

Laboratorios Farmacéuticos ROVI

Corporate update

Biosimilar enoxaparin launches

ROVI reported operating revenue of €203m for 9M17 (+ 6%), driven by exceptionally strong growth in the toll manufacturing business (+20%). The speciality pharmaceutical business grew 3%, aided by sales growth in newer product launches offsetting declines in the mature portfolio. ROVI has launched its internally developed biosimilar enoxaparin into the first European market (Germany) ahead of any competition; this is a key driver of sales and operating growth in the medium term. R&D progress continues with the long-acting DORIA (schizophrenia) and letrozole (breast cancer) having entered Phase III and Phase I of clinical-stage development respectively. Our revised valuation is €0.98bn.

Year end	Operating revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/15	246.0	22.9	0.44	0.14	37.9	0.8
12/16	265.2	30.3	0.58	0.18	28.8	1.1
12/17e	277.3	19.6	0.37	0.11	45.1	0.7
12/18e	294.7	29.7	0.56	0.17	29.8	1.0

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

Biosimilar enoxaparin launched in Germany

ROVI is the first company to launch a biosimilar enoxaparin (low molecular weight heparin [LMWH] for anti-coagulant indications) into Germany. We expect further roll-outs in 2018. Maiden guidance of €20-30m sales of biosimilar enoxaparin in 2018 is higher than our original €15m forecast and we have increased our expectation to €26.7m in 2018; we expect new territory launches plus growth in Germany to aid sales growth. We forecast operating revenues of €277.3m (+ 4.6% vs FY16), which remains unchanged. However, we have reduced our FY18 forecast to €297.4m vs €305.4m. We reduce our expectations for Sintron and for the mature portfolio of products largely offset by increasing enoxaparin forecasts.

R&D pipeline progressing

DORIA (Risperidone-ISM), ROVI's four-weekly formulation of J&J's Risperdal, has started global Phase III (PRISMA-3) clinical trials in treatment-resistant schizophrenia patients. Top-line results are expected in 2019. Our peak sales estimate for Risperidone-ISM is €76.2m, which could be conservative. We assume a launch in 2021 in Europe. A quarterly formulation of letrozole for breast cancer entered a Phase I clinical trial (LISA-1) in November.

Valuation: €0.98bn (€19.6/share)

We value ROVI at €0.98bn or €19.6/share versus €1.0bn previously. The reduced valuation is a result of the net effect of lowering 2018 revenues, rolling forward our model and updating the net debt position (at 30 September) to €1.5m. 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 33% payout ratio also adds value.

Pharma & biotech

14 November 2017

Price €16.69
Market cap €835m

Net debt (€m) at 30 September 2017	1.5
Shares in issue	50.0m
Free float	11.86%
Code	ROVI
Primary exchange	Madrid
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	5.2	5.6	29.6
Rel (local)	7.3	8.0	11.4
52-week high/low		€17.2	€11.0

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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9M17 update

ROVI reported operating revenue of €203m for 9M17 (+ 6%), driven by exceptionally strong growth in the toll manufacturing business (+20%) and 3% growth in the speciality pharmaceutical business (9M17: €133.8m reported revenues). Highlights include:

- Speciality pharmaceuticals business includes the flagship product, LMWH bempiparin, Hibor, and over 30 marketed products across nine core franchises. Hibor sales in Spain grew 2% (9M17 €40.8m) and 8% in international markets (9M17 €20.9m). ROVI has guided that it expects to maintain stable international sales growth in 2017. In the longer term, we expect moderate growth in international Hibor (2017-20 estimated CAGR of -3.9%) as ongoing launches of biosimilar enoxaparin and Hibor patent expiry in 2019 clip sales growth. Within the portfolio of in-licensed products Volutsa (BPH in-licensed from Astellas) grew 33% to €6.5m in 9M17, Neparvis (heart failure, in-licensed from Novartis and launched in December 2016) posted €2.8m in 9M17. Growth in the respiratory and cholesterol franchises also helped offset the slowdown in off-patent/mature products.
- ROVI's toll manufacturing business had an exceptionally strong nine months, reporting sales up 20% to €46.1m. This was largely driven by 33% growth in the injectable business offsetting a slowdown in the oral formulation business. (ROVI expects mid to high single-digit growth in the injectable business for FY17 and overall slight growth in the toll manufacturing business vs a decline of 9% in 2016.)
- EBITDA decreased to €27.2m in 9M17 (-13%). However, in the comparable period in 2016, it benefited from €4.0m in non-recurring revenue (as a result of the creation of a JV between ROVI and Enervit for the distribution of nutritional products in Spain and Portugal). Underlying EBITDA grew 0.4%. We forecast EBITDA of €28.7m in 2017.
- Guidance: ROVI expects mid- to single-digit growth in operating revenues for 2017. We forecast €277.3m (+ 4.6% vs FY16), which remains unchanged. However, we have reduced our FY18 forecast to €294.7m vs €305.4m. On a positive note, this includes our upwardly revised forecast for biosimilar enoxaparin (maiden guidance of €20-30m sales of biosimilar enoxaparin in 2018 is higher than our original €15m forecast) to €26.7m in 2018. This is offset by a reduction in our expectations for the mature product portfolio and Sintron.

Biosimilar enoxaparin launched in Germany

ROVI has set out a clear strategy to launch an enoxaparin biosimilar into key countries in the EU ex Spain. As expected, the first launch in Germany has occurred. 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. As of 30 September 2017 national registration approval has been granted in eight out of the 26 countries (Germany, France, the UK, Hungary, Slovenia, Estonia, Latvia and Slovakia). The national phase of the 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; 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.

Valuation

We revise our valuation of ROVI to €0.98bn or €19.6/share from €1.0bn or €20.1/share, largely resulting from a slight reduction in our FY18 revenue expectation (an increase in biosimilar expectations is largely offset by lowering our Sintron and mature products sales expectations). We roll forward our DCF model in time and update for net debt of €1.5m at 30 September. We use 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). Our standard discount rate assumption for companies with approved products and minimal development risk is 10%. We use a 15% tax rate from 2030. The current tax rate is c 8%, but over time this is expected to normalise to a mid-teens percentage.

Exhibit 1: Three-stage DCF valuation	
	€m
Sum of DCF for forecast period to 2025	352
Sum of DCF for growth 2026 to 2030 (transition period)	163
Terminal value	468
Enterprise value	983
Net cash/(debt) at 30 September 2017	(1.5)
Value of equity	981.6
Value per share	€19.6
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 by 2% a year) until 2020. Our peak sales estimate for Risperidone-ISM is €76.2m. We assume a launch in 2021 in Europe. 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).

Valuation sensitivity to biosimilar enoxaparin

As described in our initiation report, [Ace of Spain](#), 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 generate a c €3/share increase or drop in our valuation, respectively.

Exhibit 2: Financial summary

Accounts: IFRS, Year-end: December, €m	2014	2015	2016	2017e	2018e	2019e
Profit & Loss						
Hibor revenue	72.7	75.1	79.7	82.6	84.2	80.6
Enoxaparin revenue	0.0	0.0	0.0	0.4	26.7	44.5
Other (Pharma & Manufacturing)	165.4	170.9	185.5	194.3	183.9	199.5
Operating revenues	238.0	246.0	265.2	277.3	294.7	324.6
Cost of sales	(94.6)	(97.1)	(112.0)	(115.1)	(121.4)	(131.5)
Gross profit	143.5	148.9	153.1	162.2	173.3	193.1
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)	(109.1)	(116.9)
R&D costs	(12.0)	(16.5)	(17.5)	(27.7)	(26.5)	(26.0)
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	39.3	51.9
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	30.0	42.0
Reported Operating Income	27.7	21.8	28.3	16.8	26.2	38.7
Operating Margin %	11.6%	8.9%	10.7%	6.1%	8.9%	11.9%
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	29.7	42.0
Reported PBT	25.6	20.9	27.9	16.4	25.9	38.7
Income tax expense (includes exceptionals)	(1.5)	(1.1)	(1.8)	(1.1)	(1.9)	(3.1)
Normalised net income	25.6	21.8	28.5	18.4	27.8	39.0
Reported net income	24.1	19.8	26.1	15.3	24.0	35.6
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	0.48	0.71
Normalised EPS (€)	0.51	0.44	0.58	0.37	0.56	0.78
Dividend per share (€)	0.17	0.14	0.18	0.11	0.17	0.25
Balance sheet						
Property, plant and equipment	73.6	81.8	82.8	88.0	93.4	99.8
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	132.8	135.8
Cash and equivalents	26.7	29.3	41.4	24.1	25.0	37.5
Inventories	67.6	63.9	67.4	69.4	69.9	72.0
Trade and other receivables	63.7	57.0	53.8	57.0	56.5	57.8
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	155.9	171.8
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	59.8	60.8
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	68.0	66.1
Equity attributable to company	158.5	164.8	183.4	193.4	209.0	232.3
Cash flow statement						
Profit before tax	25.6	20.9	27.9	16.4	25.9	38.7
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)	(2.8)	(3.1)
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)	(1.9)	(3.1)
Cash from operations (CFO)	23.0	29.4	45.5	22.8	34.1	45.4
Capex	(25.1)	(19.9)	(18.1)	(22.3)	(14.7)	(16.2)
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	0.3
Cash used in investing activities (CFIA)	(8.5)	(19.3)	(16.3)	(21.8)	(14.5)	(16.0)
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)	(8.3)	(12.3)
Cash from financing activities (CFF)	(7.3)	(7.6)	(17.1)	(18.3)	(18.6)	(17.0)
Cash and equivalents at beginning of period	19.4	26.7	29.3	41.4	24.1	25.0
Increase/(decrease) in cash and equivalents	7.3	2.6	12.1	(17.3)	1.0	12.4
Cash and equivalents at end of period	26.7	29.3	41.4	24.1	25.0	37.5
Net (debt) cash	(9.6)	(13.5)	7.6	3.2	14.5	31.6

Source: ROVI accounts, Edison Investment Research

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