

Laboratorios Farmacéuticos ROVI

FY19 results

Investing for future growth

Laboratorios Farmacéuticos ROVI has reported a strong set of FY19 results, with all pillars of the business contributing to revenue growth of 26% and EBITDA margin expansion of 620bp to 16.0%. Total revenues of €382.5m were driven by its low molecular weight heparin (LMWH) franchise (Becat and Hibor) and toll manufacturing business. Becat (enoxaparin biosimilar) and flagship drug Hibor (bemiparin) reported combined sales of €177.6m (+46%). ROVI has consolidated its toll manufacturing units into a single entity; this division grew 20% in 2019 (€65.6m). Management has guided to mid-single digit growth in total operating revenues for 2020, which seems conservative. The MAA for DORIA has now been filed with the EMA (January 2020) and the NDA filing with the FDA is expected in H220. We value ROVI at €1.49bn.

Year end	Revenue* (€m)	PBT** (€m)	EPS** (€)	DPS (€)	P/E (x)	Yield (%)
12/18	304.8	19.2	0.38	0.08	66.8	0.3
12/19	382.5	45.6	0.77	0.18	33.0	0.7
12/20e	402.7	37.0	0.62	0.14	41.0	0.6
12/21e	438.3	40.8	0.68	0.15	37.4	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 franchise growth across the board

ROVI has successfully grown sales of both its LMWH franchise assets. Hibor sales in Spain were up a modest 3%, but international sales grew 14%. Proprietary product Becat reported sales of €80.9m (+167%), within the management guidance range of €76–82m. With performance benefiting from ongoing roll-out internationally, it is now available in 13 European countries and Costa Rica, either directly through ROVI or its regional marketing partners. Sales of other pharmaceuticals grew 9%, with Neparvis and Volutsa growth helping to offset declines in its mature asset base.

Investing for growth; DORIA MAA now filed

ROVI has been investing for future growth, including R&D expenditure on its ISM platform assets, investment in working capital, and expansionary capex to consolidate and increase its toll manufacturing capacity. The latter translated to meaningful revenue growth of 20% in 2019 in the toll manufacturing division. We forecast 12% growth in 2020/21 in this division given better visibility on contracts. ROVI has guided to low double-digit growth in FY20. Furthermore, following positive PRISMA-3 data on DORIA (risperidone ISM), ROVI has filed the MAA with the EMA. We forecast launch in Europe in 2021 and in the US in 2022.

Valuation: €1.49bn or €26.6/share

We increase our valuation of ROVI to €1.49bn or €26.6/share vs €1.42bn or €25.2/share previously. We have adjusted our forecasts and cost assumptions for 2020–23, updated for FX and rolled forward our model. Our valuation is underpinned by Becat's strong growth potential, while the opportunity for DORIA in the US and EU is key, contributing 16% and 13% to our valuation, respectively.

Pharma & biotech

28 February 2020

Price €25.4

Market cap €1,425m

\$1.09/€

Net debt (€m) at 31 December 2019 17.4

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 1.2 2.8 40.3

Rel (local) 5.5 7.1 43.9

52-week high/low €26.8 €17.0

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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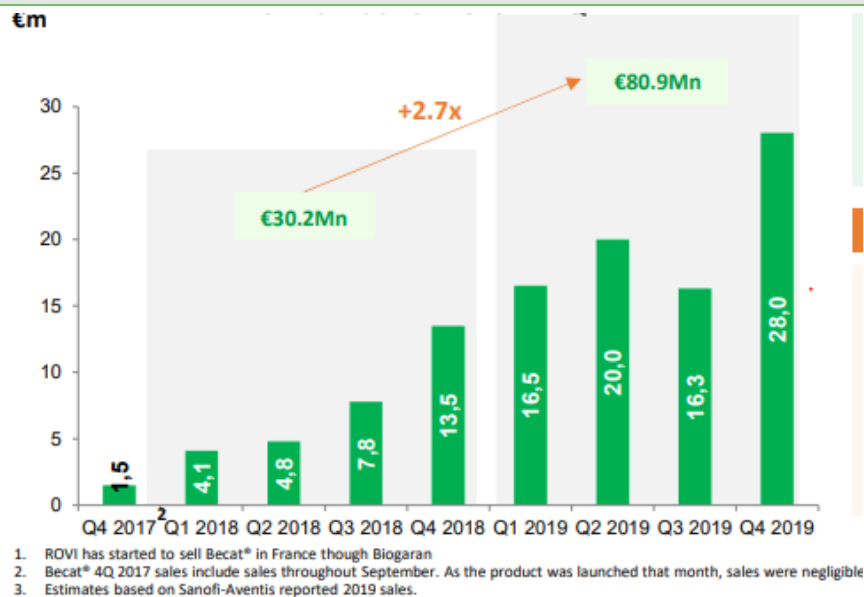
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Investing for multiple sources of growth

ROVI spent €27m in capital expenditure in 2019 (vs €17.4m in 2018). It has been investing for future growth, including R&D expenditure on its ISM platform assets (DORIA and Letrozole), investment in working capital ahead of international Becat launches, and expansionary capex to increase its toll manufacturing capacity and capabilities. We expect this investment to deliver management's future growth aspirations. The FY19 results demonstrate that management's strategy to grow all pillars of the business is succeeding, as evidenced by growth in its key revenue drivers (LMWH and toll manufacturing) and in its domestic Speciality Pharma division, which includes licensed products from multiple partners including Novartis (Neparvis) and Merck. In Spain, we continue to expect that further in-licensing deals will aid stable, low single-digit, top-line growth in the base business. In 2019, ROVI acquired rights to market three new products (Falithrom, Polaramine and Polaracrem), which had combined net sales of c €9m in 2017 (for a total cost of €22.5m).

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 85 countries). The product is now available in 13 countries (directly marketed in Germany, the UK, Italy, Spain, Portugal and Poland), approved in 26 countries in Europe and five in RoW, and pending approval in 71 countries. The strong uptake of Becat has led to significant growth in ROVI's LMWH franchise, the combined revenues of which now represent ~47% of FY19 operating revenue. Hibor reported €96.8m in sales (72% in Spain, and 28% internationally) and Becat sales increased by 167% to €80.9m in its second full year of launch. We forecast total peak sales of €200m for Becat, which includes Europe and the international opportunity ex-US. Exhibit 1 highlights the sales trajectory across the last nine quarters. ROVI no longer provides guidance on Becat sales. We conservatively forecast annual sales of Becat to grow by 20% to €97m in 2020. In 2019, the European enoxaparin market was estimated to be worth €0.7bn in sales (estimates based on Sanofi's reported 2019 sales).

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 +62% to €22m in FY19, Volutsa +18% to €13.3m in

FY19). The cholesterol franchise (Vytorin, Orvatez and Absorcol) faces challenging conditions as the active ingredient of these products (ezetimibe) is now off-patent.

ROVI is a global leader in pre-filled syringe manufacturing, which is a high-margin contributor to the toll manufacturing business. In November 2019, ROVI merged its multiple toll manufacturing units into a single entity known as Rovi Pharma Industrial Services. ROVI's contract manufacturing business provides a range of industrial services for injectable (pre-filled syringes and vials) and oral drug forms (tablets, capsules, sachets) for own use and supply to biotechnology or pharmaceutical companies that wish to outsource their manufacturing processes. ROVI has six EMA- and/or FDA-approved production plants, covering the ROVI active pharmaceutical ingredient (API) manufacturing plant in Granada, two injectable fill and finish plants in or near Madrid and a plant specialising in oral formulations, also near Madrid. By merging these into a single entity, ROVI has streamlined and increased production efficiencies to gain greater synergies. Revenues in this division grew 20% to €65.6m, representing 17% of FY19 total operating revenues. We forecast low double-digit growth in 2020/21 in this division given better visibility on contracts.

EBITDA margins expand despite gross margin squeeze

ROVI reported gross profit of €215.9m (+23%) in FY19. We note a reduction in gross margins to 56.6% from 58.1% in FY18, resulting from Becat launches in several new markets and an increase in LMWH raw material prices (prices have now risen in two consecutive years: by 30% in 2018 and by 44% in 2019) related to the increase in African swine fever in China. Gross margins are expected to remain under pressure in 2020 due to underlying raw material prices and the unknown potential impact of the coronavirus. However, EBITDA increased by 106% to €60.9m in FY19 and operating profit margins expanded to 16.0% in FY19 vs 9.7% in FY18, mainly as a result of operational leverage as revenue grew faster than operational expenses. ROVI reported €29.3m R&D expenses and €125.5m in SG&A, reflecting the end of the DORIA Phase III programme and investment in international subsidiaries (in part), respectively, in FY19.

ROVI has provided operating revenue guidance of mid-single digit growth for 2020; we forecast 5.6% 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%, mainly due to higher SG&A expenses with the ongoing Becat roll-out and ongoing raw material price pressures relating to swine flu (porcine mucosa is used in manufacturing heparins), and stable R&D expenses. We anticipate 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.

Short-term margin fluctuation, long-term expansion

Longer-term margins should continue to ramp up beyond this period as operational leverage from enoxaparin sales starts to flow through to the P&L, and the impact of high-margin asset, DORIA, becomes evident. We believe operating margins could reach 21.0% in 2023. Top-line growth will lead to an uptick in operating margin expansion in 2022/23 as gross margins normalise and R&D expenses reduce. ROVI reports pre-R&D metrics such as pre-R&D EBITDA, which helps to demonstrate the profitability (and growth) of the underlying business. Fluctuations in R&D and SG&A costs are expected, as management looks to maximise the return on internal capital by investing in R&D and SG&A as necessary for long-term growth. We expect this investment to deliver management's future growth aspirations (longer-term guidance for 2x 2018 revenues and 2.5x pre-R&D EBITDA in 2023 implies pre-R&D EBITDA margin expansion of 500bp over the next five years to 25.3% from 20.3%).

Valuation

Our revised valuation of ROVI is €1.49bn or €26.6 per share, from €1.42bn or €25.2/share previously. We have rolled forward our model, reflected the current FX spot (\$1.09/€) and updated for net debt of €17.4m at 31 December 2019. We have adjusted our forecasts and cost assumptions for 2020–23. 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 3). Compared to ROVI's current portfolio of drugs and footprint, the US opportunity for DORIA is large and a key valuation driver, accounting for 29.7% of our valuation (EU DORIA accounts for 13.2%).

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

	€m
Sum of for DCF for forecast period to 2025	330.9
Sum of DCF for growth 2026 to 2030 (transition period)	227.5
Terminal value	506.6
Enterprise value	1,065.0
Net debt at 31 December 2019	17.4
Value of equity of base business	1,047.7
Value per share of base business	18.69
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	1,047.7	18.69
rNPV of DORIA	445.4.0	7.94
Net debt at 31 December 2019	17.4	0.31
Equity valuation	1,493.1	26.63

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	331.2	75%	246.7	4.40
NPV DORIA Europe	Schizophrenia	2021	176	268.3	75%	198.7	3.54

Source: Edison Investment Research

Exhibit 5: Financial summary

Accounts: IFRS, year-end: 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	438.3
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)	97.5	97.1

Source: Company accounts, Edison Investment Research

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