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# Vernalis

FDA approval

## Tuzistra XR; US commercial potential unveiled

Pharma & biotech

**Vernalis is preparing for commercial launch of Tuzistra XR, its extended-release, codeine-based cough cold treatment following FDA approval in April. The product has greater commercial potential than previously anticipated with an addressable market of up to £1.8bn and is the only approved codeine-based, long-release liquid treatment. We forecast maiden cough cold sales in FY16 leading to profitability in FY18. We increase our valuation from £323m to £406m.**

| Year end | Revenue (£m) | PBT* (£m) | EPS* (p) | DPS (p) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 12/12 | 14.6 | (2.7) | (0.8) | 0.0 | N/A | N/A |
| 12/13 | 14.1 | (4.7) | (0.8) | 0.0 | N/A | N/A |
| 06/15e | 18.9 | (13.1) | (1.8) | 0.0 | N/A | N/A |
| 06/16e | 17.7 | (21.3) | (4.2) | 0.0 | N/A | N/A |

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments and FX gains/losses on cash holdings.

## FDA approval of Tuzistra XR

Tuzistra XR, a 12-hourly dosed or extended-release (ER) liquid narcotic cough cold treatment was FDA approved on 30 April. Tuzistra XR is indicated for the relief of cough and symptoms associated with respiratory tract allergies and common cold. Its active ingredients, disclosed at the time of the FDA approval, are codeine, a cough suppressant and chlorpheniramine, an antihistamine. Its primary market, the codeine plus antihistamines segment, has an estimated value of £510m at current net brand pricing, although Tuzistra XR has potential in other market segments.

## Commercial potential in expanded markets

Tuzistra XR has additional potential among all codeine cough cold prescribers, a c $1.2bn market, including codeine plus expectorant products. Furthermore, DEA reclassification in 2014 of hydrocodone-based cough cold products from Schedule III into the more restrictive Schedule II could drive Tuzistra XR sales into the $550m hydrocodone segment. Vernalis has a pipeline of four ER products, providing further commercial potential in the c $3.3bn prescription cough cold market.

## Maiden cough cold revenues forecast in FY16

We have increased our FY15 sales estimate from £18.4m to £18.9m, adding in a £0.5m research milestone payment. We have lowered our FY16 sales estimate from £18.3 to £17.7m, with greater caution on cough cold sales in launch year, but we increase our peak sales estimate for Tuzistra XR to $240m from $120m, c 13% of the addressable cough cold market. Our end-2015 net cash estimate is £54.6m, which we forecast is sufficient to fund Vernalis through to profitability in 2018.

## Valuation: DCF valuation of £406m

We have increased our DCF valuation of Vernalis from £323m to £406m, or 92p per share, compared to the £310m current market capitalisation. The increase is based on our higher peak sales estimate and a reduction of the WACC of Tuzistra XR from 12.5% to 10% as it moves from the development to the commercial stage.

**17 June 2015**

| | |
|---|---|
| **Price** | **70p** |
| **Market cap** | **£310m** |

| | |
|---|---|
| Net cash (£m) at end December 2014 | 70.6 |
| Shares in issue | 442.3m |
| Free float | 63% |
| Code | VER |
| Primary exchange | AIM |
| Secondary exchange | N/A |

### Share price performance


| % | 1m | 3m | 12m |
|---|---|---|---|
| Abs | 2.9 | 48.2 | 117.1 |
| Rel (local) | 6.3 | 48.9 | 113.7 |
| 52-week high/low | | 73p | 31p |

### Business description

Vernalis is a UK pharma company with one FDA-approved, prescription-only cough cold treatment, Tuzistra XR, and a late-stage US cough cold pipeline of four products. Vernalis also has an early- to mid-stage R&D pipeline of CNS and cancer projects. Its primary focus now is on commercialisation of Tuzistra XR in the US.

### Next events

| | |
|---|---|
| FY15 results | Est. September 2015 |
| Tuzistra XR commercial launch | September 2015 |

### Analysts


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# Tuzistra XR; extended commercial potential

In April 2015, Vernalis received FDA approval of Tuzistra XR, an ER or 12-hourly dosed narcotic. Tuzistra XR is a prescription-only, adult narcotic cough cold treatment with US regulatory clearance, indicated for the relief of cough and symptoms associated with upper respiratory tract allergies or the common cold. Its active pharmaceutical ingredients (APIs), undisclosed before approval, are codeine polistirex, to suppress the cough reflex and chlorpheniramine polistirex, an antihistamine for relief of allergic symptoms. Its potential competitive advantages over immediate-release (IR) treatments are its equivalent efficacy along with more convenient administration; the ER formulation means that the recommended dosing for patients aged 18 years and above is one 10ml dose per 12 hours, not exceeding 20ml in any 24-hour period, while an IR product might require four to six doses per day. Tuzistra XR carries a standard black box warning against paediatric use as a result of its codeine content.

The US prescription-only cough cold treatment market is divided broadly into its narcotic and non-narcotic segments with c 32.6m prescriptions pa.[1] Exhibit 1 illustrates the potential value of the branded cough cold market segments. This valuation per segment is a product of prescription volume and estimated current and historical average net price per prescription.

**Exhibit 1: Value of prescription-only cough cold treatments**

| | At historical pricing $65/Rx | At current brand pricing $100/Rx |
|---|---|---|
| Narcotics, total | **$1.2bn** | **$1.8bn** |
| Codeine + antihistamines | $332m | $510m |
| Codeine + expectorants | $423m | $650m |
| Hydrocodone | $358m | $550m |
| | | |
| Non-narcotics, total | **$962m** | **$1.5bn** |
| Dextromethorphan | $494m | $760m |
| Benzonatate | $442m | $680m |
| Other | $20m | $30m |
| **Total Rx market** | **$2.2bn** | **$3.3bn** |

Source: Vernalis, IMS

Tuzistra XR's APIs position it in the primary market segment of codeine plus antihistamine treatments and this is supported by physician market research sponsored by the company. This segment is valued at $510m at current or $332m at historical brand pricing. The market research, conducted in 2014 and 2015, suggests that its expanded market segments could also include the broader codeine segment, which includes codeine plus expectorants, as well as the hydrocodone segment, which would position Tuzistra XR across the c $1.8bn broader narcotics segment albeit at lower penetration in the hydrocodone segment than in the primary market.

The rationale for take-up by hydrocodone prescribers is the tightening of DEA scheduling during 2014 of all hydrocodone-based products from Schedule III into Schedule II. This change makes it more restrictive and more costly for suppliers and distributors to handle and for physicians to prescribe hydrocodone-based products. The tightening has caused a contraction of the supply of hydrocodone products, which favours other cough cold products including codeine-based products. Tuzistra XR offers the convenience of the ER formulation, and is in the less restrictive Schedule III category.

## Addressing the market

Tuzistra XR faces limited direct competition in the ER market. Tussionex, a 12-hour liquid combination product containing hydrocodone and chlorpheniramine, is the only commercialised ER product in the US cough cold market. It was first launched in 1962, although the current formulation

1 Source: IMS.

was approved in 1987, with a generic Tussionex formulation launched by Par Pharmaceuticals in 2010 using Tris technology. Generic Tussionex currently holds key market share in the Medicaid and Medicare segments, although its share is likely to be weakened by DEA tightening on hydrocodone products. Cornerstone Pharmaceuticals also launched a generic version of Tussionex in 2012, although there is little information available to show that it is being currently commercialised. Tuzistra XR is the only other FDA-approved ER liquid product (as a result of difficulty in formulating products that meet FDA requirements, creating high entry barriers in the long-release liquid formulations market. Tuzistra XR is patent protected until 2029.

Before genericisation, Tussionex achieved c 50% of the hydrocodone segment by prescription volume and in 2008, annual peak sales exceeded $200m at an assumed net sales price per prescription of $65 with 85% formulary coverage (reimbursement) at managed care organisations. The wholesale acquisition cost (WAC) of more recently approved prescription cough cold treatments is higher, for example Zutripro an IR hydrocodone-based formulation launched in 2011 marketed by Pernix, has an approximate net price per scrip of $140-182[2] and the current net price of Tussionex brand is c $100 per scrip (source: Vernalis).

The key driver of the company's ability to garner market share is achievement of formulary coverage. Vernalis aims to achieve tier 3 formulary coverage for Tuzistra XR at current brand pricing. That is to say, it is targeting inclusion of Tuzistra XR on the list of branded drugs covered by managed care plans with a goal of achieving a net price per scrip of $100. Comprehensive payer research by Ashfield, Vernalis's market access partner, suggests that tier 3 formulary coverage at current brand pricing could be secured and would require a co-pay of $50-75 per scrip by the patient, depending on the policy (vs $10-15 for IR cough cold products). Co-payment for tier 3 formulary drugs is typically higher than those in the lower tiers. Commercial success depends on minimising the cost to the patient typically by means of couponing. Ashfield is currently engaged in negotiating formulary coverage for up to 145 million lives (over 50% of the total number of lives covered in the US)[3] in the first instance, in preparation for September commercial launch ahead of the US cough cold season. As such, Tuzistra XR will be targeted at high-value prescribers as opposed to the Medicare/Medicaid sections of the market. Physician market research by Vernalis's partners suggests strong interest from all narcotic cough cold prescribers and indicates that levels of utilisation would be based on minimising the cost to the patient through coupons, and suggests a willingness to switch to Tuzistra XR given the changes to DEA scheduling for hydrocodone products. Furthermore, the price precedent set by Tussionex, as well as its achievement of tier 3 formulary coverage, bodes well for commercial potential of Tuzistra XR.

Vernalis is preparing for launch in September ahead of the 2015 US cough season and is engaged in a phased salesforce recruitment drive through its contract marketing partner inVentiv. At the outset an 80-100-strong sales team is to be deployed in time for a September launch, including up to eight district managers, to target the high-volume prescribers. The company anticipates that traction will build over time as call patterns become established and intends to implement a coupon programme in order to reduce the cost to the patient. Management envisages that in the initial phases, pharma chains may be reticent about carrying inventory until the volume of scrips starts to grow and as physician relationships become established. Furthermore, it will take time to set up a routine commercial supply of product; Vernalis has set up third-party logistics through Cardinal SPS.

Vernalis has a portfolio of four other cough cold products in development. Our estimate of aggregate peak sales by 2024 across the portfolio is unchanged at $500m by 2024 despite the greater commercial potential of Tuzistra XR, we are re-weighting our estimates of peak sales

2 Company source; approximate net price per scrip for Tussionex and Zutripro calculated from WAC per standard bottle.

3 Source: Kaiser Family Foundation.

across the portfolio. This total aggregate value equates to c 15% of the $3.3bn total branded cough cold prescription market for the five products. The APIs in the remaining four products have not been disclosed, but the company has indicated that one is a single as opposed to a combination treatment. The only product to fit into this category would be a benzonatate, a non-narcotic cough suppressant. The benzonatate segment has an addressable market of c $680m at current pricing and this is likely to be the next largest product alongside Tuzistra XR. Management has inferred that two other products are complementary to Tuzistra XR. However, the launch order of the remaining four cough cold products each with potentially varying peak sales, is undisclosed; hence we have calculated an average peak sales estimate of $65m per product.

The next most advanced products in the cough cold portfolio are CCP-07 and CCP-08. In June, Tris Pharma initiated 12-month stability testing of CCP-07 and targets NDA filing of CCP-07 and CCP-08 in 2016. By the end of CY15, it is likely that the company will have put in place the commercial infrastructure and might have overcome many of the potential constraints in the early stage of commercialising Tuzistra XR, which could help to precipitate the progress of the next products in the cough cold portfolio. For CCP-05 and CCP-06 the company anticipates that proof-of-concept (PoC) could be achieved during CY15, leading up to the c 12-month NDA filing preparation process. By way of example, the timeline for approval of Tuzistra XR was a total of c 25 months from PoC to approval.

## Financials and valuation

Vernalis is planning a staged launch of Tuzistra XR with price discounting in year one to gain market traction, with gradual acceleration of sales; we forecast maiden cough cold revenues in FY16. We have increased our estimated FY15 sales (for the 18 month period to June 2015) from £18.4m to £18.9m, adding in a £0.5m research collaboration milestone payment from Asahi Kasei Pharma announced in March. We have lowered our FY16 (12 month period) sales estimate from £18.3 to £17.7m, as a result of our more cautious estimate of initial cough cold revenues of £7.1m, previously £7.8m, and we add £7.5m from collaborations and £3.1m of Frova royalties, down from our previous estimate of £3.5m due to further euro weakening vs sterling since our last report, (revenue per batch is converted from euros to sterling).

The cost structure is set to shift as the company moves from the development to the commercial phase, hence our forecast sales and marketing expenditure increases from £8.2m in FY15 to £22.8m in FY16, while we estimate that R&D costs will fall from £25.5 in FY15 to £15m in FY16, taking total operating expenses from £33.7m in FY15e to £37.8m in FY16e. We have adjusted our FY16 tax credit estimate from £2.2m to £2.9m in line with historical years. Exhibit 2 summarises the changes to our estimates:

**Exhibit 2: FY15 and FY16 previously published and revised forecasts**

| | Old 18 months to June 2015e | New 18 months to June 2015e | Old 12 months to June 2016e | New 12 months to June 2016e |
|---|---|---|---|---|
| Revenue | 18.4 | 18.9 | 18.3 | 17.7 |
| Operating loss | (14.4) | (13.5) | (21.3) | (21.6) |
| Post tax loss | (11.4) | (10.5) | (18.9) | (18.4) |
| Loss/profit per share | (2.0) | (1.8) | (4.3) | (4.2) |

Source: Edison Investment Research, company accounts, Profitability measures are normalised. Note: We have excluded other income of £180k and £394k from our calculation of normalised profit in FY13 and FY14/15.

After these changes and some minor revisions to our working capital forecasts, our revised end-2015 net cash and equivalents estimate is £54.6m versus £51.5m, which we forecast will fund Vernalis to profitability in 2018.

We have increased our DCF valuation to £406m from £323m, or 92p per share. Our estimate of aggregate peak sales across the cough cold portfolio is unchanged at <$500m by 2024 despite the greater than previously seen commercial potential of Tuzistra XR; we are re-weighting our estimate of peak sales across the cough cold portfolio. Our previous peak sales estimate was $120m for Tuzistra at historical brand pricing, c 5% of the valuation of the then $2.2bn overall narcotics market (at $65 per scrip). Greater visibility on the product and on its APIs and the change in DEA scheduling allows us to reassess market potential. Our new peak sales estimate for Tuzistra XR is $240m, which equates to 13% penetration of the current estimated $1.8bn narcotics market (at $100 net per scrip, based on current estimate pricing of Tussionex and supported by market research by the company's expert partners) with different rates of penetration across the primary and expanded segments. We calculate an average peak sales estimate of $65m per product for the remaining four products in the cough cold pipeline, despite the potential differences in market penetration, as a result of the lack of visibility on launch order.

The summary of changes to our valuation includes:

- removal of our risk adjustment on Tuzistra XR to reflect approval and revision of the WACC for Tuzistra XR from 12.5% to 10%, reflecting the move from development to commercial stage;
- revision of our estimated peak sales for Tuzistra XR from $120m to $240m based on its extended market potential and to take account of the updated estimated net pricing. Our new estimate represents peak market share of c 13% of the total narcotics market at $100 net per scrip;
- revision of our estimated peak sales for the remaining four products in the portfolio; and
- moving the timeline back by one year, for the development and launch of AUY922 and increasing the development risk, after Novartis ceased all development on this programme in December 2014. Our valuation assumptions are summarised in Exhibit 3.

**Exhibit 3: Vernalis rNPV valuation summary**

| Source | rNPV (£m) | rNPV/share (p) | Assumptions |
|---|---|---|---|
| US Rx cough cold portfolio | 541 | 122 | Net of $12-14m of per product milestones due to Tris. 30% COGS (including Tris royalty payaway). Aggregate sales >$500m by 2024; UK tax rate of 21% from 2021. Tuzistra XR (£363m rNPV): Peak sales of $240m; launch CY15; approved. CCP-07 (£52m rNPV): peak sales of $65m; launch H216; 75% success probability (PoC achieved). CCP-08 (£54m rNPV): peak sales of $65m; launch Q416; 75% success probability (PoC achieved). CCP-05 (£36m rNPV): peak sales of $65m; launch H217; 65% success probability. CCP-06 (£36m rNPV): peak sales of $65m; launch Q417; 65% success probability. |
| NCE pipeline | 15 | 3.4 | AUY922 (£5.7m rNPV): peak NSCLC sales $1.2bn; launch 2020; 15% success probability; 4% royalty. Tosedostat (£1.2m rNPV): peak AML sales $150m; launch 2020; 15% success probability; 5% royalty. RPL554 (£4.2m rNPV): peak COPD sales $200m; launch 2019; 25% success probability, 6% royalty. Servier 1 (£0.5m rNPV): peak cancer sales $150m; launch 2023; 10% success probability, 5% royalty. V15886 (£1.9m rNPV): peak pain sales $300m; launch 2022; 15% success probability; 7% royalty. V81444 (£1.6m rNPV): peak CNS sales $200m; launch 2022; 15% success probability; 7% royalty. |
| Frova royalty stream | 9.1 | 2.0 | Europe: royalties of 25%, patent expiry Dec 2015. US: minimum sales level not reached. |
| Total pipeline rNPV | 565 | 128 | |
| R&D | (76.8) | (17.4) | Includes offset for research collaborative funding. |
| SG&A | (145.3) | (32.9) | Includes cost of US sales infrastructure from H215 (included in R&D before Tuzistra launch). |
| Capex | (7.5) | (1.7) | Tangible assets (intangible capex, ie milestones paid to Tris, captured in cough cold portfolio rNPV). |
| Total costs rNPV | (229.6) | (51.9) | |
| Cash | 70.6 | 16 | Reported net cash at end December 2014 |
| Total rNPV | 406 | 92 | |

Source: Edison Investment Research. Note: Assumes WACC of 12.5% for all products with the exception of Tuzistra XR at 10% WACC, 442.3m shares outstanding and £/$ rate of 1.54.

Potential CY15 catalysts include FY15 results expected for September, news on progress of the commercial launch preparations, post-launch market feedback on prescription volumes and interest from primary and or secondary markets. Furthermore, for the rest of the cough cold pipeline, the company anticipates achieving development milestones during 2015 and 2016, which could lead us to amend our valuation of these assets.

## Exhibit 4: Financial summary

| £'000s | 2012 | 2013 | 2015e* | 2016e |
|---|---|---|---|---|
| Year end 30 June (from 2015) previously December | IFRS | IFRS | IFRS | IFRS |
| **PROFIT & LOSS** | | | | |
| Revenue | 14,616 | 14,084 | 18,874 | 17,743 |
| of which: Cough/cold portfolio | 0 | 0 | 0 | 7,143 |
| Frova royalties | 5,740 | 6,684 | 6,500 | 3,100 |
| Collaborative income (R&D funding and milestones) | 8,676 | 7,150 | 12,100 | 7,500 |
| Other | 200 | 250 | 274 | 0 |
| Cost of Sales | (1,581) | (2,244) | (1,360) | (3,186) |
| Gross Profit | 13,035 | 11,840 | 17,514 | 14,557 |
| Sales, General & Admin | (5,249) | (3,299) | (8,215) | (22,768) |
| Research & Development | (12,975) | (14,416) | (25,523) | (15,000) |
| Other | 0 | 180 | 394 | 0 |
| Operating Profit reported | (5,189) | (5,695) | (15,830) | (23,211) |
| Intangible Amortisation | (1,349) | (1,349) | (1,062) | (733) |
| Exceptionals | 0 | 1,608 | 0 | 0 |
| Share-based payment | (784) | (876) | (1,290) | (876) |
| EBITDA | (2,637) | (4,652) | (12,828) | (21,310) |
| Operating Profit (norm) | (3,056) | (5,078) | (13,478) | (21,602) |
| Net Interest | 390 | 420 | 360 | 273 |
| Other financial income | (2,039) | (999) | 2,662 | 0 |
| Profit Before Tax (norm)** | (2,666) | (4,658) | (13,118) | (21,329) |
| Profit Before Tax (as reported) | (6,838) | (6,274) | (12,808) | (22,938) |
| Tax | 1,595 | 2,273 | 2,631 | 2,919 |
| Profit from discontinued operations | 0 | 0 | 0 | 0 |
| Profit After Tax (norm) | (1,071) | (2,385) | (10,487) | (18,410) |
| Profit After Tax (as reported) | (5,243) | (4,001) | (10,177) | (20,019) |
| Average Number of Shares Outstanding (m) | 384.9 | 442.1 | 442.3 | 442.3 |
| EPS - normalised fully diluted (p) | (0.8) | (0.8) | (1.8) | (4.2) |
| Dividend (p) | 0.0 | 0.0 | 0.0 | 0.0 |
| Gross Margin (%) | 89.2% | 84.1% | 92.8% | 82.0% |
| EBITDA Margin (%) | -18.0% | -33.0% | -68.0% | -120.1% |
| Operating Margin (before GW and except.) (%) | -20.9% | -36.1% | -71.4% | -121.8% |
| **BALANCE SHEET** | | | | |
| Fixed Assets | 6,883 | 7,730 | 20,800 | 24,026 |
| Intangible Assets | 5,665 | 6,292 | 19,182 | 22,345 |
| Tangible Assets | 1,218 | 1,438 | 1,619 | 1,682 |
| Other | 0 | 0 | 0 | 0 |
| Current Assets | 88,645 | 83,298 | 63,131 | 43,394 |
| Stocks | 250 | 130 | 329 | 1,393 |
| Debtors | 5,440 | 4,443 | 5,753 | 6,259 |
| Cash | 81,555 | 76,918 | 54,560 | 32,508 |
| Other (tax and derivatives) | 1,400 | 1,807 | 2,488 | 3,233 |
| Current Liabilities | (4,254) | (4,501) | (6,806) | (9,438) |
| Creditors | (3,206) | (3,384) | (4,323) | (6,955) |
| Other creditors | 0 | 0 | (8) | 0 |
| Short term borrowings | 0 | 0 | 0 | 0 |
| Deferred income | (897) | (962) | (1,646) | (1,646) |
| Provisions and other current liabilities | (151) | (155) | (837) | (837) |
| Long Term Liabilities | (5,819) | (4,283) | (3,764) | (3,764) |
| Long term borrowings | 0 | 0 | 0 | 0 |
| Deferred income | 0 | (156) | (360) | (360) |
| Provisions and other long-term liabilities | (5,819) | (4,127) | (3,404) | (3,404) |
| Net Assets | 85,455 | 82,244 | 73,361 | 54,218 |
| **CASH FLOW** | | | | |
| Operating Cash Flow | (5,119) | (3,486) | (13,082) | (20,248) |
| Net Interest | 381 | 446 | 374 | 273 |
| Tax | 1,816 | 1,929 | 2,221 | 2,174 |
| Capex | (785) | (646) | (823) | (355) |
| Purchase of intangibles | (3,454) | (1,976) | (13,936) | (3,896) |
| Acquisitions/disposals | 4 | 0 | 0 | 0 |
| Financing | 65,933 | 0 | 2 | 0 |
| Dividends | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | 0 |
| Net Cash Flow | 58,776 | (3,733) | (25,244) | (22,052) |
| Opening net debt/(cash) | (24,748) | (81,555) | (76,918) | (54,560) |
| HP finance leases initiated | 0 | 0 | 0 | 0 |
| Exchange rate movements | (1,921) | (904) | 759 | 0 |
| Other | (48) | 0 | 2,127 | 0 |
| Closing net debt/(cash) | (81,555) | (76,918) | (54,560) | (32,508) |

Source: Edison Investment Research, company accounts. Note: *18-month reporting period, thereafter 12 months. **Normalised PBT strips out intangible amortisation, exceptional items, share-based payments and FX gains/losses on cash resources.

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