor (20.6% of net revenues in Spain) in addition to its basket of in-licensed drugs and hospital products (9.6% total revenue CAGR 2007-16). Recently in-licensed product launches and further in-licensing deals will aid stable, low single-digit top-line growth in the base business in the near term and offset product portfolio declines. Risperidone-ISM (ROVI's four-weekly formulation of J&J's Risperdal) has likely started/will shortly start global Phase III clinical trials in schizophrenia (results 2019).

Valuation: €1.0bn (€20.1/share)

We value ROVI at €1.0bn or €20.1 per share based on a three-stage DCF, forecast to 2025, at a 10% discount rate, a long-term tax rate of 15% and a 2.0% terminal growth rate. Our valuation is underpinned by the sales potential of biosimilar enoxaparin and the base business retaining stable low single-digit growth rates from further in-licensing deals. A stable dividend with a three-year average 33% pay-out ratio additionally adds value.

12 July 2017

Price	**€15.38**
Market cap	**€769m**
Net debt (€m) at 31 March 2017	2.2
Shares in issue	50m
Free float	11.86%
Code	ROVI
Primary exchange	Madrid
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	1.5	5.3	9.6
Rel (local)	6.7	4.9	(12.9)
52-week high/low	€17.25		€11.02

Business description

Laboratorios Farmacéuticos ROVI is a fully integrated Spanish speciality pharmaceutical company involved in the development, in-licensing, manufacture and marketing of small molecule and speciality biologic drugs with a particular expertise in low molecular weight heparin (LMWH).

Next events

H1 results	26 July
Biosimilar enoxaparin launch in select European countries	H217
Risperidone-ISM Phase III data	2019

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Investment summary

Company description: Diversification reaps rewards

ROVI, a profitable, Spanish speciality pharmaceutical company founded in 1946, is engaged in the research and development, as well as the manufacturing and marketing of a broad range of small molecule and speciality biologic products primarily into its domestic market (Spain accounted for 71% of net revenues in 2016). It has 1,126 employees across three locations in Spain. Total revenues have grown at a CAGR 9.6% from 2007 to 2016, driven by sales of flagship product Hibor (bemiparin), a second-generation LMWH developed by ROVI. ROVI utilises its 250 speciality sales rep base to market ~30 proprietary in-licensed products in its domestic market. Other operations include the provision of contract manufacturing services (production, filing and packaging injectable and oral formulations) to third parties. The key near-term revenue and profit driver is biosimilar enoxaparin, and launch is expected in Germany (by end 2017) following marketing approval earlier this year via the European decentralised procedure. ROVI listed on the Madrid Stock Exchange in 2007.

Valuation: €1.0bn represents significant upside potential

We value ROVI at €1.0bn or €20.1 per share, based on a three-stage DCF including our forecasts to 2025 (10% discount rate, long-term tax rate of 15%, 2.0% terminal growth rate) and removal of net debt (€2.2m net debt at 31 March 2017). Between 2026 and 2030 we reflect a slowdown in free cash flow growth rates and apply a 2.0% terminal growth rate. Our DCF model consists of ROVI's base business (product sales and toll manufacturing revenues), our forecasts for biosimilar enoxaparin and Phase III asset Risperidone-ISM, which we include on a risk-adjusted basis.

Sensitivities: Evolution of the heparin business is key

ROVI is subject to various sensitivities common to speciality pharmaceutical companies, including commercialisation (pricing, reimbursement, uptake and competition), manufacturing and financing risks. The key sensitivities for ROVI relate to successful European commercialisation of both Hibor and biosimilar enoxaparin (two years after launch [2019] enoxaparin represents 13% of our total revenue forecasts) while crystallising value from its earlier-stage pipeline will prove critical in the longer term. Ongoing in-licensing deals are required to renew the portfolio offering in Spain and replace some of the mature products, which are facing patent expiry over the next few years. We do not value the technology platform, early-stage ISM (in situ micro particle implants) R&D pipeline and any future collaborations; all of which could represent upside. ROVI is a majority family-owned business; the principal shareholder (Norbel Inversiones) holds 69.64% of the business, thus the limited free float has an impact on liquidity.

Financials: Cash-generative and stable dividend policy

In 2016 ROVI reported total revenues of €265m (+7.8% y-o-y) and operating profit of €28.3m (+29.6%). For 2017 we forecast revenues of €277.3m and reported operating profit of €16.8m, as increased R&D costs relating to the ISM portfolio weigh on the bottom line in the near term. In the longer term we expect operational leverage from the fully vertically integrated LMWH manufacturing and distribution business to aid margin expansion. We forecast an absolute 1.30% improvement in the operating margin from 10.7% in 2016 to 12.0% in 2019; margins should continue to ramp up beyond this period. At 31 March 2017, the company held €49.1m of cash and cash equivalents and short-term investments at the group level, and debt of €51.3m. ROVI has a stable dividend policy (three-year average payout ratio of 33%) and paid out €0.1390/share in 2015 and €0.1690 in 2014. A dividend of €0.1830/share is proposed on 2016 earnings.

A business on the brink of transformation

ROVI is at a major inflection point; its internally developed biosimilar enoxaparin could be first to market in key European markets (launch expected end 2017), transforming the sales growth trajectory and operating margins of the business. ROVI already has a strong presence in the Spanish heparin market (with Hibor) and the launch of biosimilar enoxaparin outside Spain will substantiate its heparin portfolio further. While ROVI expects to continue promoting Hibor in Spain (and Portugal) in the near term (patent expiry October 2019), there is less visibility beyond that point as the strategy ROVI employs will be dependent on the evolution of the Spanish LMWH market. The evolution of the Spanish market will depend on the launch of any competing enoxaparin biosimilar, Sanofi's pricing tactics and whether Hibor's competitive profile can prevent its sales being affected by shifting market dynamics towards biosimilars.

We model a decrease in Hibor sales from October 2019 as we assume that competitor launch of biosimilar enoxaparin into the Spanish market in late 2019 will alter the dynamics of the entire LMWH market. We model that the launch of biosimilar enoxaparin will enable ROVI to expand its LMWH franchise rapidly into key EU countries such as the UK, Germany, Italy and France. These countries represent large opportunities where ROVI currently has little presence. We expect a strong ramp-up in biosimilar enoxaparin sales in 2018-20, and we expect competition from three to four other entrants in this period. By virtue of its vertically integrated structure and knowledge of the market, ROVI could compete on pricing and still enjoy substantial returns.

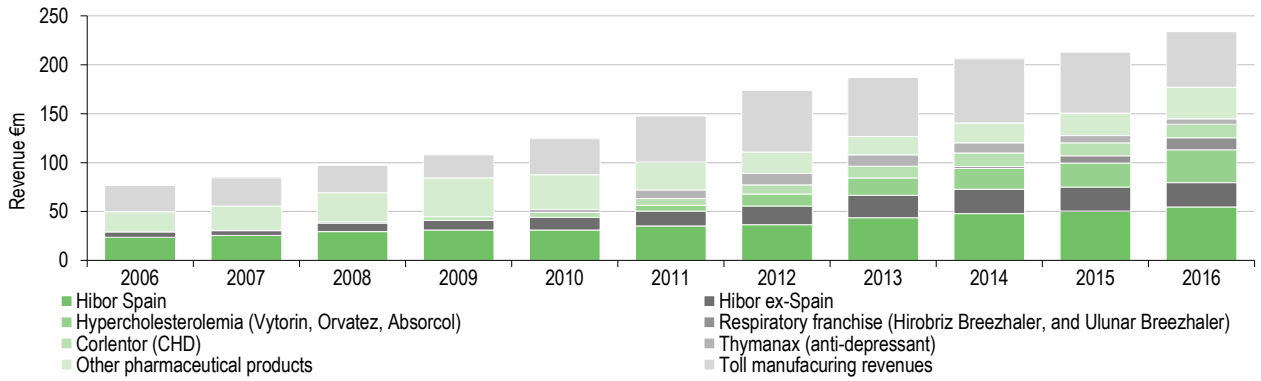
The ramp-up of enoxaparin sales has longer-term positive implications for gross margin and EBITDA development, mainly through operational leverage. Enoxaparin could be a high-margin product (similar to Hibor) and although ROVI does not disclose divisional margins we believe gross margins of around 65-75% for enoxaparin and Hibor are not unreasonable assumptions. We forecast peak sales of biosimilar enoxaparin of €160m vs Hibor peak sales of €85.0m. Furthermore, after initial launch period costs are met, we do not believe total SG&A for the group will grow in line with sales given enoxaparin will not require the same level of marketing support as for a branded product. In the near term, operating margins will be affected by the increased R&D spend relating to the Phase III risperidone and Phase I letrozole trials. However, from 2020 we expect R&D expenses to normalise close to historic levels as R&D spend in the longer term is unlikely to grow at the same rate as top-line growth. While 2016 operating margins were the highest in the company's history, we believe margin expansion will continue beyond 2019 (we estimate that the operating margin will increase by 1.3%pp to 12.0% in 2019 from 10.7% in 2016).

Base business growing ahead of the market in Spain

ROVI markets and distributes a range of healthcare products (c 30 marketed products across nine core franchises), which include branded speciality pharmaceuticals, contrast imaging agents and other hospital products. In 2016 ROVI reported total revenues of €265m (+7.8% y-o-y, 2004-16 CAGR 13%) and operating profit of €28.3m (+29.6%). Sales of prescription and OTC drugs accounted for 67% of total 2016 revenues (€177.3m, +18% y-o-y),while contrast imaging accounted for 11% (€27.9m, +6% y-o-y) and contract/toll manufacturing 21% (€56.6m, -9% y-o-y). Spain, where ROVI markets and distributes all products directly, accounted for 71% of net revenues. Notably Hibor, its flagship drug, has been the major driver of revenue growth within Spain. The remainder of sales in Spain are generated through an ever-evolving basket of in-licensed products. Additionally, ROVI's toll/contract manufacturing business accounted for 21% of 2016 revenues. In Q117, the toll manufacturing business returned to growth (up 28%) benefiting from the significant increase in capacity as a result of the acquisition of a manufacturing plant in San Sebastian de los Reyes, Spain.

The Spanish healthcare market has been challenging; growth has been affected by cost containment measures introduced by the Spanish government in 2010-12. QuintilesIMS forecasts a 1-4% growth rate in Spanish government spending to 2021. Despite this low growth, ROVI has consistently managed to grow its top-line ahead of the Spanish healthcare market (ROVI's 10-year total revenue CAGR is 9.6%). Hibor has been a large contributor to top-line growth, but the launch of multiple novel products (in-licensed assets) has enabled diversification of the product offering. Exhibit 1 highlights the historical growth trajectory of the base business.

Exhibit 1: ROVI growth trajectory



Source: ROVI, Edison Investment Research

Hibor experience drives LMWH expertise

ROVI's flagship product Hibor, a second-generation low molecular weight heparin (LMWH) for venous anticoagulation, was developed internally. It is marketed in Spain and Portugal by ROVI and in 55 international markets (ex-US) by various partners (in total, 59 countries have approved registrations, with a further 15 pending registration). Hibor accounts for 30% of total revenues (2016 sales of €79.7m, Q117 sales up 14% to €20.1m, driven by a 7% increase in Spain and a 31% increase internationally) and 69% of Hibor (bemiparin) sales in 2016 were generated in Spain. We expect low single-digit growth in Hibor sales until 2019; its composition of matter patent expires in October 2019. While we do not believe a biosimilar bemiparin could launch (to the best of our knowledge we are not aware of a product in development), there is a risk that a competitor biosimilar enoxaparin enters the Spanish market, disrupting current market economics. If a Spanish enoxaparin launch from a competitor occurs, we believe ROVI would launch its own biosimilar enoxaparin into Spain.

Hibor is designed to have an improved therapeutic profile to first-generation LMWH enoxaparin, available worldwide under the brand name Lovenox/Clexane (Sanofi). This improved profile has helped Hibor garner a 28% market share of the €200m Spanish anti-coagulant market (source: IMS and ROVI) compared to market leader Lovenox/Clexane (63% market share), a significant achievement given Hibor's premium pricing to Lovenox/Clexane in Spain and it reflects ROVI's marketing strength in its domestic market. However, Lovenox/Clexane (enoxaparin) remains the dominant LMWH, both internationally (ex US where generic enoxaparin is available) and in Spain, due to first-mover advantage, Sanofi's marketing clout and its subsequent entrenchment across hospital formularies. Lovenox/Clexane (worldwide sales in 2016 of €1.64bn, of which €1.03bn were from Europe and €0.05bn the US) is off-patent globally, but has not faced generic erosion in Europe, unlike the US market (Sanofi US sales have dropped from a peak of €1.82bn in 2009 to €54m in 2016). Higher barriers to entry in the European enoxaparin market have been created by the requirement of pharmacokinetic/pharmacodynamic comparisons and comparator Phase III trials (which have a high cost and a risk of failure in demonstrating biological and therapeutic bioequivalence) and an associated long timeframe to launch. In order to compete more broadly in the international LMWH space and to counter any revenue loss from the impending patent expiry of

Hibor (October 2019), ROVI has utilised its expertise and invested in the development of an enoxaparin biosimilar; our view is that the untapped opportunity for a biosimilar enoxaparin would more than make up for lost sales of Hibor in the longer term.

Clear strategy to expand the LMWH franchise with enoxaparin

ROVI has set out a clear strategy to launch an enoxaparin biosimilar into key countries in the EU ex Spain; we expect first launch in Germany by year end; as a 'biosimilar' drug its enoxaparin will be priced at a discount to both branded Lovenox/Clexane and own product Hibor. For its biosimilar enoxaparin, ROVI utilised the decentralised procedure (DCP) for EU drug applications with Germany acting as a reference state; the DCP completed with a positive outcome in February 2017. The national phase of the DCP in 26 countries in the EU (excluding Lithuania) is expected to be completed with marketing authorisation granted at a local country level; this national phase could last from three to 10 months. Initially we forecast launch in Germany, followed by the UK, Italy, and France within 18 months. In other regions, we expect that ROVI will use marketing partners as per its strategy. We discuss Hibor and the opportunities for branded and biosimilar LMWHs in more detail later in this note. However, we highlight here that entering the biosimilar enoxaparin market strengthens ROVI's overall franchise, enabling it to evolve into one of the top players in the LMWH anticoagulants market.

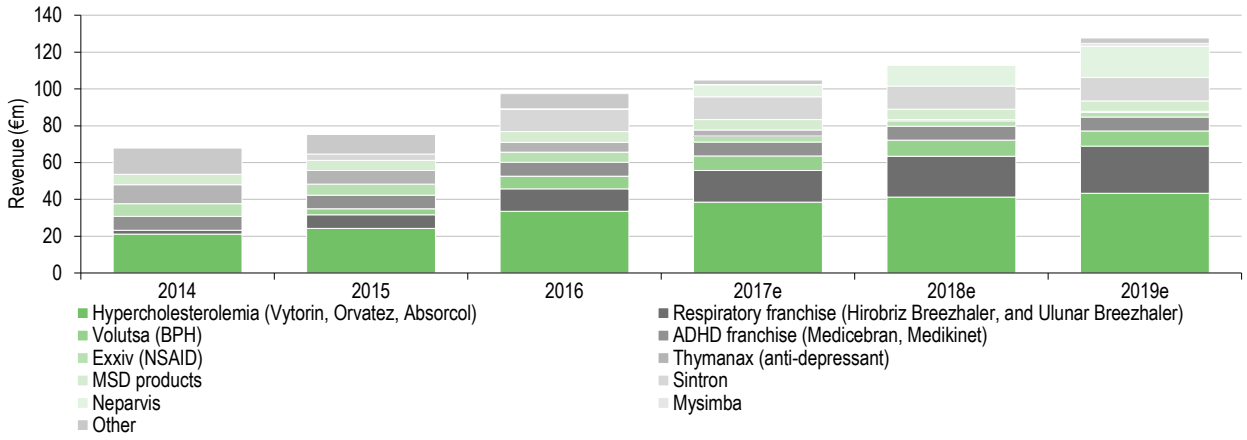
R&D: Phase III Risperidone-ISM trials

Other R&D efforts at ROVI include the development of new controlled release mechanisms based on the company's proprietary sustained-release injection technology (ISM), with the aim of formulating long-acting versions of approved pharmaceutical products. Its most advanced product Risperidone-ISM (a monthly injectable version of risperidone for schizophrenia) is expected to commence Phase III clinical trials (PRISMA) shortly (if not already done so), which should read out in 2019, with potential approval and launch in 2020/21.

In-licensed product portfolio delivers stable growth

ROVI utilises its sales and marketing infrastructure of c 250 reps across Spain to launch in-licensed products as well as internally developed assets. One of ROVI's strengths lie in its speciality salesforce, targeting mainly hospital based physicians spread across a variety of specialities. Over the last decade ROVI has successfully diversified its product offering across Spain to include over 30 brands (Exhibit 2 details ROVI's in-licensed product portfolio); the portfolio of products includes mature products facing patent expiry that ROVI continues to replace with innovative compounds in-licensed from its multiple partners. Future growth drivers include Novartis's LABA (long-acting beta agonist) and LABA/LAMA (long-acting muscarinic antagonist) inhalers for chronic obstructive pulmonary disease (COPD, launched in 2014) and the December 2016 launched products Neparvis (Novartis) and Mysimba (Orexigen). Exhibit 2 highlights the in-licensed portfolio growth trajectory.

Exhibit 2: ROVI in-licensed portfolio growth trajectory



Source: ROVI, Edison Investment Research

MSD (Merck Sharp & Dohme) agreement

ROVI and MSD reached a strategic agreement in 2009; ROVI can co-market five licences from MSD. The ezetimibe-based hypercholesterolemia franchise, consisting of Absorcol (ezetimibe) and combination drugs Vytorin (ezetimibe and simvastatin) and Orvatez (ezetimibe and atorvastatin), represents the first of these five licences. The hypercholesterolemia franchise has grown from €5.7m in 2011 to €33.5m in 2016. We forecast peak sales in 2019 of €42.3m and a decline thereafter reflecting loss of all three product patent exclusivities (between 2017 and 2019). ROVI will announce four more licences under this agreement in coming years; this should reduce the impact of these sales losses.

Neparvis better than ACE

Neparvis, a first in class angiotensin receptor Neprilysin inhibitor (ARNI) for heart failure, was in-licensed from Novartis in 2016. ROVI is responsible for promotion and distribution of the product in Spain until 2026. Neparvis, developed and marketed by Novartis under the brand name Entresto (LCZ696), is a novel mechanism of action drug for heart failure, approved by the FDA and EMA in 2015. Entresto is the first oral treatment to demonstrate a significant mortality benefit in a head-to-head trial (PARADIGM-HF) against the current gold standard heart failure treatment enalapril, an angiotensin-converting-enzyme (ACE) inhibitor. Heart failure is a major health care problem in Spain; one of the key selling features used by Novartis is that the drug can reduce hospitalisations among heart failure patients by 20%; around 3.5 million patients per annum are diagnosed with heart failure in Europe. Novartis reported worldwide sales of $84m for Entresto in Q117. We forecast Neparvis peak sales of €31.8m in 2024.

Mysimba tackling obesity

Mysimba is an extended-release oral combination of bupropion (Wellbutrin for depression) and Naltrexone (Revia for addiction) for obesity. It was in-licensed from Orexigen in 2016. Obesity rates in Spain in 2013 were reported as 22.9%, having increased dramatically from 13.3% in 2003. Mysimba is marketed in the US by Orexigen under the brand name Contrave (the international brand name is Mysimba). It is the first anti-obesity treatment approved in Europe in over a decade, being approved in September 2014 in the US and in March 2015 in the EU on the back of a large Phase III pivotal trial programme. Under the terms of ROVI alliance, Orexigen will supply Mysimba tablets to ROVI for an upfront fee, transfer price and assorted milestones (undisclosed); ROVI holds the exclusive licence to market Mysimba in Spain.

High-end contract manufacturing return to growth

The contract manufacturing business provides a range of manufacturing services for injectable (pre-filled syringes and vials) and oral drug forms (tablets, capsules, sachets) for other pharmaceutical companies that wish to outsource their manufacturing processes. ROVI has four production plants; a ROVI API manufacturing plant in Granada, two injectable fill and finish plants in/near Madrid and a plant specialising in oral formulations, additionally near Madrid. ROVI provides a start to finish service tailored to an individual client's needs including preliminary clinical trials and stability studies. ROVI reported €57m in toll manufacturing revenues in 2016 (down 9.1% vs 2015); the compound annual growth rate over the period 2004-16 was 12%. The decline in revenues during 2016 is largely attributable to a fall in production for MSD since March 2015, when the initial contract between the two companies expired. However, in Q117, ROVI reported an uplift in sales from new contracts for example the agreement with Merus Labs to supply Sintrom from Q316. The contract manufacturing consists of two key components:

- **Prefilled syringe toll manufacturing:** ROVI possesses an annual capacity of 180 million pre-filled syringe units; the facilities are GMP, FDA approved for filling syringes with active pharmaceutical ingredient (API) on behalf of numerous customers, including Novartis, Sanofi, Grifols and Hospira, as well as for ROVI-marketed products. Significant barriers to entry and limited competition in Spain translate to highly profitable contracts for ROVI; the average duration of a contract is three to five years. Given the significant opportunity for growth in both toll and ROVI's own manufacturing revenues (relating to the international expansion of Hibor and commercialisation of biosimilar enoxaparin), ROVI acquired the San Sebastian de Los Reyes plant for a €4m investment (in 2015). This investment increases the annual production capacity by 120 million syringes. ROVI is presently in numerous late-stage conversations with multinational healthcare companies and further deals could come to fruition in 2017.
- **Oral compounds toll manufacturing:** ROVI has manufacturing capacity of 3bn tablets and 100m boxes; the facilities are GMP, FDA approved for formulation and packaging of solid compounds. ROVI manufactures on behalf of numerous external clients; for example it carries out the formulation and packaging activities for Maxalt and Maxalt MLT for MSD (contracted until March 2020).

Exhibit 3: Key products sold

Franchise	Product name	2016 revenue (€m)	% of 2016 total revenues	2017-20 estimated CAGR	Active ingredients	Indication	Patent expiration	Notes
Cardiovascular	Hibor	79.671	30%	-3.9%	Bemiparin	Anti-coagulation indications including venous thromboembolic disease (VTD), deep vein thrombosis (DVT) and pulmonary embolism (PE).	Oct-19	Proprietary second-generation LMWH developed during the 1990s by ROVI. Launched in Spain in 1998 and internationally from 2002. 28% market share in Spain in 2016.
	Corlentor	13.831	5%	N/A	Ivabradine	Coronary artery disease	N/A	ROVI has been marketing under a licence from Laboratorios Servier since 2007. ROVI ceased marketing it in May 2017.
	Absorcol, Vytorin and Orvatez	33.487	13%	0.4%	Ezetimibe, ezetimibe and simvastatin, ezetimibe and atorvastatin	Hypercholesterolemia	Apr-18/Apr-19/Sept-17	Used as adjunctive therapy to diet in patients with hypercholesterolemia. All treatments licensed from MSD. Absorcol and Vytorin launched in January 2011 and Orvatez in June 2015.
	Neparvis	0.172	0%	48.6%	Sacubitril valsartan	Chronic heart failure	Nov-30	Licensed from Novartis.
	Prinivil	N/A	N/A	N/A	Lisinopril	Hypertension	Patent expired	Acquired from MSD in 2009.
Diabetes	Ameride	N/A	N/A	N/A	Glimepiride	Diabetes	Patent expired	Acquired from MSD in 2010.
Respiratory	Hirobriz Breezhaler & Ulunar Breezhaler	12.232	5%	18.0%	Indacaterol, indacaterol plus glycopyrronium	COPD	Nov-24/Sept-27	Licensed both inhaled bronchodilators from Novartis in 2013, marketed by ROVI in Spain since end 2014.
Urology	Volutsa	6.91	3%	-2.0%	Solifenacin succinate	Benign prostate hyperplasia (BPH	Jun-19	Licensed from Astellas Pharma since 2015.
Anaesthesia/pain relief	EXXIV	5.4	2%	N/A	Etoricoxib	Arthropathies	Patent expired	Selective COX-2 inhibitor licensed from MSD in 2008..
CNS	Thymanax	5.439	2%	N/A	Agomelatine	Depression	Patent expired	Licensed from Laboratoires Servier In 2010.
	Medikinet, Medicebran	7.556	3%	0.0%	Methylphenidate	ADHD	Aug-25	Licensed from Medice and ROVI has had an exclusive distribution licence in Spain since 2013.
Endocrinology	Mysimba	0	0%	171.4%	Naltrexone and bupropion	Weight reduction	Mar-25	Licensed from Orexigen and launched in Q117.
Osteoarticular	Osseor	0.09	0%	N/A	Strontium ranelate	Osteoporosis	Patent expired	ROVI has been marketing it under a licence from Laboratoires Servier since 2005.
Contrast imaging and other hospital products	Multiple brands	27.906	11%	4.5%	N/A	N/A	N/A	ROVI is one of the market leaders in Spain for contrast agents, and hospital products for imaging diagnosis. Broad portfolio including many brands under licence from Bracco.

Source: ROVI, Edison Investment Research

Evolving the heparin franchise; needs must

ROVI's second-generation LMWH, Hibor, is available in 55 countries. Hibor is clinically differentiated from Lovenox/Clexane (Lovenox is the US brand, Clexane the international brand name), and this has helped it gain some traction against Lovenox/Clexane in its domestic market (the €200m Spanish LMWH market is dominated by Hibor and Lovenox/Clexane with a 28% and 63% market share, respectively). In March 2017, ROVI received a positive outcome for its marketing authorisation application for its biosimilar enoxaparin via the decentralised procedure to market in 26 countries in the European Union. ROVI has started the national phase of the registration process, whereby each of the 26 countries grants local authorisation, and this expected to take three to ten months. We anticipate a rolling launch starting with Germany in Q3/Q417 followed by other key EU countries France, Italy and the UK. We expect that a launch within the Spanish market will depend on market dynamics primarily driven by any competing enoxaparin product, with ROVI only launching its own enoxaparin if a competitor's product becomes available.

A brief history of Heparin

Heparin, also known as unfractionated heparin (UFH), one of the oldest classes of anti-coagulation drugs, has been used for the prevention and treatment of thrombosis for several decades. UFH is derived from porcine intestine, and contains a mixture of different molecular weights, resulting in an unpredictable pharmacological profile as anticoagulation effects and pharmacological properties vary with the molecular weights. Low molecular weight heparins (LMWH) were subsequently developed to be of a more consistent molecular weight, and thus have a more predictable pharmacological profile. LMWHs are administered by subcutaneous injection (which can be self-administered) once a day and do not require a blood test to ensure efficacy. In Europe Sanofi remains the market leader with Lovenox/Clexane (enoxaparin); its enoxaparin was the first LMWH to be approved in Europe, in 1987, followed by the US in 1993 (developed by Rhone-Poulenc, which through a series of mergers ultimately became part of the Sanofi group). Other available LMWHs include dalteparin (Pfizer's Fragmin) and tinzaparin (Leo Pharma's Innohep).

Low-molecular-weight heparin is used to prevent and treat venous thromboembolic disease (VTD), deep vein thrombosis (DVT) and pulmonary embolism (PE), in surgical and medical patients. Severe complications can arise if DVT progresses, as the blood clot can travel through the veins of the body and block one of the blood vessels in the lungs, a pulmonary embolism that is potentially fatal. Patients at risk of developing venous thromboembolic embolism (VTE) are surgical patients (post abdominal surgical and orthopaedic procedures such as hip and knee replacement) and medical patients with acute illness (higher risk of clot formation due to severely restricted mobility). LMWH is used in lower doses to prevent VTD; virtually all patients undergoing the types of surgery outlined require heparin anticoagulation around the time of surgery and for some during the post-operative period. Higher doses are used to treat DVTs and additionally are indicated for the treatment of acute ST-segment myocardial infarction (heart attack) and the prevention of ischaemic complications in unstable angina and non-Q wave myocardial infarction.

Lovenox/Clexane positioning in Europe a target for biosimilars

Lovenox/Clexane is off patent globally and Hibor faces patent expiry in October 2019, so evolving the heparin franchise with an enoxaparin biosimilar has naturally been a focus for ROVI's management. Unlike small molecule drugs, the injectable, anti-coagulation drugs are biologic in nature and therefore have more complex manufacturing requirements, as highlighted by the more complicated and differing regulatory pathways (US and Europe) for biosimilars versus oral, small molecule chemical drugs. ROVI's decades-long involvement in heparin development,

manufacturing and distribution on the back of its vertically integrated structure puts it in an unparalleled position to take advantage of a biosimilar enoxaparin market. By expanding its heparin franchise to include biosimilar enoxaparin, ROVI can target so far untapped markets such as the UK, Germany, France and Italy directly.

Hibor is clinically differentiated to Lovenox/Clexane

ROVI developed Hibor (bemiparin) in the 1990s with the aim to improve on the efficacy and safety of Lovenox/Clexane (enoxaparin). Two trials noting bemiparin's clinical differentiation are described below:

- In a 7,020 patient trial studying the incidence of venous thromboembolism (VTE) in women who have given birth either by vaginal delivery or caesarean section, patients on bemiparin had marginal decreased occurrence of VTE (n=1, 0.042%) than those on enoxaparin (n=2, 0.085%). Both were markedly lower than the control group, where nine patients (0.384%) suffered a VTE. Adverse events (AE) were higher in the enoxaparin arm, including wound dehiscence (n=6, 0.256%) and haematoma (n=6, 0.256%) than with bemiparin (both 0%). The most common AE was pain, occurring in 45 (1.9%) and 20 (0.85%) of the patients in the enoxaparin and bemiparin arms, respectively.
- A post-registration trial with 381 patients (331 evaluable for efficacy) comparing both LMWHs after total knee arthroplasty demonstrated that 32.1% (n=53/165) and 36.9% (n=62/168) of patients had a venous thromboembolism in the bemiparin and enoxaparin arms, respectively. The absolute risk difference was 4.8% in favour of bemiparin (95% CI 15.1%-5.6%, non-inferiority p-value 0.02, superiority p-value 0.36). DVT occurred in 1.8% of the bemiparin (n=3/165) arm and 4.2% of the enoxaparin arm (n=7/168). Of note is that the bemiparin unlike enoxaparin was dosed post-surgery (six hours post-surgery) while enoxaparin was first dosed 12 hours before surgery. This is advantageous as it removes any LMWH related surgical complications and enables it to be given after emergency procedures.

While Hibor is marketed as a superior product to Lovenox/Clexane in Spain (28% market share) and internationally, Sanofi's first-mover advantage and substantial marketing effort has enabled it to retain market dominance. The entrenchment of enoxaparin in European markets presents a significant opportunity for any company that can launch a biosimilar.

Biosimilar enoxaparin in the US and Europe

The US and European biosimilar markets and resultant dynamics are not directly comparable across all classes of biological drugs given the differences in dynamics that exist between the regulatory bodies, the FDA and the EMA. In Europe, LMWHs are considered biological products derived from animal tissue, while in the US they are considered as non-biological chemicals (LMWHs are non-protein in nature) and are referred to as generic LMWHs. This difference in classification and arising nuances in the regulatory framework in Europe and the US has created two very different market opportunities. Generic enoxaparin has been available in the US since 2010; Sandoz's version of enoxaparin was approved by the FDA in July 2010 and launched later that year. Sanofi's sales of its originator-branded Lovenox/Clexane have been eroded almost completely by multiple generic entrants, from a peak of $2.5bn in 2009 to $60m in 2016. The European biosimilar enoxaparin market has lagged behind and the LMWH market is currently dominated by branded Lovenox/Clexane. The EMA granted marketing authorisation to two enoxaparin biosimilars in September 2016 (Thorinane [Pharmathen SA] and Inhixa [Techdow Europe AB]). Although approved, to date neither product is available on the European market; one national marketing authorisation has been granted in Poland where a biosimilar is now available (but this product is not approved for elsewhere). We note that other enoxaparin biosimilar dossiers are under assessment by the EMA, and while ROVI will likely be first to launch a biosimilar enoxaparin in Europe, others will follow in due course.

Exhibit 4: US and EU enoxaparin generics

Market	Generics on the market
Europe	No biosimilars on the market Other biosimilars approved in Europe (Techdow and Pharmathen) ROVI's biosimilar started the National Phase after DCP completed with a positive outcome
USA	Momenta/Sandoz (Novartis) since 2010 Amphastar, Actavis (acquired by TEVA) since 2012 New launches in 2015: TEVA and Fresenius (Sanofi's license)

Source: ROVI

Higher barriers to entry in Europe

ROVI's long-term expertise in the development, manufacture and marketing of heparins over numerous decades places it in good stead to compete in the biosimilar LMWH market. Higher barriers to entry in the European enoxaparin market have been created by differing regulatory requirements. Enoxaparin, an LMWH, is a semi-synthetic pharmaceutical antithrombotic agent (heparin benzyl ester), which is primarily derived from the mast cells of vertebrates. Since 2005, 23 biosimilars have been licensed in Europe. The US biosimilar market is in its infancy in comparison. In the US a regulatory framework 'The Biologics Price Competition and Innovation Act' (BPCIA) was signed in to law under the Affordable Care Act by President Obama in March 2010. Since the enactment of the BPCIA, four biosimilars have been approved through this pathway. In the US, Sanofi's Lovenox/Clexane was not approved under a Biologic Licence Application but under an NDA; hence Sandoz's enoxaparin was approved through the existing Abbreviated New Drug Approval (ANDA) process.

In the US branded and 'generic' enoxaparins are 'interchangeable' meaning the 'generic' can be substituted for the reference product regardless of the brand prescribed by the physician. The EU leaves the 'interchangeability' of a biosimilar up to the member state, so the branded product cannot be automatically substituted by the pharmacist. However, we understand from ROVI that its biosimilar enoxaparin has been deemed as non-interchangeable by the European regulators.

Biosimilar penetration is meaningful when there is a significant price difference between the branded product and biosimilar, and when there are no other treatment options than the molecule for which the biosimilar is available. As such payers are the most influential factor for market uptake of biosimilars. Market penetration of biosimilars in Europe has varied: from 5-10% in some countries to 100% in others. In the US currently eight 'generic' enoxaparins compete in a market worth $500m; substitutability and approval under ANDA means that the US market for enoxaparin is more akin to a small molecule generic market. The EU enoxaparin market presents a different opportunity and will differ from country to country, presenting higher barriers to entry. ROVI's in-depth knowledge of the heparin market and its strength in its fully vertical integrated business model places the company in a good position to exploit this untapped market in Europe.

ROVI's competitive advantage and commercial strategy

ROVI has 20 years of expertise in the LMWH market and aside from Sanofi no other company has this level of experience in Europe. ROVI's vertically integrated manufacturing process is a competitive advantage. It owns the IP/registration dossier on its biosimilar enoxaparin, has a full manufacturing process (API production, filing and packaging) and has the distribution structure in place. Its vertical integration across the board reduces the cost structure for its biosimilar enoxaparin. ROVI will manufacture the API and fill and package its biosimilar enoxaparin; thus

ROVI has invested €17.2m during the last three years to increase capacity in all of its plants including its San Sebastian de los Reyes plant (approved by authorities in Europe) and Julian Camarillo plant (approved by authorities in Europe, US, Korea, Brazil and Gulf countries) ahead of a potential launch. ROVI will have limited initial capacity over the next 20 months as manufacturing lines are gradually approved by the regulators.

ROVI will take a double-pronged approach to the commercialisation and distribution of enoxaparin in Europe and international markets (ex US):

- ROVI will market the product itself with its own salesforce in specific countries in Europe.
- ROVI will enter into distribution agreements with international players and or domestic companies in return for upfront fees, royalties and milestones on future sales.

Forecast €160m peak sales in Europe alone

Ultimately the factors determining ROVI's success in each individual market in Europe, the US and the rest of the world will be a function of pricing, the number of new entrants, potential for interchangeability, growth in existing patient demographics and the potential for non-anticoagulant indications. Unit growth drivers include an increasing prevalence of thromboembolic diseases worldwide related to demographics and growing underlying patient numbers (both surgical and medical); non-anticoagulant indications represent upside.

ROVI will stagger the European launch schedule, partly determined by near-term capacity constraints as mentioned above. We forecast launch in Germany in Q417, the UK and Italy in 2018 and France in 2019, while we assume a launch in Spain in 2020. We have focused on modelling launches in the key European markets in the near term; however, ROVI's actual launch into each country could vary in timing versus our assumptions. In Europe we assume ROVI will launch its biosimilar enoxaparin at a price discount to Lovenox/Clexane, and can achieve a peak penetration of 20%. We assume competitor biosimilars will launch not long after ROVI. ROVI intends to launch the product in emerging markets through partners; Lovenox sales in these markets were €0.5bn in 2016 (source: Sanofi 2016 annual report). We assume a 25% royalty rate on sales in these markets (based on 20% penetration and at a price discount to current Lovenox/Clexane pricing). ROVI would likely receive upfront payments as part of any licensing deal; this is not factored into our model or valuation. We forecast total peak sales of €160.2m; this includes Europe and the international opportunity ex-US. In the US market, ROVI is in advanced discussions with a partner. Once an agreement has been announced, the enoxaparin dossier will need to be resubmitted. Given the lack of visibility on the timing and launch ahead of a partnering agreement, we currently assume no sales for the US opportunity.

R&D: Next focus is ISM technology

ROVI's proprietary ISM technology is based on the formation of in situ micro particle implants (ISM) for extended release of drugs (long-acting intramuscular or subcutaneously drugs administered by injection). The focus is on targeting long-term diseases such as schizophrenia and some cancer indications where a long-acting injectable treatment could improve patient compliance. The ISM technology combines the advantages of technologies such as preformed microparticles and implants. The company believes this has the following key advantages: less variability, enhanced stability, rapid reconstitution and easier injection, to enable better compliance and therefore improved patient outcomes. Risperidone-ISM is the first clinical asset developed using its proprietary drug development technology.

Risperidone-ISM for schizophrenia

Schizophrenia is a chronic and severe mental disorder involving a breakdown in the relation between thought, emotion and behaviour, leading to faulty perception and the inability to function normally. The condition affects 0.4% of the world's population and usually requires long-term maintenance treatment using one or more atypical antipsychotic drugs. Long-term drug treatment of schizophrenia has major limitations; the US National Centre for Biotechnology Information (NCBI) estimates that 25-33% of patients are treatment resistant and relapse rates remain high (relapse rates over two years in medication treated chronic schizophrenia patients approaches 41%).

Janssen's Risperdal (risperidone), a second-generation atypical antipsychotic drug, was approved for use in schizophrenia by the FDA in 1998. Generic risperidone flooded the market in 2004 following the expiry of Janssen's exclusive marketing rights (following paediatric extension). Risperidone is available in liquid, oral and depot forms. While the majority of schizophrenia patients take daily tablets, long-acting depot versions have been developed for use in patients with poor treatment adherence. Janssen's long-acting injectable risperidone, Risperdal Consta is administered once every two weeks but requires concomitant oral therapy initially. ROVI's Risperidone-ISM is an extended-release, long-acting product that is administered at intervals of four weeks (and does not require oral therapy to start alongside it). The primary target is agitated patients in the acute setting. ROVI's formulation is fully constituted and can be stored at room temperature. Data presented so far from the Phase II study (PRISMA-2) show Risperidone-ISM to be safe and well tolerated. This drug formulation achieved therapeutic levels from the first hours after drug administration and provided a sustained release throughout the four-week dosing period over multiple intramuscular injections independently of the injection site. This supports its use as a standalone medication without concomitant oral drug treatment which could result in improved compliance. Following positive Phase II data (PRISMA-2), the Phase III (PRISMA 3) study protocol has been submitted, and we believe the first patients have been recruited or will be recruited shortly. ROVI management expects to launch the drug in 2020/21 itself in markets such as Spain, Portugal and Germany. Partners would be sought for international markets. We model that schizophrenia patients treated with risperidone fall from 10% as of 2017 to a stable 5% from 2022 (consensus estimates: EP Vantage). We forecast that Risperidone-ISM achieves a peak penetration of 10% of total risperidone sales and assume a launch in 2021 in Europe with an initial price of €12.5k and peak sales of €76.18m in 2025. We note that other long-acting risperidone products are in development, notably from Indivior (RBP-7000), which could materially affect market dynamics.

Sensitivities

ROVI is subject to various sensitivities common to speciality pharmaceutical companies, including commercialisation (pricing, reimbursement, uptake and competition), manufacturing and financing risks. The key sensitivities for ROVI relate to successful European commercialisation of both Hibor and its biosimilar enoxaparin, and crystallising value from the earlier-stage pipeline. Enoxaparin represents 13% of our total revenue forecasts in 2019 (its second year of commercial availability). Our model assumes a pricing discount is applied to the biosimilar enoxaparin market; however, if Sanofi decides to rebate its Lovenox/Clexane aggressively then there is downside risk to our forecasts and valuation. Furthermore we assume three to four competitors in this space (including Sanofi's own biosimilar enoxaparin); if more companies were to launch then this would put significant pressure on pricing and ROVI's ability to achieve €160m peak sales (Edison forecasts). If fewer competitors enter the market, then ROVI could achieve a higher penetration than our current 20% assumption.

Ongoing in-licensing deals are required to renew the portfolio offering in Spain and replace some of the mature products that are facing patent expiry over the next few years. We do not value the technology platform, early stage ISM R&D pipeline and future collaborations, which could represent upside. The largest single driver of our sales and net profit expectations is enoxaparin.

ROVI generates 70% of its revenues from its domestic Spanish market. While its revenues in Spain have been growing, overall the healthcare environment in Spain is challenging. The Spanish government has submitted a new €550m reduction in pharmaceutical expenditure expected for 2017 to the European Commission. QuintilesIMS forecasts zero growth in spending on medicine in Spain for the period 2017-2020.

ROVI is a majority family owned business; the principal shareholder (Norbel Inversiones) holds 69.64% of the business. Family ownership does raise concerns for some investors about the pitfalls of being a minority shareholder. The large shareholding also limits the liquidity of the shares.

Valuation

We value ROVI at €1.0bn or €20.1 per share based on a three-stage DCF valuation. We utilise our sales and P&L model out to 2026, from 2026 to 2030 we apply a transition growth rate (reflecting that the company is growing at a high rate during our forecast period) and finally we apply a 2.0% terminal growth rate (terminal value represents 47% of our total ROVI valuation). 10% is our standard discount rate assumption for companies with approved products and minimal development risk. We use a 15% tax rate from 2030. The current tax rate is circa 8% but over time this is expected to normalise to mid-teens.

Exhibit 5: Three-stage DCF valuation

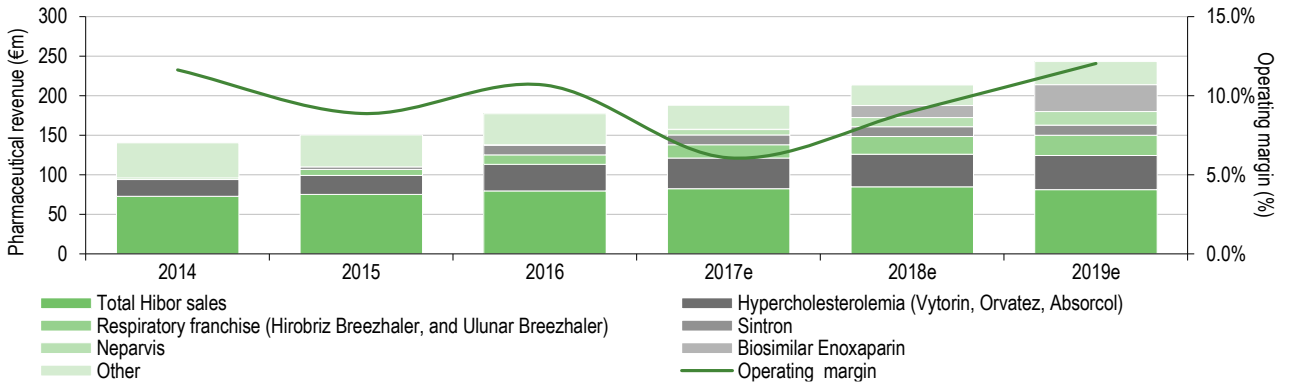
	€m
Sum of for DCF for forecast period to 2025	360
Sum of DCF for growth 2026 to 2030 (transition period)	167
Terminal value	478
Enterprise value	1,005
Net cash/(debt) at 31 March 2017	(2.2)
Value of equity	**1,002.6**
Value per share	**€20.1**
Discount rate	10%
Terminal growth rate	2.0%
Number of shares outstanding (m)	50

Source: Edison Investment Research

For biosimilar enoxaparin in Europe and international (ex US) markets, our peak sales forecasts include in-market sales in the four major countries (the UK, Germany, France and Italy) initially with a launch in Spain in 2020 after Hibor's patent expires in October 2019. We model a decline in Hibor sales post patent expiration. We also include a modest revenue growth contribution from in-licensed products and the toll manufacturing business (growing 2% a year) until 2020. We do not explicitly value the US opportunity for biosimilar enoxaparin, although ROVI is investigating the regulatory pathway options for this market and a partner for this territory. We note that the European and international (ex-US) opportunity is more significant given the number of biosimilar/non-branded biosimilars available on the US market.

Our peak sales estimate for Risperidone-ISM is €76.2m. We assume a launch in 2021 in Europe with an initial price of €12.5k. Our sales forecasts are risk-adjusted (we assume 90% probability of success given its Phase III status and position as a new formulation of a widely available drug).

Exhibit 6: Total pharmaceutical revenue including key franchises



Source: ROVI, Edison Investment Research

Valuation sensitivity to biosimilar enoxaparin

As previously described in this report, the potential market for biosimilar enoxaparin is significant in Europe and in international markets (ex-US), with our peak sales forecasts based on assumed penetration rates that we believe are achievable. How the market transpires will depend on the number of new entrants, pricing and underlying volume growth; unit growth in the LMWH market is increasing, and use in other non-anti-coagulant indications could drive upside to our forecast. However, more than three or four other biosimilar entrants could pressure pricing in the market and thus our 20% peak penetration assumptions. We note that all other things being equal, a 5% increase or decrease in peak market share (equivalent to €30m in peak sales) and the trajectories required to reach that would generates a circa €3/share increase or drop in our valuation, respectively.

Financials

ROVI reported 8% growth in operating revenue to €265.2m in 2016, aided by strong growth in the prescription-based pharmaceutical drug business, which posted a healthy 18% growth in sales in 2016. Total revenue (which includes recognition of government grants on non-financial assets at €1.6m but not €4.0m in other income as per company reporting), reported at €266.7m in 2016, represents a doubling of the revenue base since 2007, when ROVI first listed on the Madrid Exchange. In Q117, total revenue increased by 11% to €67.8m; operating revenue benefited from a strong quarter for the toll manufacturing business, where revenue was up 28% to €15.5m (Q116: €12.2m). For FY17, ROVI has guided low- to mid-single-digit revenue growth in operating revenue, excluding any contribution from enoxaparin, which is likely to launch in Germany in Q3/Q417. We forecast 4.6% growth in operating revenues in 2017 to €277.2m, and our forecast includes a €428k contribution for biosimilar enoxaparin. For 2018 and 2019 we forecast operating revenues of €305.4m and €337.5m, respectively. We expect both years to benefit from the ongoing enoxaparin roll out and growth in the newer in-licensed portfolio to offset loss of sales in off-patent products. We forecast Hibor growth to 2018 but forecast a decline in sales post its October 2019 patent expiry.

We forecast 2017 operating profit of €16.8m (-40%), translating to a large dip in operating margin to 6.1%, as we expect operating costs in 2017 to be affected by higher R&D costs relating to the ISM portfolio and enoxaparin related launch costs. Gross margins have been in slight decline (57.8% in 2016 vs 60.5% in 2015). Given the product mix of the business we would expect some volatility at the gross margin level from year to year (the proprietary heparins are higher-margin than in-licensed products). However, as enoxaparin sales ramp up and account for a higher proportion of

sales, this should translate to a steady growth in gross margins, the caveat to that being pricing. In the longer term we expect operational leverage from the fully vertically integrated LMWH manufacturing and distribution business to aid margin expansion. We forecast an absolute 1.3% improvement in operating margin from 10.7% in 2016 to 12.0% in 2019; margins should continue to ramp up beyond this period as the operational leverage from enoxaparin sales starts to flow through the P&L, offset by an increase in R&D over the period.

The effective tax rate of 8.5% in Q117 (2016 6.4% vs 5.2% in 2015) reflect margins the deduction of R&D expenses and the capitalisation of tax losses from Frosst Ibérica (as of 31 December 2016, Frosst Ibérica tax losses amounted to €36.7m, of which €1.6m was used to offset 2016 income tax liability and €0.3m in Q117). ROVI expects to maintain an effective tax rate from high-single digit to low-double-digits for the foreseeable future.

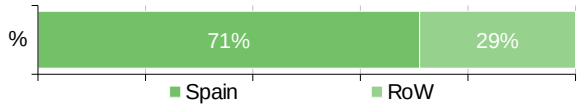
Over the last few years ROVI has been investing heavily in manufacturing capex ahead of its enoxaparin launch and also to increase capacity at its three manufacturing plants. Of the €18.1m capex spend in 2016 (€19.9m in 2015), ~50% related to maintenance capex.

ROVI maintains a low leveraged capital structure; at 31 December 2016 ROVI debt position of €33.8m consisted of €20.9m in bank borrowings (long-term debt) and €12.9m in government debt (at 0% interest). At 31 March 2017 ROVI's total debt stood at €51.3m as a result in increased bank borrowings, after adjusting for cash, cash and equivalents, net debt was €2.2m (we do not include available for sale financial assets in our calculation of net debt).

Exhibit 7: Financial summary

Accounts: IFRS; year end: 31 December; €m	2014	2015	2016	2017e	2018e	2019e
PROFIT & LOSS						
Hibor revenue	72.7	75.1	79.7	82.6	85.0	81.4
Enoxaparin revenue	0.0	0.0	0.0	0.4	15.2	34.1
Other (Pharma & Manufacturing)	165.4	170.9	185.5	194.3	205.2	222.0
Operating revenues	238.0	246.0	265.2	277.3	305.4	337.5
Cost of sales	(94.6)	(97.1)	(112.0)	(115.1)	(125.8)	(136.7)
Gross profit	143.5	148.9	153.1	162.2	179.6	200.8
Gross margin %	60.3%	60.5%	57.8%	58.5%	58.8%	59.5%
SG&A (expenses)	(97.8)	(101.7)	(101.9)	(107.3)	(113.0)	(121.5)
R&D costs	(12.0)	(16.5)	(17.5)	(27.7)	(27.5)	(27.0)
Other income/(expense)	2.9	1.0	5.6	1.6	1.6	1.6
EBITDA (reported)	36.6	31.8	39.3	28.7	40.7	53.9
Depreciation and amortisation	(8.9)	(10.0)	(11.0)	(11.9)	(13.1)	(13.2)
Normalised Operating Income	29.2	23.8	30.7	20.0	31.4	44.0
Reported Operating Income	27.7	21.8	28.3	16.8	27.6	40.6
Operating Margin %	11.6%	8.9%	10.7%	6.1%	9.0%	12.0%
Finance income/(expense)	(2.1)	(0.9)	(0.5)	(0.4)	(0.3)	(0.0)
Exceptionals and adjustments	0.0	0.0	0.0	0.0	0.0	0.0
Normalised PBT	27.1	22.9	30.3	19.6	31.1	43.9
Reported PBT	25.6	20.9	27.9	16.4	27.3	40.6
Income tax expense (includes exceptionals)	(1.5)	(1.1)	(1.8)	(1.1)	(2.0)	(3.2)
Normalised net income	25.6	21.8	28.5	18.4	29.1	40.7
Reported net income	24.1	19.8	26.1	15.3	25.2	37.4
Basic average number of shares, m	49.8	49.5	49.0	50.0	50.0	50.0
Basic EPS (€)	0.48	0.40	0.53	0.31	0.50	0.75
Normalised EPS (€)	0.51	0.44	0.58	0.37	0.58	0.81
Dividend per share (€)	0.17	0.14	0.18	0.11	0.18	0.26
BALANCE SHEET						
Property, plant and equipment	73.6	81.8	82.8	88.0	94.0	100.9
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0
Intangible assets	17.2	18.9	24.9	30.1	26.3	22.9
Other non-current assets	8.5	9.1	13.1	13.1	13.1	13.1
Total non-current assets	99.3	109.8	120.8	131.1	133.3	136.9
Cash and equivalents	26.7	29.3	41.4	24.1	22.9	35.6
Inventories	67.6	63.9	67.4	69.4	72.4	74.9
Trade and other receivables	63.7	57.0	53.8	57.0	58.6	60.1
Other current assets	4.1	3.9	4.5	4.5	4.5	4.5
Total current assets	162.0	154.1	167.1	154.9	158.3	175.0
Non-current loans and borrowings	32.0	32.6	20.8	10.6	5.9	4.2
Other non-current liabilities	8.7	7.2	7.2	6.4	5.7	4.9
Total non-current liabilities	40.7	39.8	28.0	17.0	11.6	9.2
Trade and other payables	55.0	45.7	59.9	61.7	61.9	63.2
Current loans and borrowings	4.3	10.1	13.0	10.3	4.7	1.6
Other current liabilities	2.8	3.3	3.6	3.6	3.6	3.6
Total current liabilities	62.1	59.2	76.4	75.6	70.2	68.5
Equity attributable to company	158.5	164.8	183.4	193.4	209.9	234.3
CASH FLOW STATEMENT						
Profit before tax	25.6	20.9	27.9	16.4	27.3	40.6
Depreciation and amortisation	8.9	10.0	11.0	11.9	13.1	13.2
Share based payments	0.0	0.0	0.0	0.0	0.0	0.0
Other adjustments	2.5	(1.1)	(2.7)	0.4	0.3	0.0
Movements in working capital	(7.4)	2.3	12.7	(4.0)	(5.2)	(3.4)
Interest paid / received	(2.7)	(0.6)	0.0	(0.9)	(0.5)	(0.3)
Income taxes paid	(3.9)	(2.0)	(3.4)	(1.1)	(2.0)	(3.2)
Cash from operations (CFO)	23.0	29.4	45.5	22.8	32.9	46.9
Capex	(25.1)	(19.9)	(18.1)	(22.3)	(15.3)	(16.9)
Acquisitions & disposals net	0.0	0.0	0.0	0.0	0.0	0.0
Other investing activities	16.6	0.6	1.7	0.4	0.2	0.2
Cash used in investing activities (CFIA)	(8.5)	(19.3)	(16.3)	(21.8)	(15.0)	(16.6)
Net proceeds from issue of shares	(2.0)	(5.1)	(0.5)	0.0	0.0	0.0
Movements in debt	2.7	5.9	(9.7)	(13.0)	(10.3)	(4.7)
Other financing activities	(8.0)	(8.3)	(6.9)	(5.3)	(8.8)	(13.0)
Cash from financing activities (CFF)	(7.3)	(7.6)	(17.1)	(18.3)	(19.0)	(17.6)
Cash and equivalents at beginning of period	19.4	26.7	29.3	41.4	24.1	22.9
Increase/(decrease) in cash and equivalents	7.3	2.6	12.1	(17.3)	(1.2)	12.7
Cash and equivalents at end of period	26.7	29.3	41.4	24.1	22.9	35.6
Net (debt) cash	(9.6)	(13.5)	7.6	3.2	12.3	29.7

Source: ROVI accounts, Edison Investment Research

Contact details	Revenue by geography
Laboratorios Farmacéuticos ROVI Julian Camarillo 3528037 Madrid Spain +34 91 375 62 30 www.rovi.es	

Management team

Chairman: Juan López-Belmonte López

Juan López-Belmonte López has been the chairman of ROVI for the last 22 years. He graduated in economic and business sciences from the Universidad Complutense de Madrid in 1969. He is also president of the Madrid Chamber of Commerce, a member of the Plenary Session of the Spanish Chamber of Commerce and a member of the governing body of the IFEMA (Madrid Trade Fair Institute). He is a shareholder of Norbel Inversiones (ROVI's controlling shareholder).

Chief Executive officer: Juan López-Belmonte Encina

Juan López-Belmonte Encina has been CEO since October 2007. He has been working for the company since 1994 and was appointed general manager in 2001. He graduated in economic and business sciences from CEU San Pablo, Madrid, specialising in auditing, in 1993. Prior to this he worked for international pharmaceutical companies (Nielsen Group, Tyco Group and Boots Pharmaceuticals). He is a vice-president of the board of governors and executive board of Farmaindustria and chairman of the R&D&I Commission of the CEOE (Spanish Confederation of Business Organizations). He is a shareholder of Norbel Inversiones (ROVI's controlling shareholder).

Chief Financial Officer: Javier López-Belmonte Encina

Javier López-Belmonte Encina has been CFO since 2001 and is second deputy chairman of ROVI's board of directors. He graduated in economic and business sciences from CUNEF, Madrid, specialising in financing, in 1998. He began his professional career in the banking sector in 1998, working for Argentaria in the UK as an analyst and in the pharmaceutical sector with Medeva Pharma. He joined ROVI in 2000. He is a member of the board of governors and vice-president of the executive committee of the CEIM (Madrid Business Confederation). He is chairman of the Health and Social Affairs Commission of the CEIM and a member of the board of directors of Avalmadrid, representing the Madrid Business Confederation-CEOE. He is also a member of the Social Council of the Universidad Autónoma de Madrid and a shareholder of Norbel Inversiones (ROVI's controlling shareholder).

Principal shareholders	(%)
Norbel Inversiones S.L.	69.64%
JO Hambro Capital	5.47%
Alantra asset management	5.02%
Indumenta Pueri	5.00%
T. Rowe Price	3.01%

Companies named in this report

Sanofi (SAN FP), Indivior (INDV), Novartis (NOVN), Orexigen (ORX), Johnson & Johnson (JNJ), Merck Serono (private)

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