EDISON

Vernalis

Corporate update

Operational initiatives in place, execution is key

Pharma & biotech

Tuzistra XR prescriptions (Rx) grew threefold to ~35k in FY16/17 (2nd year on the market) vs ~12k in FY15/16. Investment into addressing the barriers to higher Tuzistra XR prescribing is translating into higher Rx rates, although this has not been matched by revenue growth due to higher inventory stocking in the same period last year. In H217 FDA issued partner Tris with two complete response letters to Vernalis's CCP-07 and CCP-08 NDAs and we now model launch during the 2018/19 cough cold season. Our updated forecasts reflect this and lower Tuzistra XR revenues due to a slower than anticipated sales trajectory in the near term.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
06/16	12.0	(16.3)	(3.4)	0.0	N/A	N/A
06/17	20.8	(21.3)	(3.6)	0.0	N/A	N/A
06/18e	13.9	(34.0)	(6.3)	0.0	N/A	N/A
06/19e	26.9	(30.0)	(5.4)	0.0	N/A	N/A

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

US commercial operations: All about execution

During FY16/17 Vernalis made significant moves to improve the effectiveness of its US commercial platform, dynamically managing sales rep effectiveness, pharmacy stocking and patient access (formulary coverage, patient coupons). We have lowered our near-term cough/cold net sales forecasts to reflect slower ramp-up in Tuzistra XR and delays to CCP-07 and CCP-08. We note that management expects a threefold increase in Rx in the year. In addition, full promotion of Moxatag has started in the US which should further leverage the salesforce.

CCP-07 and CCP-08 await US NDA refile

The CRLs raised outstanding questions that must be resolved prior to NDA resubmission and an FDA approval decision. We conservatively assume a one-year delay to approval and launch for both.

Financials: Funded into 2019 on current forecasts

We update FY18 forecasts with lower Tuzistra XR revenue plus a delay of our CCP-07 and CCP-08 launch date by a year to FY19. Lower FY18 and FY19 cough cold revenue delays our expectation of sustainable profitability by one year to FY21. Net cash of £61.3m provides sufficient runway into FY19. We estimate a funding gap in 2019 and include an illustrative £30m financing, nominally attributed to debt, in our FY19 forecasts.

Valuation: DCF valuation of £358.5m (68p per share)

Our revised valuation of £358.5m or 68p/share (from £399m) results from our new financial forecasts (see above), rolling forward our model, updating FX ($1.32/£) and a lower net cash position at June 2017 (£61.3m). Our valuation consists of US cough cold and NCE pipeline rNPV, explicit cost modelling and inclusion of cash; we assume zero NPV for the research business. Clarity on CCP-07/08 NDA resubmission, portfolio progress, launches and sales upgrades would unlock upside.

22 November 2017

Price	**12.88p**
Market cap	**£68m**
	$1.32/£
Net cash (£m) at 30 June 2017	61.3
Shares in issue	526.4m
Free float	12.4%
Code	VER
Primary exchange	AIM
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(1.0)	(16.9)	(64.2)
Rel (local)	0.4	(18.0)	(67.6)
52-week high/low		34.8p	12.9p

Business description

Vernalis is a UK speciality pharma company with an FDA-approved, prescription-only cough cold treatment, Tuzistra XR; an FDA-approved amoxicillin, Moxatag; and a late-stage US cough cold pipeline of four products. It also has an early- to mid-stage R&D pipeline of CNS and cancer.

Next events

CCP-07 NDA resubmission	2018
CCP-08 NDA resubmission	2018
Tuzistra XR: End 2017/18 season update	June/July 2018

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Investment summary

Company description: Commercial execution to drive value

Vernalis is a revenue-generating UK speciality pharma company focused on the development and marketing of prescription-only (Rx) cough cold medicines for the US market. The company has two marketed cough cold products: Tuzistra XR (extended release, prescription-only codeine cough syrup launched in 2015/16 cough/cold season) and Moxatag (once-a-day, oral formulation of amoxicillin for tonsillitis and pharyngitis caused by Streptococcus pyogenes), and full promotion has begun. Royalty income from frovatriptan (acute migraine) is in decline from peak following patent expiry in 2015. The cough cold development pipeline, in partnership with privately owned Tris Pharma, consists of four extended-release products: CCP-07 and CCP-08 were issued complete response letters following the respective April and August PDUFA dates, while CCP-05 and CCP-06 are in development. Vernalis also has a legacy portfolio of early- to mid-stage development projects in cancer, CNS and inflammation (to be developed exclusively through partners), and significant expertise in fragment and structure-based drug discovery. Under existing management, who joined in 2009, Vernalis has raised c £155m net in four fund-raisings (2009, 2010, 2012 and 2016). The March 2012 fund-raise of £65.9m (net) enabled the company to strike the collaboration with Tris Pharma. A further £38.9m (net) was raised in May 2016. Vernalis employs 90 staff at UK sites in Winnersh and Cambridge, with 20 employees at its US head office in Berwyn, Pennsylvania and 110 salesforce field operatives in the US (this includes regional sales directors).

Valuation: £358.5m (68p/share) based on DCF-based rNPV

Our updated valuation reflects lower anticipated net sales of Tuzistra XR in FY18, peak sales reduced to $220m (from $240m) and the launch of CCP-07 and CCP-08 pushed back to the 2018/19 cough cold season following receipt of the CRLs. We apply an rNPV approach to the US cough cold and NCE pipelines, explicitly model costs (R&D, SG&A, capex) and include cash; we assume an NPV of zero for the research business (offsetting FTE income with R&D spend). Milestone receipts represent pure upside. Our valuation incorporates a 12.5% WACC (10% for launched products), with a revised 18% (from 21%) UK corporate tax rate after 2021 applied to cough cold cash flows (reflecting accumulated tax losses). Further upside would come from portfolio progress, launches and upgrades to cough cold sales expectations.

Sensitivities: A focus on execution

Key sensitivities relate to Tuzistra XR sales growth drivers; ensuring supply and distribution of Tuzistra XR; maintaining existing formulary coverage; and the speed and efficiency of the salesforce in executing its strategy and converting prescribers from immediate release to ER formulations. Addressing barriers to increased prescribing will determine the trajectory of Tuzistra XR uptake and both the level of and the timeframe over which it can achieve peak sales. The timing and outcome of the CCP-07 and CCP-08 NDA resubmission (partner Tris is responsible for refiling both post the CRL) is critical for investor sentiment towards the cough/cold portfolio.

Financials: Cash runway into 2019

Our new forecast for Tuzistra XR is for FY18 net sales of $5.7m (previously $18m) to reflect the combined impact of coupons and pharmacy stocking incentives and the slower than expected sales ramp up. FY18 cost guidance is at the similar run rate to 2016/17 and this could be higher if sterling weakens. Our new FY18 EBITDA loss is £34.0m (vs £34.5m previously). We expect sustainable profitability in FY21. However, this is contingent on sales of Tuzistra XR meeting or exceeding our expectations during the next two cough cold seasons and FY18 launches of CCP-07 and CCP-08. Net cash of £61m provides sufficient runway into FY19. We estimate a funding gap in FY19 and include an illustrative £30m financing, nominally attributed to debt, in our FY19 forecasts.

Cough cold franchise: Operational initiatives in place

Two years on from the launch of Tuzistra XR into the US prescription cough cold market, prescriptions are starting to ramp up after a modest maiden year. During the 2016/17 cough cold season Vernalis reviewed its operations and addressed all the major factors affecting potential market share and the rate of Tuzistra XR uptake. This led to a threefold increase in prescriptions vs the prior year. FY17/18 Tuzistra XR should benefit from the 25% expansion of the salesforce (all reps have been brought in-house), patient access and brand awareness initiatives providing better insight into its longer-term sales potential. Near term, execution is critical; successful operational execution in FY18 will lay important foundations for subsequent launches from its extended release (ER) prescription only (Rx) cough cold pipeline, enabling Vernalis to successfully build a speciality franchise. Our updated forecasts reflect a delay to CCP-07 and CCP-08 launch by one year coupled with lower Tuzistra XR revenues due to a slower than anticipated sales trajectory in the near term.

2018/19 target is threefold increase in Tuzistra XR prescriptions

The operational initiatives to address barriers to prescribing and uptake (Exhibit 1) are starting to bear fruit. Increased momentum in Tuzistra XR Rx has been supported by the refined commercial plan and a moderately severe season. This has resulted in material growth in Rx rates to 35,000 in FY17 (vs 12,000 in FY16) with a peak run rate of 55,000 prescriptions. However, Rx growth has not been matched by revenue growth as highlighted previously; for FY17 (year end 30 June), Tuzistra XR net revenues (on a delivered-to-wholesaler basis) were £2.1m (vs £1.1m for FY16). This is due to pharmacy/wholesaler stocking versus underlying demand. The third year of Tuzistra XR's launch should see the impact of the expansion of the salesforce to 100 sales reps (all of whom are now in-house – converted from inVentiv to Vernalis in July 2017), patient access and brand awareness initiatives, providing better insight into its longer-term sales potential. Management is targeting a threefold increase in Rx during the 2017/18 financial year (guided to total Rx of ~105,000-115,000). Longer term, the average target price is expected to reach $80/Rx.

Exhibit 1: Drivers of increased Rx numbers

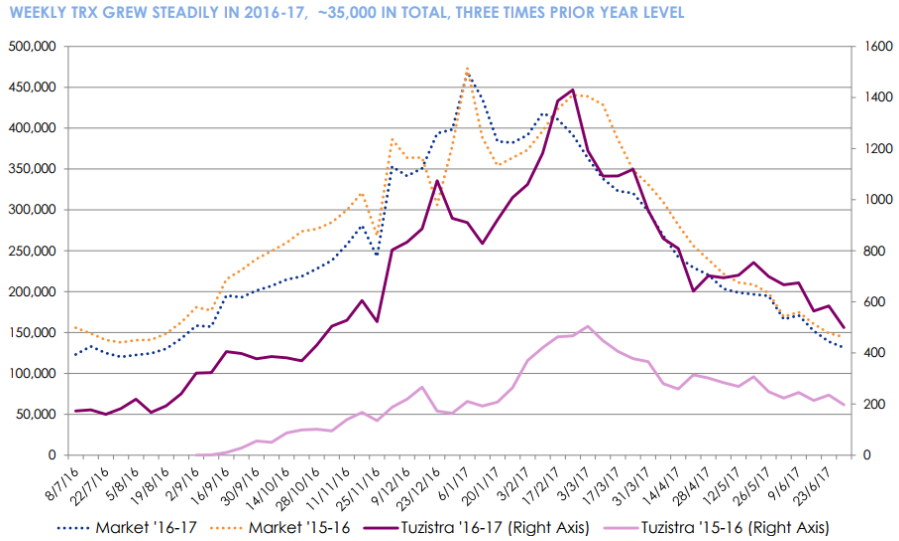
Issue	Initiative	Comment
Need to improve salesforce effectiveness	Salesforce expansion	25% increase in rep headcount to cover 100 territories (100 reps), now brought in-house. Vernalis believes it has critical mass to target a prescriber audience from which it can secure a meaningful proportion of Rx for cough cold products.
	Salesforce effectiveness	Territory re-alignment. Refined physician targeting and marketing message (all day, all night cough relief). High-performing reps across all US regions, although increasing proportion of high performing sales reps is a key focus. Currently, the top 15 territories account for c 50% of the annualised Rx run rate; 14 territories have a >1k TRx run rate pa, with the highest performing having achieved >71k.
Limited pharmacy stocking	Increase pharmacy stocking	Ongoing discussions with national and regional chains. Stocked at 9k pharmacies (out of potential 16k in territories where reps are deployed). One national chain auto-stocking. Reps promoting consistent message to pharmacies and physicians. Pharmacies more receptive to stocking a commercially attractive product (ie patient/physician demand, benefit to patients, affordable etc). National accounts group responsible for contracting and selective incentivisation/rebating.
Insurance coverage gap	Improve patient access	Tier III unrestricted insurance coverage of Tuzistra XR is now c 75% of US commercial lives (up from c 60%). Major coverage gap addressed.
Lack of brand awareness	Improve awareness with marketing message and sampling	Physician samples introduced from October 2016. Shipped to c 2k of 17k physician audience and is growing. As a codeine-based drug, some states do not permit sampling, while others require physician authorisation. Provide bridge to Rx with first 24-hour dose.
High out of pocket costs	Improve patient affordability	Enhanced patient assistance programmes (cash coupon) established. c 80% coupon utilisation.

Source: Edison Investment Research, Vernalis

Commercial execution is a critical driver of Tuzistra XR performance and Exhibit 2 illustrates both the overall steady progress throughout the 2016/17 cough cold season and also the sensitivity of weekly Rx rates to active promotion. Vernalis's strategy is validated by the presence of high performing sales reps in all US regions; the aim is to improve performance across the 71% of territories that have an annualised run rate <600/Rx. A more established and effective salesforce

should also benefit the launches of CCP-07 and CCP-08, which we now forecast for 2018/19 following on from the CRL issuances by FDA.

Exhibit 2: Tuzistra XR



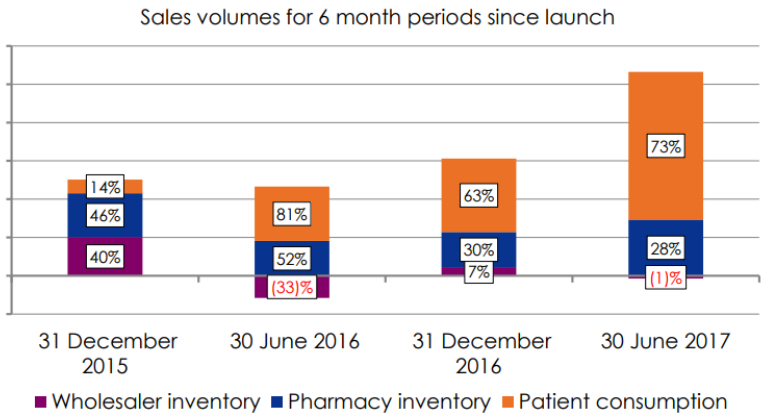
Source: Vernalis analysis, FY17 presentation (IMS and Bloomberg Symphony weekly TRx data)

Tuzistra XR: Extended release is the differentiating factor

12-hourly dosing with XR cough cold medicines offers greater convenience over immediate-release counterparts (requiring four to six doses daily) with deemed equivalent efficacy based on bioequivalence data. 12-hourly dosing means patients can rely on one dose through the night and one dose through the day allowing the potential for improved patient compliance. Tussionex (chlorpheniramine/hydrocodone) is the only other commercialised liquid ER product available in the US Rx market. Three Tussionex generics (one based on legacy UCB formulation technology, one on Tris's technology and one on Neos Therapeutics') are also available. DEA reclassification of hydrocodone may mean that hydrocodone prescribers find it easier and less costly and restrictive to prescribe Tuzistra XR than Tussionex. Physician market research conducted by Vernalis's partners suggests there is willingness to prescribe Tuzistra XR among prescribers in the broader $1.6bn narcotics segment (which also includes codeine plus expectorants, as well as the hydrocodone segment), albeit at lower penetration in the hydrocodone segment than in the primary market.

The 25% expansion of the field force from 80 reps to 100, coupled with refined physician targeting and marketing tactics (including sampling) should improve brand awareness and usage of Tuzistra XR. Sampling of cough cold products, in particular of controlled substances such as codeine, is not standard practice. Nevertheless, Vernalis will offer samples to enable physicians to provide the first 24-hour dose, providing a bridge to pharmacy stocking and increasing physician confidence that the patient will be able to obtain a course of Tuzistra XR. Vernalis is offering continued incentives for pharmacy stocking and exploring contracting with pharmacy chains directly. The intention is to ensure that Tuzistra XR scrips can be filled when presented at a pharmacy rather than abandoned due to lack of, or a delay in, stocking. This is especially important so that the investment into enhanced promotion to drive Rx will result in increased sales. Exhibit 3 highlights how these incentives have translated successfully into higher patient consumption percentages (73%), an expansion of pharmacy stocking to 29% and consistent wholesaler levels.

Exhibit 3: Breakdown of Tuzistra XR sales volumes



Source: Company reports

The net $/Rx for Tuzistra XR will be affected by discounts offered to pharmacies, as well as ongoing coupon programmes. Coupons are being offered to improve out-of-pocket costs for cash patients, while efforts are being made to improve formulary coverage. Vernalis has achieved its formulary coverage goals of 75% Tier 3 unrestricted coverage two years post launch. Expansion of formulary coverage should increase market share/minimise insurance rejections and have a longer-term effect as formulary listings are typically multi-year.

Longer term, Vernalis is targeting a net $/Rx of $80 and achieved c $60 at end June 2017. Net $/Rx should rise in future years as insurance coverage improves and brand awareness and physician loyalty is more established, although the pace at which this normalises (and the average net $/Rx achieved) will depend on the relative payer mix (cash vs commercial insurance). We have moderated our peak sales potential to $220m from $240m given the slower than anticipated initial take up.

Moxatag full promotion resumed

Moxatag (once a day, extended release, oral formulation of amoxicillin for tonsillitis and pharyngitis) was launched in September 2016, albeit in a limited number of regions due to the need to secure a new supplier. Net revenues in the first four months of its US launch were £0.1m, reflecting the drug's restricted promotion due to supply constraints. Vernalis has made progress qualifying a new supplier and intends to re-establish manufacture of Moxatag in 2018, consequently the whole salesforce resumed full promotion of Moxatag nationwide in the US market in September 2017. High decile paediatricians have been added to the territory call plan for this season – Moxatag is approved for adults and also for children above the age of 12 years. Currently held inventories (good inventory levels from the original 2016 launch) will be utilised to meet near-term demand. Moxatag enables the company to leverage its existing fixed commercial infrastructure and relationships (with physicians, pharmacies, wholesalers and payers). As a result, we expect modest Moxatag sales in FY18 with an uptick in sales from FY19 when supply constraints are lifted and manufacturing resumes.

Vernalis is targeting a similar WAC to Tuzistra XR in the long term and a similar level of insurance coverage (Tier 3 unrestricted at 75-80% of commercial plans). The ability to sample Moxatag once routine supply is re-established should circumvent issues with pharmacy stocking or reversals by ensuring that a patient has a dose for the first 24 hours of treatment (a treatment course is 10 tablets over 10 days) and allowing the pharmacy to see demand before routine stocking. Vernalis estimates that each year c 2.1m patients are treated with amoxicillin by primary care physicians; these are the target audience for switching to an ER antibiotic. Peak net sales potential is c $20m.

Building a cough cold franchise

Vernalis's pipeline of ER reformulated cough cold medicines offers greater convenience and patient compliance than the immediate release (IR) counterparts and is being developed in collaboration with licensee Tris Pharma. Tris's patented LiquiXR sustained-release liquid reformulation technology is a key factor in creating high barriers to entry given the difficulty in creating a liquid formula that the FDA will approve. From the Vernalis collaboration with Tris, Tuzistra XR is the first product to be launched and Exhibit 4 summarises the status of the other four products in development covered by this collaboration.

Exhibit 4: Vernalis cough cold pipeline

Product	Status	Next news event
CCP-05	Pre-proof of concept (POC)	POC (targeted by the end of 2017/18)
CCP-06	Pre-POC	POC (targeted by the end of 2017/18)
CCP-07	CRL issued	Partner Tris to resubmit NDA addressing the questions raised by FDA (timing unknown); possible launch timeframe 2018/19 season
CCP-08	CRL issued	Partner Tris to resubmit NDA addressing the questions raised by FDA (timing unknown); possible launch timeframe 2018/19 season

Source: Edison Investment Research, Vernalis

FDA has issued two complete response letters (CRL) to CCP-07 NDA (following its April PDUFA date) and CCP-08 NDA (following its August PDUFA date), outlining questions that need to be addressed in an NDA resubmission for potential FDA approval. While we continue to expect CCP-07 and CCP-08 to be approved, given the limited disclosure regarding possible timelines for dealing with these questions (partner Tris is responsible for the resubmission) and the probable class of resubmission, we conservatively push back our CCP-07 and CCP-08 approval assumptions by one year, delaying launch into the 2018/19 cough cold season. We are expecting a six-month FDA review cycle.

Regulatory approval will trigger the disclosure of the active pharmaceutical ingredient(s) (API) in CCP-07 and CCP-08, which will reveal which market segment each drug will target and enable a more meaningful peak sales assessment to be made. We currently forecast peak sales of $65m for each asset in Exhibit 4. Trends in the overall prescription cough cold market for 2016-17 highlight a continual shift towards non-narcotic treatments; a key beneficiary are the benzonatate class of drugs. Vernalis does not disclose the identity of the active pharmaceutical ingredients in its cough cold products ahead of approval. Tuzistra XR, a codeine/chlorpheniramine combination, targets the narcotic segment of the market; the remainder of the portfolio is understood to cover the other API market segments including a benzonatate but excluding dextromethorphan (which would be an over-the-counter product).

Overall, the 2016/17 season had 3.0% higher Rx written vs 2015/16 (34.5m vs 33.5m); however, this masked a change in the weighting of the various segments. The narcotic segment (codeine and hydrocodone products) is in decline as the impact of the general concerns of the use of prescription opiate abuse stemming from use in the pain setting spills over to the cough-cold segment. Despite the decline in narcotic market share to 44% of TRx (14.1m), the codeine segment – which Tuzistra XR addresses – is now the second largest segment with 30% of TRx (10.4m). The main beneficiary has been the non-narcotic segment, in particular benzonatate (36% market share in 2016/17, up from 31% market share in 2015/16), and as such Vernalis's ER benzonatate is likely to be the largest product alongside Tuzistra XR.

CCP-05 and CCP-06 remain in active development, in the formulation stage; proof of concept is now targeted before the end of 2017/18 (FY18) rather than before the end of December 2017 (CY17).

Partners drive NCE pipeline development

In addition to commercialising its cough cold portfolio, Vernalis also aims to realise value from its NCE (new chemical entity) pipeline of eight assets focused on CNS, cancer and inflammation. Five of the NCE programmes are partnered (Exhibit 5) and Vernalis is seeking to out-license the remaining three assets (Exhibit 6) as it does not intend to invest further in the pipeline. Development timelines and newsflow are subject to partner decisions and disclosures for the partnered assets; however, Vernalis is eligible for downstream economics on development, regulatory and commercial success without incurring any financial cost. Deal terms are largely undisclosed, but could include meaningful milestones.

FY17 benefited from a strong contribution in research collaboration income with Vernalis booking £12m in FY17 versus £8.0m in FY16. The partnered pipeline has made steady progress over the course of FY17, with several noteworthy developments including:

- Entry into a new multi-year collaboration with lead partner Servier in March 2017; Vernalis received an upfront payment of €2m.
- In April 2017 Vernalis received two research milestones and one clinical milestone (€2m in total) from the existing oncology drug discovery collaboration with Servier related to the advancement of a compound targeting Mcl-1 into Phase I studies.
- The receipt of a $3m milestone payment in February from Corvus Pharmaceuticals triggered by the advancement of CPI-444 into renal cell carcinoma patients.
- Vernalis collaborated with Verona Pharma on RPL554 (Exhibit 5). For the $78m NASDAQ IPO of **Verona Pharma** in April, the listing documents confirmed that its proceeds would be utilised for the development plans for RPL554 in COPD and in cystic fibrosis. Verona Pharma has initiated four clinical studies across these indications: a new Phase IIb COPD trial of the nebulised formulation to treat severe COPD exacerbations in hospital (slated to start in 2017), additional Phase II studies in COPD and exploratory trials in cystic fibrosis.

Exhibit 5: Vernalis's NCE development pipeline

Product	Indication(s)	Stage	Notes	Next catalyst
RPL554	Chronic obstructive pulmonary disease (COPD), Cystic fibrosis	Phase IIb	PDE3/PDE4 inhibitor (bronchodilator and anti-inflammatory). Licensed to **Verona Pharma**. Five positive Phase I/IIa trials in both asthma and COPD (mild-to-moderate disease). Verona's development/commercialisation focus is as a nebulised drug of choice for COPD, initially for exacerbations in hospitalised patients, with at-home maintenance therapy targeted as a line extension. Feasibility studies also carried out for DPI (dry powder inhaler) and pMDI (pressurised metered dose inhaler) formulations: pharma partner sought to exploit the chronic COPD maintenance therapy market.	Phase IIb COPD data: (2017/18).
CHR2797 (tosedostat)	AML/MDS	Phase II	Aminopeptidase inhibitor. Licensed to **CTI BioPharma**: low single-digit royalties. Phase II co-operative group-sponsored/investigator-led studies ongoing in acute myeloid leukaemia (AML)/ myelodysplastic syndromes (MDS) in combination with hypomethylating agents.	Phase II data (timing undisclosed).
V2006 (vipadenant)	Cancer	Phase I	Adenosine A2A receptor antagonist Phase I-ready. Licensed to **Juno Therapeutics** (which purchased original partner **RedoxTherapies**): deal terms include clinical and regulatory milestones, and royalties on sales.	Phase I study start
CPI-444 (V81444)	Cancer	Phase I/Ib	Adenosine A2A receptor antagonist. Licensed to **Corvus Pharmaceuticals** for a $1m upfront payment (less an undisclosed pay-away to Biogen) with ongoing development, regulatory and sales milestones up to $200m. Clinical trial collaboration with Genentech to assess CPI-444 as a single agent and in combination with Genentech's PD-L1 antibody, atezolizumab (Tecentriq). Development focus is on immuno-oncology. Prior Phase II studies in CNS. Phase I/Ib solid tumour trial underway: data from dose-selection part (n=28, four cohorts: three single agent, one in combination with atezolizumab) presented at ESMO 2016. Phase Ib part will evaluate CPI-444 as a single agent in five disease-specific cohorts, and in combination with atezolizumab in five additional matched disease-specific cohorts. N=14 for each cohort.	Phase I data (June 2018).
S-55746 (Servier 1)	Cancer	Phase I	BCL-2 inhibitor. First compound from the **Servier 1** research collaboration. Phase I start triggered €1m milestone: Vernalis eligible for potential development milestones and royalties. Licensed to **Novartis** by Servier (deal terms undisclosed).	Further data from the ongoing Phase I/Ib expanded study (February 2018).

Source: Edison Investment Research, Vernalis, company websites, Clinicaltrials.gov

Exhibit 6: Vernalis's unpartnered NCE development pipeline

Product	Indication(s)	Development stage/notes
AUY922 (luminespib)	Cancer	IV Hsp90 inhibitor. Rights returned from Novartis (December 2014). Phase II proof-of-concept achieved; studied in 26 clinical trials for a variety of solid tumours.
V158411	Cancer	Checkpoint 1 (Chk1) kinase inhibitor. Phase I-ready.
V158866	Pain	Fatty acid amide hydrolase inhibitor (FAAH). Phase II POC study in neuropathic pain failed to meet primary endpoint.

Source: Edison Investment Research, Vernalis

A self-financing research business

Vernalis's Cambridge-based research business leverages its extensive experience in fragment- and structure-based drug design in target-agnostic research collaborations. These collaborations enable the division to be self-financing. Currently, there are three collaboration partners and six active collaborations, while business development activities are ongoing to secure further collaborations.

- Servier: two development-stage collaborations (targeting BCL-2 proteins) with four ongoing research collaborations;
- Lundbeck: research collaboration targeting LRRK2; and
- Asahi Kasei Pharma: undisclosed collaboration for rheumatoid arthritis and other autoimmune diseases.

Collaborations not only contribute to the staff costs (FTE funding) during the research phases, but also include milestones and future royalties if the compounds succeed through the development and regulatory phases. The early nature of these collaborations means sizeable economics only accrue when (and if) the compounds progress successfully through development and approach the market. Progress during FY17 was evidenced by the receipt of milestones totalling £2.4m.

Sensitivities

Vernalis's transition to commercialisation has shifted the key near-term sensitivities away from development risk towards execution risk for the cough cold portfolio, particularly in relation to initiatives to support Tuzistra XR sales growth. The company is making significant additional investment in initiatives to support patient access (pharmacy stocking) and affordability (supporting coupons to minimise out-of-pocket expenses), and brand awareness to grow prescription levels. Addressing barriers to increased prescribing will determine average net $/Rx, the trajectory of Tuzistra XR uptake and both the level of and the timeframe over which it can achieve peak sales. Optimising salesforce effectiveness is therefore a key sensitivity. The third year post-Tuzistra XR launch will also lay the foundations for the cough cold franchise ahead of the potential launch of CCP-07 and CCP-08 into the 2018/19 cough cold season. The timing and outcome of the CCP-07 and CCP-08 NDA resubmission (partner Tris is responsible for refiling both post the CRL) is critical for investor sentiment towards the cough/cold portfolio.

The SWOT analysis presented in Exhibit 7 (overleaf) highlights the dynamics of the US cough cold market, Vernalis's opportunity and the key challenges to be addressed.

Exhibit 7: Vernalis cough/cold franchise SWOT analysis

Strengths	Weaknesses
■ **Potential for improved patient compliance:** 12-hourly dosing with XR cough cold medicines offers greater convenience over immediate-release counterparts (requiring four to six doses daily) with deemed equivalent efficacy based on bioequivalence data. ■ **High barriers to entry:** Manufacturing know-how as Tris's patented LiquiXR sustained-release liquid reformulation technology is a key factor in creating high barriers to entry given the difficulty in creating a liquid formula that the FDA will approve due to the challenges in maintaining the stability of the formulation. Additionally, manufacturing and formulation patents covering Tuzistra XR run until 2029. 20-year licence from approval translates to long-life assets. ■ **Limited direct competition:** Tussionex (chlorpheniramine/ hydrocodone) is the only other commercialised liquid ER product available in the US Rx market. Three Tussionex generics (one based on legacy UCB formulation technology, one on Tris's technology and one on Neos Therapeutics') are also available. ■ **Potential for switching from Tussionex:** DEA reclassification of hydrocodone may mean that hydrocodone prescribers find it easier and less costly and restrictive to prescribe Tuzistra XR than Tussionex. Physician market research conducted by Vernalis's partners suggests there is willingness to prescribe Tuzistra XR among prescribers in the broader $1.6bn narcotics segment (which also includes codeine plus expectorants, as well as the hydrocodone segment), albeit at lower penetration in the hydrocodone segment than in the primary market.	■ **General sentiment to prescription opiate addiction:** Legislation to address the prescription opiate addiction market which, relating to abuse in the analgesic setting, could extend to lower dose opiate products for cough colds. Note Tuzistra XR prescription is 7-10 days maximum use versus chronic opiate use for pain indications. Development of benzonatate products is important to offset any potential threat. ■ **High level of reversals:** approximately 20% of Rx lost are through patient abandonment or pharmacy reversals. Vernalis is seeking to reduce this by introducing incentives **to increase pharmacy stocking** and lowering patient co-pay cost via its coupon programme. ■ **Variability in salesforce effectiveness:** the field force is located around pockets of high-prescribing doctors. However, there is variability in territory performance. Focus is on identifying and addressing performance barriers (eg formulary coverage, training, pharmacy stocking). ■ **Seasonal variability means variable income streams:** the fluctuating severity of the cold and flu season means that Rx levels will vary year-on-year. IMS Health data indicate that 29-35m Rx were filled annually between 2012 and 2016. As such, there will be fluctuations in Vernalis's future income streams and profit once all its products are on the market. ■ **Trends in the cough cold market** ■ **Delays to pipeline products:** timing and outcome of the CCP-07 and CCP-08 NDA resubmission (partner Tris is responsible to refile both post the CRLs)
Opportunities	**Threats**
■ **Significant market opportunity:** focus is on the prescription-only (Rx) cough cold market, which in the US is valued at up to $3.5bn at brand pricing (c 35m Rx annually assuming a net price per Rx of $100). ■ **Broad product portfolio:** in collaboration with Tris Pharma, Vernalis is developing four other XR products. The APIs are undisclosed, but are understood to cover the other API market segments, with the exception of dextromethophan (which would be an OTC product). ■ **Non-narcotic product(s) in development:** the portfolio includes benzonatate-based product(s) that would address a market segment worth north of c $1bn at current pricing. This segment has benefited from the drop in opiate market share and is likely to be the largest product alongside Tuzistra XR. ■ **Operational leverage:** Moxatag (extended release amoxicillin) was launched in September 2016, albeit in a limited number of regions due to the need to secure a new supplier. Full promotion begun in September 2017. Vernalis is also seeking to in-license other commercial- or late-stage developmental assets that fit its business model. This would enable the company to leverage its existing fixed commercial infrastructure and relationships (with physicians, pharmacies, wholesalers and payers).	■ **Physician Inertia:** Converting physicians over to prescribing newer products ■ **Perceived room for dosing errors with a liquid product:** a key sales message from solid dose forms is that there is less potential for dosing errors using a solid product. Nevertheless, liquid products are the mainstay of cough cold therapy in the US market, and arguably errors are less likely with an ER product vs an IR equivalent. ■ **Government policy changes:** market dynamics are sensitive to policy changes such as the 2014 DEA rescheduling of hydrocodone from Schedule III to the more restrictive Schedule II, whereby the market share by value of this segment fell, with codeine- and benzonatate-based products being the beneficiaries. As Vernalis is developing a range of products covering various APIs, in-market dynamics should have a net neutral effect. ■ **Potential for increased coupon levels:** level of patient co-pay (ie the out-of-pocket expense paid by a patient) is important. If regulations change or managed care providers significantly alter their reimbursement levels, this may need to rise.

Source: Edison Investment Research

Valuation

We have updated our financial model and valuation, which results in a lower DCF valuation of £358.5m or 68p/share (previously £399m or 76p/share). Our underlying valuation assumptions are summarised in Exhibit 8, with the following adjustments made since our last note:

- Financial forecasts reflect lower net sales of Tuzistra XR in FY18 (we forecast $5.65m versus $18m previously) and beyond; we reduce our peak sales expectations to $220m from $240m. This is mainly a function of slower than expected uptake and a slightly lower average net selling price at end FY17. Longer term we expect average net $/Rx to move to $80/Rx.
- Unchanged CCP-08 and CCP07 probability of success (90%) following CRL letter issuance as we expect partner Tris to refile both NDAs in 2017/18 and now assume launch during the

2018/19 cough cold season. We have tweaked our assumed timing of payment of cough cold milestones to Tris pushing back CCP-08 and CCP-07 approval into FY19.

- We have rolled forward our model and updated the number of shares outstanding and the prevailing FX rate to $1.32/£ (previously $1.29/£).
- Net cash at June 2017 reported at £61.3m vs £84m at end June 2016.

Exhibit 8: Vernalis rNPV valuation summary

Source	rNPV (£m)	rNPV/share (p)	Assumptions
US Rx cough cold portfolio	586.6	111.4	Net of $12-14m of per product milestones due to Tris. 30% COGS (including Tris royalty pay-away). Aggregate sales >$500m by 2024; UK tax rate of 18% from 2021. **Tuzistra XR** (£401.5m rNPV): Peak sales of $220m; launched September 2015. **CCP-07** (£64.9m rNPV): peak sales of $65m; launch 2018/19; 90% success probability (CRL received). **CCP-08** (£60.7m rNPV): peak sales of $65m; launch 2018/19; 90% success probability (CRL received). **CCP-05** (£25.6m rNPV): peak sales of $65m; launch 2020/21; 65% success probability. **CCP-06** (£25.6m rNPV): peak sales of $65m; launch 2020/21; 65% success probability.
Moxatag	30.4	5.8	Peak sales of $20m; Fully promoted from September 2017 Undisclosed royalties/milestones payable to Pragma.
NCE pipeline	10.5	2.0	**RPL554** (£4.9m rNPV): peak COPD sales $200m; launch 2021; 30% success probability, 6% royalty. **Tosedostat** (£1.6m rNPV): peak AML sales $150m; launch 2020; 15% success probability; 5% royalty. **CPI-444** (£2.2m rNPV): peak immuno-oncology sales $200m; launch 2022; 15% success; 7% royalty. **Servier 1** (£0.6m rNPV): peak cancer sales $150m; launch 2023; 10% success probability, 5% royalty.
Frova royalty stream	7.9	1.5	Europe (Menarini): royalties of 25.25%, patent expiry Dec 2015, generic entry in main markets increasing price and volume pressure. US (Endo): min. sales level not reached; Mylan generic launched May 2016.
Total pipeline rNPV	**635.5**	**120.7**	
R&D	(72.1)	(13.7)	Includes offset for research collaborative funding.
SG&A	(258.0)	(49.0)	Includes cost of US sales infrastructure (included in R&D before Tuzistra launch).
Capex	(8.1)	(1.5)	Tangible assets (intangible capex, ie milestones paid to Tris, captured in cough cold portfolio rNPV).
Cash	61.3	11.6	Reported net cash at end-June 2017.
Valuation	**358.5**	**68.1**	

Source: Edison Investment Research. Note: Assumes WACC of 12.5% for all products with the exception of Tuzistra XR, Frova and Moxatag at 10% WACC, 526.2m shares outstanding and £/$ rate of 1.29.

We continue to apply a DCF-based rNPV approach to the US cough cold and NCE pipelines, explicitly model costs (R&D, SG&A, capex) and include cash. We do not explicitly value the research business, instead netting off collaborative FTE funding against R&D spending (research remained self-financing in FY16); thus any milestones received from research partners represent pure upside. We also highlight that unpartnered assets in the NCE pipeline, as well as V2006 (partnered with Juno/Redox) are not included in our current valuation; deal(s) for the former, or clarity on development timelines and strategy for the latter, would unlock potential valuation upside.

We apply a 12.5% WACC across the R&D portfolio with the exception of the launched products (Tuzistra XR, Moxatag and Frova) where we use 10%, our standard WACC for a commercial-stage product. We also apply an 18% (from 21%) UK corporate tax rate after 2021 to cough cold cash flows only, reflecting accumulated tax losses. Cash flows from the NCE pipeline are untaxed, based on our assumption that these will benefit from the UK patent box, as well as tax loss offset.

Financials

Vernalis's FY17 revenues (12 months to 30 June 2017) were £20.8m vs £12.0m for the 12 months to 30 June. The company reported increased US commercial sales of £2.1m (FY16 £1.1m), higher research collaboration income and higher Frova income in the prior year. US commercial net revenues include sales of Tuzistra XR (£2.0m) and Moxatag (£0.1m) and are reported on the basis of deliverable to wholesalers net of any rebates, discounts and returns provisions.

Research collaboration income grew 50% to £12.4m (FY16: £8.0m) largely due to milestone payments of £5m in the year vs £0.6m from Servier in FY16 and £7m of FTE income vs £7.4m in 2016. Other collaboration income was reported as £2.4m in FY17 (vs zero in FY16). Following frovatriptan composition of matter patent expiry in December 2015, generic competition has

affected Menarini's in-market sales in both volume and price terms. Frova royalties booked by Vernalis correspond to API supply; in FY17 three12.5kg API batches were delivered (£4.3m in royalties) vs two 12.5kg batches (royalties of £2.9m) during FY16. Management has guided for two 12.5kg batches for FY18.

US commercial infrastructure costs drove the 23% increase in operating costs to £45.2m (FY16: £36.9m pre-exceptional; £34.0m including the £2.65m gain on settlement of an onerous lease obligation). Sales and marketing costs showed the most significant increase (£28.6m vs £20.4m) reflecting salesforce expansion during FY17 and only ten months of salesforce activity in FY16 (following recruitment in August). Broadly flat R&D costs of £11.1m (FY16: £10.9m) were mainly associated with internal R&D, while G&A increased modestly to £5.5m (FY16: £5.3m).

Increased investment in US commercial infrastructure was offset by an increase in revenue thus the operating loss for the year was similar to the prior year £26.4m (FY16: loss of £26.2m pre-exceptional, £23.6m post exceptional gain). Net loss of £21.64m (FY16: pre-exceptional loss of £17.9m) again benefitted from unrealised FX gains on cash and equivalents (£2.2m) and tax credits (mainly connected to the CCP-07 and CCP-08 regulatory filing milestones). At 30 June 2017, cash and equivalents stood at £61.3m (£84m at end-June 2016). Cash and equivalents of £84m at end-June 2016 benefited from 15% £/US$ weakening post the Brexit vote; c 73% of cash is held in US$ to hedge against US costs and future milestones to Tris. A translation loss or gain is recognised at the end of each period at the prevailing exchange rate.

For FY18, Vernalis has guided towards lower research collaboration income as FY17 benefited from milestones which are lumpy by nature. Two Frova API batches are projected by Menarini, with one in each half-year period. We lower Tuzistra XR FY18 net sales to $5.65m (£4.4m), previously $18m (£14m) to reflect a slower than anticipated ramp up. We have delayed our launch expectation for CCP-07 and CCP-08 by one year to 2018/19. The net impact is that our new revenue forecasts are £13.9m for FY18 (previously £25.8m) and £26.9m for FY19.

Management's operating cost guidance for FY18 is for a similar run rate to 2016/17. The increase in these US$-denominated costs is magnified when translated back into sterling given the impact of US$ strengthening vs sterling. We forecast S&M costs of £35.7m for FY18 (but broadly maintain our R&D and G&A expectations). FY19 SG&A costs rise as expected to support the launch of CCP-07 and CCP-08 (contingent on approval); we forecast £40.0m.

Exhibit 9: Changes to estimates

	Revenue (£m)			EBITDA (£m)			EPS (p)		
	Old	New	Change	Old	New	Change	Old	New	Change
2018e	25.8	13.9	-46.1%	(32.3)	(34.0)	5.3%	(6.0)	(6.3)	5.0%
2019e		26.9			(28.7)			(5.4)	

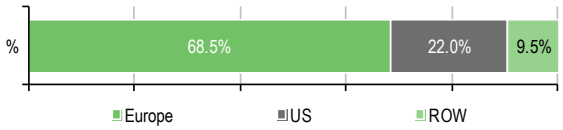
Source: Edison Investment Research. Note: Normalised PBT includes net financial interest but excludes other financial income from FX gains and losses. FX rate updated to $1.32/£ (previously $1.29/£).

On our updated forecasts (Exhibit 10), we expect Vernalis to reach sustainable profitability in FY21. However, this is contingent on Tuzistra XR sales meeting or exceeding our expectations during the next two cough cold seasons and FY19 launches of CCP-07 and CCP-08. Net cash of £61m provides sufficient runway into FY19. We estimate a funding gap in 2019 and include an illustrative £30m financing, nominally attributed to debt, in our FY19 forecasts.

Exhibit 10: Financial summary

£'000s	2015*	2016	2017	2018e	2019e
Year end 30 June (from 2015), previously December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	19,882	12,034	20,790	13,927	26,875
of which: Cough/cold portfolio & Moxatag	0	1,100	2,089	4,727	16,875
Frova royalties	6,648	2,894	4,300	2,200	2,000
Collaborative income (R&D funding and milestones)	13,022	8,035	14,401	7,000	8,000
Other	212	5	0	0	0
Cost of Sales	(1,373)	(2,004)	(2,469)	(3,161)	(8,309)
Gross Profit	18,509	10,030	18,321	10,765	18,566
Sales, General & Admin	(8,635)	(25,717)	(34,156)	(35,717)	(40,011)
Research & Development	(22,563)	(10,932)	(11,084)	(11,105)	(10,772)
Other	611	396	509	0	0
Operating Profit reported	(11,835)	(23,572)	(26,410)	(36,057)	(32,217)
Intangible Amortisation	(571)	(713)	(911)	(1,523)	(3,047)
Exceptionals	243	2,651	0	0	0
Share-based payment	(1,855)	(984)	(1,535)	(247)	(247)
EBITDA	(8,855)	(23,919)	(23,338)	(34,033)	(28,678)
Operating Profit (norm)	(9,652)	(24,526)	(23,964)	(34,286)	(28,923)
Net Interest	2,733	8,315	2,776	306	(1,118)
Other financial income	(157)	(42)	(112)	0	0
Profit Before Tax (norm)	(7,076)	(16,253)	(21,300)	(33,980)	(30,041)
Profit Before Tax (as reported)	(9,259)	(15,299)	(23,746)	(35,750)	(33,335)
Tax	2,858	804	2,184	610	1,500
Profit from discontinued operations	0	0	0	0	0
Profit After Tax (norm)	(4,218)	(15,449)	(19,116)	(33,370)	(28,541)
Profit After Tax (as reported)	(6,401)	(14,495)	(21,562)	(35,140)	(31,835)
Average Number of Shares Outstanding (m)	442.3	449.9	526.4	526.4	526.4
EPS - normalised (p)	(1.0)	(3.4)	(3.6)	(6.3)	(5.4)
Dividend per share (p)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	93.1%	83.3%	88.1%	77.3%	69.1%
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets	15,066	19,949	24,035	27,811	44,131
Intangible Assets	12,895	17,645	21,626	25,446	41,743
Tangible Assets	1,637	1,673	1,409	1,364	1,387
Other	534	631	1,000	1,000	1,000
Current Assets	71,509	92,541	70,133	35,409	23,158
Stocks	0	233	933	866	2,277
Debtors	7,017	7,225	5,860	3,052	5,154
Cash	61,258	84,018	61,258	29,409	13,645
Other (tax and derivatives)	3,234	1,065	2,082	2,082	2,082
Current Liabilities	(5,215)	(7,711)	(9,675)	(13,620)	(19,276)
Creditors	(3,373)	(5,175)	(6,369)	(2,353)	(3,009)
Other creditors	(5)	(80)	(64)	(64)	(64)
Short term borrowings	0	0	0	0	0
Deferred income	(1,688)	(922)	(382)	(382)	(382)
Provisions and other current liabilities	(154)	(1,614)	(2,924)	(10,885)	(15,885)
Long Term Liabilities	(4,254)	(2,048)	(1,717)	(1,717)	(31,717)
Long term borrowings	0	0	0	0	(30,000)
Deferred income	(744)	(1,459)	(1,271)	(1,271)	(1,271)
Provisions and other long-term liabilities	(3,510)	(589)	(446)	(446)	(446)
Net Assets	77,106	102,731	82,776	47,883	16,295
CASH FLOW					
Operating Cash Flow	(12,135)	(23,682)	(20,916)	(27,213)	(26,534)
Net Interest	353	230	730	306	(1,118)
Tax	1,887	2,912	459	610	1,500
Capex	(1,005)	(212)	(424)	(209)	(269)
Purchase of intangibles	(7,474)	(71)	(4,779)	(5,344)	(19,344)
Acquisitions/disposals	0	(3,677)	0	0	0
Financing	13	39,236	2	0	0
Dividends	0	0	0	0	0
Other	1,644	0	0	0	0
Net Cash Flow	(16,717)	14,736	(24,928)	(31,849)	(45,764)
Opening net debt/(cash)	(76,918)	(61,258)	(84,018)	(61,258)	(29,409)
HP finance leases initiated	0	0	0	0	0
Exchange rate movements	1,057	8,024	203	0	0
Other	0	0	1,965**	0	0
Closing net debt/(cash)	(61,258)	(84,018)	(61,258)	(29,409)	16,355

Source: Edison Investment Research, Vernalis accounts. Note: *18-month reporting period, thereafter 12-month reporting. **Other relates to forex gain within movement in held to maturity financial assets.

Contact details	Revenue by geography
Vernalis 100 Berkshire Place Wharfedale Road Winnersh RG41 5RD 0118 938 0000 www.vernalis.com	

Management team

CEO: Ian Garland	CFO: David Mackney
CEO since December 2008, having previously been CEO of Acambis (May 2007-September 2008) until its sale to Sanofi-Aventis, and CFO of Arrow Therapeutics (2004-07) until its acquisition by AstraZeneca. Before this, he was chief operating officer at Celltech Pharmaceuticals, and at KPMG.	CFO since February 2009, having been interim CFO of Acambis between February 2008 and January 2009. Previously CFO of Akubio, group financial controller at Shire (2002-05), and a senior manager in audit at Arthur Andersen (1996-2001).
Chairman: Peter Fellner	**President & COO, Vernalis Therapeutics Inc.: Sandford Sommer**
Appointed chairman in 2003. Also chairman of Ablynx, Consort Medical and Optos. Peter was previously director at Evotec and UCB, vice chairman of Astex Pharmaceuticals, and chairman of Acambis, Biotie, Premier Research Group and Celltech (2003-05; CEO from 1990-2003). Ex-CEO of Roche UK (1986-90).	President & COO of Vernalis Therapeutics since May 2016. Previous 24-year career at AstraZeneca in roles including president of Columbia operations, global VP of CNS, infection and flu vaccines; executive director US Seroquel.

Principal shareholders	(%)
Invesco	36.9
Woodford Investment Management	29.9
GAM	9.1
Legal & General Investment Managers	5.8
Aviva Investors	5%

Companies named in this report

Corvus Pharmaceuticals, CTI Biopharma, Juno Therapeutics, Lundbeck, Menarini, Servier, Tris Pharma, Verona Pharma

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