

# Laboratorios Farmacéuticos ROVI

Corporate update

## Stunning growth in speciality pharmaceuticals

Laboratorios Farmacéuticos ROVI (ROVI) reported Q118 operating revenue of €75.8m (+12% y-o-y), driven by strong growth in the speciality pharmaceutical business (+23%). Flagship drug Hibor (bemiparin) grew 19% (y-o-y) and the majority of the portfolio of drugs posted robust growth. Biosimilar enoxaparin reported sales of €4.1m (despite only being available in Germany since September 2017 and the UK since March 2018), and ROVI has announced a distribution and marketing agreement in the MENA region with Hikma. This asset remains a key driver of near-term top-line growth and medium-term operating profit growth. Toll manufacturing sales declined 23% y-o-y, but we note that Q117 was an exceptionally buoyant year for the injectables division. We value ROVI at €956.7m.

Year end	Operating revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/16	265.2	30.3	0.58	0.18	29.7	1.0
12/17	275.6	20.3	0.40	0.12	43.0	0.7
12/18e	293.6	16.4	0.31	0.09	55.5	0.5
12/19e	314.9	27.1	0.52	0.16	33.1	0.9

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

## Enoxaparin Becat launched in Germany and the UK

ROVI's internally developed biosimilar enoxaparin (Enoxaparin Becat, EB) is now available in Germany and the UK. The majority of the €4.1m sales booked in Q118 relate to Germany; this initial ramp-up is impressive and EB is well on track to hit FY18 guidance of €20-30m in sales. ROVI has signed a licensing agreement with Hikma for the distribution and marketing of its enoxaparin biosimilar across 17 countries in the MENA region. Hikma has a strong and long-established presence in these countries and this partnership bodes well for enoxaparin in these regions.

## Speciality pharmaceuticals picking up speed

Q118 was a robust quarter for ROVI's speciality pharmaceutical portfolio. Flagship drug Hibor (bemiparin) grew 20% in Spain and 17% internationally. In-licensed products, Volutsa, Neparvis and the hypercholesterolemia and respiratory franchises are continuing to drive prescription drug sales growth (+27%, +667%, +47%, +11% respectively in Q118 vs Q117, offsetting mature portfolio declines.

## EBITDA margin decline reflects higher R&D

Reported Q118 EBITDA of €10.2m (-1% y-o-y) was a function of higher sales offsetting lower gross margin and higher R&D spend on the ISM (in situ micro particle implants) pipeline. Sustainable long-term growth is dependent on successful R&D investment and we would expect a near-term fluctuation in the margin to pave the way to long-term margin expansion from 2020.

## Valuation: €0.96bn or €19.1/share

Our valuation of ROVI is unchanged at €0.96bn or €19.1/share. Our valuation is underpinned by the sales potential of biosimilar enoxaparin and the base business retaining stable, low single-digit growth rates. A stable dividend with a three-year average 35% payout ratio also adds value.

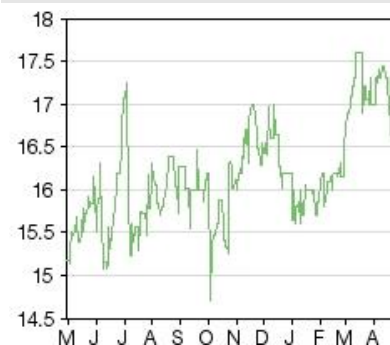
Pharma & biotech

27 April 2018

**Price** €17.20  
**Market cap** €860m

Net debt (€m) at 31 March 2018	1.5
Shares in issue	50m
Free float	11.86%
Code	ROVI
Primary exchange	Madrid
Secondary exchange	NA

### Share price performance



%	1m	3m	12m
Abs	0.9	7.5	15.1
Rel (local)	(3.9)	15.5	25.8
52-week high/low		€17.6	€14.7

### 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

Biosimilar enoxaparin launch in select European countries	Ongoing
Risperidone-ISM Phase III data	2019

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## Q118 a robust quarter for sales

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ROVI reported operating revenue of €75.8m for Q118 (+12% y-o-y), driven by strong growth in the speciality pharmaceutical business (+23% to €63.8m) offsetting declines in the toll manufacturing business (-23% to €12m). Total revenues grew 12% to €76.0m in Q118. Highlights include:

- The speciality pharmaceutical business consists of recently launched biosimilar enoxaparin (EB), the low molecular weight heparin (Hibor) and more than 30 marketed products across nine core franchises. Hibor sales in Spain grew 20% (Q117 €24.0m) and 17% in international markets (Q117 €16.9m). Hibor sales acceleration through Q118 is due to the impact of the European Medicines Agency (EMA) changing the posology of enoxaparin in Europe (for Clexane and biosimilar enoxaparin) in 2017. This translates to the need for two injections a day for the treatment dose for enoxaparin. However, for Hibor only one injection of the same dose is required, so ROVI's salesforce has been actively promoting this advantage (one injection a day vs two). If this growth trend is sustainable, it would bode well for Hibor sales in FY18. However, in Spain in 2018, the major unknown is if and when competitor Techdow will submit a dossier for its biosimilar enoxaparin (Inhixa). Biosimilar enoxaparin reported fledgling sales of €4.1m despite only being available in Germany since September 2017 and in the UK since March 2018.
- In the portfolio of in-licensed products, Volutsa (benign prostate hyperplasia, in-licensed from Astellas and launched in Spain in February 2015) grew 27% to €2.6 in Q118, and Neparvis (heart failure, in-licensed from Novartis and launched in Spain in December 2016) posted €2.7m in Q118 (+667%). Growth in the respiratory and cholesterol franchises (11% and 47% respectively in Q118) also helped offset the slowdown in off-patent/mature products. The cholesterol franchise consists of Vytorin, Orvatez and Absorcol. We highlight that in Q218 the API ezetimibe will be off-patent and a price reduction for Absorcol is to be expected.
- Toll manufacturing sales declined 23% to €12m in Q118, largely due to declines in the injectables business. We note that the comparative quarter (Q117) benefited from exceptionally high volumes for some customers. For FY18 ROVI expects a moderate decline in toll manufacturing sales.
- ROVI expects mid-single digit growth in operating revenues for 2018. This guidance includes €20-30m EB sales, which seems reasonable. Acceleration of EB sales in 2018 and 2019 will depend on growth in Germany (one of the largest enoxaparin markets in Europe by value) and on launching in further countries in Europe. Our FY18 operating revenue forecast remains unchanged at €293.6m. Our forecasts for biosimilar enoxaparin remain unchanged at €26.7m in 2018. We will monitor the evolution of sales in Q218, as a continuation of growth at a similar speed to Q1 would imply an upgrade to our numbers.
- Lower-volume sales of high-margin injectables in the toll manufacturing business (-46%) negatively affected the mix and, as a consequence, ROVI reported a 370bp decline in gross margin in the quarter to 57.8%. However, higher volumes of Hibor offset the gross margin decline somewhat.
- Reported EBITDA decreased to €10.2m in Q118 (-1%), leading to a lower EBITDA margin of 13.4% vs 15.2% in Q117. Q118 saw a rise in R&D expenses (29% y-o-y) to €8m to support investment in portfolio products Risperidone-ISM and Letrozole ISM, which are in Phase III and Phase I clinical trials respectively. Excluding the R&D expenses, EBITDA 'pre-R&D' as reported by ROVI increased by 10% to €18.1m (€16.4m in Q117). EBIT remained flat (€7.3m in Q118, reflecting a 120bp decrease in EBIT margin (to 9.6% from 10.8% in Q117). The effective tax rate was 2.6% in Q118 vs 8.5% in Q117, which was due to the deduction of existing R&D expenses plus the capitalisation of negative tax bases from Frosst Ibérica. As of 31 March

2018, ROVI expects to maintain a mid-single digit effective tax rate for the foreseeable future. Net profit increased by 7%, to €6.8m from €6.4 m in Q117.

## Short-term R&D pain for long-term gains

We believe that investors should focus on longer-term margin growth prospects. While measuring 'pre R&D' metrics such as 'pre-R&D EBITDA' helps to demonstrate the profitability (and growth) of the underlying business as it stands currently, fluctuations in R&D and SG&A costs are likely to vary as management looks to maximise return on internal investment by investing in R&D and SG&A as necessary and should be seen as part and parcel of the business. ROVI has given guidance for R&D expenses (October 2017 DORIA presentation) in the region of €32m pa in 2018-19 and €22m in 2020 and 2021 to support clinical trials for Risperidone-ISM and Letrozole ISM. EB is a product of the R&D invested by ROVI and the ramp-up of enoxaparin sales has positive longer-term 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. Furthermore, after the costs of the initial launch period 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 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. We expect operating margins to further decrease in 2018 (from 10.7% in 2016 and 6.9% in 2017) to 4.6% in 2018, mainly due to higher R&D expenses but also to the increase in SG&A to support new product launches. We anticipate margin growth in 2019 to 7.7%, mainly due to operational leverage as we still anticipate c €32m in R&D costs in 2019. We forecast an absolute 1.3pp improvement in operating margin from 10.7% in 2016 to 12.0% in 2020; margins should continue to ramp up beyond this period as the operational leverage from enoxaparin sales starts to flow through to the P&L, while R&D levels will decrease to €22m pa in 2020-21.

## Enoxaparin Becat update

ROVI has set out a clear strategy to launch a biosimilar enoxaparin into key countries in the EU ex Spain. Biosimilar enoxaparin reported sales of €4.1m despite only being available in Germany since September 2017 and in the UK since March 2018. As of April 2018, national registration approval has been granted in 16 out of the 26 countries (Germany, France, the UK, Italy, Norway, Sweden, Austria, Hungary, Slovenia, Estonia, Latvia, Slovakia, Bulgaria, Romania, Spain and Croatia). The national phase of the decentralised procedure (DCP) in the rest of the 26 countries in the EU (excluding Lithuania) is expected to be completed, with marketing authorisation granted at local country level in 2018. We forecast launch in Italy and France during 2018. Launch timings are dependent on capacity coming online; ROVI will have limited initial capacity over the next 12 months as manufacturing lines are gradually approved by the regulators.

ROVI has signed a licensing agreement with Hikma for the distribution and marketing of its enoxaparin biosimilar across 17 countries in the MENA region (Kingdom of Saudi Arabia, Jordan, Algeria, Egypt, Tunisia, Sudan, Syria, Yemen, Iraq, Oman, UAE, Kuwait, Qatar, Bahrain, Libya, Palestine and Lebanon). Hikma has strong and long-established presence in these countries and this partnership bodes well for enoxaparin in these regions.

**Exhibit 1: Financial summary**

Accounts: IFRS, Year-end: December, €m	2014	2015	2016	2017	2018e	2019e
<b>PROFIT &amp; LOSS</b>						
Hibor revenue	72.7	75.1	79.7	83.9	86.3	82.6
Enoxaparin revenue	0.0	0.0	0.0	1.5	26.7	44.5
Other (Pharma & Manufacturing)	165.4	170.9	185.5	190.3	180.7	187.8
Operating revenues	238.0	246.0	265.2	275.6	293.6	314.9
Cost of sales	(94.6)	(97.1)	(112.0)	(110.2)	(120.4)	(127.5)
Gross profit	143.5	148.9	153.1	165.5	173.2	187.4
Gross margin %	60.3%	60.5%	57.8%	60.0%	59.0%	59.5%
SG&A (expenses)	(97.8)	(101.7)	(101.9)	(108.5)	(116.6)	(119.7)
R&D costs	(12.0)	(16.5)	(17.5)	(28.3)	(32.0)	(32.0)
Other income/(expense)	2.9	1.0	5.6	1.8	1.8	1.8
EBITDA (reported)	36.6	31.8	39.3	30.5	26.4	37.5
Depreciation and amortisation	(8.9)	(10.0)	(11.0)	(11.5)	(12.8)	(13.5)
Normalised Operating Income	29.2	23.8	30.7	21.8	17.1	27.4
Reported Operating Income	27.7	21.8	28.3	19.0	13.6	24.0
Operating Margin %	11.6%	8.9%	10.7%	6.9%	4.6%	7.6%
Finance income/(expense)	(2.1)	(0.9)	(0.5)	(0.9)	(0.7)	(0.3)
Exceptionals and adjustments	0.0	0.0	0.0	0.0	0.0	0.0
Normalised PBT	27.1	22.9	30.3	20.3	16.4	27.1
Reported PBT	25.6	20.9	27.9	17.5	12.9	23.6
Income tax expense (includes exceptionals)	(1.5)	(1.1)	(1.8)	(0.3)	(0.7)	(1.2)
Normalised net income	25.6	21.8	28.5	20.0	15.7	25.9
Reported net income	24.1	19.8	26.1	17.2	12.3	22.4
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	0.34	0.25	0.45
Normalised EPS (€)	0.51	0.44	0.58	0.40	0.31	0.52
Dividend per share (€)	0.17	0.14	0.18	0.12	0.09	0.16

**BALANCE SHEET**

Property, plant and equipment	73.6	81.8	82.8	89.1	95.6	102.6
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0
Intangible assets	17.2	18.9	24.9	27.1	27.1	23.7
Other non-current assets	8.5	9.1	13.1	14.1	14.1	14.1
Total non-current assets	99.3	109.8	120.8	130.2	136.8	140.3
Cash and equivalents	26.7	29.3	41.4	40.7	35.9	39.8
Inventories	67.6	63.9	67.4	75.5	69.3	69.9
Trade and other receivables	63.7	57.0	53.8	49.7	56.3	56.1
Other current assets	4.1	3.9	4.5	2.2	2.2	2.2
Total current assets	162.0	154.1	167.1	168.2	163.7	168.0
Non-current loans and borrowings	32.0	32.6	20.8	27.0	22.4	20.7
Other non-current liabilities	8.7	7.2	7.2	6.4	5.9	5.3
Total non-current liabilities	40.7	39.8	28.0	33.5	28.2	26.0
Trade and other payables	55.0	45.7	59.9	52.9	63.9	62.3
Current loans and borrowings	4.3	10.1	13.0	16.2	4.7	1.6
Other current liabilities	2.8	3.3	3.6	4.1	4.1	4.1
Total current liabilities	62.1	59.2	76.4	73.2	72.6	68.0
Equity attributable to company	158.5	164.8	183.4	191.7	199.7	214.2

**CASH FLOW STATEMENT**

Profit before tax	25.6	20.9	27.9	17.5	12.9	23.6
Depreciation and amortisation	8.9	10.0	11.0	11.5	12.8	13.5
Share based payments	0.0	0.0	0.0	0.0	0.0	0.0
Other adjustments	2.5	(1.1)	(2.7)	(1.2)	0.7	0.3
Movements in working capital	(7.4)	2.3	12.7	(9.8)	10.0	(2.5)
Interest paid / received	(2.7)	(0.6)	0.0	0.0	(1.1)	(0.7)
Income taxes paid	(3.9)	(2.0)	(3.4)	0.1	(0.7)	(1.2)
Cash from operations (CFO)	23.0	29.4	45.5	18.0	34.7	33.0
Capex	(25.1)	(19.9)	(18.1)	(19.9)	(19.4)	(17.1)
Acquisitions & disposals net	0.0	0.0	0.0	0.0	0.0	0.0
Other investing activities	16.6	0.6	1.7	0.7	0.4	0.4
Cash used in investing activities (CFIA)	(8.5)	(19.3)	(16.3)	(19.2)	(19.0)	(16.7)
Net proceeds from issue of shares	(2.0)	(5.1)	(0.5)	0.5	0.0	0.0
Movements in debt	2.7	5.9	(9.7)	9.0	(16.2)	(4.7)
Other financing activities	(8.0)	(8.3)	(6.9)	(9.0)	(4.3)	(7.9)
Cash from financing activities (CFF)	(7.3)	(7.6)	(17.1)	0.5	(20.5)	(12.5)
Cash and equivalents at beginning of period	19.4	26.7	29.3	41.4	40.7	35.9
Increase/(decrease) in cash and equivalents	7.3	2.6	12.1	(0.7)	(4.8)	3.8
Cash and equivalents at end of period	26.7	29.3	41.4	40.7	35.9	39.8
Net (debt) cash	(9.6)	(13.5)	7.6	(2.5)	8.9	17.4

Source: Company accounts, Edison Investment research

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