

Laboratorios Farmacéuticos ROVI

H119 results

Outperforming the market

Interim results highlight the momentum at Laboratorios Farmacéuticos ROVI, as both H119 operating revenue (21% y-o-y to €177.5m) and EBITDA (99% y-o-y to €26.5m) grew by double-digit percentages. The focus on new, proprietary products continues to benefit ROVI, as evidenced by the ongoing success in rolling out its enoxaparin biosimilar (Becat) in Europe. Becat sales grew fourfold y-o-y to €36.5m and continue to aid ROVI's expansion of its low molecular weight heparin (LMWH) franchise (H119 revenues: €81.7m vs H118: €57.2m). ROVI has upgraded its revenue growth guidance for the year to high double-digit growth from low double digits. We value ROVI at €1.33bn vs €1.17bn previously.

Year end	Revenue* (€m)	PBT** (€m)	EPS** (€)	DPS (€)	P/E (x)	Yield (%)
12/17	277.4	20.3	0.40	0.12	52.3	0.6
12/18	304.8	19.3	0.39	0.08	53.6	0.4
12/19e	364.6	31.6	0.54	0.12	38.7	0.6
12/20e	391.0	36.6	0.62	0.13	33.7	0.6

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

LMWH franchise going from strength to strength

We have upgraded our forecast for enoxaparin biosimilar (Becat) following strong growth in H119. We now forecast FY19 Becat revenue of €74.1m (vs €60.5m previously). We have adjusted our FY19 gross margin upwards to 56.5% (vs 54.5% previously), noting that the effect on Q219 margins from higher LMWH raw material prices and increased sales of the lower-margin Becat was less than we had expected. R&D expenses fell 12% y-o-y, mainly due to completion of the Phase III DORIA study (risperidone long-acting injectable). SG&A costs grew 16% to €60.7m, driven by the Europe-wide subsidiary expansion for Becat. The significant revenue growth mentioned above contributed to H119 net income of €16.2m (114% y-o-y).

ISM platform hitting key milestones

Successful completion of Phase III PRISMA-3 has served as validation of ROVI's recent investment in R&D. ROVI now expects to submit an NDA to the FDA in H120 (vs H219 previously) and an MAA to the EU before then. We believe our forecast launch in both markets in 2021 remains viable. In addition, preliminary Phase I data for Letrozole ISM were recently presented and have confirmed the technology's ability to provide a prolonged release version of letrozole.

Valuation: €1.33bn or €23.7/share

We increase our valuation of ROVI to €1.33bn or €23.7/share vs €1.17bn or €20.9/share previously, driven predominately by upgraded Becat forecasts. We have also rolled our DCF/rNPV model forward, and updated for FX and net cash of €19.1m at 30 June 2019. Our valuation is underpinned by the strong growth potential of Becat, 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.

Pharma & biotech

1 August 2019
Price €20.9

Market cap €1,172m

\$1.11/€

Net cash (€m) at 30 June 2019 19.1

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 4.0 13.6 29.4

Rel (local) 6.6 21.2 42.4

52-week high/low €21.10 €14.80

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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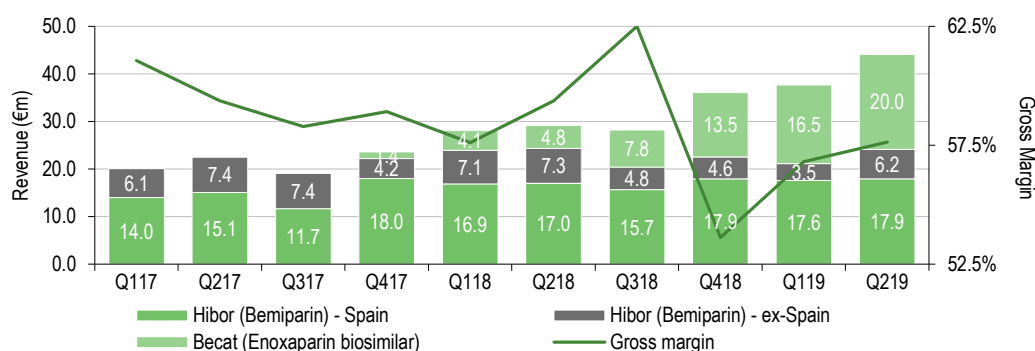
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H119 financials: Growth across divisions

H119 results demonstrated substantial growth for ROVI's LMWH franchise and toll manufacturing business, driving a 21% y-o-y revenue increase to €177.5m for H119. ROVI has upgraded its FY19 revenue growth guidance to high double-digit growth from low double digit.

Revenue from the LMWH franchise grew 43% y-o-y to €81.7m (H118: €57.2m), see Exhibit 1. Becat sales were the main driver of franchise growth as ROVI continues to roll out the product across Europe (H119: €36.5m vs H118: €8.9m). Hibor sales in Spain remain strong and increased slightly to €35.5m in H119 vs €33.9m in H118. These increases were offset slightly by a 33% reduction in Hibor international sales due to an uncharacteristically weak Q119. However, management expected this to rebound, as has now been evidenced in Q2 sales (Q219: €6.2m vs Q119: €3.5m).

Exhibit 1: LMWH franchise quarterly performance



Source: ROVI, Edison Investment Research

H119 toll manufacturing revenues grew 15% y-o-y to €26.5m (H118: €23.0m), with Q219 picking up substantially from a slow Q119 (€10.7m). Oral form drug manufacturing continues its trend from Q119, with a 13% reduction in sales to €11.4m (H118: €13.1m). However, the injectable business picked up significantly with 53% y-o-y growth to €15.2m. ROVI has upgraded its toll manufacturing revenue forecasts for FY19 to a low double-digit rate. We have updated our forecasts to reflect this and now 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 ageing franchises. Notably in H1, sales of Neparvis increased 63% to €9.6m, Volutsa increased 20% to €6.4m and contrast imaging agents 9% to €16.7m, while ageing franchises Absorcol, Vytorin and Orvatez decreased 22% to €15.4m. In H119, ROVI acquired the rights to market TEVA's osteoporosis drug Tetridar (five-year agreement, undisclosed financials). It also 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 (+35% above H118 prices) and sales of the lower-margin Becat continue to affect gross margin. However, the impact was less than we had expected in Q2 and, overall, we adjust our FY19 gross margin upwards to 56.5% vs 54.5% previously. SG&A costs grew 16% to €60.7m, driven mainly by the Europe-wide subsidiary expansion for Becat.

H119 EBITDA increased to €26.5m (+99%), 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 €22.8m in assets under property plant and equipment, offset by an increase of €22.8m in debt under financial liabilities for current (€3.7m) and non-current (€19.1m) leases, which has reduced ROVI's reported net cash to €19.1m at 30 June 2019. 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), resulting in a €1.6m uplift in EBITDA. We have reflected the changes resulting from IFRS 16 accounting and the acquisition of new assets in our financial estimates (Exhibit 3), forecasting end-2019 net cash of €21.8m.

At ROVI's general shareholder meeting on 12 June, a dividend of €0.0798/share was approved on FY18 earnings, representing a 25% payout. This was paid on 4 July.

Valuation

We increase our valuation of ROVI to €1.33bn (or €23.7/share) vs €1.17bn (or €20.9/share) previously, driven predominately by upgraded Becat forecasts. In addition, we have rolled our DCF/rNPV model forward and, updated for FX and net cash of €19.1m at 30 June 2019. Our valuation is underpinned by the strong growth potential of Becat, 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	912.9	16.28
rNPV of DORIA	394.3	7.03
Cash at 30 June 2019	19.1	0.34
Valuation	1,326.3	23.66
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)	(158.6)	(177.9)
Gross profit	153.1	167.2	176.2	206.0	213.1
Gross margin %	57.8%	60.3%	57.8%	56.5%	54.5%
SG&A (expenses)	(101.9)	(108.5)	(113.2)	(131.3)	(136.8)
R&D costs	(17.5)	(28.3)	(32.4)	(29.8)	(22.0)
Other income/(expense)	5.6	(0.6)	(1.1)	0.0	0.0
EBITDA (reported)	39.3	29.9	29.5	45.0	54.2
Depreciation and amortisation	(11.0)	(11.5)	(12.0)	(17.8)	(22.7)
Normalised Operating Income	30.7	21.2	20.1	31.5	37.2
Reported Operating Income	28.3	18.4	17.5	27.1	31.5
Operating Margin %	10.7%	6.6%	5.7%	7.4%	8.1%
Finance income/(expense)	(0.5)	(0.9)	(0.7)	0.1	(0.6)
Exceptionals and adjustments	0.0	0.0	0.0	0.0	0.0
Normalised PBT	30.3	20.3	19.3	31.6	36.6
Reported PBT	27.9	17.5	16.7	27.2	30.9
Income tax expense (includes exceptionals)	(1.8)	(0.3)	1.2	(1.4)	(1.7)
Normalised net income	28.5	20.0	20.6	30.3	34.9
Reported net income	26.1	17.2	17.9	25.8	29.2
Basic average number of shares, m	49.0	50.0	53.0	56.1	56.1
Basic EPS (€)	0.53	0.34	0.34	0.46	0.52
Normalised EPS (€)	0.58	0.40	0.39	0.54	0.62
Dividend per share (€)	0.18	0.12	0.08	0.12	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	44.5	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	184.3	181.1
Cash and equivalents	41.4	40.7	95.5	76.7	48.4
Inventories	67.4	75.5	94.9	108.6	146.2
Trade and other receivables	53.8	49.7	60.2	64.9	64.3
Other current assets	4.5	2.2	3.5	3.5	3.5
Total current assets	167.1	168.2	254.0	253.7	262.3
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	64.0	67.5
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	85.1	73.1
Equity attributable to company	183.4	191.7	287.5	306.8	328.7
CASH FLOW STATEMENT					
Profit before tax	27.9	17.5	16.7	27.2	30.9
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)	0.6
Movements in working capital	12.7	(9.8)	(24.4)	(23.2)	(34.0)
Interest paid / received	0.0	0.0	0.0	(0.9)	(1.4)
Income taxes paid	(3.4)	0.1	(3.1)	(1.4)	(1.7)
Cash from operations (CFO)	45.5	18.0	8.5	19.5	17.1
Capex	(18.1)	(19.9)	(26.5)	(32.5)	(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	0.8
Cash used in investing activities (CFIA)	(16.3)	(19.2)	(26.2)	(31.5)	(18.7)
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)	(6.5)	(7.3)
Cash from financing activities (CFF)	(17.1)	0.5	72.5	(6.8)	(26.7)
Cash and equivalents at beginning of period	29.3	41.4	40.7	95.5	76.7
Increase/(decrease) in cash and equivalents	12.1	(0.7)	54.8	(18.8)	(28.3)
Cash and equivalents at end of period	41.4	40.7	95.5	76.7	48.4

Source: Laboratorios Farmacéuticos ROVI accounts, Edison Investment Research. Note: We have updated our financial model to include the new IFRS 16 accounting rules, which mean operating leases are recognised on the balance sheet as financial liabilities.

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