

Laboratorios Farmacéuticos ROVI

Outlook post
capital markets day

All good things come in threes

Laboratorios Farmacéuticos ROVI's (ROVI's) recent capital markets day (CMD) highlighted the strong positioning of its three key franchises. Combined unit sales of Becat and Hibor have now overtaken incumbent Clexane sales, establishing ROVI as a leader in low molecular weight heparins (LMWHs). The US DORIA (risperidone ISM) NDA has been filed for schizophrenia. Near-term inflection points include DORIA EU approval and launch (2021e). The COVID-19 opportunity has led to a significant rally in the shares, since Moderna reported primary efficacy data on its COVID-19 vaccine (mRNA-1273). ROVI has signed a deal to provide finished mRNA-1273 vaccine for supply ex US; this is a strong validation of its prefilled syringe fill and finish capabilities. We value ROVI at €1.86bn.

Year end	Revenue* (€m)	PBT** (€m)	EPS** (€)	DPS (€)	P/E (x)	Yield (%)
12/18	304.8	19.2	0.38	0.08	97.4	0.2
12/19	382.5	45.6	0.77	0.18	48.1	0.5
12/20e	402.6	63.3	1.03	0.24	35.9	0.6
12/21e	425.8	54.3	0.88	0.20	42.0	0.5

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

A global leader in low molecular weight heparins

Sales of LMWHs Becat and Hibor increased 25% to €153.1m (9M20); the franchise gained from increased heparin use for hospitalised COVID-19 patients offset by fewer elective surgical procedures. Becat continues to benefit from the ongoing roll-out in Europe by ROVI and partners. Given our Becat FY20 sales forecast of €107m, our peak of €200m has been moved to 2024.

Moderna tie up highlights manufacturing expertise

ROVI's new guidance is 10–15% growth in FY21 in toll manufacturing revenues; this excludes the production of the Moderna vaccine (deal terms undisclosed). The CMD highlighted ROVI's industrial footprint (three state-of-the-art manufacturing sites) and long-standing expertise in producing injectable drugs for global partners.

DORIA PRISMA-3 data PANSS reduction from day 8

The DORIA US NDA has been filed under the 505(b)(2) pathway (potential approval early 2022). The recently published results of the PRISMA-3 trial demonstrated that once-monthly DORIA injections led to rapid (from day 8) and progressive reduction of symptoms (without need for oral supplementation or loading dose) in acute schizophrenia; if the improvement in PANSS from day 8 is included in its label, DORIA would have a unique selling point versus its competitor LAIs.

Valuation: €1.86bn or €33.2 per share

Our revised valuation is €1.86bn or €33.2 per share (€1.57bn previously). We include Letrozole ISM in breast cancer for the first time and bring forward our Becat peak sales timeframe by two years to 2024. ISM products (DORIA and Letrozole) contribute 31% to our valuation. Our valuation does not include the specific impact of the Moderna deal, but we have increased our near-term growth rates for the toll manufacturing business to reflect the higher value strategy for this business.

Pharma & biotech

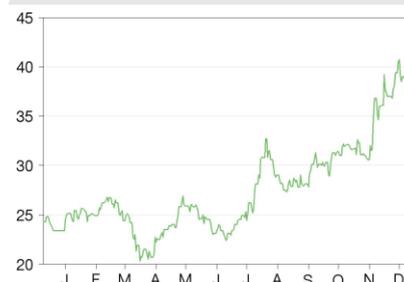
10 December 2020

Price **€37.0**

Market cap **€2,076m**

	\$1.22/€
Net debt (€m) at 30 September 2020	38.1
Shares in issue	56.1m
Free float	31%
Code	ROVI
Primary exchange	Madrid
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	5.1	20.5	50.4
Rel (local)	(4.8)	2.7	70.8
52-week high/low	€40.70	€20.70	

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. Its pipeline of drugs is focused on its proprietary ISM technology.

Next events

DORIA EU approval and launch	Q121/2021
Letrozole ISM regulatory discussions	Q121
DORIA US approval	Early 2022

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The future is bright for ROVI

ROVI's recent capital markets day highlighted the future international aspirations of the company with a focus on its internally developed pipeline established from its ISM technology. ROVI has established commercial sales in more than 75 countries for its biosimilar enoxaparin Becat and Hibor (bemiparin) through its own commercial presence (in seven countries in Europe including Germany, the UK and Italy) and via multiple international partners. In the near term the focus remains on the Becat European roll-out and the upcoming catalysts for DORIA (EU and US approvals, and potential worldwide launch). Both assets are key top-line growth drivers, and DORIA could be transformative to operative margins given it is a high gross margin asset (85–95%). These assets are part of a wider portfolio at ROVI, which consists of three pillars: speciality pharma (encompasses LMWH franchise and licensing products for domestic commercialisation), ISM R&D technology (DORIA and Letrozole) and the toll manufacturing division. Combined they represent a fully integrated speciality pharma business, which provides strong foundations for growth (Exhibit 1). ROVI's fully integrated toll manufacturing business (20% of FY19 revenues) has made significant strides following a reorganisation and a realigned strategy to focus on high-value products. Notwithstanding recent growth guidance, the icing on the cake is its tie up with Moderna for the manufacture of COVID-19 vaccine candidate mRNA-1273 for countries outside the US. The latter is a significant endorsement of ROVI's manufacturing capabilities and could be the gateway for additional deals with Moderna given its broad mRNA pipeline in vaccines and oncology.

ROVI's FY21 guidance is for mid-single-digit growth in operating revenues, excluding any contribution from production of the Moderna vaccine. We believe this is on the conservative side given the momentum in Becat sales and increasing potential for Moderna's mRNA-based vaccine. At its CMD, 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 2.5x (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 four 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.

Exhibit 1: ROVI now and future aspirations

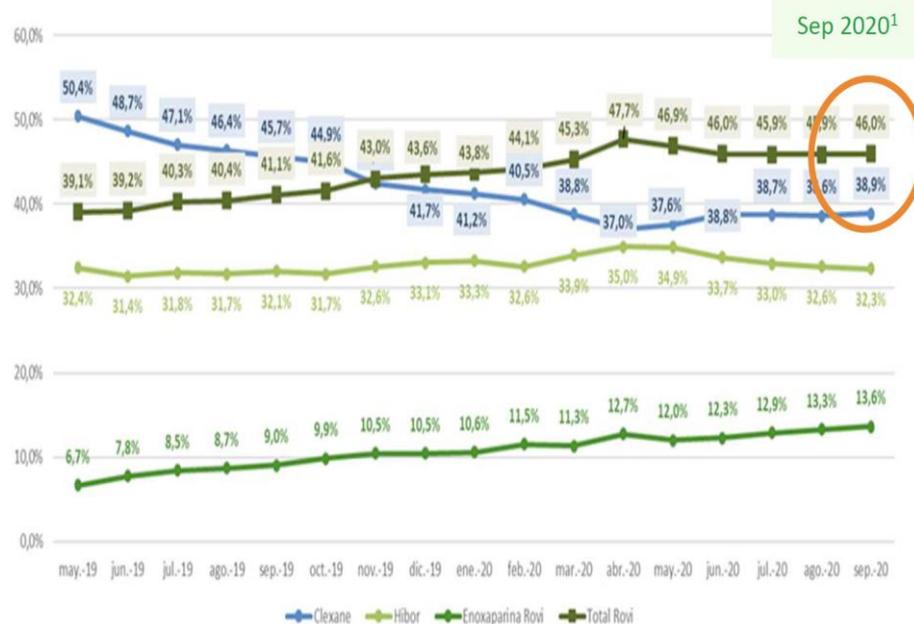


Source: ROVI corporate presentation

A global leader in low molecular weight heparins

In our initiation note [Ace of Spain](#), published on 12 July 2017, we described ROVI's established history in the LMWH market. The franchise consists of proprietary products, second-generation LMWH Hibor (bemiparin) and enoxaparin biosimilar Becat. The strong uptake of Becat has led to significant growth in ROVI's LMWH franchise, combined revenues of which now represent ~51% of operating revenue in the first nine months of 2020 (9M20). In 9M20, Becat reported €76.6m in sales (31% in Spain, and 69% ex Spain). During 9M20, Becat sales reached critical mass and the same level as Hibor for the first time. ROVI's flagship heparin Hibor is marketed in 56 countries and reported sales of €76.5m in 9M20, 25% of total revenues (with 66% attributable to Spain and 34% international sales). To compete more broadly in the international LMWH space, ROVI utilised its long-standing expertise in heparins to successfully develop and launch an enoxaparin biosimilar (Becat), which was approved in Europe in 2017. ROVI achieved its aspiration to be one of the world leaders in LMWHs, with its two brands combined overtaking Clexane's (branded enoxaparin) market share in the last 12 months; Hibor and Becat's market share was 46% versus Clexane's 38.9% (source: IMS and ROVI), a significant rise from September 2019 (Exhibit 2). This is a significant achievement given Hibor's premium pricing in Spain versus Lovenox/Clexane. Hibor sales in Spain benefit from an improved profile compared to first-generation LMWH enoxaparin, which encompasses flexible administration (once-a-day injection that can be administered peri- or post-operatively, particularly beneficial for day surgery cases), compared with Clexane, which is a twice-a-day administration.

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



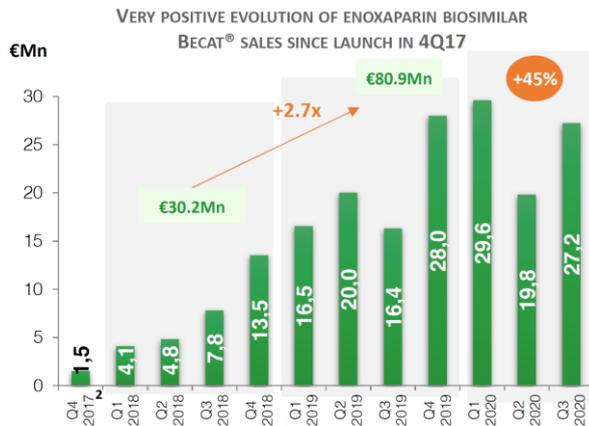
Source: ROVI corporate presentations

Becat sales momentum benefiting from ongoing launches

Becat is approved in 26 countries in Europe and 15 internationally (ex US). Becat continues to benefit from ongoing roll-out in Europe by ROVI and internationally by its partners, Exhibit 3. ROVI has set out a clear commercial launch strategy for Becat into key countries in the EU. ROVI will directly market Becat in these seven key European countries, which make up c 75% of the European market (and include Germany, the UK, Spain, Portugal and Poland) by value. ROVI has now established European sales offices to provide the pan-European infrastructure, which will be further leveraged by its heparin franchise and broader portfolio. Furthermore, it has agreements

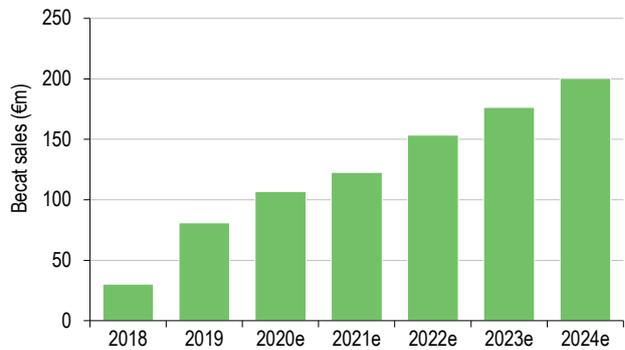
with multiple international partners including Sandoz in 14 countries and regions and Hikma Pharmaceuticals in 17 Middle East and North African countries for commercialisation; agreements cover 95 countries already. Rolling launches continue in 2020 (eg South Africa, Israel and Peru). In 2021/22 expected launches include other countries in Europe, Canada, Latin America and Asia. ROVI's vertically integrated structure with its own LMWH manufacturing plant should enable P&L leverage as volumes grow. At the CMD, 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 €1.3bn (IQVIA MIDAS Q120 report). In Europe, the EMA has granted marketing authorisation to two other enoxaparin biosimilar (Techdow's Inhixa and Italfarmaco's GhemaXan). According to IQVIA MIDAS data, as at Q120, Becat garnered a 57% market share in European retail market in units vs Techdow's 23% and Italfarmaco's 20%. We forecast FY20 Becat sales of €107m. Our forecast total peak sales remains unchanged at €200m but we have bought forward our peak sales timeline by two years from 2026 to 2024. Exhibit 4 highlights our forecast sales trajectory to 2024. We will revisit our peak sales assumptions based on how Becat sales perform in 2021.

Exhibit 3: Becat quarterly sales progression since launch in Q417



Source: ROVI corporate presentations

Exhibit 4: Edison forecast Becat sales trajectory



Source: Company accounts, Edison Investment Research

Given the smaller commercial opportunity in the US, ROVI is prioritising its European launch and RoW partnering activities and does not plan to launch in the US. 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.

DORIA EU approval to validate ISM technology

ROVI's proprietary, patented ISM technology is based on the formation of in situ micro particle implants for extended sustained release of compounds administered by injection (long-acting intramuscular or subcutaneously monthly or quarterly). The ISM 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. ROVI's focus is on targeting

long-term diseases such as schizophrenia and some cancer indications where a long-acting injectable (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. ROVI's LAI formulation of risperidone DORIA (risperidone ISM) is the first clinical asset developed using this proprietary drug development technology, and as well as rapid onset of action, key advantages are that there is no need for a loading dose or oral supplementation. This is of importance in the treatment of schizophrenia given the nature of the illness as compliance with follow-up psychiatric visits can be an issue.

PRISMA-3 significant reduction in PANSS score at week 12

The [complete data](#) for the registration-enabling [PRISMA-3](#) Phase III study (n=438) that evaluated the efficacy and safety of monthly intramuscular injections of DORIA in patients with acute exacerbation of schizophrenia was recently published. In March 2019 the [trial met its primary endpoint](#), with a significant reduction ($p < 0.0001$) in Positive and Negative Syndrome Scale (PANSS) total score at week 12 for both the 75mg and 100mg doses of the once-monthly intramuscular injection (adjusted differences vs placebo of -13.0 and -13.3 respectively). Importantly, both doses also showed statistically significant improvement (-0.7 vs placebo, $p < 0.0001$) in the key secondary endpoint of total score on the Clinical Global Impressions-Severity scale (CGI-S). The statistically significant improvement for both efficacy results was observed as early as eight days after the first injection (numerical improvement observed at day 4), without requiring a loading dose or supplementation with oral risperidone, giving DORIA a unique selling point versus its competitor LAIs. Both doses of DORIA were well tolerated and adverse events were in line with those expected for therapeutic doses of oral risperidone and other LAIs, and were consistent with observations in previous studies. These impressive results have led to regulatory filings with both the EMA and FDA, with approval and launch expected in 2021 in Europe and 2022 in the US. The PRISMA-3 trial is also looking at health economic-related outcomes, which could be relevant in pricing and reimbursement negotiations. The completed [BORIS study](#), which compared the bioavailability of multiple doses of oral risperidone with multiple doses of DORIA in stable schizophrenic patients was also included in the registration dossier to the EMA and FDA.

Data presented thus far supports the use of DORIA as an immediate first-line treatment for schizophrenic patients admitted to hospital with an acute exacerbation with severe or moderate psychotic symptoms. We note that long-term safety and durability data from the [PRISMA-3 extension study](#) of DORIA in more than 100 patients was included in regulatory filings. This extension data could confirm DORIA's utility as a maintenance treatment for schizophrenia in addition to use in the acute setting.

DORIA international distribution plan

ROVI has established its regional distribution strategy for the international commercialisation of DORIA. In Europe, where ROVI has built a presence in seven European countries with the launch of Becat, ROVI plans to directly market DORIA in these territories (Germany, UK, France, Spain, Italy, Poland and Portugal). 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; the US strategy will become evident during 2021.

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%. 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 5 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.

Although there has been an increase in approved LAI antipsychotic drugs on the market, DORIA's overall profile is a differentiating factor (Exhibit 5) as there is no need for an oral loading dose/supplementation and therapeutic dosing is reached very early in treatment (eight days after the first injection). Acknowledging the usual caveats associated with comparing studies (such as variability of patient characteristics), we note the improvement in PANSS total score with DORIA was [approximately twice](#) that achieved with similar doses of risperidone Atrigel and paliperidone palmitate, positioning it favourably against competitors. More importantly, as penetration of LAIs in schizophrenia is low, LAI antipsychotics are often used only when oral medications have failed, although evidence increasingly supports their use as a first choice.

Exhibit 5: 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®)	DORIA® (Risperidone) ★
Once Monthly Administration	✗	✓	Quarterly	✓	✓	✓	✓
No Oral Supplementation / Loading dose	✗	✗	✓	✗	✗	✓	✓
Therapeutic Levels within First 2 Hours	✗	✗	✗	✗	✗	✓	✓
Currently Marketed in Europe	✓	✓	✓	✓	✗	✗	Targeted
Stability at Room Temperature	✗	✓	✓	✓	✓	✗	✓
PANSS Reduction from Day 8	✗	✗	✗	✗	✗	✗	Targeted Endpoint for Phase III

Source: ROVI corporate presentation

We forecast DORIA peak sales of \$412m in schizophrenia

Following positive PRISMA-3 data on DORIA (risperidone ISM), ROVI filed a marketing authorisation (MAA) with the EMA in January 2020. ROVI is investing in a psychiatrist focused commercialisation team ahead of potential launch in Europe in 2021. ROVI has now submitted the NDA filing for DORIA to the US FDA under 505(b)(2) pathway for approval. This pathway will be utilised for Letrozole ISM and this translates to a faster development timeframe and lower development costs versus NDA filing under the 505(b)(1) pathway for new chemical entities. We forecast launch in the US in 2022.

The schizophrenia market is vast and growing steadily. DORIA is an improved version of the long-acting antipsychotic drug risperidone, currently available on the market (J&J's Risperdal Consta). Risperidone is a well-established drug within the psychiatry community. While multiple long-acting formulations of different antipsychotic drugs are approved, none has the perfect profile. DORIA will provide another product in the LAI schizophrenia treatment armament that will benefit physicians and patients as it addresses some of the issues with other LAIs on the market and in late-stage development. While multiple LAI antipsychotic drug formulations should be available by the time we assume DORIA launches (EU in 2021 and US in 2022), and DORIA's key advantages aside, our analysis shows that the overall LAI market in the US is underutilised. Improved LAI formulations (no loading or maintenance dose, early effect on efficacy after administration) are key to increasing uptake. According to IQVIA data (MAT Q319), in the US, 5.8% of patients were treated with LAI vs 8.4% in Europe. A multitude of scientific literature and a change in World Federation of Societies of Biological Psychiatry (WFSBP) guidelines (2013) point to increased use of LAIs. 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.

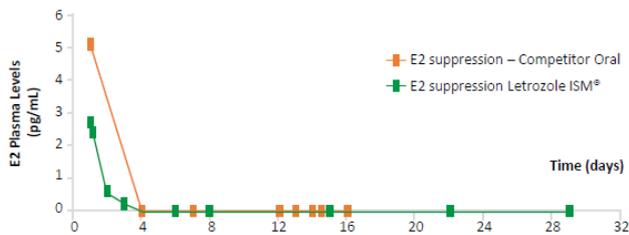
Letrozole ISM for hormone receptor-positive breast cancer

ROVI is developing Letrozole ISM for hormone receptor-positive breast cancer. Letrozole ISM is currently in [Phase I](#) and ROVI plan to discuss next steps with the regulatory authorities in Q121. Preliminary Phase I results thus far highlight that sustained long-term hormone suppression may lead to a superior clinical outcome in breast cancer vs oral daily drug treatment regimens. With DORIA filed under the 505(b)(2) pathway in the US, this opens up this approval pathway for other products developed utilising ISM technology based on approved active pharmaceutical ingredients (APIs). On this basis Letrozole ISM will likely advance into Phase III clinical trials during 2021. We now include Letrozole ISM forecasts for the first time. We forecast US peak sales of \$567m (€467m) and EU peak sales of \$458m (€377m) in 2029; this is predicated on achieving a 7% peak penetration rate of the worldwide aromatase inhibitor market for breast cancer (3.2m annual treatments worldwide). We assume a probability of launch of 25% and apply a 12.5% discount rate commensurate with our treatment of clinical-stage assets. We have priced Letrozole ISM at \$8,800 per annum in the US; we utilise the pricing of Zoladex (Goserelin), a prostate cancer treatment used as palliative treatment for advanced breast cancer, as the base, with the EU pricing assumption 50% of the US. We forecast NDA submission via the 505(b)(2) pathway in 2023 leading to 2024 launch.

Advances in the treatment of breast cancer over the last 20 years have, in some cases (hormone receptor-positive HER2 negative patients, which represent [c 70% of patients](#)), 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 over 10 years). However, once a

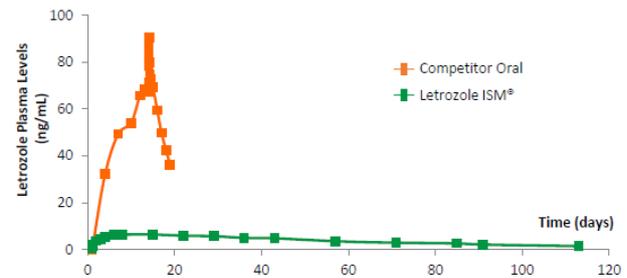
patient is breast cancer free, adherence to an oral daily ‘cancer medication’ can be an issue as some patients elect not to, or forget to, take the product. The opportunity for a once every three month, slow-release, intramuscular depot formulation of the drug is multi-fold and benefits include improved patient quality of life (lower dose frequency and reminder of illness), reduced healthcare costs and possible improved clinical outcomes. Specifically sustained lower effective doses (compared to oral treatment) could lower the side effects (bone mass loss, bone/joint/muscle pain, dyslipidemia) due to lower drug exposure.

Exhibit 6: Letrozole ISM rapid and sustained oestrogen suppression with lower doses



Source: ROVI corporate presentations

Exhibit 7: Rapid and sustained Letrozole ISM plasma levels



Source: ROVI corporate presentations

Speciality pharma business shows sustainable growth

ROVI’s Speciality Pharma division has a long-established presence (since 1946) in its domestic market. The portfolio consists of 20 proprietary and 28 in-licensed 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 to include over 30 brands. While some mature products face patent expiry, ROVI continues to replenish its portfolio with innovative compounds in-licensed from its multiple partners. 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.

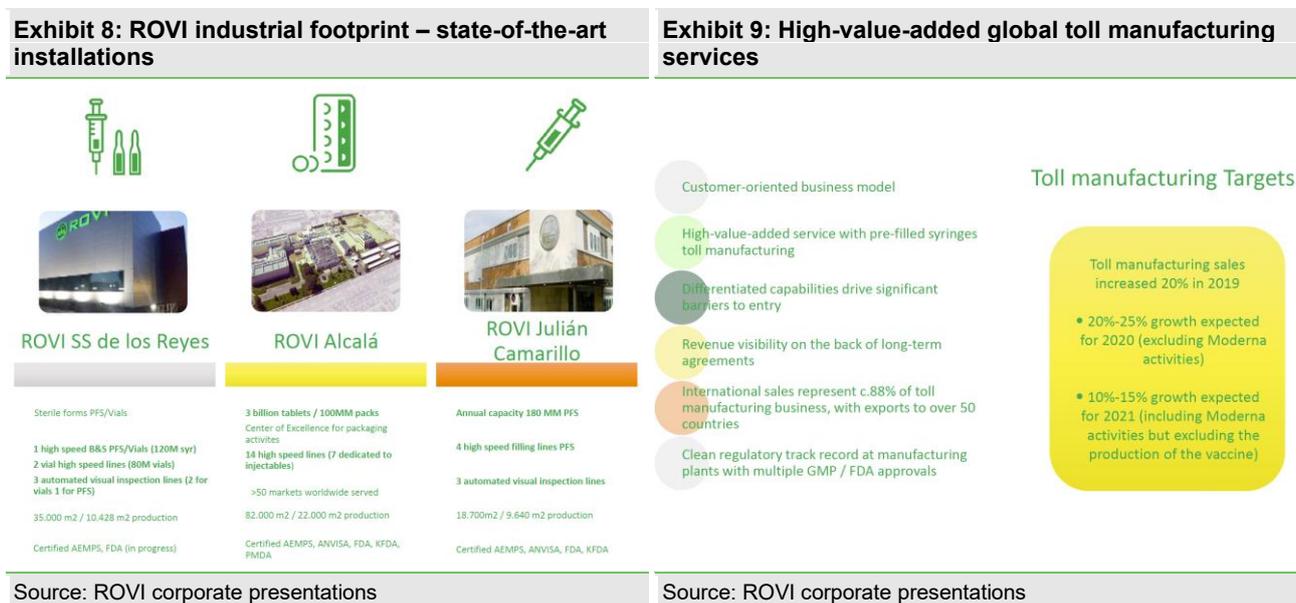
Toll manufacturing a jewel in the crown

ROVI reported €62.7m in toll manufacturing revenues in 9M20, an increase of 38% y-o-y. This division has witnessed a significant uplift in growth in recent years driven in part by demand for high value prefilled syringes, which is a high-margin contributor to the toll manufacturing business. International sales represent c 88% of toll manufacturing business, and ROVI exports to over 50 countries. 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. Investment over the last few years has enabled an increase in the injectables production lines.

In November 2019, ROVI merged its multiple toll manufacturing units into a single entity known as Rovi Pharma Industrial Services. ROVI has six EMA- and/or FDA-approved production plants,

covering the ROVI 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 (Exhibits 8 and 9).

At the capital markets 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 a 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's proficiency in the latter has been validated by the 2020 deal with Moderna to provide vial filling and packaging for its COVID-19 vaccine (mRNA-1273) candidate, which is likely to receive approval shortly (dossiers are now filed with EMA and FDA).



Moderna deal upside to 2021 guidance

ROVI guidance for 2020 is 20–25% growth in toll manufacturing revenues and 10–15% in 2021 (this excludes the production of Moderna's vaccine candidate mRNA-1273). During Q220 ROVI signed a collaboration agreement with US-based biotech Moderna to provide fill-finish manufacturing for Moderna's COVID-19 vaccine candidate outside of the US (deal terms undisclosed). In November Moderna reported positive top-line Phase III data from vaccine candidate mRNA-1273, and reported point estimate efficacy of 94% at the primary efficacy analysis based on 196 cases, of which 185 cases of COVID-19 were observed in the placebo group vs 11 cases observed in the mRNA-1273 group; no significant safety concerns were noted. Moderna has now filed an Emergency Use Authorization (EUA) application with the FDA and a conditional marketing approval with the EMA. In our view this is a positive signal for all the vaccines in development as these data go some way to validating the approach taken by most (immunisation against the coronavirus spike protein). We note that Moderna aims to manufacture 500m to 1bn doses globally in 2021 and that its mRNA vaccine technology means that mRNA-1273 is able to be stored in standard refrigeration units for up to 30 days (and six months in normal freezers). This is an improvement on the Pfizer/BioNTech vaccine cold-chain storage requirements, but we note downstream challenges in fill-finish, cold-chain storage, as well as the logistical hurdle of vaccinating the public en masse could present bottlenecks for mass vaccination.

ROVI has expertise in providing influenza vaccines (filing inspection/packaging) since 2001, has delivered ~150 doses of influenza vaccine to date and has experience in managing the full cold chain requirements (from work in progress to final transportation). Under the Moderna agreement, ROVI will provide vial filling and packaging capacity by installing a new production line plus equipment for compounding, filling, automatic visual inspection and labelling to support production of hundreds of millions of doses of Moderna's vaccine candidate for the supply of markets outside the US. ROVI possesses an annual production capacity of 600 million pre-filled syringe units; its facilities are GMP, FDA approved for filling syringes with API. We note that Gerresheimer has highlighted that its assumption for COVID-19 vials are proving conservative and has stated it expects global demand of 2–3bn units for COVID-19 vaccination in 2021/22, with customers demanding single- and multi-dose vials, and it expects at least 800m units to be delivered over the next two years. We do not explicitly forecast for Moderna's vaccine manufacturing given the low visibility of timing and the economic impact on ROVI at this point.

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 26.5% of our total revenue forecasts in 2020 (its third 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. The COVID-19 opportunity has led to a significant rally in the shares and remains a key sensitivity as the magnitude of the potential impact of the undisclosed terms of the Moderna deal is still unknown. We therefore do not explicitly include forecasts for Moderna's COVID-19 vaccine in our toll manufacturing division numbers, but expect more clarity on deal economics to crystallise in 2021 as ROVI announces sales from this division. 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 12% of our valuation; EU DORIA accounts for 10%). Timely partnering activity or an effective own commercialisation strategy will be key to crystallising value from this high gross margin asset.

Valuation

We value ROVI at €1.86bn or €33.2 per share (Exhibit 11). We have reassessed our sales forecasts and have made three major changes: 1) the inclusion of Letrozole ISM for breast cancer for the first time; 2) we have brought forward our Becat €200m peak sales potential to 2024 from 2026 given the current sales ramp (we forecast \$107m in FY20); and 3) we revise our prior medium-term mid-single-digit growth expectations for the toll manufacturing division upward to 10%. We do not explicitly include forecasts for Moderna's COVID-19 vaccine in our toll manufacturing division numbers, but we will revisit this once we have more clarity on deal economics and value add to ROVI once the vaccine starts to roll out and it affects the P&L.

In addition, we have rolled forward our model. Our valuation reflects net debt of €38.1m at 30 September 2020. 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 12% and 10% to our valuation, respectively. Our sum-of-the-parts valuation consists of:

- NPV calculation for DORIA US and EU opportunity. We forecast US peak sales of \$236m (€194m) 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 assume a probability of launch of 75% and apply a 12.5% discount rate commensurate with our treatment of clinical-stage assets.
- NPV calculation for Letrozole ISM US and EU opportunity. We forecast US peak sales of \$567m (€467m) and EU peak sales of \$458m (€377m) in 2029; this is predicated on achieving a 7% peak penetration rate of the worldwide aromatase inhibitor market for breast cancer. We assume a probability of launch of 25% 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 and Letrozole ISM sales and associated costs). We use our sales and P&L forecasts in these cash flows (out to 2026) and from 2027 to 2031 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 34% 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 2031. The current tax rate is c 10%, but this is expected to normalise to the mid-teens.

Exhibit 10: Three-stage DCF valuation of base business (excludes DORIA and Letrozole ISM cash flows)

	€m
Sum of DCF for forecast period to 2026	400.1
Sum of DCF for growth 2027 to 2031 (transition period)	279.9
Terminal value	641.7
Enterprise value	1,321.7
Net cash/(debt) at 30 September 2020	(38.1)
Value of equity of base business	1,283.6
Value per share of base business (€)	22.9
Discount rate	10–12.5%
Terminal growth rate	2%
Number of shares outstanding (m)	56.1

Source: Edison Investment Research

Exhibit 11: ROVI sum-of-the-parts valuation

	Value (€m)	Value per share (€)
DCF of base business	1,321.65	23.57
rNPV of DORIA	400.22	7.14
rNPV of Letrozole ISM	177.90	3.17
Net cash/(debt) at 30 September 2020	(38.10)	(0.68)
SOTP valuation	€1,861.7m	€33.2

Source: Edison Investment Research

Exhibit 12: DORIA and Letrozole ISM net present value

Product	Indication	Launch	Peak sales (\$m)	Value (€m)	Probability	rNPV (€m)	rNPV per share (€)
NPV DORIA US	Schizophrenia	2022	235.6	294.0	75%	216.0	3.9
NPV DORIA Europe	Schizophrenia	2021	175.9	249.3	75%	184.3	3.3
NPV Letrozole ISM US	Breast cancer	2024	567.2	393.5	25%	98.1	1.4
NPV Letrozole ISM Europe	Breast cancer	2024	458.1	320.1	25%	79.8	3.2

Source: Edison Investment Research. Note: \$1.22/€

Financials

ROVI's results for 9M20 demonstrated substantial growth in its LMWH franchise and toll manufacturing business, driving a 12% y-o-y operating revenue increase to €302.1m. ROVI maintained its FY20 revenue growth guidance of mid-single-digit growth, and growth in its toll manufacturing business of 20–25%. We believe this is on the conservative side given the momentum in Becat sales and increasing potential for Moderna's mRNA-based vaccine (given the reported point estimate efficacy of 94% at the primary efficacy analysis and read across from Pfizer and BioNTech's mRNA vaccine candidate BTN162b2). At the 9M20 results ROVI issued FY21 guidance of mid-single-digit growth in operating revenues, excluding any contribution from production of the Moderna COVID-19 vaccine. At the CMD it issued 10–15% guidance in its toll manufacturing division (excluding the impact of the Moderna vaccine production). Our forecasts reflect 15% growth y-o-y in FY21.

We forecast 5.8% growth in FY21, our estimates take guidance into consideration, but we believe our forecasts to be conservative and expect to upgrade them during FY21. We forecast EBITDA for FY21 of €71.6m. We expect the margin to decline slightly in 2021 (to 12.1%), reflecting SG&A investment in international subsidiaries to support the DORIA launch, offset by lower R&D expenses. We expect steady margin growth in 2022 and beyond; 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 launch through the newly established European subsidiaries. We believe operating margins could reach 20.5% in 2023. Our financial forecasts are unchanged.

Exhibit 13: Financial summary

Accounts: IFRS; year-end 31 December; €m	2016	2017	2018	2019	2020e	2021e
PROFIT & LOSS						
Hibor revenue	79.7	83.9	91.3	96.8	100.1	93.4
Enoxaparin revenue	0.0	1.5	30.2	80.9	106.7	122.8
Other (Pharma & Manufacturing)	185.5	192.1	183.3	204.8	195.8	209.7
Total revenues	265.2	277.4	304.8	382.5	402.6	425.8
Cost of sales	(112.0)	(110.2)	(128.6)	(166.6)	(173.1)	(186.9)
Gross profit	153.1	167.2	176.2	215.9	229.5	238.9
Gross margin %	57.8%	60.3%	57.8%	56.4%	57.0%	56.1%
SG&A (expenses)	(101.9)	(108.5)	(113.2)	(125.5)	(124.8)	(150.3)
R&D costs	(17.5)	(28.3)	(32.4)	(29.3)	(24.8)	(17.0)
Other income/(expense)	5.6	(0.6)	(1.1)	(0.2)	0.0	0.0
EBITDA (reported)	39.3	29.9	29.5	60.9	79.9	71.6
Depreciation and amortisation	(11.0)	(11.5)	(12.0)	(18.2)	(19.4)	(20.0)
Normalised Operating Income	30.7	21.2	20.0	46.5	64.8	56.0
Reported Operating Income	28.3	18.4	17.5	42.6	60.5	51.6
Operating Margin %	10.7%	6.6%	5.7%	11.2%	15.0%	12.1%
Finance income/(expense)	(0.5)	(0.9)	(0.7)	(0.9)	(1.5)	(1.7)
Exceptionals and adjustments	0.0	0.0	0.0	0.0	0.0	0.0
Normalised PBT	30.3	20.3	19.2	45.6	63.3	54.3
Reported PBT	27.9	17.5	16.7	41.9	59.0	49.9
Income tax expense (includes exceptionals)	(1.8)	(0.3)	1.2	(2.6)	(5.8)	(5.2)
Normalised net income	28.5	20.0	20.4	43.0	57.5	49.1
Reported net income	26.1	17.2	17.9	39.3	53.2	44.7
Basic average number of shares, m	49.0	50.0	53.0	56.1	56.1	56.1
Basic EPS (€)	0.53	0.34	0.34	0.70	0.95	0.80
Normalised EPS (€)	0.58	0.40	0.38	0.77	1.03	0.88
Dividend per share (€)	0.18	0.12	0.08	0.18	0.24	0.20
BALANCE SHEET						
Property, plant and equipment	82.8	89.1	95.8	131.6	138.2	143.0
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0
Intangible assets	24.9	27.1	34.7	45.1	50.7	51.3
Other non-current assets	13.1	14.1	18.2	16.6	16.6	16.6
Total non-current assets	120.8	130.2	148.7	193.3	205.6	211.0
Cash and equivalents	41.4	40.7	95.5	67.4	13.9	28.1
Inventories	67.4	75.5	94.9	158.8	222.9	230.5
Trade and other receivables	53.8	49.7	60.2	81.5	88.2	87.5
Other current assets	4.5	2.2	3.5	10.1	10.1	10.1
Total current assets	167.1	168.2	254.0	317.9	335.2	356.2
Non-current loans and borrowings	20.8	27.0	16.6	72.1	68.2	66.5
Other non-current liabilities	7.2	6.4	11.1	4.2	3.7	3.2
Total non-current liabilities	28.0	33.5	27.7	82.1	77.7	75.5
Trade and other payables	59.9	52.9	68.2	91.9	94.9	92.2
Current loans and borrowings	13.0	16.2	17.6	12.7	3.9	1.7
Other current liabilities	3.6	4.1	1.7	2.1	2.1	2.1
Total current liabilities	76.4	73.2	87.5	106.7	100.9	96.0
Equity attributable to company	183.4	191.7	287.5	322.4	362.3	395.8
CASHFLOW STATEMENT						
Profit before tax	27.9	17.5	16.7	41.9	59.0	49.9
Depreciation and amortisation	11.0	11.5	12.0	18.2	19.4	20.0
Share based payments	0.0	0.0	0.0	0.0	0.0	0.0
Other adjustments	(2.7)	(1.2)	7.4	(0.4)	1.5	1.7
Movements in working capital	12.7	(9.8)	(24.4)	(63.7)	(68.4)	(10.0)
Interest paid / received	0.0	0.0	0.0	(0.1)	(2.1)	(1.8)
Income taxes paid	(3.4)	0.1	(3.1)	(8.1)	(5.8)	(5.2)
Cash from operations (CFO)	45.5	18.0	8.5	(9.0)	3.5	54.6
Capex	(18.1)	(19.9)	(26.5)	(40.5)	(31.7)	(25.4)
Acquisitions & disposals net	0.0	0.0	0.0	0.0	0.0	0.0
Other investing activities	1.7	0.7	0.1	0.1	0.7	0.1
Cash used in investing activities (CFIA)	(16.3)	(19.2)	(26.2)	(40.5)	(31.0)	(25.3)
Net proceeds from issue of shares	(0.5)	0.5	88.0	0.2	0.0	0.0
Movements in debt	(9.7)	9.0	(9.2)	25.8	(12.7)	(3.9)
Other financing activities	(6.9)	(9.0)	(6.3)	(4.5)	(13.3)	(11.2)
Cash from financing activities (CFF)	(17.1)	0.5	72.5	21.4	(26.0)	(15.1)
Cash and equivalents at beginning of period	29.3	41.4	40.7	95.5	67.4	13.9
Increase/(decrease) in cash and equivalents	12.1	(0.7)	54.8	(28.1)	(53.5)	14.2
Cash and equivalents at end of period	41.4	40.7	95.5	67.4	13.9	28.1
Net (debt) cash	7.6	(2.5)	61.3	(17.4)	(58.2)	(40.1)

Source: Company accounts, Edison Investment Research

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Revenue by geography (FY19)

Management team
Chairman: Juan López-Belmonte López

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).

Chief executive officer: Juan López-Belmonte Encina

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.	63.1
Indumentia Pueri S.L.	5.1
Wellington Management Group LLP	4.9
T. Rowe Price Group Inc	3.4

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