

Laboratorios Farmacéuticos ROVI

Robust growth across key franchises

Laboratorios Farmacéuticos ROVI (ROVI) has reported operating revenue of €270.8m (+24% y-o-y) for the first nine months of FY19 (9M19), driven by substantial growth in the prescription-based pharmaceutical business (9M19: €199.2m, +27% y-o-y). The focus on new, proprietary products continues to benefit ROVI, as evidenced by ongoing success in the European roll-out of Becat (enoxaparin biosimilar), sales of which grew threefold y-o-y to €52.9m. Total LMWH franchise sales were reported at €122.6m (9M19, +44%), aided by Hibor sales growth in Spain. Management has guided to mid-single digit growth in operating revenues in 2020. We believe this is slightly cautious given the potential for growth across multiple areas of the business, despite the loss of some mature product sales. We value ROVI at €1.35bn.

Year end	Revenue* (€m)	PBT** (€m)	EPS** (€)	DPS (€)	P/E (x)	Yield (%)
12/17	277.4	20.3	0.40	0.12	61.5	0.5
12/18	304.8	19.3	0.39	0.08	63.1	0.3
12/19e	364.6	40.2	0.68	0.17	36.2	0.7
12/20e	391.0	36.3	0.62	0.13	40.0	0.5

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

Strength in multiple franchises

ROVI's low molecular weight heparin (LMWH) is a key franchise (~45% of operating revenues and Becat sales growth remains a key contributor. Becat continues its launch trajectory (by ROVI in key EU markets and by partners elsewhere) and during 9M19 was launched in Portugal, Poland and Costa Rica. Toll manufacturing sales grew 18% to €45.4m, driven by strong performance in the injectables business (+39% to €27.6m 9M19). We expect further new contracts to be announced in this division given the available capacity in ROVI's injectable manufacturing plants.

ISM platform – more to come

Successful completion of the Phase III PRISMA-3 trial served as validation of ROVI's recent investment in R&D. Together with data from the BORIS studies, this completes the clinical trial programme for the NDA submission to the FDA in H120 and an MAA to the EU before then (we forecast launch in both markets in 2021). Preliminary Phase I data for Letrozole ISM presented earlier in the year confirmed the technology's ability to provide a prolonged release version of letrozole.

Valuation: €1.35bn or €24.1/share

We increase our valuation of ROVI to €1.35bn or €24.1/share vs €1.33bn or €23.7/share previously. We make no changes to product forecasts but have nudged down R&D and significantly reduced SG&A for FY19, which has positively affected forecast operating profit for FY19. Our FY20 estimates are unchanged. In addition, we have rolled forward our DCF/rNPV model, and updated for FX and net cash of €0.2m at 30 September. Our valuation is underpinned by Becat's strong growth potential, while the opportunity for DORIA in the US and EU is key, contributing 17% and 13% to our valuation, respectively.

Quarterly results

Pharma & biotech

8 November 2019

Price €24.6

Market cap €1380m

\$1.11/€

Net cash (€m) at 30 September 2019 0.2

Shares in issue 56.1m

Free float 32.1%

Code ROVI

Primary exchange MADRID

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 15.5 14.4 46.4

Rel (local) 10.6 5.9 42.1

52-week high/low €24.6 €17.0

Business description

Laboratorios Farmacéuticos ROVI is a fully integrated Spanish speciality pharmaceutical company involved in developing, in-licensing, manufacturing and marketing small molecule and speciality biologic drugs, with particular expertise in low molecular weight heparin.

Next events

DORIA NDA/MAA filings with the US FDA and the EMA 2020

LISA-1 and European approvals/launches. 2020/21

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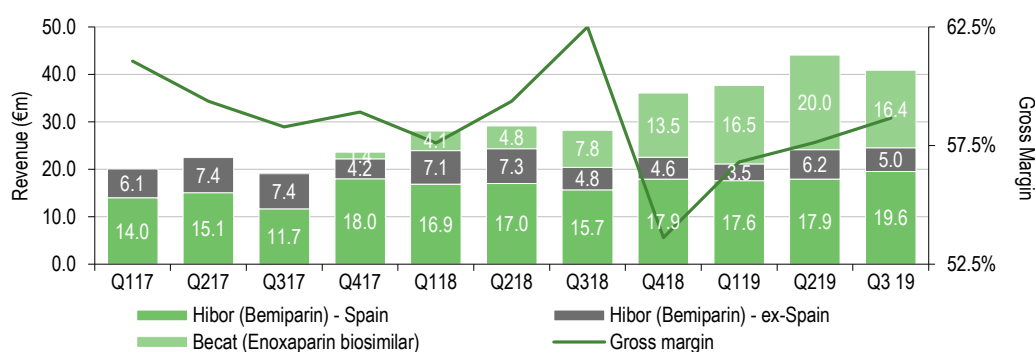
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9M19 financials: Strength in numbers

ROVI's 9M19 results demonstrated substantial growth in its LMWH franchise and toll manufacturing business, driving a 24% y-o-y operating revenue increase to €270.8m. ROVI has maintained its previously upgraded FY19 revenue growth guidance to the high double digits and provided guidance for FY20 for the first time. Management expects a mid-single digit growth rate in operating revenue. We believe this is on the cautious side given the momentum in the LMWH business and capacity for growth within the toll manufacturing (specifically injectables) business.

9M19 revenue from the LMWH franchise grew 44% y-o-y to €122.6m (9M18: €85.4m), as shown in Exhibit 1. Becat sales were the main driver of franchise growth as ROVI continues to roll out the product across Europe (9M19: €52.9m). Hibor sales in Spain remain strong and increased slightly to €55.1m in 9M19 (+11%). These increases were slightly offset by a 24% reduction in Hibor international sales to €14.7m. Management expects international Bemiparin sales to remain stable in 2019. We believe ongoing investor focus should be on Becat as it launches internationally (ex US) and sales of Hibor in Spain.

Exhibit 1: LMWH franchise quarterly performance



Source: ROVI, Edison Investment Research

9M19 toll manufacturing revenues grew 18% y-o-y to €45.4m (9M18: €38.5m), with the period benefiting from higher manufacturing volumes for some customers. At the interim results, ROVI upgraded its toll manufacturing revenue forecasts for FY19 to a low double-digit rate. We continue to forecast toll manufacturing revenue of €60.6m in FY19 (FY18: €54.6m).

The product portfolio outside the LMWH franchise continues to perform well, with new products replacing mature and off-patent franchises. Notably, in 9M19 sales of Neparvis increased 63% to €15.2m, and Volutsa increased 19% to €9.7m, while ageing franchises Absorcol, Vytarin and Orvatez decreased 17% to €23.2m. In 9M19, ROVI acquired MSD's dexchlorpheniramine maleate antihistamines (ROVI paid €13.5m to MSD) and Falithrom (ROVI paid €9m to Hexal), which is used for the treatment of thromboembolic diseases, for the German market.

Increasing LMWH raw material prices (+39% above 9M18 prices) and sales of the lower-margin Becat continue to affect gross margin. Gross profit increased by 20% to €157m, while gross margins declined by 170bp to 58.0%. SG&A costs grew 11% to €88.0m, driven mainly by the Europe-wide subsidiary expansion for Becat.

9M19 EBITDA increased to €47.5m (+83%), reflecting a significant increase in revenue and a reduction in R&D spend related to DORIA as the Phase III clinical trial costs start to reduce. R&D expenses will fluctuate as reducing requirements for DORIA are offset by increasing investment in Letrozole ISM.

ROVI's reported financial statements have been affected by changes in IFRS 16 accounting rules, which came into effect on 1 January 2019 and required operating leases to be recognised on the balance sheet as a financial liability. The primary impact of this was recognition of €21.7m in assets under property plant and equipment, offset by an increase of €21.9m in debt under financial liabilities for current (€3.6m) and non-current (€18.3m) leases. Operating lease payments, which originally went through the SG&A line, are now recognised as depreciation (for use of the asset) and financial expense (for discounting the lease).

Valuation

We increase our valuation of ROVI to €1.35bn or €24.1/share vs €1.33bn or €23.7/share previously. We make no changes to product forecasts but have nudged down R&D and significantly reduced SG&A for FY19, which has positively affected forecast operating profit for 2019. This has been offset by a 100bp reduction in gross margin forecast to 55.5% from 56.5% in 2019. Our FY20 estimates are unchanged and will be reviewed as we progress through the year. In addition, we have rolled forward our DCF/rNPV model, and updated for FX and net cash of €0.2m at 30 September 2019. Our valuation is underpinned by Becat's strong growth potential, while the base business remains stable with low single-digit growth rates. The opportunity for DORIA in the US and EU is key, contributing 17% and 13% to our valuation, respectively.

Exhibit 2: ROVI sum-of-the-parts valuation

	Value (€m)	Value per share (€)
DCF of base business	940.2	16.77
rNPV of DORIA	410.7	7.33
Net cash at 30 September 2019	0.2	0.00
Equity valuation	1,351.1	24.10
Source: Edison Investment Research		

Exhibit 3: Financial summary

Accounts: IFRS, year-end: December, €m	2016	2017	2018	2019e	2020e
PROFIT & LOSS					
HiBOR revenue	79.7	83.9	91.3	96.8	99.4
Enoxaparin revenue	0.0	1.5	30.2	74.1	88.9
Other (Pharma & Manufacturing)	185.5	192.1	183.3	193.7	202.6
Total revenues	265.2	277.4	304.8	364.6	391.0
Cost of sales	(112.0)	(110.2)	(128.6)	(162.3)	(177.9)
Gross profit	153.1	167.2	176.2	202.4	213.1
Gross margin %	57.8%	60.3%	57.8%	55.5%	54.5%
SG&A (expenses)	(101.9)	(108.5)	(113.2)	(120.3)	(136.8)
R&D costs	(17.5)	(28.3)	(32.4)	(28.5)	(22.0)
Other income/(expense)	5.6	(0.6)	(1.1)	0.0	0.0
EBITDA (reported)	39.3	29.9	29.5	53.6	54.2
Depreciation and amortisation	(11.0)	(11.5)	(12.0)	(17.8)	(22.7)
Normalised Operating Income	30.7	21.2	20.1	40.1	37.2
Reported Operating Income	28.3	18.4	17.5	35.7	31.5
Operating Margin %	10.7%	6.6%	5.7%	9.8%	8.1%
Finance income/(expense)	(0.5)	(0.9)	(0.7)	0.1	(0.9)
Exceptionals and adjustments	0.0	0.0	0.0	0.0	0.0
Normalised PBT	30.3	20.3	19.3	40.2	36.3
Reported PBT	27.9	17.5	16.7	35.8	30.6
Income tax expense (includes exceptionals)	(1.8)	(0.3)	1.2	(1.8)	(1.7)
Normalised net income	28.5	20.0	20.6	38.4	34.6
Reported net income	26.1	17.2	17.9	34.0	28.9
Basic average number of shares, m	49.0	50.0	53.0	56.1	56.1
Basic EPS (€)	0.53	0.34	0.34	0.61	0.52
Normalised EPS (€)	0.58	0.40	0.39	0.68	0.62
Dividend per share (€)	0.18	0.12	0.08	0.15	0.13
BALANCE SHEET					
Property, plant and equipment	82.8	89.1	95.8	121.7	124.2
Goodwill	0.0	0.0	0.0	0.0	0.0
Intangible assets	24.9	27.1	34.7	44.6	38.9
Other non-current assets	13.1	14.1	18.2	18.2	18.1
Total non-current assets	120.8	130.2	148.7	184.4	181.2
Cash and equivalents	41.4	40.7	95.5	49.6	55.2
Inventories	67.4	75.5	94.9	147.6	151.1
Trade and other receivables	53.8	49.7	60.2	71.9	69.6
Other current assets	4.5	2.2	3.5	3.5	3.5
Total current assets	167.1	168.2	254.0	272.5	279.4
Non-current loans and borrowings	20.8	27.0	16.6	35.5	31.6
Other non-current liabilities	7.2	6.4	11.1	10.6	10.0
Total non-current liabilities	28.0	33.5	27.7	46.1	41.6
Trade and other payables	59.9	52.9	68.2	76.8	78.7
Current loans and borrowings	13.0	16.2	17.6	19.4	3.9
Other current liabilities	3.6	4.1	1.7	1.7	1.7
Total current liabilities	76.4	73.2	87.5	97.9	84.3
Equity attributable to company	183.4	191.7	287.5	313.0	334.7
CASH FLOW STATEMENT					
Profit before tax	27.9	17.5	16.7	35.8	30.6
Depreciation and amortisation	11.0	11.5	12.0	17.8	22.7
Share based payments	0.0	0.0	0.0	0.0	0.0
Other adjustments	(2.7)	(1.2)	7.4	(0.1)	0.9
Movements in working capital	12.7	(9.8)	(24.4)	(56.4)	0.2
Interest paid/received	0.0	0.0	0.0	(0.9)	(1.4)
Income taxes paid	(3.4)	0.1	(3.1)	(1.8)	(1.7)
Cash from operations (CFO)	45.5	18.0	8.5	(5.5)	51.3
Capex	(18.1)	(19.9)	(26.5)	(32.6)	(19.5)
Acquisitions & disposals net	0.0	0.0	0.0	0.0	0.0
Other investing activities	1.7	0.7	0.1	1.0	0.5
Cash used in investing activities (CFIA)	(16.3)	(19.2)	(26.2)	(31.6)	(19.0)
Net proceeds from issue of shares	(0.5)	0.5	88.0	0.0	0.0
Movements in debt	(9.7)	9.0	(9.2)	(0.3)	(19.4)
Other financing activities	(6.9)	(9.0)	(6.3)	(8.5)	(7.2)
Cash from financing activities (CFF)	(17.1)	0.5	72.5	(8.8)	(26.6)
Cash and equivalents at beginning of period	29.3	41.4	40.7	95.5	49.6
Increase/(decrease) in cash and equivalents	12.1	(0.7)	54.8	(45.9)	5.7
Cash and equivalents at end of period	41.4	40.7	95.5	49.6	55.2
Net (debt)/cash	7.6	(2.5)	61.3	(5.3)	19.8

Source: Company accounts, Edison Investment Research

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