EDISON

Laboratorios Farmacéuticos ROVI

Investor day

Multiple growth drivers lie ahead

Pharma & biotech

Following Laboratorios Farmacéuticos ROVI's (ROVI's) recent investor day, we have reviewed our near-term forecasts. Specifically, we upgrade our Becat (enoxaparin biosimilar) peak sales forecasts and increase toll manufacturing revenue growth rates for 2020/21, as we now have more confidence in the underlying demand for heparins and the pre-filled syringe business. Highlights from the investor day include a review of ROVI's operational performance in the last few years, including successful development of Becat, positive data from proprietary ISM asset DORIA and the multiple catalysts expected in 2020–22 that we forecast will enable ROVI's top-line sales to double to ~€600m in 2023. Next events include the ongoing Becat roll-out and EU and US submission of DORIA in Q120 and H220 respectively. We value ROVI at €1.42bn or €25.2 per share.

Year end	Revenue* (€m)	PBT** (€m)	EPS** (€)	DPS (€)	P/E (x)	Yield (%)
12/17	277.4	20.3	0.40	0.12	58.9	0.5
12/18	304.8	19.3	0.39	0.08	60.3	0.3
12/19e	370.2	41.5	0.71	0.16	33.1	0.7
12/20e	397.7	33.6	0.57	0.12	41.2	0.5

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

Investing for multiple sources of growth

ROVI 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. ROVI is positioned as a global leader in pre-filled syringe manufacturing, which is a high-margin contributor in the toll manufacturing business. We forecast double-digit growth in 2020/21 in this division given better visibility on contracts.

Ongoing Becat launches and DORIA approval 2020

Guidance for FY19 Becat sales is €76–82m, a significant achievement given that FY19 is only the second full year on the market. We expect Becat to benefit from growth in established markets, and new launches internationally (ex US). We upgrade our peak sales forecast to €200m from €160m (2026). ROVI has reported positive data from the Phase III PRISMA-3 trial for DORIA in schizophrenia. It expects to file an MAA with the EMA in Q120 and an NDA submission with the FDA in H220. We forecast launch in 2021 and 2022 respectively.

Valuation: €1.42bn or €25.2/share

We increase our valuation of ROVI to €1.42bn or €25.2/share vs €1.35bn or €24.1/share previously. We have upgraded our sales forecasts following the investor day. Our valuation is underpinned by Becat's strong growth potential, while the opportunity for DORIA in the US and EU is key, contributing 17% and 13% to our valuation, respectively. Longer-term guidance for 2x 2018 revenues and 2.5x pre-R&D EBITDA in 2023 is achievable and implies pre-R&D EBITDA margin expansion of 500bp over the next five years to 25.3% from 20.3%. A stable dividend with a three-year average 33% pay-out ratio also adds value.

4 December 2019

Price	**€23.5**
Market cap	**€1,318m**
	$1.11/€
Net cash (€m) at 30 September 2019	0.2
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	7.3	2.6	34.3
Rel (local)	9.6	(1.0)	34.9
52-week high/low		€25.5	€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. Its pipeline of drugs is focusing on its proprietary ISM technology.

Next events

DORIA NDA/MAA filings with the US FDA and the EMA	Q1/H220
LISA-1 and European approvals/launches	2020/21

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Edison profile page

Investment summary

Company description: Next step ISM technology validation

ROVI, a profitable, Spanish speciality pharmaceutical company, is engaged in the research and development, manufacturing and marketing of a broad range of small molecule and speciality biologic products. ROVI is a leader in the development of low molecular weight heparin (LMWH, branded as Hibor and Becat). Historically, its domestic market had been the focus with flagship product Hibor, while recently it has been increasing its international presence with the launch of Becat (enoxaparin biosimilar) in its first European markets (launched in Germany in 2017). ROVI has now established subsidiaries in five European countries, with initial marketing focus on Becat, expanding to the potential launch of DORIA (long-acting risperidone in the EU/US in 2021/22 respectively. Headquartered in Madrid, Spain, at end December 2018 it had 1,224 employees, the majority of whom are based in three locations in Spain.

Valuation: €1.42bn or €25.2/share

We value ROVI at €1.42bn or €25.2 per share, using a sum-of-the-parts basis, based on a three-stage DCF including our forecasts to 2026 (10% discount rate, long-term tax rate of 15%, 2.0% terminal growth rate) for the core business (excluding DORIA), and risk-adjusted NPV for DORIA US and the EU opportunity. Our DCF model consists of ROVI's base business (product sales and toll manufacturing revenues), including our forecasts for biosimilar enoxaparin. We value the Phase III asset, risperidone ISM (DORIA) separately, which we include on a risk-adjusted basis. Compared to ROVI's current footprint and portfolio of drugs, the US opportunity for DORIA is large and a key value driver (accounting for 17% of our valuation; EU DORIA accounts for 13%).

Sensitivities: Evolution of the heparin business is key

ROVI is subject to various sensitivities common to speciality pharmaceutical companies, including commercialisation (pricing, reimbursement, uptake and competition), manufacturing and financing risks. The key sensitivities for ROVI relate to successful European commercialisation of both Hibor and Becat (two years after launch (2019) enoxaparin represents 21.6% of our total revenue forecasts), while crystallising value from its R&D pipeline will prove critical in the longer term. Ongoing in-licensing deals are required to renew the portfolio offering in Spain and replace some of the mature products, which are facing patent expiry over the next few years. We do not value the technology platform, early-stage ISM (in situ micro particle implants) R&D pipeline and any future collaborations, all of which could represent upside. ROVI is a majority family-owned business. The principal shareholder (Norbel Inversiones) holds 63.107% of the business, thus the limited free float has an impact on liquidity.

Financials: Cash-generative and stable dividend policy

ROVI's 9M19 results demonstrated substantial growth in its LMWH franchise and toll manufacturing business, driving a 24% y-o-y operating revenue increase to €270.8m. ROVI's guidance is high double-digit operating revenue growth in FY19 and mid-single digit growth in FY20. We believe the latter is cautious given the momentum in the LMWH business and capacity for growth within the toll manufacturing (specifically injectables) business. In the medium term, we expect operational leverage from the fully vertically integrated LMWH business to aid margin expansion. However, the game changer will be DORIA. By 2023, we believe this high-margin asset could support operating margins of 21.2%. ROVI remains cash generative and committed to a stable dividend policy. At 30 September 2019, the company had $0.2m in net cash.

Diverse business model with multiple growth drivers

Much of the near-term focus on ROVI relates to the recent European roll-out of its in-house developed biosimilar enoxaparin (Becat) and the upcoming catalysts for DORIA (regulatory submissions and potential worldwide launch). Both assets are certainly key top-line growth drivers, and DORIA could be transformative to operative margins given it is a high gross margin asset (85–95%). Both assets are part of a wider portfolio at ROVI, with the two pillars of its business (Speciality Pharma and ISM R&D technology) providing strong foundations for growth (Exhibit 1).

Exhibit 1: ROVI business overview

Business division	Subdivision	Overview	9M19 revenues (€m)	% of 2018 revenues
Speciality pharmaceuticals business	Heparin franchise	Long established heparins business (since 1998), **strong European footprint** **2018 LVMH revenue €121.5m, 2010–18 CAGR 14%**	122.6	40
		Leading player in manufacturing heparins		
		Flagship product Hibor (bemiparin) available in Spain and international markets	69.8	30
		Enoxaparin biosimilar (Becat) second product to launch within this franchise, directly by ROVI into top EU markets and through partners in Europe and internationally 2018 revenues €30.2m	52.9	10
	Spanish speciality pharmaceuticals business	ROVI has one of the largest drug distribution business in Spain, ~250 reps distribute proprietary and in-licensed products to the domestic market **2018 revenues of €127.1m, 2010–18 CAGR 6%**	127.1	38.5
		14 new in-licensed products over last 12 years		
	Toll manufacturing business	Six fully invested manufacturing facilities, vertically integrated to provide product from API to fill and finish in injectables – manufacturing for own use and for third-party contracts **2018 revenues €54.6m, 2010–18 CAGR 5%**	45.4	21
ISM technology platform	R&D	ISM technology develops once a month or six-monthly depot injection		
Total operating revenues			270.8	303.2

Source: Edison Investment Research. Note: API: active pharmaceutical ingredient.

At its investor day, ROVI gave longer-term financial targets of doubling its operating revenues in 2023 (from €303.2m in 2018) and increasing recurrent 'pre-R&D' EBITDA 2.5x (from €63m generated in 2018). This suggests revenues of €606m and pre-R&D EBITDA of €154.7m in 2023. Both are achievable in 2023 driven by growth in Becat, DORIA and toll manufacturing revenues, and with stabilisation in Hibor sales. Importantly, the guidance implies pre-R&D EBITDA margins of 25.3% in 2023 compared to 20.3% in 2018.

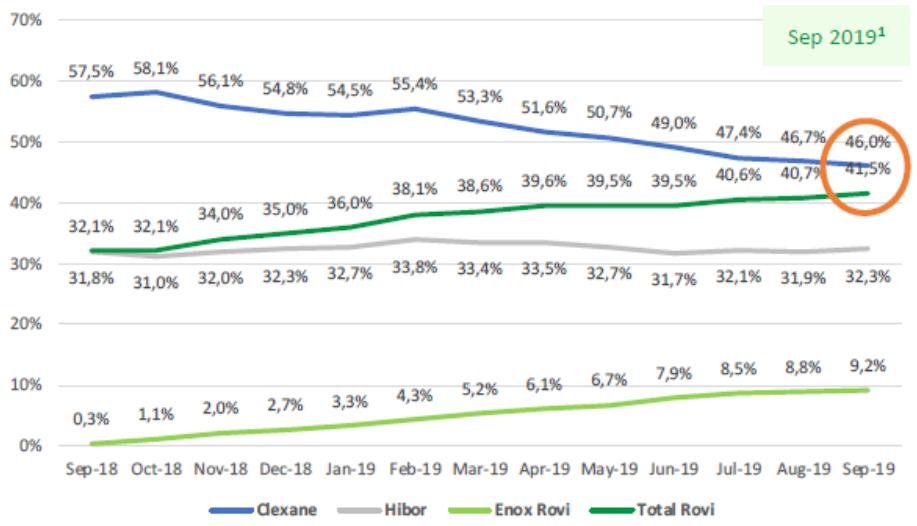
ROVI will benefit from its recent capital allocation decisions of investing in R&D, working capital and plant capacity. Top-line growth will lead to an uptick in operating margin expansion in 2022/23 as gross margins normalise and R&D expenses reduce and through operational leverage as multiple products launch through the newly established European subsidiaries.

We expect operating margins to decrease in 2020 (from 10.0% in 2019) to 7.2%, mainly due to higher SG&A expenses with the ongoing Becat roll-out, ongoing raw material price pressures relating to swine flu (porcine mucosa is used in manufacturing heparins), offset by a slight decline in R&D expenses. We anticipate margin growth from 2021 to 8.9% and beyond, mainly due to operational leverage and lowering R&D costs offsetting DORIA-related launch costs in 2021. 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 21.2% in 2023.

Heparin franchise a tale of two brands

In our initiation note, Ace of Spain, published on 12 July 2017, we described ROVI's established history in the LMWH market. ROVI's second-generation LMWH, Hibor, is marketed in 56 countries, pending registration in 14 countries. In 2018, ROVI reported Hibor sales of €91.2m (30% of total revenues), with 74% attributable to Spain and the rest to international sales. To compete more broadly in the international LMWH space and counter any revenue loss from the patent expiry of Hibor (October 2019), ROVI has used its expertise and invested in the development of an enoxaparin biosimilar (Becat), which was approved in 2017. In Spain, ROVI see this as a franchise effort and expects the two brands combined will overtake Clexane's (branded enoxaparin) market share. At September 2019, Hibor's and Becat's market share was 41.5% versus Clexane's 46.0%, a significant rise from September 2018 (Exhibit 2). In international markets we expect Becat to cannibalise Hibor sales, as Hibor is less established than Clexane outside Spain. Nonetheless, new launches of Hibor internationally will reduce the contraction elsewhere. In anticipation of significant growth in demand for LMWH, ROVI has announced the construction of a second heparin plant in Granada, Spain. It has committed €24m in investment over three years, which will double the group's Heparin production capacity by 2023.

Exhibit 2: ROVI LMWH market share in Spain (%)



Source: Corporate presentations

Hibor sales in Spain benefit from improved therapeutic profile

Hibor is designed to have an improved therapeutic profile compared to first-generation LMWH enoxaparin, available worldwide under the brand name Lovenox/Clexane (Sanofi). This improved profile has helped Hibor garner a 32% market share of the €224m Spanish anti-coagulant market (source: IMS and ROVI) compared to market leader Lovenox/Clexane (46% market share at end September 2019). This is a significant achievement given Hibor's premium pricing versus Lovenox/Clexane in Spain and reflects ROVI's marketing strength in its domestic market. Furthermore, Hibor is a once-a-day injection that can be administered peri- or post-operatively so is very flexible to administer, especially in day surgery, compared with Clexane, which is a twice-a-day administration. We expect single-digit growth in Hibor sales in Spain to offset double-digit declines internationally (note 2018 sales split 74% Spain, 26% ROW).

Becat off to a flying start in Europe

Internally developed biosimilar enoxaparin, Becat, continues to benefit from ongoing roll-out in Europe by ROVI and its partners. The strong uptake of Becat (Exhibit 3) has led to significant

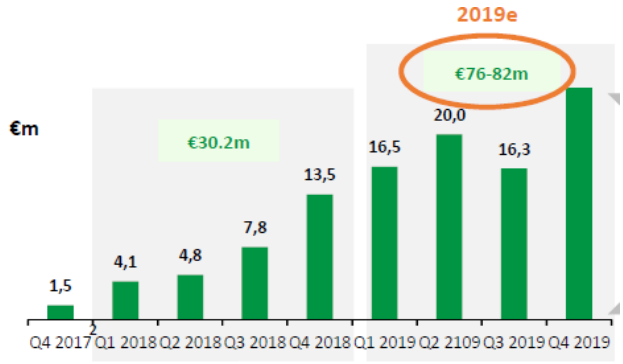
growth in ROVI's LMWH franchise, combined revenues of which now represent ~45% of operating revenue in 9M19. In 9M19, Becat reported €52.9m in sales (26% in Spain, and 74% ex Spain).

ROVI has set out a clear commercial launch strategy for Becat into key countries in the EU. It is directly marketing Becat in Germany, the UK, Spain, Portugal and Poland (initial launch in Germany in 2017, the UK and Spain in 2018, Portugal and Poland in 2019). ROVI plans to directly market Becat in these seven key European countries, which make up 75% of the European market (source: Quintiles IMS 2015) by value. Furthermore, it has agreements with multiple international partners including Sandoz in 14 countries and regions and Hikma in 17 Middle East and North African countries for commercialisations; agreements cover 85 countries already. During Q419, Becat will be launched in five countries (Germany, Italy, Finland Sweden and the Netherlands). Partners Teva and CABER will launch Becat in Germany and Italy respectively. In 2020, the product is expected to launch in Israel, Ireland, New Zealand, Belgium, Luxemburg, Norway, Denmark and Albania. In 2021/22 launches include other countries in Europe, Canada, Latin America and Asia.

At the Investor day, management highlighted that European roll-outs remain the priority given the size of the EU and RoW market versus the US LMWH market. Europe is the largest market for enoxaparin, estimated at €0.9bn. In Europe, the EMA had granted marketing authorisation to another enoxaparin biosimilar in September 2016 (Inhixa, Techdow). According to Iqvia MIDASdata, as at Q219, Becat has garnered a 67% market share in Europe (excluding Poland) in units vs Techdow's 26%.

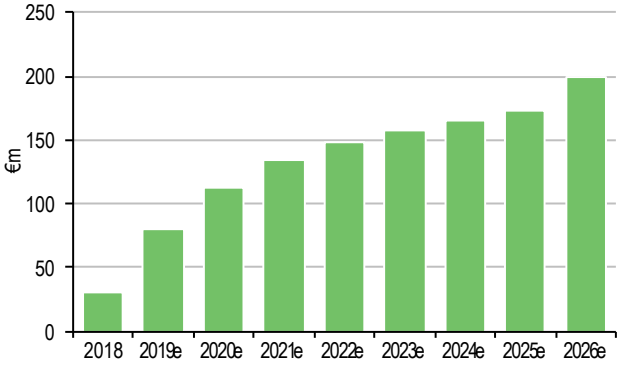
We have reassessed our Becat sales forecasts. We have increased our FY19 estimate to €80m from €74m (vs guidance of €7682m) given better than anticipated sales ytd. We have upgraded our forecast total peak sales to €200m from €160.2m, which includes Europe and the international opportunity ex-US. Exhibit 4 highlights our forecast sales trajectory to peak sales expectations in 2026.

Exhibit 3: Becat quarterly sales progression since launch in Q417



Source: Corporate presentations

Exhibit 4: Edison forecast Becat sales trajectory



Source: Edison Investment Research

US limited market size; EU the priority

Given the smaller commercial opportunity in the US, ROVI is prioritising its European launch and RoW partnering activities. In Europe, LMWHs are considered biological products derived from animal tissue, whereas in the US they are considered non-biological chemicals (LMWHs are non-protein in nature) and are referred to as generic LMWHs. This difference in classification and nuances in the regulatory framework in Europe and the US have created two very different market opportunities. Generic enoxaparin has been available in the US since 2010; Sandoz's version of enoxaparin was approved by the FDA in July 2010 and launched later that year. Sanofi's sales of its originator-branded Lovenox/Clexane have been eroded almost completely by multiple generic entrants, from a peak of $2.5bn in 2009 to $60m in 2016. In the US currently, eight 'generic'

enoxaparins compete in a market worth $500m. Substitutability and approval under ANDA means the US market for enoxaparin is more like a small molecule generic market.

Speciality pharma business shows sustainable growth

ROVI's Speciality Pharma division achieved 8% CAGR in 2008–18, driven by in-licensing products from multiple partners including Novartis, Merck and Servier. ROVI uses its sales and marketing infrastructure of c 250 reps across Spain to market in-licensed products as well as internally developed assets. One of its strengths is in its speciality salesforce, targeting mainly hospital-based physicians spread across a variety of specialities. Over the last decade, ROVI has successfully diversified its product offering across Spain to include over 30 brands (Exhibit 5 details ROVI's in-licensed product portfolio). The portfolio includes mature products facing patent expiry that ROVI continues to replace with innovative compounds in-licensed from its multiple partners.

Exhibit 5: Timeline of ROVI's strategic alliances in Spain

Source: Corporate presentations

During 2019 ROVI announced the acquisition of three products that will form localised operating leverage strategies for its international subsidiaries. Note that most of these products will not be launched in Spain.

- Falithrom: acquired from Hexal (part of Sandoz) and used for the treatment of thromboembolic diseases, for the German market. ROVI paid €9m to Hexal, 2019 estimated sales of €2.9m and estimated EBITDA of €2.8m.
- Polaramine: acquired from MSD (a subsidiary of Merck) for distribution in Spain and France. Polaramine (dexchlorpheniramine maleate) is an antihistamine product approved for several conditions including hay fever, rhinitis and allergic conjunctivitis. ROVI paid €13.5m to MSD and the company estimated sales in 2019 of €1.6m and estimated EBITDA of €1.1m.
- Sodium heparin: for the Italian market, strategic acquisition as synergetic with LMWH franchise.

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 the near term and offset product portfolio declines. Future growth drivers include Volutsa for benign prostate hypertrophy, Novartis's long-acting beta agonist (LABA) and LABA/long-acting muscarinic receptor antagonist inhalers for chronic obstructive pulmonary disease (launched in 2014) and Neparvis (Novartis) launched in December 2016.

DORIA EU approval to validate ISM technology

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. ROVI's proprietary technology is intended to overcome some of the disadvantages of prolonged-release oral or injectable formulations of established, widely used oral drugs that are available as generics. DORIA (risperidone ISM) is the first clinical asset developed using this proprietary drug development technology. It is a fast onset of action, long duration, long-acting injectable (LAI) version of off-patent drug risperidone for the treatment of schizophrenia.

We forecast DORIA peak sales of $412m in schizophrenia

ROVI has completed the clinical trial programme (PRISMA-3 and BORIS studies) that will form the basis of the dossier for the EU marketing authorisation submission (expected in Q120, suggesting potential approval in late 2020 and launch in 2021). ROVI plans to file the US NDA in H220 (we forecast a 2022 launch). As well as rapid onset of action, 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 LAI market and drive peak sales of $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.

PRISMA-3 significant reduction in PANSS score at week 12

The PRISMA-3 Phase III study (n=438) is a placebo-controlled trial designed to evaluate the efficacy and safety of monthly intramuscular injections of DORIA in patients with acute exacerbation of schizophrenia. Top-line data published in March 2019 showed that DORIA achieved the primary endpoint of a statistically significant reduction ($p<0.0001$) in Positive and Negative Syndrome Scale (PANSS) score at week 12 (both the 75mg and 100mg doses of once-monthly intra-muscular injection). PRISMA-3 is also assessing whether an improvement in PANSS from day four is achievable and statistically significant. If so, and if included in its label, DORIA would have a unique selling point versus its competitor LAIs. Full publication of PRISMA-3 is expected at a scientific conference next year. The trial is also looking at health economic-related outcomes, which could be relevant in pricing and reimbursement negotiations. Additionally, ROVI will include long-term safety data on more than 100 patients exposed to at least one year's duration of treatment with DORIA, as recommended in the International Conference on Harmonization of Technical Requirements Guideline E1. ROVI has also announced completion of the BORIS study, which compares the bioavailability of multiple doses of oral risperidone with multiple doses of risperidone ISM in stable schizophrenic patients. This will also be included in the registration dossier to the EMA and FDA.

Competitive landscape increasing in LAI antipsychotics

In our note, DORIA low risk, high reward, published on 9 May 2018, we outlined the market opportunity for long-acting antipsychotic drugs in schizophrenia. Long-term drug treatment of schizophrenia has major limitations. The US National Center for Biotechnology Information estimates that 25–33% of patients are treatment resistant and relapse rates remain high (relapse rates over two years in medication-treated chronic schizophrenia patients are approaching 41% (source: Crow et al, 1986). The cumulative relapse rate for first-episode patients with good adherence over a three-year period was 36%, whereas the rate for poorly adherent patients was 57% (Chen et al, Schizophrenia Research, 2005). Non-adherence to antipsychotic medication is common among patients with schizophrenia and is the greatest challenge for recovery and prevention of relapse with greater risk of hospitalisation. LAI antipsychotics are often used when oral medications have failed rather than as first-line therapy. Evidence increasingly supports their use as a first choice (WFSBP 2013 updated guidelines). Multiple effectiveness studies show the superiority of LAI antipsychotics, particularly in the case of risperidone. Exhibit 6 highlights the main

competitors in the LAI antipsychotic market and DORIA's competitive positioning on key clinical and practical metrics. An important general comment is that the choice of LAI will first depend on the antipsychotic drug itself. Some patients will fare better with risperidone rather than aripiprazole or paliperidone or vice versa.

Exhibit 6: DORIA profile versus approved long-acting antipsychotics

	RISPERDAL CONSTA® (Risperidone)	INVEGA SUSTENNA®/ XEPLION® (Paliperidone)	INVEGA TRINZA® / TREVICTA® (Paliperidone)	ABILIFY MAINTENA® (Aripiprazole)	ARISTADA® (Aripiprazole Lauroxil)	PERSERIS® (Risperidone Atrigel®) [13]	★ DORIA®[1,3] (Risperidone)
Once Monthly Administration [4, 12]	✗	✓	Quarterly	✓	✓	✓	✓
No Oral Supplementation / Loading dose [4, 12]	✗	✗	✓	✗	✗	✓	✓
Therapeutic Levels[2] within First 8 Hours [4, 12]	✗	✗[8]	✗	✗	✗	✓	✓
Currently Marketed in Europe [5, 7]	✓	✓	✓	✓	✗	✗	Targeted
Stability at Room Temperature [4, 14]	✗	✓	✓	✓	✓	✗	✓
PANSS Reduction from Day 4[3]	✗[6]	✗[8,9]	✗[4]	✗[10]	✗[11]	✗[12]	Targeted Endpoint for Phase III

Source: Company presentations

Although there has been an increase in approved LAI antipsychotic drugs on the market, DORIA's overall profile is a differentiating factor (Exhibit 6) as there is no need for oral loading dose/supplementation and therapeutic dosing is reached very early in treatment. On the latter point, we await the PANSS reduction from day four, a targeted endpoint of PRISMA-3, details of which will be published at a scientific conference in 2020. More importantly, as penetration of LAIs in schizophrenia is low, LAI antipsychotics are often used only when oral medications have failed and evidence increasingly supports their use as a first choice.

DORIA international distribution plan

ROVI plans to execute a double distribution strategy for DORIA. ROVI has built a presence in the top seven European countries with the launch of Becat. ROVI plans to directly market in these countries (Germany, UK, France, Spain, Italy, Poland and Portugal) and we expect it to hire 80 reps to focus on specialist psychiatrists. Outside of the above seven countries and internationally (ex US), ROVI will partner local or international players for the usual deal economics of upfront payments, royalties and milestones on sales. ROVI will decide the US commercial strategy nearer to approval and it may market DORIA in pockets of the US directly or out-licence the asset fully.

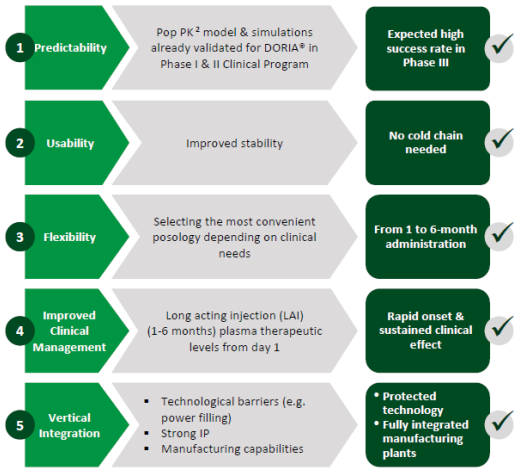
ISM platform forms second pillar for growth

ROVI's proprietary ISM technology is based on the formation of in situ micro particle implants for extended sustained release of compounds (long-acting intramuscular or subcutaneously administered by injection). The focus is on targeting long-term diseases such as schizophrenia and some cancer indications where a LAI treatment could improve patient compliance.

The ISM technology combines the advantages of technologies such as preformed microparticles and implants and is based on two separate syringes, one containing the drug and polymer (solid state) and the other the solvent (liquid). ROVI believes this has the key advantages of less

variability, enhanced stability, rapid reconstitution and easier injection to enable better compliance and therefore improved patient outcomes.

Exhibit 7: Key ROVI highlights of its ISM platform



Source: Company presentation

Letrozole ISM for hormone receptor-positive breast cancer

ROVI is developing ISM letrozole for treating hormone receptor-positive breast cancer. The asset is in Phase I and further established molecules will be targeted for development once full proof of concept has been achieved (through the approval of DORIA). Advances in the treatment of breast cancer over the last 20 years have, in some cases (hormone-dependent or HER-2 status), led to improved survival and many patients becoming cancer free. Novartis's Femara (letrozole), an aromatase inhibitor, is used to treat post-menopausal women with oestrogen receptor-positive primary breast cancer. Letrozole is prescribed as an adjuvant to surgery. The drug is usually continued for five years, as aromatase inhibitors decrease the risk of developing new breast cancer in the same or opposite breast (studies are underway to evaluate longer-term use, eg over 10 years). However, once a patient is breast cancer free, adherence to an oral daily 'cancer medication' can be an issue as some patients elect not to, or forget to, take the product. The opportunity for a once every three month, slow-release, intramuscular depot formulation of the drug is multi-fold and benefits include improved patient quality of life (lower dose frequency and reminder of illness), reduced healthcare costs and possible improved clinical outcomes. We do not currently reflect Letrozole explicitly in our ROVI valuation.

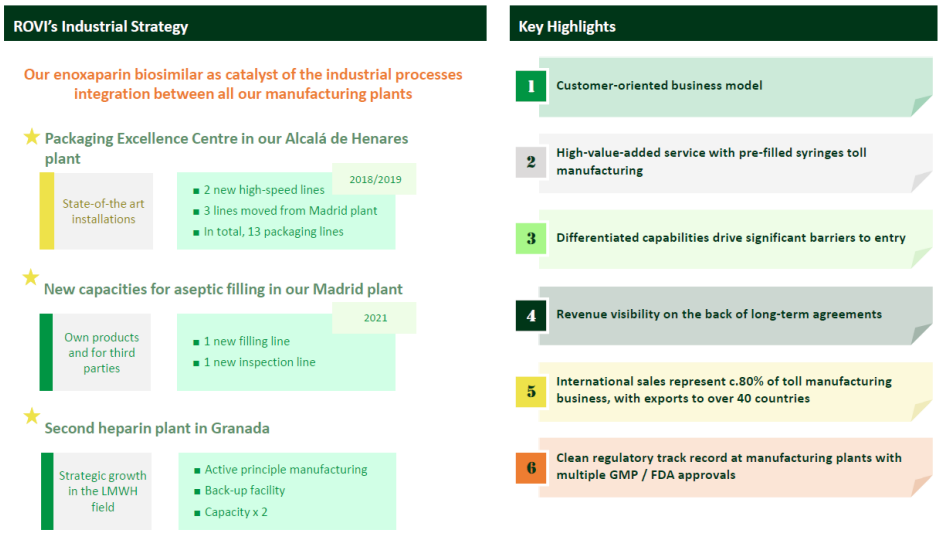
High-end contract manufacturing return to growth

ROVI reported €54.6m in toll manufacturing revenues in 2018; the compound annual growth rate over the period 2010–18 was 5%. ROVI's contract manufacturing business provides a range of manufacturing 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. ROVI provides a start-to-finish service tailored to an individual client's needs including preliminary clinical trials and stability studies. Investment over the last few years has enabled an increase in the injectables production lines. At Frosst Iberica in Alcala Henares, ROVI employs 243 people and has the capacity to manufacture 3,000m tablets, 300m hard capsules and 30m sachets.

Prefilled syringe toll manufacturing

At the investor day, ROVI highlighted its pre-filled syringes have applications for biological products, immunological products, LAIs and biotech products. ROVI is a local leader in the prefilled syringe production market, which is dominated globally by three large players (Becton-Dickinson, Gerresheimer and SCHOTT). This market is estimated to be growing at 9.4% CAGR (source: technavio), with demand-supply gap in the industry. Pre-filled syringe capacity is at a premium, due to the global lack of capacity, increasing demand and technical challenges in production. ROVI have given guidance for double-digit growth in revenues in 2019 and 2020 and although individual contacts cannot be detailed due to confidentiality agreements, we believe ROVI has visibility on near term-revenue growth based on the long-term agreements now in place.

Exhibit 8: High value-added toll manufacturing services



Source: Corporate presentations

ROVI possesses an annual production capacity of 300 million pre-filled syringe units; the facilities are GMP, FDA approved for filling syringes with API on behalf of numerous customers, including Novartis, Sanofi, Grifols and Hospira, as well as for ROVI-marketed products. Significant barriers to entry and limited competition in Spain translate to highly profitable contracts for ROVI; the average duration of a contract is three to five years. Furthermore, ROVI has created synergies through integrating two of its manufacturing plants. Given the significant opportunity for growth in both toll and ROVI's own manufacturing revenues (relating to the international expansion of Hibor and commercialisation of biosimilar enoxaparin), ROVI acquired the San Sebastian de Los Reyes plant for a €4m investment in 2015. This increased the annual production capacity by 120 million syringes to 300 million units.

Sensitivities

ROVI is subject to various sensitivities common to speciality pharmaceutical companies, including commercialisation (pricing, reimbursement, uptake and competition), manufacturing and financing risks. The key sensitivities for ROVI relate to successful European commercialisation of both Hibor and Becat its biosimilar enoxaparin and crystallising value from the ISM pipeline. Enoxaparin represents 22% of our total revenue forecasts in 2019 (its second year of commercial availability). Competition in the biosimilar enoxaparin space could come by way of new entrants. Although Hibor sales in Spain have not been affected by Becat, future cannibalisation is a risk. The largest near-term driver of our sales and net profit expectations is Becat. Compared to ROVI's current portfolio of drugs and its footprint, the US opportunity for DORIA is large and a key valuation driver

(accounting for 17% of our valuation; EU DORIA accounts for 13%). Timely partnering activity or effective own commercialisation strategy will be key to crystallising value from this high gross margin asset.

Valuation

We increase our valuation of ROVI to €1.42bn or €25.2/share vs €1.35bn or €24.1/share previously. Since the recent investor day, we have reviewed our individual key driver forecasts to 2023, given ROVI's long-term guidance.

Our sum-of-the-parts valuation consists of:

- NPV calculation for DORIA US and EU opportunity. We forecast US peak sales of $236m (€195m) and EU peak sales of $176m (€145m) in 2027; this is predicated on achieving a 5% peak penetration rate of the LAI antipsychotic market in both territories. We discuss our DORIA-related cost assumptions above. We assume a probability of launch of 75% and apply a 12.5% discount rate commensurate with our treatment of clinical-stage assets.
- DCF for ROVI's base business of marketed products and toll manufacturing revenue (we strip out DORIA sales and associated costs). We use our sales and P&L forecasts in these cash flows (out to 2025) and from 2026 to 2030 apply a transition growth rate (reflecting the fact that ROVI is growing at a high rate during our forecast period). Finally, we apply a 2.0% terminal growth rate (terminal value represents 30% of our total ROVI valuation); 10% is our standard discount rate assumption for companies with approved products and minimal development risk.
- We use a 15% tax rate from 2030. The current tax rate is c 8%, but this is expected to normalise to the mid-teens.

In addition, we have rolled forward our DCF/rNPV model and continue to reflect net cash of €0.2m at 30 September 2019. 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 17% and 13% to our valuation, respectively.

Exhibit 9: Three-stage DCF valuation of base business (excludes DORIA cash flows)

	€m
Sum of for DCF for forecast period to 2025	302.2
Sum of DCF for growth 2026 to 2030 (transition period)	222.0
Terminal value	493.5
Enterprise value	**1,017.8**
Net cash at 30 September 2019	0.2
Value of equity of base business	**1,018.0**
Value per share of base business	6
Discount rate	10%
Terminal growth rate	2%
Number of shares outstanding (m)	56.06

Source: Edison Investment Research

Exhibit 10: ROVI sum-of-the-parts valuation

	Value (€m)	Value per share (€)
DCF of base business	1,017.8m	18.15
rNPV of DORIA	397.1m	7.08
Net cash at 30 September 2019	0.2	0.00
Equity valuation	1,415.1m	25.24

Source: Edison Investment Research

Exhibit 11: DORIA NPV

	Indication	Launch	Peak sales ($m)	Value (€m)	Probability	rNPV (€m)	rNPV per share
NPV DORIA US	Schizophrenia	2022	236	301.5	75%	222.9	3.97
NPV DORIA Europe	Schizophrenia	2021	176	238.9	75%	174.31	3.11

Source: Edison Investment Research

Financials

ROVI's 9M19 results showed substantial growth in its LMWH franchise and toll manufacturing business, driving a 24% y-o-y operating revenue increase to €270.8m. ROVI has maintained its previously upgraded FY19 revenue growth guidance to the high double digits and provided guidance for FY20 for the first time. Management expects a mid-single-digit growth rate in operating revenue. We believe this is cautious given the momentum in the LMWH business and capacity for growth within the toll manufacturing (specifically injectables) business.

The 9M19 revenue from the LMWH franchise grew 44% y-o-y to €122.6m (9M18: €85.4m. Becat sales have been the main driver of franchise growth as ROVI rolls out the product across Europe (9M19: €52.9m). Hibor sales in Spain remain strong and increased slightly to €55.1m in 9M19 (+11%). These increases were slightly offset by a 24% reduction in Hibor international sales to €14.7m. The 9M19 toll manufacturing revenues grew 18% y-o-y to €45.4m (9M18: €38.5m), with the period benefiting from higher manufacturing volumes for some customers. At the interim results, ROVI upgraded its toll manufacturing revenue forecasts for FY19 to a low double-digit rate. We continue to forecast toll manufacturing revenue of €60.6m in FY19 (FY18: €54.6m).

The product portfolio outside the LMWH franchise continues to perform well, with new products replacing mature and off-patent franchises. Notably, in 9M19 sales of Neparvis increased 63% to €15.2m and Volutsa increased 19% to €9.7m, whereas ageing franchises Absorcol, Vytorin and Orvatez decreased 17% to €23.2m.

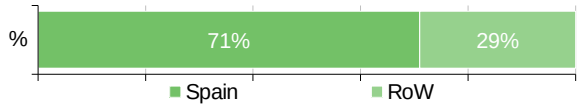
Increasing LMWH raw material prices (+39% above 9M18 prices) and sales of the lower-margin Becat continue to affect gross margin. Gross profit increased by 20% to €157m, while gross margins declined by 170bp to 58.0%. The 9M19 EBITDA increased to €47.5m (+83%), reflecting a significant increase in revenue and a reduction in R&D spend related to DORIA as the Phase III clinical trial costs start to reduce.

We forecast operating revenues of €370.2m in FY19 and €397.7m in FY20 (FY18: €304.8m). We expect operating margins to decrease in 2020 to 7.2% (10.0% in 2019) mainly due to higher SG&A expenses ahead of DORIA launch, ongoing raw material price pressures relating to swine flu (porcine mucosa is used in manufacturing heparins) offset by slight a decline in R&D expenses. We anticipate margin growth from 2021 to 8.9% and beyond, mainly due to operational leverage and lowering of R&D costs. Longer-term margins should continue to ramp up beyond this as the 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 21.2% in 2023. At 31 September 2019 ROVI had €0.2m in net cash.

Exhibit 12: Financial summary

Accounts: IFRS, year-end: December, €m	2016	2017	2018	2019e	2020e	2021e
PROFIT & LOSS						
Hibor revenue	79.7	83.9	91.3	96.8	98.3	98.6
Enoxaparin revenue	0.0	1.5	30.2	80.2	96.2	125.0
Other (Pharma & Manufacturing)	185.5	192.1	183.3	193.2	203.2	249.5
Total revenues	265.2	277.4	304.8	370.2	397.7	473.1
Cost of sales	(112.0)	(110.2)	(128.6)	(164.7)	(184.9)	(212.3)
Gross profit	153.1	167.2	176.2	205.5	212.8	260.8
Gross margin %	57.8%	60.3%	57.8%	55.5%	53.5%	55.1%
SG&A (expenses)	(101.9)	(108.5)	(113.2)	(122.2)	(139.2)	(174.3)
R&D costs	(17.5)	(28.3)	(32.4)	(28.5)	(22.0)	(22.0)
Other income/(expense)	5.6	(0.6)	(1.1)	0.0	0.0	0.0
EBITDA (reported)	39.3	29.9	29.5	54.8	51.6	64.5
Depreciation and amortisation	(11.0)	(11.5)	(12.0)	(17.8)	(22.8)	(22.4)
Normalised Operating Income	30.7	21.2	20.1	41.4	34.5	47.0
Reported Operating Income	28.3	18.4	17.5	37.0	28.8	42.1
Operating Margin %	10.7%	6.6%	5.7%	10.0%	7.2%	8.9%
Finance income/(expense)	(0.5)	(0.9)	(0.7)	0.1	(0.9)	(0.4)
Exceptionals and adjustments	0.0	0.0	0.0	0.0	0.0	0.0
Normalised PBT	30.3	20.3	19.3	41.5	33.6	46.6
Reported PBT	27.9	17.5	16.7	37.1	27.9	41.7
Income tax expense (includes exceptionals)	(1.8)	(0.3)	1.2	(1.9)	(1.6)	(2.5)
Normalised net income	28.5	20.0	20.6	39.6	32.0	44.1
Reported net income	26.1	17.2	17.9	35.2	26.3	39.1
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	0.63	0.47	0.70
Normalised EPS (€)	0.58	0.40	0.39	0.71	0.57	0.79
Dividend per share (€)	0.18	0.12	0.08	0.16	0.12	0.17
BALANCE SHEET						
Property, plant and equipment	82.8	89.1	95.8	121.9	124.7	130.0
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0
Intangible assets	24.9	27.1	34.7	44.6	38.9	34.0
Other non-current assets	13.1	14.1	18.2	18.2	18.1	18.1
Total non-current assets	120.8	130.2	148.7	184.7	181.8	182.0
Cash and equivalents	41.4	40.7	95.5	48.0	47.8	58.7
Inventories	67.4	75.5	94.9	149.8	157.1	174.5
Trade and other receivables	53.8	49.7	60.2	73.0	70.8	77.8
Other current assets	4.5	2.2	3.5	3.5	3.5	3.5
Total current assets	167.1	168.2	254.0	274.3	279.1	314.5
Non-current loans and borrowings	20.8	27.0	16.6	35.5	31.6	29.9
Other non-current liabilities	7.2	6.4	11.1	10.6	10.0	9.5
Total non-current liabilities	28.0	33.5	27.7	46.1	41.6	39.4
Trade and other payables	59.9	52.9	68.2	78.0	80.1	90.7
Current loans and borrowings	13.0	16.2	17.6	19.4	3.9	1.7
Other current liabilities	3.6	4.1	1.7	1.7	1.7	1.7
Total current liabilities	76.4	73.2	87.5	99.1	85.7	94.2
Equity attributable to company	183.4	191.7	287.5	313.9	333.6	362.9
CASH FLOW STATEMENT						
Profit before tax	27.9	17.5	16.7	37.1	27.9	41.7
Depreciation and amortisation	11.0	11.5	12.0	17.8	22.8	22.4
Share based payments	0.0	0.0	0.0	0.0	0.0	0.0
Other adjustments	(2.7)	(1.2)	7.4	(0.1)	0.9	0.4
Movements in working capital	12.7	(9.8)	(24.4)	(58.6)	(3.5)	(14.3)
Interest paid/received	0.0	0.0	0.0	(0.9)	(1.4)	(0.9)
Income taxes paid	(3.4)	0.1	(3.1)	(1.9)	(1.6)	(2.5)
Cash from operations (CFO)	45.5	18.0	8.5	(6.5)	45.2	46.7
Capex	(18.1)	(19.9)	(26.5)	(32.9)	(19.9)	(22.7)
Acquisitions & disposals net	0.0	0.0	0.0	0.0	0.0	0.0
Other investing activities	1.7	0.7	0.1	1.0	0.5	0.5
Cash used in investing activities (CFIA)	(16.3)	(19.2)	(26.2)	(31.9)	(19.4)	(22.2)
Net proceeds from issue of shares	(0.5)	0.5	88.0	0.0	0.0	0.0
Movements in debt	(9.7)	9.0	(9.2)	(0.3)	(19.4)	(3.9)
Other financing activities	(6.9)	(9.0)	(6.3)	(8.8)	(6.6)	(9.8)
Cash from financing activities (CFF)	(17.1)	0.5	72.5	(9.1)	(26.0)	(13.7)
Cash and equivalents at beginning of period	29.3	41.4	40.7	95.5	48.0	47.8
Increase/(decrease) in cash and equivalents	12.1	(0.7)	54.8	(47.5)	(0.2)	10.9
Cash and equivalents at end of period	41.4	40.7	95.5	48.0	47.8	58.7
Net (debt)/cash	7.6	(2.5)	61.3	(6.9)	12.3	27.1

Source: Company Accounts, Edison Investment Research

Contact details	Revenue by geography
Laboratorios Farmacéuticos ROVI Calle José Isbert, 2. 28223 Pozuelo de Alarcón (Madrid) Spain +34 91 021 30 00 https://www.rovi.es/en/	

Management team

Chairman: Juan López-Belmonte López	Chief executive officer: Juan López-Belmonte Encina
Juan López-Belmonte López has been the chairman of ROVI for the last 22 years. He graduated in economic and business sciences from the Universidad Complutense de Madrid in 1969. He is also president of the Madrid Chamber of Commerce, a member of the Plenary Session of the Spanish Chamber of Commerce and a member of the governing body of the IFEMA (Madrid Trade Fair Institute). He is a shareholder of Norbel Inversiones (ROVI's controlling shareholder).	Juan López-Belmonte Encina has been CEO since October 2007. He has been working for the company since 1994 and was appointed general manager in 2001. He graduated in economic and business sciences from CEU San Pablo, Madrid, specialising in auditing, in 1993. Before that he worked for international pharmaceutical companies (Nielsen Group, Tyco Group and Boots Pharmaceuticals). He is a vice-president of the board of governors and executive board of Farmaindustria and chairman of the R&D&I Commission of the CEOE (Spanish Confederation of Business Organizations). He is a shareholder of Norbel Inversiones (ROVI's controlling shareholder).
Chief financial officer: Javier López-Belmonte Encina	
Javier López-Belmonte Encina has been CFO since 2001 and is second deputy chairman of ROVI's board of directors. He graduated in economic and business sciences from CUNEF, Madrid, specialising in financing, in 1998. He began his professional career in the banking sector in 1998, working for Argentaria in the UK as an analyst and in the pharmaceutical sector with Medeva Pharma. He joined ROVI in 2000. He is a member of the board of governors and vice-president of the executive committee of the CEIM (Madrid Business Confederation). He is chairman of the Health and Social Affairs Commission of the CEIM and a member of the board of directors of Avalmadrid, representing the Madrid Business Confederation-CEOE. He is also a member of the Social Council of the Universidad Autónoma de Madrid and a shareholder of Norbel Inversiones (ROVI's controlling shareholder).	

Principal shareholders	(%)
Norbel Inversiones S.L.	63.107
Wellington Management group	4.924
Indumenta Pueri	5.057
T. Rowe Price	3.390

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