

Laboratorios Farmacéuticos ROVI

Interim results

Top-line growth, significant margin expansion

Laboratorios Farmacéuticos ROVI reported H120 operating revenue of €191.1m (+8% y-o-y), driven by strong growth in heparins (+23% to €104.0m) and in toll manufacturing (+31% to €34.8m), which offset a decrease in sales of low-margin, mature specialty pharmaceuticals. EBITDA increased by 60% to €42.4m in H120, which reflects operational leverage plus a significant benefit from improved gross margin, and reduction in R&D and SG&A. For FY20, ROVI has maintained guidance of mid-single-digit growth in total operating revenues. Despite the overall strength of heparins and toll manufacturing revenues, the company remains prudent given the COVID-19 related uncertainties. During Q220 ROVI signed a collaboration agreement with US-based biotech Moderna to provide fill-finish manufacturing for Moderna's COVID-19 vaccine candidate outside of the US, which could provide upside if successful depending on the undisclosed terms of the deal. The US NDA filing for DORIA remains on track for H220. We value ROVI at €1.64bn.

Year end	Revenue* (€m)	PBT** (€m)	EPS** (€)	DPS (€)	P/E (x)	Yield (%)
12/18	304.8	19.2	0.38	0.08	77.9	0.3
12/19	382.5	45.6	0.77	0.18	38.4	0.6
12/20e	394.5	54.3	0.88	0.20	33.6	0.7
12/21e	449.2	60.8	0.98	0.23	30.2	0.8

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

Significant growth in sales and operating profit

The H120 numbers highlight strength in sales across key franchises, and importantly margin expansion as costs reduced significantly. Sales of low molecular weight heparin (LMWH) products (Becat and Hibor) increased by 23% to €104.0m; sales have benefited from increased heparin use for hospitalised COVID-19 patients offset by fewer elective surgical procedures. Becat continues to benefit from the ongoing roll-out in Europe by ROVI and its partners (it is now available in 13 countries); we have increased our Becat forecast to c €100m in FY20.

Moderna deal benefits toll manufacturing

ROVI's toll manufacturing division has benefited from consolidation and the redirection of its strategy toward high-value products. ROVI will provide vial filling and packaging capacity to support production of Moderna's COVID-19 vaccine candidate to supply markets outside of the US starting in early 2021. ROVI expects the toll manufacturing business to post high double-digit growth in FY20; we forecast 18% growth in 2020 in this division given better visibility on contracts.

Valuation: €1.64bn or €29.2/share

Our revised valuation is €1.64bn or €29.2/share, vs €1.53bn or €27.2/share previously. We have adjusted our sales forecasts with a small increase in heparins and toll manufacturing offsetting declines in mature areas. The faster growth of higher-margin products and reduced opex for 2020 have positively affected future margin forecasts despite DORIA launch cost assumptions. Our valuation is underpinned by Becat's strong growth potential, while the opportunity for DORIA in the US and EU is key, contributing 15.9% and 12.9% to our valuation, respectively.

Pharma & biotech

29 July 2020

Price €29.6

Market cap €1,660m

\$1.08/€

Net debt (€m) at 30 June 2020 38.0

Shares in issue 56.1m

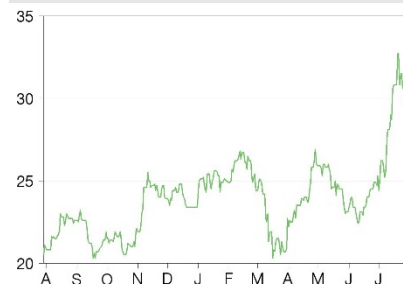
Free float 32.1%

Code ROVI

Primary exchange Madrid

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 18.9 10.1 47.3

Rel (local) 17.8 3.8 87.4

52-week high/low €32.7 €20.3

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. 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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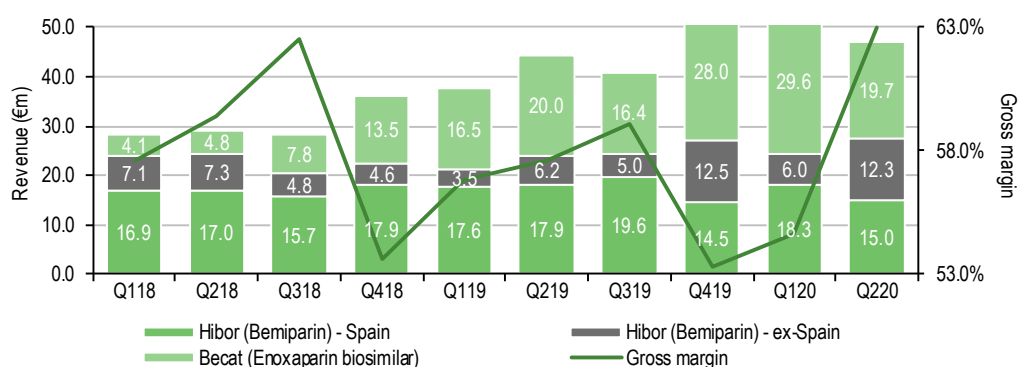
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H120 financials

ROVI's H120 results highlight ongoing momentum in the speciality pharmaceuticals business within a challenging COVID-19 environment. The strong uptake of Becat (+35% to €49.3m) has grown ROVI's LMWH franchise significantly; it now represents 54% of operating revenue in H120 (H119: 48%). Hibor (bemiparin) international sales grew 88% to €18.3m (H119: €9.7m), offsetting a 6% decline in sales in Spain to €33.3m (H119: €35.5m), which saw a greater impact from the reduction in the number of elective surgical procedures. This significant increase internationally was related to higher transfer prices to some partners (related to the rise in LMWH raw material prices); ROVI now expects international Hibor sales to increase by a high double-digit percentage in FY20. We note that the World Health Organization (WHO) has recommended LMWHs, such as Hibor and Becat, as essential medicines in the treatment of hospitalised COVID-19 patients. This is due to the documented [COVID-19 related coagulopathies](#), which are believed to be a major feature of the underlying pathophysiology of severe COVID-19 that requires treatment. We believe higher sales of ROVI's overall heparin franchise reflects increased use in COVID-19 patients offset by declines of usage in elective surgical settings (especially Becat in Spain). Exhibit 1 highlights the sales evolution within the heparin franchise. The majority of ROVI's innovation products treat chronic diseases and therefore sales would be expected to remain stable in the short term. However, due to COVID-19 confinement measures, the company's salesforce has been unable to promote its products, which may have contributed to the declining sales of mature speciality pharmaceutical products.

Since the start of the COVID-19 pandemic, ROVI has negotiated an additional €45m in credit facilities, placing it in a resolute position to meet any short- to medium-term additional cash needs. As of 30 June 2020, these facilities remain unused. The company also recorded €2.5m in personal and other expenses related to implemented COVID-19 measures.

Exhibit 1: LMWH franchise quarterly performance



Source: Laboratorios Farmacéuticos ROVI accounts, Edison Investment Research

Gross margin rose 1.4% from 57.4% in H119 to 58.8% in H120; the margin was positively affected by: 1) higher toll manufacturing sales' contribution to improved margin at the group level; 2) an increased Hibor price; and 3) the improvement in Becat margin in Spain offsetting the drop in international Becat margin contribution. This is a significant turnaround as gross margin has been under pressure in recent years, but ROVI has been able to pass through the rising costs of porcine LMWH raw materials due to the backdrop of higher demand for anti-coagulants relating to COVID-19. ROVI expects LMWH raw material prices to stabilise during H220.

Toll manufacturing revenues increased by 31% to €34.8m, driven by a focus on sales of high-value products. EBITDA increased to €42.4m (+60%), reflecting significant operating leverage, improvement in gross margins and a 27% reduction in R&D spend (€10.8m in H120). 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 a three-monthly injection formulation are ongoing) are offset by increasing investment in Letrozole ISM. We have revised down our forecast €25.8m in R&D expenses for the year; ROVI has now guided to a low double-digit reduction for FY20.

ROVI has provided operating revenue guidance of mid-single-digit growth for 2020; we now forecast 3.1% growth in FY20 from 5.3% previously as increased Becat and toll manufacturing offset older product sales expectations and fewer elective surgical procedures due to the pressures of COVID-19. We have revisited our operating cost assumptions for FY20 and now forecast an operating margin improvement in 2020 to 13.0% (from 11.2% in 2019). We expect the margin to decline slightly in 2021 (to 12.9%), 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 €1.64bn or €29.2/share, from €1.53bn or €27.2/share previously. Our heparin product forecasts have been revised upwards while forecasts for several mature specialty pharmaceutical products have been brought down for FY20 and we have rolled forward our model and updated for net debt of €38.0m at 30 June 2020. The major source of valuation uplift relates to improved margin assumptions from FY20. We expect SG&A to rise in FY21 reflecting DORIA launch, but have reduced other opex to be in line with lower FY20 expectations. 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 15.9% of our valuation (DORIA's EU opportunity accounts for 12.9%).

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

	€m
Sum of for DCF for forecast period to 2026	393.5
Sum of DCF for growth 2027 to 2031 (transition period)	250.6
Terminal value	557.8
Enterprise value	1,201.9
Net debt at 30 June 2020	38.0
Value of equity of base business	1,163.9
Value per share of base business (€)	20.76
Discount rate	10%
Terminal growth rate	2%
Number of shares outstanding (m)	56.07

Source: Edison Investment Research

Exhibit 3 ROVI sum-of-the-parts valuation

	Value (€m)	Value per share (€)
DCF of base business	1,201.9	21.44
rNPV of DORIA	471.1	8.40
Net debt at 30 June 2020	(38.0)	(0.68)
SOTP valuation	1,635.0	29.16

Source: Edison Investment Research

Exhibit 4: DORIA net present value

	Indication	Launch	Peak sales (\$m)	Value (€m)	Probability	rNPV (€m)	rNPV per share (€)
NPV DORIA US	Schizophrenia	2022	236	353.1	75%	260.4	4.64
NPV DORIA Europe	Schizophrenia	2021	176	284.4	75%	210.7	3.76

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	102.8	101.1
Enoxaparin revenue	0.0	1.5	30.2	80.9	99.5	124.3
Other (Pharma & Manufacturing)	185.5	192.1	183.3	204.8	192.2	223.8
Total revenues	265.2	277.4	304.8	382.5	394.5	449.2
Cost of sales	(112.0)	(110.2)	(128.6)	(166.6)	(169.6)	(197.2)
Gross profit	153.1	167.2	176.2	215.9	224.9	252.0
Gross margin %	57.8%	60.3%	57.8%	56.4%	57.0%	56.1%
SG&A (expenses)	(101.9)	(108.5)	(113.2)	(125.5)	(128.2)	(156.8)
R&D costs	(17.5)	(28.3)	(32.4)	(29.3)	(25.8)	(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	70.9	78.2
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	55.8	62.5
Reported Operating Income	28.3	18.4	17.5	42.6	51.5	58.1
Operating Margin %	10.7%	6.6%	5.7%	11.2%	13.0%	12.9%
Finance income/(expense)	(0.5)	(0.9)	(0.7)	(0.9)	(1.5)	(1.7)
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	54.3	60.8
Reported PBT	27.9	17.5	16.7	41.9	50.0	56.4
Income tax expense (includes exceptionals)	(1.8)	(0.3)	1.2	(2.6)	(5.0)	(5.9)
Normalised net income	28.5	20.0	20.4	43.0	49.4	55.0
Reported net income	26.1	17.2	17.9	39.3	45.1	50.6
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	0.80	0.90
Normalised EPS (€)	0.58	0.40	0.38	0.77	0.88	0.98
Dividend per share (€)	0.18	0.12	0.08	0.18	0.20	0.23
BALANCE SHEET						
Property, plant and equipment	82.8	89.1	95.8	131.6	137.8	143.7
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	205.2	211.7
Cash and equivalents	41.4	40.7	95.5	67.4	12.6	13.4
Inventories	67.4	75.5	94.9	158.8	218.4	243.1
Trade and other receivables	53.8	49.7	60.2	81.5	86.5	92.3
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	327.6	358.9
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	92.9	97.3
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	98.9	101.0
Equity attributable to company	183.4	191.7	287.5	322.4	356.2	394.1
CASH FLOW STATEMENT						
Profit before tax	27.9	17.5	16.7	41.9	50.0	56.4
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	1.7
Movements in working capital	12.7	(9.8)	(24.4)	(63.7)	(64.0)	(26.8)
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)	(5.0)	(5.9)
Cash from operations (CFO)	45.5	18.0	8.5	(9.0)	(0.3)	43.7
Capex	(18.1)	(19.9)	(26.5)	(40.5)	(31.2)	(26.6)
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	0.1
Cash used in investing activities (CFIA)	(16.3)	(19.2)	(26.2)	(40.5)	(30.6)	(26.4)
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)	(11.3)	(12.6)
Cash from financing activities (CFF)	(17.1)	0.5	72.5	21.4	(24.0)	(16.5)
Cash and equivalents at beginning of period	29.3	41.4	40.7	95.5	67.4	12.6
Increase/(decrease) in cash and equivalents	12.1	(0.7)	54.8	(28.1)	(54.8)	0.8
Cash and equivalents at end of period	41.4	40.7	95.5	67.4	12.6	13.4
Net (debt) cash	7.6	(2.5)	61.3	(17.4)	(59.5)	(54.8)

Source: Laboratorios Farmacéuticos ROVI accounts, Edison Investment Research

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