

Laboratorios Farmacéuticos ROVI

Q320 results

Momentum continues across key franchises

Reported 9M20 numbers highlight continual strength in sales across key franchises and ongoing margin expansion. ROVI reported operating revenue of €302.1m (+12%). Within the low molecular weight heparin (LMWH) franchise (+26% to €157.7m), biosimilar enoxaparin (Becat) performed strongly, while the toll manufacturing division (+38% to €62.7m) benefited from the redirection of strategy to high value-added products. EBITDA increased 47% to €69.7m in 9M20, reflecting lower R&D costs and increasing operational leverage. ROVI has given guidance for FY21 of mid-single-digit growth in total operating revenues (excluding the manufacture of Moderna's COVID-19 vaccine candidate). The US NDA filing for DORIA is expected in Q420, and in Europe we expect approval and launch in 2021. We value ROVI at €1.57bn.

Year end	Revenue* (€m)	PBT** (€m)	EPS** (€)	DPS (€)	P/E (x)	Yield (%)
12/18	304.8	19.2	0.38	0.08	91.1	0.2
12/19	382.5	45.6	0.77	0.18	44.9	0.5
12/20e	402.6	63.3	1.03	0.24	33.6	0.7
12/21e	426.5	54.5	0.88	0.20	39.3	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 momentum continues

Sales of LMWHs Becat and Hibor increased 25% to €153.1m; sales have benefited from increased heparin use for hospitalised COVID-19 patients offset by fewer elective surgical procedures. Becat (+45% to €76.6m) continues to benefit from the ongoing roll-out in Europe by ROVI and its partners and we have increased our Becat sales forecast to c €100m in FY20. ROVI has maintained FY20 guidance of mid-single-digit growth in total operating revenues.

Toll manufacturing growth in high value-add products

ROVI has increased guidance for toll manufacturing revenues to 20–25% growth (from high double digits) in FY20; we now forecast 25% (from 18%) growth in FY20 in this division given better visibility on contracts. The Q220 collaboration agreement with US-based biotech Moderna to provide fill-finish manufacturing for its COVID-19 vaccine candidate outside the US could provide upside in FY21 if successful, depending on the undisclosed terms of the deal.

DORIA 2021 catalysts ahead

Marketing authorisation for DORIA (risperidone ISM) in Europe is expected in Q121; we continue to forecast launch in Europe in 2021. The US NDA filing for DORIA is still expected in Q420. We also await publication of the full PRISMA-3 data at a scientific congress next year to give further insight into DORIA's profile.

Valuation: €1.57bn or €28.1 per share

Our revised valuation of €1.57bn or €28.1 per share (€1.64bn previously) reflects the impact of FX and lower expectations for mature products from FY21. We increase FY20 Becat and toll manufacturing sales forecasts slightly. Our valuation is underpinned by Becat's strong growth potential, while the opportunity for DORIA in the US and EU is key, contributing 26.4% to our valuation.

Pharma & biotech

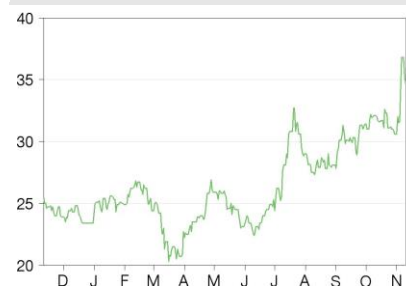
11 November 2020

Price €34.6

Market cap €1,940m

	\$1.19/€
Net debt (€m) at 30 September 2020	38.1
Shares in issue	56.1m
Free float	31%
Code	ROVI
Primary exchange	Madrid
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	7.8	26.7	40.7
Rel (local)	(2.8)	15.9	71.3
52-week high/low	€36.80	€20.30	

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 focused on its proprietary ISM technology.

Next events

DORIA US NDA filing	Q420
DORIA EU approval	Q121

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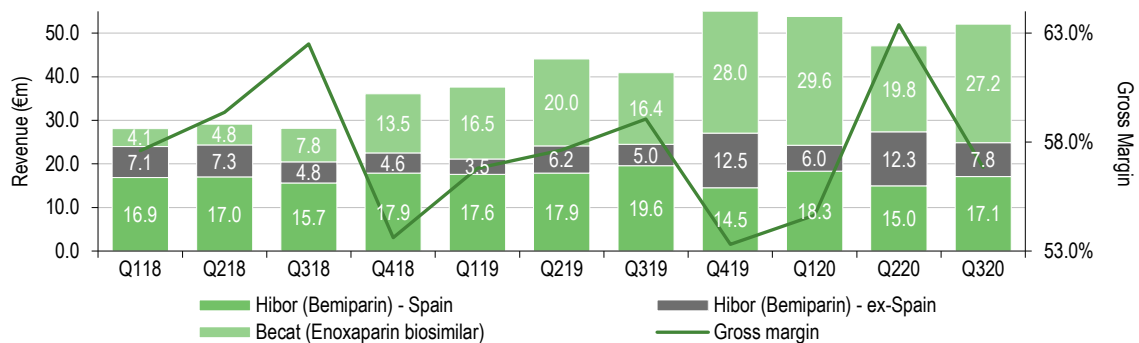
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9M20 financials: Strength in numbers

ROVI's results for the first nine months of 2020 (9M20) demonstrated substantial growth in its LMWH franchise and toll manufacturing business, driving a 12% y-o-y operating revenue increase to €302.1m. ROVI has maintained its FY20 revenue growth guidance of mid-single-digit growth, but has revised its guidance upward for growth in its toll manufacturing business to 20–25% from high double digits. ROVI has now issued FY21 guidance at mid-single-digit growth in operating revenues, excluding any contribution from the Moderna COVID-19 deal. We believe this is on the conservative side given the momentum in Becat sales and increasing potential for Moderna's mRNA-based vaccine (given read across from the [preliminary data of efficacy of >90%](#) from Pfizer and BioNTech's mRNA vaccine candidate BTN162b2).

In 9M20, revenues from the LMWH franchise grew 25% y-o-y to €153.1m (9M19: €122.6m), as shown in Exhibit 1. The strong uptake of Becat (+45% to €76.6m) has increased ROVI's LMWH franchise significantly; it represented 52% of operating revenue in 9M20 (vs 46% in 9M19). Becat is now available in 18 countries worldwide (it is approved in 26 countries in Europe and 15 in RoW), and additional roll outs are expected in 2021. Hibor's (bemiparin) international (ie outside of Spain) sales grew 43% to €26.1m (9M19 €18.2m), benefiting from higher transfer prices to some partners related to the increase in raw material costs, offsetting a 2% decline in sales in Spain to €50.4m (9M19: €51.5m), which saw a greater impact from the reduction in the number of elective surgical procedures performed during the COVID-19-related lockdown. Within the speciality pharmaceutical portfolio (ex-heparins), Neparvis sales increased 42% to €21.6m, while mature franchises (cholesterol treatments and respiratory drugs) continued to decline. Sales of contrast imaging agents and other hospital products declined 9% to €22.1m in 9M20, reflecting the reduction in diagnostic testing during lockdown (Q3 rebounded to +26% from Q220). Our revised sales forecast for 2020 is €402.6m (+5.3% vs FY19) and we have made minor upgrades to heparins, notably Becat sales, and have lowered the discount to the NHS to be in line with the 9M20 reported figure.

Exhibit 1: LMWH franchise quarterly performance



Source: Laboratorios Farmacéuticos ROVI accounts, Edison Investment Research

Toll manufacturing revenues increased by 38% to €62.7m in 9M20, driven by a focus on sales of high-value products. We note that ROVI did not book any Moderna COVID-19 vaccine-related income in Q320. ROVI has started initial preparation work for COVID-19 vaccine production under the agreement with Moderna and expects to start booking income related to these activities in Q420. We have revised our forecast toll manufacturing revenue upwards to €82.1m in FY20 (vs €77.5m previously) to reflect sales evolution so far this year and the revised guidance.

EBITDA increased to €69.7m (+47%), reflecting significant operating leverage, 0.1% improvement in gross margin and a 27% reduction in R&D spend (€15.6m in 9M20). 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. R&D expenses are expected to decline by 15–20% in FY20, and we have reduced our R&D forecast very slightly (€1m) to reflect guidance. We have also reduced our SG&A forecasts for the year by c €3.4m to reflect reported spend in 9M20. Our revised FY20 EBITDA is €79.9m versus €70.9m previously.

ROVI has provided operating revenue guidance of mid-single-digit growth for 2021; we now forecast 5.9% growth in FY21 versus 13.9% previously. We have increased our forecast Becat and toll manufacturing revenues and offset this with a greater decline in Hibor and the mature product sales expectations. We have adjusted our estimates to consider guidance but believe our revised forecasts to be conservative and expect to upgrade them during FY21. The revised sales forecasts for FY21 have led to a decrease in forecast EBITDA for FY21 to €71.7m from €78.2m. We have revisited our operating cost assumptions for FY20 and now forecast an operating margin improvement in 2020 to 15.0% (from 11.2% in 2019). We expect the margin to decline slightly in 2021 (to 12.1%), 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.

Valuation

Our adjusted valuation of ROVI is €1.57bn or €28.1 per share, versus €1.64bn previously (Exhibit 3). The major impact is FX on DORIA sales forecasts (which originate in US dollars in our modelling assumptions), but we have also made slight downward adjustments to the mature product portfolio expectations in FY21 with an impact on the later years. We make minor changes to our FY20 product forecasts (increasing Becat and toll manufacturing sales) and have nudged R&D down slightly, which has positively affected forecast operating profit for 2020. In addition, we have rolled forward our DCF/rNPV model and include net debt of €38.1m at 30 September 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 using a DCF of our sales and P&L model excluding DORIA (Exhibit 2). Our DORIA valuation has been affected by FX, as our sales across both territories are denominated in US dollars and translated into euros. 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 14.3% and 12.1% to our valuation, respectively.

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

	€m
Sum of DCF for forecast period to 2026	389.5
Sum of DCF for growth 2027 to 2031 (transition period)	250.2
Terminal value	556.7
Enterprise value	1,196.4
Net debt at 30 September 2020	38.1
Value of equity of base business	1,158.3
Value per share of base business (€)	20.66
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	1,196.4	21.34
rNPV of DORIA	414.3	7.39
Net debt at 30 September 2020	38.1	0.68
SOTP valuation	1,572.6	28.05

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	305.7	75%	224.8	4.01
NPV DORIA Europe	Schizophrenia	2021	176	256.4	75%	189.6	3.38

Source: Edison Investment Research. Note: \$1.19/€

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	100.1	93.4
Enoxaparin revenue	0.0	1.5	30.2	80.9	106.7	122.8
Other (Pharma & Manufacturing)	185.5	192.1	183.3	204.8	195.8	210.3
Total revenues	265.2	277.4	304.8	382.5	402.6	426.5
Cost of sales	(112.0)	(110.2)	(128.6)	(166.6)	(173.1)	(187.2)
Gross profit	153.1	167.2	176.2	215.9	229.5	239.3
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)	(124.8)	(150.5)
R&D costs	(17.5)	(28.3)	(32.4)	(29.3)	(24.8)	(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	79.9	71.7
Depreciation and amortisation	(11.0)	(11.5)	(12.0)	(18.2)	(19.4)	(20.0)
Normalised Operating Income	30.7	21.2	20.0	46.5	64.8	56.1
Reported Operating Income	28.3	18.4	17.5	42.6	60.5	51.7
Operating Margin %	10.7%	6.6%	5.7%	11.2%	15.0%	12.1%
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	63.3	54.5
Reported PBT	27.9	17.5	16.7	41.9	59.0	50.1
Income tax expense (includes exceptionals)	(1.8)	(0.3)	1.2	(2.6)	(5.8)	(5.2)
Normalised net income	28.5	20.0	20.4	43.0	57.5	49.2
Reported net income	26.1	17.2	17.9	39.3	53.2	44.9
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	0.95	0.80
Normalised EPS (€)	0.58	0.40	0.38	0.77	1.03	0.88
Dividend per share (€)	0.18	0.12	0.08	0.18	0.24	0.20
BALANCE SHEET						
Property, plant and equipment	82.8	89.1	95.8	131.6	138.2	143.1
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	211.0
Cash and equivalents	41.4	40.7	95.5	67.4	13.9	27.9
Inventories	67.4	75.5	94.9	158.8	222.9	230.8
Trade and other receivables	53.8	49.7	60.2	81.5	88.2	87.6
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	335.2	356.4
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	94.9	92.3
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	100.9	96.1
Equity attributable to company	183.4	191.7	287.5	322.4	362.3	395.9
CASHFLOW STATEMENT						
Profit before tax	27.9	17.5	16.7	41.9	59.0	50.1
Depreciation and amortisation	11.0	11.5	12.0	18.2	19.4	20.0
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)	(68.4)	(10.3)
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)	(5.8)	(5.2)
Cash from operations (CFO)	45.5	18.0	8.5	(9.0)	3.5	54.4
Capex	(18.1)	(19.9)	(26.5)	(40.5)	(31.7)	(25.5)
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)	(31.0)	(25.3)
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)	(13.3)	(11.2)
Cash from financing activities (CFF)	(17.1)	0.5	72.5	21.4	(26.0)	(15.1)
Cash and equivalents at beginning of period	29.3	41.4	40.7	95.5	67.4	13.9
Increase/(decrease) in cash and equivalents	12.1	(0.7)	54.8	(28.1)	(53.5)	13.9
Cash and equivalents at end of period	41.4	40.7	95.5	67.4	13.9	27.9
Net (debt) cash	7.6	(2.5)	61.3	(17.4)	(58.2)	(40.3)

Source: Company accounts, Edison Investment Research

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