

Laboratorios Farmacéuticos ROVI

Q120 results

COVID-19 stockpiling positive impact

Laboratorios Farmacéuticos ROVI (ROVI) reported Q120 operating revenue of €101.0m (+23% y-o-y), driven by strong growth both in the speciality pharmaceutical business (+24% to €88.2m) and in the toll manufacturing business (+19% to €12.7m). Top-line growth has, in part, benefited from COVID-19 related stockpiling across all divisions. As a result of operating leverage, EBITDA increased by 68% to €20.0m in Q120 reflecting a 530bp improvement vs Q119. Sales of low molecular weight heparin (LMWH) products (Becat and Hibor) increased by 43% to €53.9m; sales have benefited from increased heparin use for hospitalised COVID-19 patients during the quarter and this could be a source of further uplift in subsequent quarters. ROVI is maintaining FY20 guidance of mid-single-digit growth in total operating revenues, but in light of these results, this seems conservative. The MAA for DORIA has now been filed with the EMA (January 2020); we forecast launch in 2021. We value ROVI at €1.53bn.

Year end	Revenue* (€m)	PBT** (€m)	EPS** (€)	DPS (€)	P/E (x)	Yield (%)
12/18	304.8	19.2	0.38	0.08	64.7	0.3
12/19	382.5	45.6	0.77	0.18	31.9	0.7
12/20e	402.7	37.0	0.62	0.14	39.7	0.6
12/21e	438.4	40.8	0.68	0.15	36.2	0.6

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

LMWH sales strong: COVID-19 related uplift

ROVI has reported Becat (enoxaparin biosimilar) sales of €29.6m (+79%) and Hibor (bemiparin) sales of €24.3m (+15%) in Q120. We believe increased sales may in part be related to increasing treatment of COVID-19 related [coagulopathies](#), which are now being documented as a major feature in the underlying pathophysiology of severe COVID-19. Becat, additionally continues to benefit from ongoing roll-out in Europe by ROVI and its partners (now available in 13 countries). We forecast Becat sales of €97.0m in 2020. The toll manufacturing division has benefited from consolidation and the redirection of strategy toward high-value products. ROVI expects the toll manufacturing business to post low double-digit growth in FY20. We forecast 12% growth in 2020/21 in this division given better visibility on contracts.

DORIA MAA filed; US filing to come

Following positive PRISMA-3 data on DORIA (risperidone ISM), ROVI has filed the MAA with the EMA. We continue to forecast launch in Europe in 2021. The NDA filing with the FDA is expected in H220 and we forecast launch in the US in 2022.

Valuation: €1.53bn or €27.2/share

We increase our valuation of ROVI to €1.53bn or €27.2/share vs €1.49bn or €26.6/share previously. Our forecasts and cost assumptions are unchanged, but we have updated for FX, rolled forward our model and reflect net cash of €19.0m at 31 March 2020. Our valuation is underpinned by Becat's strong growth potential, while the opportunity for DORIA in the US and EU is key, contributing 16.8% and 13.5% to our valuation, respectively.

Pharma & biotech

18 May 2020

Price €24.6

Market cap €1,379m

\$1.08/€

Net debt (€m) at 31 March 2020 19.0

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 2.1 (7.9) 37.8

Rel (local) 7.8 41.7 95.3

52-week high/low €26.9 17.5

Business description

Laboratorios Farmacéuticos ROVI is a fully integrated Spanish speciality pharmaceutical company involved in developing, manufacturing and marketing small molecule and speciality biologic drugs, with expertise in low molecular weight heparin (LMWH). Its pipeline of drugs is focusing on its proprietary ISM technology.

Next events

DORIA US NDA filing H220

DORIA EU approval and launch 2020/21

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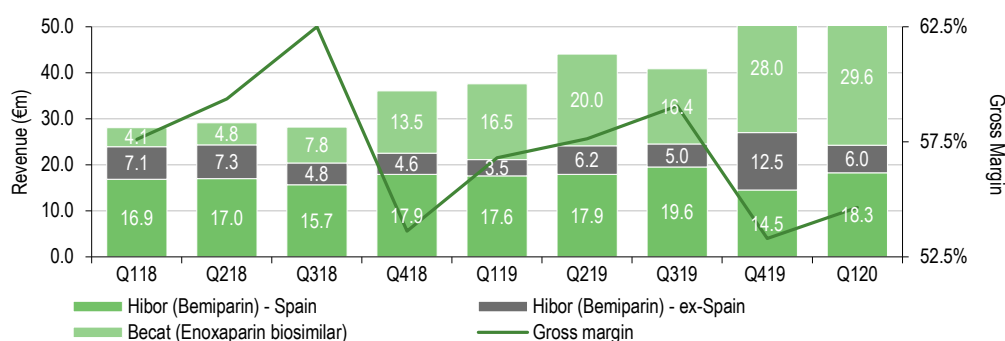
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Q120 financials

ROVI's Q120 results highlight ongoing momentum in the speciality pharmaceuticals business within a challenging COVID-19 environment. The strong uptake of Becat (+79% to €29.6m) has grown ROVI's LMWH franchise significantly, which now represents 55% of the operating revenue in Q120 (Q119: 48%). We note that the World Health Organization (WHO) has recommended ROVI's LMWHs, bemiparin and Becat, as essential medicines in the treatment of COVID-19 patients hospitalised in intensive care units. We believe increased use in COVID-19 patients will offset decreased use in elective surgical settings. Exhibit 1 highlights the sales evolution within the heparin franchise. Gross margin declined 2.3% from 57.0% in Q119 to 54.7% in Q120; the margin was affected by: 1) a €4.6m increase in potential discounts to the NHS related to COVID-19; 2) the ongoing roll-out of Becat; and 3) rising costs of heparin raw materials (+40%) due to African swine fever.

Exhibit 1: LMWH franchise quarterly performance



Source: Laboratorios Farmacéuticos ROVI accounts, Edison Investment Research

In the broader portfolio of in-licensed products, growth in sales of Neparvis (heart failure, in-licensed from Novartis) and Volutsa (benign prostate hyperplasia, in-licensed from Astellas) offset declines in the mature portfolio (Neparvis +85% to €7.9m in Q120, Volutsa +23% to €3.8m in Q120). The cholesterol franchise (Vytorin, Orvatez and Absorcol) increased 31% to €9.5m in Q120; growth in prior quarters has been declining since patent expiry in Q218 of the active ingredient of these products (ezetimibe).

Toll manufacturing revenues increased by 19% to €12.7m, driven by redirection of the strategy toward high-value products. ROVI has capacity in this division and expects new contracts to drive low double-digit growth overall in its toll manufacturing business. EBITDA increased to €20.0m (+68%), reflecting significant operating leverage as a 23% increase in operating revenue (€101.0m) was partially offset by a 29% increase in the cost of sales (€46.0m). EBITDA was positively affected by a 35% reduction in R&D spend (€4.5m). R&D expenses will fluctuate from quarter to quarter as the reducing requirements for DORIA (lower Phase III costs, but regulatory filing costs and development of three-monthly formulation are ongoing) are offset by increasing investment in Letrozole ISM. We forecast €29m in R&D expenses for the year, which may prove too high, but the Q120 R&D amount may in part reflect phasing throughout the year.

ROVI has provided operating revenue guidance of mid-single-digit growth for 2020; we forecast 5.3% growth in FY20 but believe this could be conservative. We expect operating margins to decrease in 2020 (from 11.2% in 2019) to 8.5% (note Q120 reported EBIT margin was 15.0%), mainly due to higher SG&A expenses (+10% to €30.8m in Q120) with the ongoing Becat roll-out and ongoing raw material price pressures relating to African swine flu (porcine mucosa is used in manufacturing heparins), and stable R&D expenses. If R&D expenses in Q220 remain at the level

of Q120, we will revisit our FY20 operating margin forecasts. We expect the margin to flatten in 2021 (8.6%), reflecting SG&A investment in international subsidiaries to support the DORIA launch, offset by lower R&D expenses. We expect steady margin growth in 2022 and beyond, mainly due to operational leverage and lower R&D costs offsetting DORIA-related launch costs in 2021.

Valuation

Our revised valuation of ROVI is €1.53bn or €27.2 per share, from €1.49bn or €26.6 per share previously. Our product forecasts remain unchanged and we have rolled forward our model, reflected the current FX spot (\$1.08/€) and updated for net debt of €19.0m at 31 March 2020. We value DORIA in the US and EU using a standalone NPV calculation (Exhibit 4) and derive value for the rest of the business by using a DCF of our sales and P&L model excluding DORIA (Exhibit 2). Compared to ROVI's current portfolio of drugs and footprint, the US opportunity for DORIA is large and a key valuation driver, accounting for 16.8% of our valuation (EU DORIA accounts for 13.5%).

Exhibit 2: Three-stage DCF valuation of base business (excludes DORIA cash flows)

	€m
Sum of for DCF for forecast period to 2025	336.6
Sum of DCF for growth 2026 to 2030 (transition period)	231.4
Terminal value	515.1
Enterprise value	1,083.1
Net debt at 31 March 2020	19.0
Value of equity of base business	1,064.1
Value per share of base business (€)	18.98
Discount rate	10%
Terminal growth rate	2%
Number of shares outstanding (m)	56.06

Source: Edison Investment Research

Exhibit 3: ROVI sum-of-the-parts valuation

	Value (€m)	Value per share (€)
DCF of base business	1,064.1	18.98
rNPV of DORIA	462.2	8.24
Net debt at 31 March 2020	19.0	0.34
SOTP valuation	1,526.3	27.22

Source: Edison Investment Research

Exhibit 4: DORIA NPV

	Indication	Launch	Peak sales (\$m)	Value (€m)	Probability	rNPV (€m)	rNPV per share (€)
NPV DORIA US	Schizophrenia	2022	236	344.1	75%	256.4	4.57
NPV DORIA Europe	Schizophrenia	2021	176	277.8	75%	205.8	3.67

Source: Edison Investment Research

Exhibit 5: Financial summary

Accounts IFRS; year-end 31 December; €m	2016	2017	2018	2019	2020e	2021e
PROFIT & LOSS						
HiBOR revenue	79.7	83.9	91.3	96.8	97.5	97.1
Enoxaparin revenue	0.0	1.5	30.2	80.9	97.0	121.3
Other (Pharma & Manufacturing)	185.5	192.1	183.3	204.8	208.2	220.0
Total revenues	265.2	277.4	304.8	382.5	402.7	438.4
Cost of sales	(112.0)	(110.2)	(128.6)	(166.6)	(187.3)	(205.5)
Gross profit	153.1	167.2	176.2	215.9	215.5	232.8
Gross margin %	57.8%	60.3%	57.8%	56.4%	53.5%	53.1%
SG&A (expenses)	(101.9)	(108.5)	(113.2)	(125.5)	(132.9)	(158.2)
R&D costs	(17.5)	(28.3)	(32.4)	(29.3)	(29.0)	(17.0)
Other income/(expense)	5.6	(0.6)	(1.1)	(0.2)	0.0	0.0
EBITDA (reported)	39.3	29.9	29.5	60.9	53.6	57.7
Depreciation and amortisation	(11.0)	(11.5)	(12.0)	(18.2)	(19.4)	(20.1)
Normalised Operating Income	30.7	21.2	20.0	46.5	38.5	42.0
Reported Operating Income	28.3	18.4	17.5	42.6	34.1	37.6
Operating Margin %	10.7%	6.6%	5.7%	11.2%	8.5%	8.6%
Finance income/(expense)	(0.5)	(0.9)	(0.7)	(0.9)	(1.5)	(1.2)
Exceptionals and adjustments	0.0	0.0	0.0	0.0	0.0	0.0
Normalised PBT	30.3	20.3	19.2	45.6	37.0	40.8
Reported PBT	27.9	17.5	16.7	41.9	32.7	36.4
Income tax expense (includes exceptionals)	(1.8)	(0.3)	1.2	(2.6)	(2.2)	(2.6)
Normalised net income	28.5	20.0	20.4	43.0	34.8	38.2
Reported net income	26.1	17.2	17.9	39.3	30.5	33.8
Basic average number of shares, m	49.0	50.0	53.0	56.1	56.1	56.1
Basic EPS (€)	0.53	0.34	0.34	0.70	0.54	0.60
Normalised EPS (€)	0.58	0.40	0.38	0.77	0.62	0.68
Dividend per share (€)	0.18	0.12	0.08	0.18	0.14	0.15
BALANCE SHEET						
Property, plant and equipment	82.8	89.1	95.8	131.6	138.2	143.6
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0
Intangible assets	24.9	27.1	34.7	45.1	50.7	51.3
Other non-current assets	13.1	14.1	18.2	16.6	16.6	16.6
Total non-current assets	120.8	130.2	148.7	193.3	205.6	211.6
Cash and equivalents	41.4	40.7	95.5	67.4	60.8	70.5
Inventories	67.4	75.5	94.9	158.8	161.6	168.9
Trade and other receivables	53.8	49.7	60.2	81.5	88.3	90.1
Other current assets	4.5	2.2	3.5	10.1	10.1	10.1
Total current assets	167.1	168.2	254.0	317.9	320.8	339.6
Non-current loans and borrowings	20.8	27.0	16.6	72.1	68.2	66.5
Other non-current liabilities	7.2	6.4	11.1	4.2	3.7	3.2
Total non-current liabilities	28.0	33.5	27.7	82.1	77.7	75.5
Trade and other payables	59.9	52.9	68.2	91.9	97.5	101.3
Current loans and borrowings	13.0	16.2	17.6	12.7	3.9	1.7
Other current liabilities	3.6	4.1	1.7	2.1	2.1	2.1
Total current liabilities	76.4	73.2	87.5	106.7	103.5	105.1
Equity attributable to company	183.4	191.7	287.5	322.4	345.2	370.6
CASH FLOW STATEMENT						
Profit before tax	27.9	17.5	16.7	41.9	32.7	36.4
Depreciation and amortisation	11.0	11.5	12.0	18.2	19.4	20.1
Share based payments	0.0	0.0	0.0	0.0	0.0	0.0
Other adjustments	(2.7)	(1.2)	7.4	(0.4)	1.5	1.2
Movements in working capital	12.7	(9.8)	(24.4)	(63.7)	(4.5)	(5.8)
Interest paid/received	0.0	0.0	0.0	(0.1)	(2.1)	(1.8)
Income taxes paid	(3.4)	0.1	(3.1)	(8.1)	(2.2)	(2.6)
Cash from operations (CFO)	45.5	18.0	8.5	(9.0)	44.7	47.5
Capex	(18.1)	(19.9)	(26.5)	(40.5)	(31.7)	(26.0)
Acquisitions & disposals net	0.0	0.0	0.0	0.0	0.0	0.0
Other investing activities	1.7	0.7	0.1	0.1	0.7	0.6
Cash used in investing activities (CFIA)	(16.3)	(19.2)	(26.2)	(40.5)	(31.0)	(25.4)
Net proceeds from issue of shares	(0.5)	0.5	88.0	0.2	0.0	0.0
Movements in debt	(9.7)	9.0	(9.2)	25.8	(12.7)	(3.9)
Other financing activities	(6.9)	(9.0)	(6.3)	(4.5)	(7.6)	(8.4)
Cash from financing activities (CFF)	(17.1)	0.5	72.5	21.4	(20.3)	(12.3)
Cash and equivalents at beginning of period	29.3	41.4	40.7	95.5	67.4	60.8
Increase/(decrease) in cash and equivalents	12.1	(0.7)	54.8	(28.1)	(6.6)	9.7
Cash and equivalents at end of period	41.4	40.7	95.5	67.4	60.8	70.5
Net (debt)/cash	7.6	(2.5)	61.3	(17.4)	(11.3)	2.3

Source: Company accounts, Edison Investment Research

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