EDISON

Laboratorios Farmacéuticos ROVI

Full year results

2021: A pinnacle year

Pharma & biotech

Laboratorios Farmacéuticos ROVI (ROVI) has reported a strong set of FY20 results, with all pillars of the business contributing to revenue growth of 10% and EBITDA margin expansion of 650bp to 22.4%. Total revenues of €421.1m were driven by its LMWH franchise (+14%) and high-value, toll manufacturing business (+39%), which has been catapulted into the international spotlight. In July 2020, ROVI signed a deal with US biotech Moderna to provide finished COVID-19 vaccine mRNA-1273 for supply ex-US. ROVI's revised FY21 guidance is for 20–30% revenue growth and we expect toll manufacturing to be a substantial contributor. DORIA remains on track in the US for potential approval and launch in 2022, while the EMA's request for an additional PK study has delayed European approval and launch to 2022. We value ROVI at €2.34bn or €41.7/share.

Year end	Revenue* (€m)	PBT** (€m)	EPS** (€)	DPS (€)	P/E (x)	Yield (%)
12/18	304.8	19.2	0.38	0.08	109.7	0.2
12/19	382.5	45.6	0.77	0.18	54.2	0.4
12/20	421.1	77.6	1.18	0.38	35.3	0.9
12/21e	505.3	97.3	1.56	0.37	26.7	0.9

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

DORIA EU and US launch expected in 2022

ROVI has requested a clock stop on the European approval process to complete an additional bioequivalence study comparing DORIA to a European reference product required by the EMA. ROVI had expected that the US bioequivalence study would be sufficient for the regulatory submission dossier, which makes sense. The result is a short delay in the expected approval and launch to early 2022.

Moderna tie-up highlights manufacturing expertise

ROVI's guidance of 10–15% growth in toll manufacturing revenues in FY21 excludes production of the Moderna COVID-19 vaccine. Including production of the vaccine, we forecast 60% growth in this division in FY21. We anticipate that in the near term ROVI will benefit from ongoing demand for COVID-19 vaccines, and in the future the partnership could expand to Moderna's mRNA oncology portfolio.

Financials: Capitalise on share price strength

We note that US DORIA approval (expected in H221) and launch (expected in 2022) will be a key inflection point. ROVI may partner the product in this key territory or elect to self-commercialise. Given the improved visibility across all parts of the business, if it decides to self-commercialise, a secondary listing in the US would be a good way to strengthen its balance sheet ahead of DORIA launch.

Valuation: €2.34bn or €41.7 per share

Our revised valuation is €2.34bn or €41.7per share (versus €1.86bn or €33.2/share previously). Our major forecast upgrades relate to the toll manufacturing division and minor adjustments across the speciality pharma portfolio reflecting ongoing stable growth for some products. We delay DORIA EU launch by one year to 2022. ISM products (DORIA and Letrozole) contribute 23% to our valuation, with peak sales forecasts unchanged for both.

10 March 2021

Price	**€41.7**
Market cap	**€2,338m**
	$1.21/€
Net debt (€m) at 31 December 2020	21.3
Shares in issue	56.1m
Free float	31%
Code	ROVI
Primary exchange	Madrid
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(3.9)	12.7	83.7
Rel (local)	(8.4)	9.2	66.7
52-week high/low		€47.6	€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 heparins (LMWHs). Its pipeline of drugs is focused on its proprietary ISM technology.

Next events

Letrozole ISM regulatory discussions	H121
DORIA US approval	H221
DORIA EU approval and launch	Early 2022

Analysts

Dr Susie Jana +44 (0)20 3077 5700

Dr John Priestner +44 (0)20 3077 5700

healthcare@edisongroup.com

Edison profile page

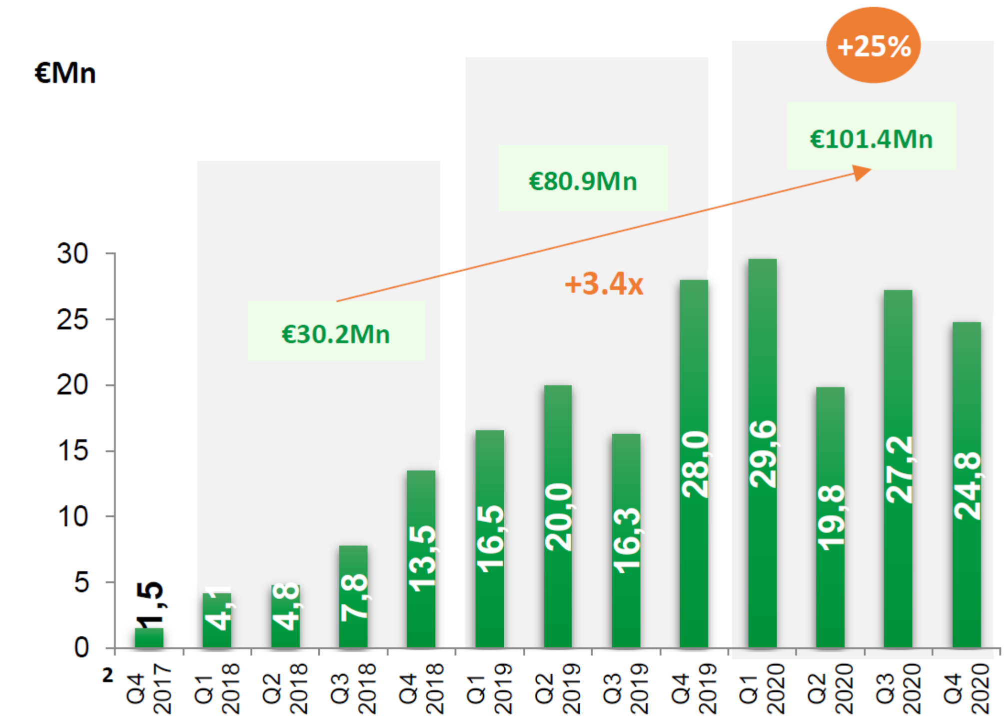
Laboratorios Farmacéuticos ROVI is a research client of Edison Investment Research Limited

2021: Unprecedented growth ahead

The future looks bright, despite the slight slippage of DORIA's potential EU launch into 2022. ROVI has been investing (€39.7m in capital expenditure in 2020 vs €27.0m in 2019, the latter excluding asset acquisitions) for future growth. This includes investment in R&D expenditure on its ISM platform assets (DORIA and Letrozole), in working capital ahead of international Becat launches, and expansionary capex to increase its toll manufacturing capacity and capabilities. Investment in the latter has enabled the deal with Moderna to provide finished mRNA-1273 COVID-19 vaccine for supply ex-US, This is a significant endorsement of ROVI's manufacturing capabilities and could provide the gateway for additional deals with Modena given its broad mRNA pipeline in vaccines and oncology. ROVI has provided revised FY21 guidance, significantly upgrading to 20–30% growth in operating revenues vs prior guidance for mid-single digit (although this excluded any contribution from production of the Moderna vaccine).

FY20 was a remarkable year, with all areas of the business growing rapidly, including speciality pharmaceuticals and its high-value toll manufacturing business. Total revenues increased by 10% to €421.1m, driven by its low molecular weight heparin (LMWH) franchise (+14%, €202.8m) and high-value, toll manufacturing business (+39%, €91.6m). ROVI's internally developed biosimilar enoxaparin, Becat, continues to benefit from ongoing roll-out in Europe by ROVI and its marketing partners (ROVI has already signed out-licensing agreements covering 95 countries). The strong uptake of Becat has led to significant growth in ROVI's heparin franchise, which now represent ~50% of FY20 operating revenue. Sales of LMWHs Becat and Hibor increased by 25% to €101.4m and 5% to €101.4m respectively. Hibor grew 21% internationally, offsetting a 2% decline in Spain. We forecast total peak sales of €200m for Becat, including Europe and the international opportunity ex-US, which at the current growth rate looks conservative. Exhibit 1 highlights the sales trajectory across the last 13 quarters. We conservatively forecast annual sales of Becat to grow by 20% to €126.7m in 2021.

Exhibit 1: Becat sales ramp since launch



Source: ROVI corporate presentation

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 +34% to €29.6m in FY20, Volutsa +7% to €14.2m in FY20). The cholesterol franchise (Vytorin, Orvatez, Absorcol) and respiratory franchise (Ulunar and Hirobriz) face challenging conditions as the active ingredient of these products is now off-patent.

Toll manufacturing successful evolution

ROVI is a global leader in pre-filled syringe manufacturing, which is a high-margin contributor to the toll manufacturing business. ROVI's contract manufacturing business provides a range of industrial services including injectables (pre-filled syringes and vials) for own use and supply to biotechnology or pharmaceutical companies that wish to outsource their manufacturing processes. Revenues in this division grew 39% to €91.6m, representing 22% of FY20 total operating revenues (17% in FY19). The recent upsurge in growth is related to reorientation of the toll manufacturing activities towards higher value-add products (with the income received from Moderna making a small contribution). ROVI's guidance of 10–15% growth in toll manufacturing revenues in FY21 excludes production of the Moderna vaccine. For total operating revenue, management has revised guidance up to 20–30% in FY21 and, taking this into account, a significant chunk of growth will be related to production of the Moderna vaccine. We therefore forecast 60% growth in FY21 to €146.5m in the toll manufacturing division. Beyond the pandemic opportunity, we believe ongoing revenue growth will be secured as the virus becomes endemic requiring annual vaccinations, and we expect leverage into other mRNA products at Moderna and potentially across the industry, given the high technical specialisation required for the manufacturer of pre-frilled syringes.

DORIA launch in 2022 in US and EU

Following positive PRISMA-3 data on DORIA (risperidone ISM), ROVI filed a marketing authorisation (MAA) with the EMA in January 2020. In March 2021, ROVI announced a clock stop on the European approval process as the CHMP had requested an additional pharmacokinetic (PK) study comparing the bioequivalence of multiple doses of DORIA versus a European reference product (risperidone product approved in Europe). The EU dossier submitted by ROVI included bioequivalence data that compare DORIA to a risperidone product available in the US (BORIS study). In our view, the request is surprising. Nonetheless, it is a requirement and ROVI expects to complete the study and submit the data in November this year. This is a low-risk trial as the European and US reference products can be considered bioequivalent on the basis of in vitro and in vivo studies performed by ROVI (the products use the same formulation and excipient) and the cost is not material (c €6m). In the US, ROVI has submitted the NDA filing for DORIA to the FDA under the 505(b)(2) pathway for approval and the PDUFA date has been set for 24 September 2021. We forecast launch in the US and Europe in 2022. ROVI does not expect the short delay in the European approval process to affect its guidance for FY21 or long-term guidance for 2023.

Valuation

Our revised valuation is €2.34bn or €41.7per share (versus €1.86bn or €33.2/share previously). We have reviewed our sales forecasts and made the following changes: 1) faster Becat ramp-up, but we maintain our peak forecasts; 2) significantly increased toll manufacturing growth rates in the near term to 60% growth in FY21 and 20% in FY22, reflecting income relating to the manufacture of the Moderna COVID-19 vaccine; and 3) reflect better than previously expected growth for Neparvis and Volutsa within the pharmaceutical portfolio. This has been offset by the delay of DORIA launch in EU by one year to 2022. In terms of valuation, the opportunity for DORIA in the US and EU is key, contributing 16%. We roll forward our model, update FX and reflect net debt of €21.3m at end December 2020.

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

	€m
Sum of DCF for forecast period to 2026	574.6
Sum of DCF for growth 2027 to 2031 (transition period)	376.6
Terminal value	858.2
Enterprise value	**1,809.3**
Net debt at 30 December 2020	(21.3)
Value of equity of base business	**1,788.0**
Value per share of base business (€)	**31.9**
Discount rate	10–12.5%
Terminal growth rate	2%
Number of shares outstanding (m)	56.1

Source: Edison Investment Research

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

	Value (€m)	Value per share (€)
DCF of base business	1,809.33	32.27
rNPV of DORIA	364.80	6.51
rNPV of Letrozole ISM	183.88	3.28
Net debt at 31 December 2020	(21.28)	(0.38)
SOTP valuation	**€2,336.7m**	**€41.7m**

Source: Edison Investment Research

Financials

ROVI reported gross profit of €242.5m in FY20 (+12% versus 215.9m in FY19), with 1.1% margin expansion attributable to higher-margin toll manufacturing sales, higher Hibor pricing related to pushing through higher raw material prices and improving Becat margins. EBITDA increased by 55% to €94.2m in FY20 (€60.9m in FY19) and EBIT margins expanded to 18% in FY20 vs 11% in FY19, mainly as a result of operational leverage as revenue grew faster than operating expenses. ROVI reported €23.8m R&D expenses and €124.4m in SG&A, respectively, in FY20.

ROVI has issued revised operating revenue guidance of mid-single digit growth for 2020. We had highlighted that previous guidance was conservative and we now upgrade our forecasts, as expected. Our revised forecast is 20% from prior 6% growth in total operating revenues in FY21. We have increased near-term growth rates for the LMWH franchise and other key products like Neparvis, such that we forecast ~10% growth in speciality pharmaceuticals. We significantly increase toll manufacturing growth expectations to 60% from 15% in FY21. Our revised EBITDA forecast for FY21 is €116.4m from €71.6m. We expect the operating margin to increase slightly in 2021 (to 18.8% vs 17.7% in FY20), reflecting gross margin expansion relating to higher margin toll manufacturing contribution, lower SG&A investment in international subsidiaries to support the DORIA launch, partially offset by higher R&D expenses. ROVI will benefit from its recent capital allocation decisions of investing in R&D, working capital and plant capacity. We expect top-line growth will lead to an uptick in operating margin expansion in 2022/23 as gross margins normalise and R&D expenses reduce, and through operational leverage as multiple products are launched through the newly established European subsidiaries. We believe operating margins could reach 23.2% in 2023.

At its capital markets day in November 2020, ROVI reiterated the longer-term financial targets of doubling its operating revenues by 2023 (from €303.2m in 2018) and increasing recurrent 'pre-R&D' EBITDA two and a half times (from €63.0m generated in 2018). This suggests revenues of c €606m and pre-R&D EBITDA of c €158m in 2023. This implies pre-R&D EBITDA margin expansion of 500bp over the next three years to 25.3% from 20.3%, which is achievable in 2023 driven by growth in Becat, DORIA and toll manufacturing revenues (even excluding Moderna opportunities), and with stabilisation in Hibor sales. These targets could prove conservative.

Exhibit 4: Financial summary

Accounts: IFRS, year-end: December, €m	2016	2017	2018	2019	2020	2021e
PROFIT & LOSS						
Hibor revenue	79.7	83.9	91.3	96.8	101.4	105.0
Enoxaparin revenue	0.0	1.5	30.2	80.9	101.4	126.7
Other (Pharma & Manufacturing)	185.5	192.1	183.3	204.8	218.3	273.7
Total revenues	265.2	277.4	304.8	382.5	421.1	505.3
Cost of sales	(112.0)	(110.2)	(128.6)	(166.6)	(178.7)	(207.2)
Gross profit	153.1	167.2	176.2	215.9	242.5	298.1
Gross margin %	57.8%	60.3%	57.8%	56.4%	57.6%	59.0%
SG&A (expenses)	(101.9)	(108.5)	(113.2)	(125.5)	(124.4)	(152.8)
R&D costs	(17.5)	(28.3)	(32.4)	(29.3)	(23.8)	(29.0)
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	94.2	116.4
Depreciation and amortisation	(11.0)	(11.5)	(12.0)	(18.2)	(19.6)	(21.3)
Normalised Operating Income	30.7	21.2	20.0	46.5	78.6	98.7
Reported Operating Income	28.3	18.4	17.5	42.6	74.7	95.0
Operating Margin %	10.7%	6.6%	5.7%	11.2%	17.7%	18.8%
Finance income/(expense)	(0.5)	(0.9)	(0.7)	(0.9)	(1.1)	(1.4)
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	77.6	97.3
Reported PBT	27.9	17.5	16.7	41.9	72.6	93.7
Income tax expense (includes exceptionals)	(1.8)	(0.3)	1.2	(2.6)	(11.5)	(9.7)
Normalised net income	28.5	20.0	20.4	43.0	66.1	87.6
Reported net income	26.1	17.2	17.9	39.3	61.1	83.9
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	1.09	1.50
Normalised EPS (€)	0.58	0.40	0.38	0.77	1.18	1.56
Dividend per share (€)	0.18	0.12	0.08	0.18	0.38	0.37
BALANCE SHEET						
Property, plant and equipment	82.8	89.1	95.8	131.6	155.4	162.0
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0
Intangible assets	24.9	27.1	34.7	45.1	41.4	42.8
Other non-current assets	13.1	14.1	18.2	16.6	13.1	13.1
Total non-current assets	120.8	130.2	148.7	193.3	209.9	217.8
Cash and equivalents	41.4	40.7	95.5	67.4	53.2	56.8
Inventories	67.4	75.5	94.9	158.8	227.2	255.4
Trade and other receivables	53.8	49.7	60.2	81.5	76.4	103.8
Other current assets	4.5	2.2	3.5	10.1	7.8	7.8
Total current assets	167.1	168.2	254.0	317.9	364.6	423.9
Non-current loans and borrowings	20.8	27.0	16.6	72.1	68.4	66.7
Other non-current liabilities	7.2	6.4	11.1	4.2	3.6	3.1
Total non-current liabilities	28.0	33.5	27.7	82.1	77.9	75.7
Trade and other payables	59.9	52.9	68.2	91.9	91.4	102.2
Current loans and borrowings	13.0	16.2	17.6	12.7	6.0	1.7
Other current liabilities	3.6	4.1	1.7	2.1	25.5	25.5
Total current liabilities	76.4	73.2	87.5	106.7	122.9	129.4
Equity attributable to company	183.4	191.7	287.5	322.4	373.7	436.7
CASHFLOW STATEMENT						
Profit before tax	27.9	17.5	16.7	41.9	72.6	93.7
Depreciation and amortisation	11.0	11.5	12.0	18.2	19.6	21.3
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)	1.8	1.4
Movements in working capital	12.7	(9.8)	(24.4)	(63.7)	(63.8)	(45.4)
Interest paid/received	0.0	0.0	0.0	(0.1)	(0.2)	(1.9)
Income taxes paid	(3.4)	0.1	(3.1)	(8.1)	(6.0)	(9.7)
Cash from operations (CFO)	45.5	18.0	8.5	(9.0)	46.9	59.4
Capex	(18.1)	(19.9)	(26.5)	(40.5)	(39.7)	(29.3)
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	0.0	0.5
Cash used in investing activities (CFIA)	(16.3)	(19.2)	(26.2)	(40.5)	(39.6)	(28.7)
Net proceeds from issue of shares	(0.5)	0.5	88.0	0.2	0.2	0.0
Movements in debt	(9.7)	9.0	(9.2)	25.8	(11.7)	(6.0)
Other financing activities	(6.9)	(9.0)	(6.3)	(4.5)	(10.0)	(21.0)
Cash from financing activities (CFF)	(17.1)	0.5	72.5	21.4	(21.5)	(27.0)
Cash and equivalents at beginning of period	29.3	41.4	40.7	95.5	67.4	53.2
Increase/(decrease) in cash and equivalents	12.1	(0.7)	54.8	(28.1)	(14.3)	3.7
Cash and equivalents at end of period	41.4	40.7	95.5	67.4	53.2	56.8
Net (debt)/cash	7.6	(2.5)	61.3	(17.4)	(21.3)	(11.6)

Source: Company accounts, Edison Investment Research

General disclaimer and copyright

Australia

New Zealand

United Kingdom

United States

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia