

Laboratorios Farmacéuticos ROVI

Interim results

Top-line strength as R&D costs rise

Laboratorios Farmacéuticos ROVI (ROVI) has reported H118 operating revenue of €146.3m (+5.4% y-o-y), driven by substantial growth in the speciality pharmaceutical business (H118: €123.2m, +14% y-o-y). Flagship product Hibor (bemiparin) sales grew to €48.3m (H117: €42.6m) as ROVI takes advantage of changing market dynamics, notably in Spain (+16% y-o-y). Enoxaparin biosimilar (EB) has now launched in Germany, UK and Italy, with further rollout across Europe ongoing. ROVI continues to expect FY18 sales of between €20m and €30m (H118: €8.9m). Net profit for H118 was down to €7.6m (H117: €15.8m) mainly due to significantly increased R&D costs from the ongoing Risperidone-ISM Phase III trial and Letrozole-ISM Phase I trial. We value ROVI at €1.21bn or €24.1 per share.

Year end	Operating revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/16	265.2	30.3	0.58	0.18	27.8	1.1
12/17	275.6	20.3	0.40	0.12	40.3	0.7
12/18e	293.6	16.4	0.31	0.09	51.9	0.6
12/19e	314.9	27.0	0.52	0.16	31.0	1.0

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

LMWH franchise continues to lead product growth

ROVI's low molecular weight heparin (LMWH) products Hibor (H118: +13% y-o-y to €48.3m) and newly launched EB Becat (H118: €8.9m) continue to be core growth drivers. Becat Q2 sales of €4.8m only slightly increased on Q1 (€4.1m), as Q1 was boosted in Germany from initial inventory stocking. Internationally, ROVI has out-licensing agreements with Sandoz and Hikma.

Pharma products stable as Toll struggles

Growth in sales for Volutsa (+25% y-o-y to €5.4m), Neparvis (+388% increase y-o-y to €5.9m), the hypercholesterolemia (+3% y-o-y to €19.6m) and respiratory franchise (+9% y-o-y to €7.7m) continue to support the pharmaceutical product portfolio. Toll manufacturing revenues were down 25% to €23.0m in H118 as a result of exceptionally high volumes for its injectable business in H117. ROVI anticipates new manufacturing contracts to be announced by the year end.

R&D investment in future growth

R&D expenses increased substantially y-o-y by 79.2% to €16.8m, driven by both the ongoing Risperidone-ISM Phase III trial and Letrozole-ISM Phase I trial. Sustainable, long-term growth is dependent on successful R&D investments in DORIA (schizophrenia) and Letrozole-ISM. Please see our recently published outlook note for more detail on these assets ([DORIA low risk, high reward](#)).

Valuation: €1.21bn or €24.1 per share

Our valuation of ROVI has increased to €1.21bn or €24.1 per share, we have rolled forward the model and updated for net debt. Our valuation is underpinned by the sales potential of EB and the base business retaining stable, low single-digit growth rates. We also include risk-adjusted sales for Phase III DORIA.

Pharma & biotech

30 July 2018

Price €16.10
Market cap €805m

Net debt (€m) at 30 June 2018	7.0
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	(5.0)	(0.4)
Rel (local)	(1.2)	(4.5)	7.0
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 particular expertise in low molecular weight heparin.

Next events

Enoxaparin biosimilar launch in select European countries	Ongoing
PRISMA-3 DORIA data	Q219

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H118: Substantial growth in prescription pharma sales

ROVI reported operating revenue of €146.3m for H118 (+5.4% y-o-y), driven by strong growth in the prescription based pharmaceutical products (+17% to €106.7m) offsetting declines in the toll manufacturing business (-25% to €23m). Total revenues grew 5% to €147.1m in H118. Highlights include:

- The speciality pharmaceutical business consists of approximately 40 marketed products across nine core franchises. Hibor total sales grew 13% y-o-y to €48.3m, where sales in Spain grew 16% to €33.9m and 7% in international markets to €14.4m. Hibor sales acceleration through H118 has been due to shifts in the market dynamics, caused by both the launch of EB into Europe and the impact of the European Medicines Agency in 2017 introducing new posology (dosing) guidelines for enoxaparin. 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).
- EB (Becat) reported H118 sales of €8.9m, despite only being available in Germany since September 2017, UK since March 2018 and Italy since April 2018. H118 sales were split 86% to Germany, 11% Italy and 3% to the UK. Sales in the UK have been slower than initially anticipated due to difficulties in getting on formulary; however, ROVI believes this to be a short-term problem. Becat is approved to be directly marketed in four other EU countries and ROVI will continue its process in H218 to begin selling in these regions. In addition to the EU, ROVI has signed out-licensing agreements that cover 45 international countries, notably with Sandoz and Hikma.
- In the portfolio of in-licensed products, Volutsa (benign prostate hyperplasia, in-licensed from Astellas and launched in Spain in February 2015) grew 25% to €5.4 in H118, and Neparvis (heart failure, in-licensed from Novartis and launched in Spain in December 2016) posted €5.9m in H118 (+388%). Growth in the respiratory and cholesterol franchises (9% to €7.7m and 3% to €19.6m, respectively, in H118) also helped offset the slowdown in off-patent/mature products. The cholesterol franchise consists of Vytorin, Orvatez and Absorcol, which are facing challenging conditions due to expiry of key patents. In H218, the active principle of these products went off-patent; as a result of this, Absorcol and Vytorin prices were reduced to remain competitive.
- Toll manufacturing sales declined 25% to €23m in H118, largely due to declines in the injectables business (-45% y-o-y to €9.9m). H117 benefited from exceptionally high volumes for some customers, which resulted in the dramatic drop-off in 2018. In the second half of 2018, ROVI is expecting to announce new toll contracts.
- ROVI expects mid-single-digit growth in operating revenues for 2018. This guidance includes €20–30m Becat sales. Our FY18 operating revenue forecast remains unchanged at €293.6m (implying a 6.5% y-o-y growth), as do our EB sales forecasts at €26.7m. We have made adjustments to our working capital forecasts which have adjusted our FY18 net cash down to €1.9m from €8.9m previously.
- Reported EBITDA decreased to €13.3m in H118 (-44%), leading to a lower EBITDA margin of 9.1% vs 17.0% in H117. H118 saw a significant rise in R&D expenses (79% y-o-y) to €16.8m to support investment in portfolio products Risperidone-ISM (DORIA) and Letrozole-ISM, which are in Phase III (data expected in 2019) and Phase I clinical trials, respectively. EBIT also negatively decreased to €7.5m in H118 versus €17.7m in H117, reflecting an absolute 7.7% decrease in EBIT margin to 5.1% from 12.8%. The effective tax rate was -7.4% in H118, resulting in a positive tax income of €0.5m vs 8.6% in H117 (negative income tax of €1.5m). This 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 decreased by 52.1% to €7.6m from €15.8m in H117.

Exhibit 1: Financial summary							
Accounts: IFRS, Year-end: December, €m	2014	2015	2016	2017	2018e	2019e	
PROFIT & LOSS							
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)	(0.4)	
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	27.0	
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	25.8	
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	28.9	30.9	
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	156.7	159.1	
Non-current loans and borrowings	32.0	32.6	20.8	27.0	17.5	0.2	
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	23.4	5.5	
Trade and other payables	55.0	45.7	59.9	52.9	56.8	58.4	
Current loans and borrowings	4.3	10.1	13.0	16.2	9.5	17.3	
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	70.4	79.7	
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	0.4	
Movements in working capital	(7.4)	2.3	12.7	(9.8)	3.0	0.5	
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	27.7	36.1	
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	0.3	
Cash used in investing activities (CFIA)	(8.5)	(19.3)	(16.3)	(19.2)	(19.0)	(16.8)	
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)	(9.5)	
Other financing activities	(8.0)	(8.3)	(6.9)	(9.0)	(4.3)	(7.8)	
Cash from financing activities (CFF)	(7.3)	(7.6)	(17.1)	0.5	(20.5)	(17.3)	
Cash and equivalents at beginning of period	19.4	26.7	29.3	41.4	40.7	28.9	
Increase/(decrease) in cash and equivalents	7.3	2.6	12.1	(0.7)	(11.8)	2.0	
Cash and equivalents at end of period	26.7	29.3	41.4	40.7	28.9	30.9	
Net (debt) cash	(9.6)	(13.5)	7.6	(2.5)	1.9	13.4	
Source: Company accounts, Edison Investment Research							

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