

Laboratorios Farmacéuticos ROVI

FY18 results

Strength in heparins; next up DORIA

Laboratorios Farmacéuticos ROVI has reported strong revenue growth in FY18, with total revenues up 10% (€304.8m) beating guidance for the year. Its low molecular weight heparin (LMWH) franchise consisting of Becat (enoxaparin biosimilar) and flagship drug Hibor (bemiparin) reported sales of €121.5m (+42%). Hibor sales in Spain rose 14.7%, outperforming our 4% expectation. Becat (enoxaparin biosimilar) reported sales of €30.2m; its performance benefitted in 2018 from the ongoing roll-out in several European countries. Gross proceeds of the €88m capital raise will be used partly to fund the acquisition or in-licensing of additional products and sustain R&D efforts; of importance is Phase III DORIA (LA risperidone for schizophrenia) and data are anticipated in Q219. We value ROVI at €1.23bn.

Year end	Revenue* (€m)	PBT** (€m)	EPS** (€)	DPS (€)	P/E (x)	Yield (%)
12/17	277.4	20.3	0.40	0.12	45.9	0.7
12/18	304.8	19.3	0.39	0.08	47.1	0.4
12/19e	335.4	26.9	0.49	0.10	37.4	0.5
12/20e	363.2	46.5	0.83	0.19	22.1	1.0

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

Strong LMWH franchise

Flagship product Hibor (bemiparin) sales grew to €91.3m (+9%) with sales in Spain up to €74.2m (+14.7%), more than compensating for a decline in international sales to €22.7m (-5%). Proprietary product Becat (enoxaparin biosimilar) is now available in eight European countries and is directly marketed by ROVI in Germany, the UK, Italy and Spain. ROVI's commercial strategy for Becat is to market the product in Europe itself and internationally via out-licensing deals (agreements are now in place with Sandoz and Hikma). ROVI has grown its pharmaceutical offering by acquiring three additional products and has committed to broadening its portfolio further; revenue contribution from these in 2019 onwards should offset declines in the mature product portfolio.

DORIA Phase III top-line results next

PRISMA-3 data for DORIA (long-acting risperidone injection) is an important near-term inflection point; results are due in Q219 (trial has completed). The schizophrenia market is vast and growing steadily. We believe DORIA's profile will provide it with a 5% share of the long-acting injectable (LAI) market and drive peak sales of US\$412m (US and Europe) in 2027. DORIA is a high gross-margin asset (85–95%) and will be the critical long-term driver of operating margins.

Valuation: €1.23bn or €21.9 per share

Our revised valuation of ROVI is €1.23bn or €21.9 per share, up from €1.13bn. We have rolled our model forward and updated for net cash of €61.3m at 31 December 2018. We have made changes to our sales forecasts in 2019, mainly increasing Hibor in Spain and Becat, offset by some minor downward tweaks to mature products. Gross proceeds of €88m from a capital raise in October 2018 will ensure near-term costs are covered and, more importantly, provide an increase in liquidity to the stock with the improvement in free float.

Pharma & biotech

6 March 2019

Price €18.35

Market cap €1,029m

\$1.14/€

Net cash (€m) at 31 December 2018 61.3

Shares in issue 56.1m

Free float 32%

Code ROVI

Primary exchange MADRID

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (1.6) 5.8 8.6

Rel (local) (4.6) 3.5 11.8

52-week high/low €19.4 €14.8

Business description

Laboratorios Farmacéuticos ROVI is a fully integrated Spanish speciality pharmaceutical company involved in developing, in-licensing, manufacturing and marketing small molecule and speciality biologic drugs, with particular expertise in low molecular weight heparin.

Next events

PRISMA-3 DORIA data Q219

DORIA US NDA filing H219

Enoxaparin biosimilar launch in select European countries Ongoing

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FY18: Strength in heparins

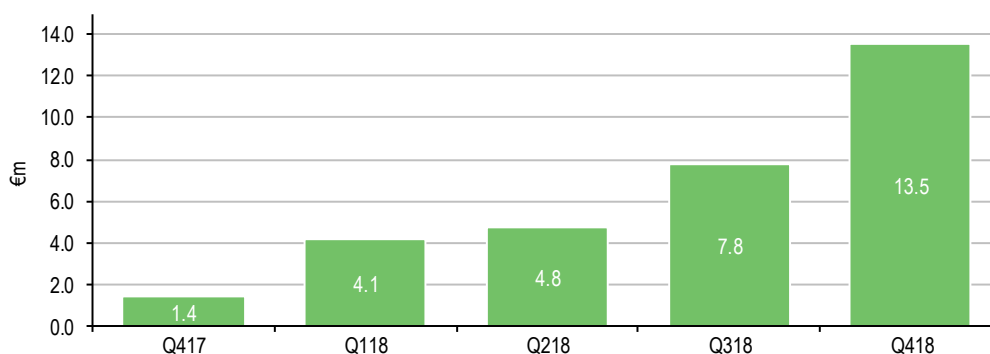
ROVI reported operating revenue of €303.2m for FY18 (+10.0% y-o-y), driven by strong growth in the speciality pharmaceutical business (+15.8% to €248.6m), offsetting declines in the toll manufacturing business (-10.6% to €54.6m). The speciality pharmaceutical business consists of approximately 40 marketed products across nine core franchises. Total revenues (including other operating income of €1.6m) grew 9.9% to €304.8m in FY18.

Revenue growth led by LMWH franchise

ROVI reported strong growth in its internally developed LMWH franchise (anticoagulants), which consists of its flagship, second-generation LMWH Hibor (bemiparin) and Becat, a biosimilar of enoxaparin (first-generation LMWH). Since launching Becat in Europe (end 2017), ROVI has strengthened its franchise with both Hibor and Becat growing simultaneously in Spain, and will build on over 20 years of experience in the LMWH market as it looks to evolve into one of the top players in the LMWH market.

Becat has experienced a strong uptake in sales (€30.2m) in FY18, beating guidance of €20–30m for the year. The product has received approval in 24 EU countries and is available in eight, including the core EU5 (UK, Germany, France, Spain and Italy). Becat launched in France in September 2018 through an agreement with Biogaran, a leading player in the French biosimilar market; ROVI expects to be directly marketing in France by end Q119. We continue to forecast total peak sales of €160.2m for Becat, which includes Europe and the international opportunity ex-US. Exhibit 1 highlights the sales trajectory across the last five quarters. ROVI is no longer providing guidance for FY19 Becat sales expectations; we forecast Becat annual sales to grow by 80% to €54.4m in 2019 based on the strong quarterly growth seen in H218.

Exhibit 1: Becat sales ramp since launch



Source: ROVI, Edison Investment Research

Sales of Hibor in Spain grew to €67.4m in FY18 (+14.7%), which is better than we had expected. In Spain, Hibor has partially benefited from the launch of Becat; Hibor is administered once a day vs Becat twice a day and Hibor has been placed on preferred formulary positioning. Furthermore, availability of enoxaparin biosimilars has translated to reduced detailing by Sanofi for its branded enoxaparin (Clexane) in Spain. Hibor sales in international markets declined 5% (€23.8m), reflecting shifts in market dynamics caused by the launch of Becat (enoxaparin biosimilar) in Europe and the impact of exchange rates (particularly the TRL/euro rate). We forecast Hibor sales of €96.8m in 2019.

In the broader portfolio of in-licensed products, growth in Neparvis (heart failure, in-licensed from Novartis) and Volutsa (benign prostate hyperplasia, in-licensed from Astellas) sales offset declines

in the mature portfolio. The cholesterol franchise (Vytorin, Orvatez and Absorcol) faces challenging conditions as the active principle of these products (ezetimibe) went off-patent in Q218. ROVI has provided operating revenue guidance of high single-digit growth for 2019. We have increased our FY19 total revenue forecast to €335.4m from €322.0m (implying 10.6% y-o-y growth) from an increase in our expectation of Hibor and Becat, mitigating reducing the sales expectation of mature products.

Gross margins squeezed in the short term

In October 2018 ROVI raised gross proceeds of €88m from a capital raise that will be used to fund R&D efforts (DORIA Phase III and Letrozole ISM Phase I), ongoing marketing of Becat, and the in-licensing or acquisition of additional products. ROVI is a profit-generating company and the capital raise ensures these near-term costs are covered, importantly, it has also provided an increase in liquidity to the stock with an improvement in the free float. ROVI reported end-FY18 net cash at €61.3m (FY17 net debt at €2.5m) based on cash of €95.5m and debt of €34.2m (FY17: cash of €40.7m and debt of €43.2m).

ROVI reported gross profit of €176.2m (+5.4%) in FY18; we note a reduction of gross margins to 57.8% from 60.3% in FY17. This is a function of lower volumes in the higher-margin injectables business, Becat launches in several new markets and an increase in LMWH raw material prices (30% higher in 2018). Operating profit decreased to €17.5m in FY18 and operating profit margins declined to 5.7% FY18 (6.6% in FY17), reflecting higher R&D and SG&A expenses plus €1.1m non-recurring expense linked to compensating employees for a change in the working conditions at the Frost Iberica plant.

We believe investors should focus on longer-term margin growth prospects for the group. While ROVI reports pre-R&D metrics such as pre-R&D EBITDA, which helps to demonstrate the profitability (and growth) of the underlying business as it stands, fluctuations in R&D and SG&A costs are likely to vary as management looks to maximise return on internal investment by investing in R&D and SG&A as necessary, and should be seen as part and parcel of the business. We forecast an absolute 1.1pp improvement in operating margin from 10.7% in 2016 to 11.8% in 2020. Margins should ramp up beyond this as the operating leverage from enoxaparin sales starts to flow through to the P&L, whereas R&D levels will decrease to €22m pa in 2020–21.

ROVI has given guidance for R&D expenses (October 2017 DORIA presentation) in the region of €32m pa in 2018–19 and €22m in 2020 and 2021 to support clinical trials for Risperidone ISM and Letrozole ISM. Becat is a product of the R&D invested by ROVI and the ramp-up in sales of this enoxaparin biosimilar has positive longer-term implications for development, mainly through operational leverage.

In terms of operating margin, we believe that after the costs of the initial launch period for Becat are met (as ROVI invests in European selling infrastructure) and DORIA is launched in the US and European markets, longer-term total SG&A for the group will grow at a slower rate than sales, which should provide the operational leverage to enable operating margin expansion. Gross margin evolution should benefit from 2022 as the high-margin asset DORIA starts to contribute to the top line. In the nearer term, given management's guidance the gross margin depression is likely to persist until 2020 (due to the inflation in LMWH raw materials). We have reduced our guidance for gross margin to 57.5% for 2019 (from 58.5%); however, our guidance for PBT has increased slightly to €26.9m (from €26.1m), driven by the 24.5% growth we now anticipate in revenues from the LMWH franchise (€151.2m).

2019 drivers: DORIA data and portfolio expansion

ROVI's internally developed biosimilar of enoxaparin, Becat, is a key driver of near-term, top-line growth. With proceeds set aside from the capital raise to rejuvenate the product portfolio, ROVI has recently 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).

- Falithrom (phenprocoumon) is an oral antithrombotic from the same class of anticoagulants as Warfarin (vitamin K antagonists). Phenprocoumon is generically available, and a widely prescribed anticoagulant in Germany. In December 2018, ROVI acquired marketing rights in Germany from Hexal AG (a Sandoz subsidiary) for €9m. Management has guided that in-market sales of Falithrom (Germany) totalled €3.5m in 2017; we would expect that with ROVI's current LMWH anticoagulant franchise (Hibor and Becat), and its growing foothold in Germany, it should be able to leverage its existing sales infrastructure to maintain a similar level of sales once the marketing authorisation has been transferred.
- In February ROVI announced that it has acquired certain rights to Merck Sharp & Dohme's (MSD) antihistamine product line of dexchlorpheniramine maleate formulations (for €13.5m), namely, marketing and distribution rights to oral and iv formulations (Polaramine) and topical formulations (Polaracrem) in Spain, and iv formulations (Polaramine) in France. Management has guided that 2017 sales were \$6.5m for these two products; given the seasonality of antihistamine usage, we would expect a cyclicity in reported sales by quarter.

DORIA Phase III data expected in Q219

ROVI's R&D focus is on its proprietary ISM technology, which centres on developing novel, long-acting (once a month or once every three months) formulations of approved drugs. Assets include DORIA ISM (Phase III schizophrenia) and Letrozole ISM (Phase I breast cancer). DORIA is a fast onset of action LAI version of risperidone (off-patent). As well as rapid onset of action, the key advantages are that there is no need for a loading dose or oral supplementation. The schizophrenia market is vast and growing steadily. We believe DORIA's profile will provide it with a 5% share of the long-acting injectable (LAI) market and drive peak sales of US\$411m (US and Europe) in 2027. DORIA is a high gross margin asset (85–95%) and will be the critical long-term driver of operating margins. ROVI expects to present PRISMA-3 DORIA data in Q219 and file the US NDA in H219.

Exhibit 2: Interview with Javier López-Belmonte, vice president and chief financial officer

 EDISON TV

Javier López-Belmonte
Vice president & CFO, ROVI



ROVI is a profitable biopharmaceutical company – please talk us through the different areas of the business.

Source: Edison

Valuation

Our revised valuation of ROVI is €1.23bn or €21.9 per share, from €1.13bn. We have rolled forward our model, reflected the current FX spot (\$1.14/€) and updated for net cash of €61.3m at 31 December 2018. We have tweaked up our Hibor and Becat sales forecasts for 2019 and 2020, and lowered expectations for the mature pipeline. We value DORIA US and EU using a standalone NPV calculation (Exhibit 5) and derive value for the rest of the business by using a DCF of our sales and P&L model excluding DORIA (Exhibit 4). Compared to ROVI's current portfolio of drugs and footprint, the US opportunity for DORIA is large and a key valuation driver, accounting for 17.7% of our valuation (EU DORIA accounts for 10.4%).

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

	Value (€m)	Value per share (€)
DCF of base business	880.4	15.7
rNPV of DORIA	344.8	6.2
Valuation	1,225.2	21.9

Source: Edison Investment Research

Exhibit 4: Three-stage DCF valuation of base business (excludes DORIA cash flows)

	€m
Sum of for DCF for forecast period to 2025	286
Sum of DCF for growth 2026 to 2030 (transition period)	159
Terminal value	375
Enterprise value	819
Net cash at 31 December 2018	61.3
Value of equity of base business	880.4
Value per share of base business (€)	15.7
Discount rate	10%
Terminal growth rate	2%
Number of shares outstanding (m)	56.07

Source: Edison Investment Research.

Exhibit 5: DORIA NPV

	Indication	Launch	Peak sales (\$m)	NPV (€m)	Probability	rNPV (€m)	rNPV per share (€)
NPV DORIA US	Schizophrenia	2022	236	296.4	75%	217.2	3.9
NPV DORIA Europe	Schizophrenia	2022	176	178.1	75%	127.6	2.3
Total				474.5	75%	344.8	6.2

Source: Edison Investment Research

Exhibit 6: Financial summary

Accounts: IFRS, Yr end: December, EUR: Millions	2015A	2016A	2017A	2018A	2019E	2020E
Hibor revenue	75.1	79.7	83.9	91.3	96.8	99.4
Enoxaparin revenue	0.0	0.0	1.5	30.2	54.4	70.8
Other (Pharma & Manufacturing)	170.9	185.5	192.1	183.3	184.2	193.0
Total revenues	246.0	265.2	277.4	304.8	335.4	363.2
Cost of sales	(97.1)	(112.0)	(110.2)	(128.6)	(142.5)	(154.4)
Gross profit	148.9	153.1	167.2	176.2	192.9	208.8
Gross margin %	60.5%	57.8%	60.3%	57.8%	57.5%	57.5%
SG&A (expenses)	(101.7)	(101.9)	(108.5)	(113.2)	(123.9)	(129.3)
R&D costs	(16.5)	(17.5)	(28.3)	(32.4)	(32.0)	(22.0)
Other income/(expense)	1.0	5.6	(0.6)	(1.1)	0.0	0.0
EBITDA (reported)	31.8	39.3	29.9	29.5	36.9	57.5
Depreciation and amortisation	(10.0)	(11.0)	(11.5)	(12.0)	(14.5)	(14.8)
Normalised Operating Income	23.8	30.7	21.2	20.1	26.8	46.6
Reported Operating Income	21.8	28.3	18.4	17.5	22.4	42.8
Operating Margin %	8.9%	10.7%	6.6%	5.7%	6.7%	11.8%
Finance income/(expense)	(0.9)	(0.5)	(0.9)	(0.7)	0.1	(0.1)
Exceptionals and adjustments	0.0	0.0	0.0	0.0	0.0	0.0
Normalised PBT	22.9	30.3	20.3	19.3	26.9	46.5
Reported PBT	20.9	27.9	17.5	16.7	22.5	42.7
Income tax expense (includes exceptionals)	(1.1)	(1.8)	(0.3)	1.2	(1.1)	(2.4)
Normalised net income	21.8	28.5	20.0	20.6	25.8	44.1
Reported net income	19.8	26.1	17.2	17.9	21.4	40.3
Basic average number of shares, m	49.5	49.0	50.0	53.0	53.0	53.0
Basic EPS (€)	0.40	0.53	0.34	0.34	0.40	0.76
Normalised EPS (€)	0.44	0.58	0.40	0.39	0.49	0.83
Dividend per share (€)	0.14	0.18	0.12	0.08	0.10	0.19
Balance sheet	2015A	2016A	2017A	2018A	2019E	2020E
Property, plant and equipment	81.8	82.8	89.1	95.8	103.8	112.4
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0
Intangible assets	18.9	24.9	27.1	34.7	30.2	26.4
Other non-current assets	9.1	13.1	14.1	18.2	18.2	18.1
Total non-current assets	109.8	120.8	130.2	148.7	152.2	156.9
Cash and equivalents	29.3	41.4	40.7	95.5	77.3	78.0
Inventories	63.9	67.4	75.5	94.9	117.2	126.9
Trade and other receivables	57.0	53.8	49.7	60.2	59.7	59.7
Other current assets	3.9	4.5	2.2	3.5	3.5	3.5
Total current assets	154.1	167.1	168.2	254.0	257.6	268.0
Non-current loans and borrowings	32.6	20.8	27.0	16.6	16.6	12.7
Other non-current liabilities	7.2	7.2	6.4	11.1	10.6	10.0
Total non-current liabilities	39.8	28.0	33.5	27.7	27.2	22.7
Trade and other payables	45.7	59.9	52.9	68.2	60.4	63.8
Current loans and borrowings	10.1	13.0	16.2	17.6	17.3	3.9
Other current liabilities	3.3	3.6	4.1	1.7	1.7	1.7
Total current liabilities	59.2	76.4	73.2	87.5	79.5	69.4
Equity attributable to company	164.8	183.4	191.7	287.5	303.2	332.8
Cashflow statement	2015A	2016A	2017A	2018A	2019E	2020E
Profit before tax	20.9	27.9	17.5	16.7	22.5	42.7
Depreciation and amortisation	10.0	11.0	11.5	12.0	14.5	14.8
Share based payments	0.0	0.0	0.0	0.0	0.0	0.0
Other adjustments	(1.1)	(2.7)	(1.2)	0.7	(0.1)	0.1
Movements in working capital	2.3	12.7	(9.8)	(24.4)	(30.1)	(6.9)
Interest paid / received	(0.6)	0.0	0.0	0.0	(0.9)	(0.9)
Income taxes paid	(2.0)	(3.4)	0.1	(3.1)	(1.1)	(2.4)
Cash from operations (CFO)	29.4	45.5	18.0	8.5	4.8	47.4
Capex	(19.9)	(18.1)	(19.9)	(26.5)	(18.1)	(19.5)
Acquisitions & disposals net	0.0	0.0	0.0	0.0	0.0	0.0
Other investing activities	0.6	1.7	0.7	0.1	1.0	0.8
Cash used in investing activities (CFIA)	(19.3)	(16.3)	(19.2)	(26.2)	(17.0)	(18.7)
Net proceeds from issue of shares	(5.1)	(0.5)	0.5	88.0	0.0	0.0
Movements in debt	5.9	(9.7)	9.0	(9.2)	(0.3)	(17.3)
Other financing activities	(8.3)	(6.9)	(9.0)	(6.0)	(5.6)	(10.6)
Cash from financing activities (CFF)	(7.6)	(17.1)	0.5	72.5	(6.0)	(27.9)
Cash and equivalents at beginning of period	26.7	29.3	41.4	40.7	95.5	77.3
Increase/(decrease) in cash and equivalents	2.6	12.1	(0.7)	54.8	(18.2)	0.7
Cash and equivalents at end of period	29.3	41.4	40.7	95.5	77.3	78.0
Net (debt) cash	(13.5)	7.6	(2.5)	61.3	43.4	61.4

Source: Laboratorios Farmacéuticos ROVI accounts, Edison Investment Research

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