

Laboratorios Farmacéuticos ROVI

Q119 results

Becat roll-out benefits top-line growth

Laboratorios Farmacéuticos ROVI (ROVI) reported Q119 operating revenue of €82.2m (+8% y-o-y), driven by strong growth in the speciality pharmaceutical business (+12%). Sales of its low molecular weight heparin (LMWH) franchise grew 34% to €37.6m, driven by the continued uptake of Becat (enoxaparin biosimilar) (+398% to €16.5m) and growth in domestic Hibor (bemiparin) sales (+4% to €17.6m). International Hibor sales struggled (-50% to €3.5m), but management believes this was a one-off stocking effect, and expects that full year sales should stabilise. Operating revenue guidance for 2019 has been raised to low double-digit growth. The next milestone will be finalised clinical data from the Phase III study of DORIA, ROVI's long-acting formulation of risperidone for schizophrenia, which met its primary efficacy endpoint in March 2019. We value ROVI at €1.17bn or €20.9 per share.

Year end	Revenue* (€m)	PBT** (€m)	EPS** (€)	DPS (€)	P/E (x)	Yield (%)
12/17	277.4	20.3	0.40	0.12	45.0	0.7
12/18	304.8	19.3	0.39	0.08	46.2	0.4
12/19e	341.0	19.7	0.34	0.06	52.9	0.3
12/20e	370.4	34.7	0.59	0.12	30.5	0.7

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

Becat driving LMWH franchise growth

ROVI's internally developed biosimilar enoxaparin, Becat, continues to benefit from ongoing roll-out in Europe by ROVI and its partners. We forecast Becat sales of €60.5m for 2019 and increase our total revenue forecasts from 10.0% growth to 11.9% growth, reflecting better expectation of Becat and the rest of the product portfolio. Acquired products should offset declines in the mature portfolio from 2019 onwards. Furthermore, ROVI expects toll manufacturing contracts to aid growth in this division. EBITDA increased to €11.9m (+17%), reflecting a reduction in R&D spend related to the Phase III study for DORIA.

DORIA Phase III top-line positive, full data next up

Phase III data for DORIA (long-acting risperidone injection) are an important near-term inflection point; final data are due in Q219 (the trial has completed). The schizophrenia market is vast and growing steadily. We believe DORIA's profile will provide ROVI with a 5% share of the long-acting injectable (LAI) market and drive peak sales of US\$412m (US and Europe) in 2027. DORIA is a high gross margin asset (85–95%) and will be the critical long-term driver of operating margins.

Valuation: €1.17bn or €20.9 per share

Our revised valuation of ROVI is €1.17bn or €20.9 per share (from €1.23bn or €21.9 per share). We have rolled our model forward and updated for net cash of €22m at 31 March 2019, which was affected by implementation of IFRS 16 and the near-term heparin-related gross margin erosion. Our valuation is underpinned by the sales potential of Becat and DORIA (assuming US and EU launch in 2021), with the base business remaining stable, with low single-digit growth rates. A stable dividend with a three-year average 35% payout ratio also adds value.

Pharma & biotech

10 May 2019

Price €18.00

Market cap €1,010m

\$1.12/€

Net cash (€m) at 31 March 2019 22.0

Shares in issue 56.1m

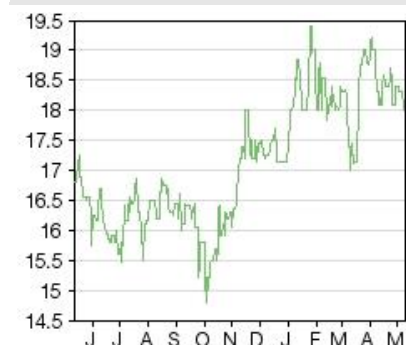
Free float 32.1%

Code ROVI

Primary exchange MADRID

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (2.7) (3.0) 5.9

Rel (local) 0.6 (5.5) 19.0

52-week high/low €19.40 €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

PRISMA-3 DORIA data Q219

DORIA US NDA filing H219

Enoxaparin biosimilar launch in select European countries Ongoing

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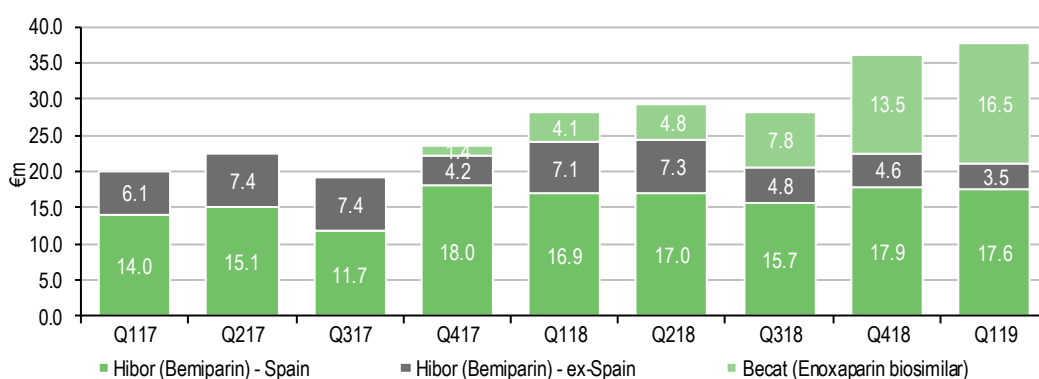
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Q119 financials

ROVI's Q119 highlights ongoing momentum in the speciality pharmaceuticals business. While management believes that the decline in international Hibor sales is a one-off effect for Q119 and guides that full-year sales should stabilise, we highlight that this could potentially be due to erosion as Becat launches across Europe (by ROVI in key EU markets and by partners elsewhere). The strong uptake of Becat has grown ROVI's LMWH franchise significantly, which now represents 46% of the operating revenue in Q119 (Q118: 37%). An 80bp reduction to gross margin in Q119 (57.0% vs 57.8%) was a consequence of the increasing contribution from the LMWH franchise, rising costs of heparin raw materials (+30%) due to increased demand as competitors build inventories prior to launch, and the ongoing roll-out of Becat. We have adjusted our forecast gross margins for 2019 and 2020 to 54.5% (from 57.5% previously) to reflect this shifting dynamic, but forecast recovery in subsequent years as high gross margin asset DORIA reaches the market in the US and EU.

Exhibit 1: LMWH franchise quarterly performance



Source: Laboratorios Farmacéuticos ROVI accounts, Edison Investment Research

Toll manufacturing revenues declined by 11% to €10.7m, driven by declines in oral form drug manufacturing. However, the injectables business grew 22% to €6.1m. ROVI has capacity in this division and expects new contracts to drive mid-single digit growth overall in its toll manufacturing business. EBITDA increased to €11.9m (+17%), reflecting in part 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 the 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 €21.0m in assets under property plant and equipment, offset by an increase of €21.0m in debt under financial liabilities for current (€2.1m) and non-current (€18.9m) leases, which has reduced ROVI's reported net cash to €22.0m at 31 March 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 of the lease), resulting in a €0.8m uplift in EBITDA for Q119 and aiding the €1.7m total increase in q-o-q EBITDA. For FY19 and FY20, we reduce our EBITDA forecasts as a consequence of the near-term gross margin erosion. We have reflected the changes due to IFRS 16 accounting and the acquisition of new assets into our financial forecasts (Exhibit 3), forecasting end-2019 net cash of €13.7m (vs €43.3m previously).

Valuation

Our revised valuation of ROVI is €1.17bn or €20.9 per share, from €1.23bn or €21.9 per share. We have rolled forward our model, and updated for exchange rates (\$1.12/€) and net cash of €22m at 31 March 2019. We have also increased our Becat sales forecasts for 2019. We value DORIA US and EU using a standalone NPV calculation and derive value for the rest of the business using a DCF of our sales and P&L model excluding DORIA. Compared to ROVI's current portfolio of drugs and footprint, the US opportunity for DORIA is large and a key valuation driver, accounting for 19.2% of our valuation (the EU opportunity for DORIA accounts for 11.2%).

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

	Value (€m)	Value per share (€)
DCF of base business	813.9	14.5
rNPV of DORIA	356.7	6.4
Valuation	1,170.6	20.9

Source: Edison Investment Research

Exhibit 3: Financial summary

Accounts: IFRS, year-end: December, €m	2015	2016	2017	2018	2019e	2020e
PROFIT & LOSS						
HiBOR revenue	75.1	79.7	83.9	91.3	96.8	99.4
Enoxaparin revenue	0.0	0.0	1.5	30.2	60.5	78.6
Other (Pharma & Manufacturing)	170.9	185.5	192.1	183.3	183.7	192.4
Total revenues	246.0	265.2	277.4	304.8	341.0	370.4
Cost of sales	(97.1)	(112.0)	(110.2)	(128.6)	(155.1)	(168.5)
Gross profit	148.9	153.1	167.2	176.2	185.8	201.9
Gross margin %	60.5%	57.8%	60.3%	57.8%	54.5%	54.5%
SG&A (expenses)	(101.7)	(101.9)	(108.5)	(113.2)	(122.8)	(129.7)
R&D costs	(16.5)	(17.5)	(28.3)	(32.4)	(32.0)	(22.0)
Other income/(expense)	1.0	5.6	(0.6)	(1.1)	0.0	0.0
EBITDA (reported)	31.8	39.3	29.9	29.5	31.1	50.2
Depreciation and amortisation	(10.0)	(11.0)	(11.5)	(12.0)	(15.9)	(20.5)
Normalised Operating Income	23.8	30.7	21.2	20.1	19.6	35.4
Reported Operating Income	21.8	28.3	18.4	17.5	15.2	29.7
Operating Margin %	8.9%	10.7%	6.6%	5.7%	4.4%	8.0%
Finance income/(expense)	(0.9)	(0.5)	(0.9)	(0.7)	0.1	(0.7)
Exceptionals and adjustments	0.0	0.0	0.0	0.0	0.0	0.0
Normalised PBT	22.9	30.3	20.3	19.3	19.7	34.7
Reported PBT	20.9	27.9	17.5	16.7	15.3	29.0
Income tax expense (includes exceptionals)	(1.1)	(1.8)	(0.3)	1.2	(0.8)	(1.6)
Normalised net income	21.8	28.5	20.0	20.6	18.9	33.1
Reported net income	19.8	26.1	17.2	17.9	14.5	27.4
Basic average number of shares, m	49.5	49.0	50.0	53.0	56.1	56.1
Basic EPS (€)	0.40	0.53	0.34	0.34	0.26	0.49
Normalised EPS (€)	0.44	0.58	0.40	0.39	0.34	0.59
Dividend per share (€)	0.14	0.18	0.12	0.08	0.06	0.12
BALANCE SHEET						
Property, plant and equipment	81.8	82.8	89.1	95.8	123.7	128.8
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0
Intangible assets	18.9	24.9	27.1	34.7	44.5	38.9
Other non-current assets	9.1	13.1	14.1	18.2	18.2	18.1
Total non-current assets	109.8	120.8	130.2	148.7	186.4	185.8
Cash and equivalents	29.3	41.4	40.7	95.5	68.5	41.4
Inventories	63.9	67.4	75.5	94.9	106.3	138.5
Trade and other receivables	57.0	53.8	49.7	60.2	60.7	60.9
Other current assets	3.9	4.5	2.2	3.5	3.5	3.5
Total current assets	154.1	167.1	168.2	254.0	239.0	244.3
Non-current loans and borrowings	32.6	20.8	27.0	16.6	35.5	31.6
Other non-current liabilities	7.2	7.2	6.4	11.1	10.6	10.0
Total non-current liabilities	39.8	28.0	33.5	27.7	46.1	41.6
Trade and other payables	45.7	59.9	52.9	68.2	59.9	63.9
Current loans and borrowings	10.1	13.0	16.2	17.6	19.4	3.9
Other current liabilities	3.3	3.6	4.1	1.7	1.7	1.7
Total current liabilities	59.2	76.4	73.2	87.5	81.0	69.5
Equity attributable to company	164.8	183.4	191.7	287.5	298.3	318.9
CASH FLOW STATEMENT						
Profit before tax	20.9	27.9	17.5	16.7	15.3	29.0
Depreciation and amortisation	10.0	11.0	11.5	12.0	15.9	20.5
Share based payments	0.0	0.0	0.0	0.0	0.0	0.0
Other adjustments	(1.1)	(2.7)	(1.2)	0.7	(0.1)	0.7
Movements in working capital	2.3	12.7	(9.8)	(24.4)	(20.8)	(28.9)
Interest paid/received	(0.6)	0.0	0.0	0.0	(0.9)	(1.4)
Income taxes paid	(2.0)	(3.4)	0.1	(3.1)	(0.8)	(1.6)
Cash from operations (CFO)	29.4	45.5	18.0	8.5	8.6	18.3
Capex	(19.9)	(18.1)	(19.9)	(26.5)	(32.7)	(19.9)
Acquisitions & disposals net	0.0	0.0	0.0	0.0	0.0	0.0
Other investing activities	0.6	1.7	0.7	0.1	1.0	0.7
Cash used in investing activities (CFIA)	(19.3)	(16.3)	(19.2)	(26.2)	(31.6)	(19.2)
Net proceeds from issue of shares	(5.1)	(0.5)	0.5	88.0	0.0	0.0
Movements in debt	5.9	(9.7)	9.0	(9.2)	(0.3)	(19.4)
Other financing activities	(8.3)	(6.9)	(9.0)	(6.0)	(3.6)	(6.8)
Cash from financing activities (CFF)	(7.6)	(17.1)	0.5	72.5	(4.0)	(26.2)
Cash and equivalents at beginning of period	26.7	29.3	41.4	40.7	95.5	68.5
Increase/(decrease) in cash and equivalents	2.6	12.1	(0.7)	54.8	(27.0)	(27.1)
Cash and equivalents at end of period	29.3	41.4	40.7	95.5	68.5	41.4
Net (debt)/cash	(13.5)	7.6	(2.5)	61.3	13.7	5.9

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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