

# Vernalis

## FDA issues CCP-07 complete response letter

FDA approval decision

Pharma & biotech

24 April 2017

**Price** **22.13p**

**Market cap** **£117m**

US\$1.28/£

Net cash (£m) end-December 2016 74.2

Shares in issue 526.4m

Free float 12.4%

Code VER

Primary exchange AIM

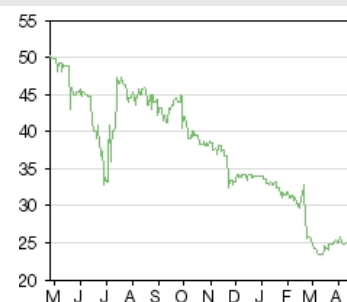
Secondary exchange N/A

FDA has issued a complete response letter (CRL) to Vernalis' CCP-07 NDA following its 20 April PDUFA date, outlining questions that need to be addressed in an NDA resubmission for potential FDA approval. Given limited disclosure regarding possible timelines for dealing with these questions and the probable class of resubmission, we conservatively push back our CCP-07 approval assumption by one year, delaying launch into the 2018/19 cough cold season. However, we acknowledge that there are scenarios under which CCP-07 could still be launched into the 2017/18 season, albeit later than previously anticipated. Separately, Vernalis has received a \$2m milestone relating to an existing research collaboration.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
06/15**	19.9	(6.9)	(1.0)	0.0	N/A	N/A
06/16	12.0	(16.2)	(3.4)	0.0	N/A	N/A
06/17e	17.5	(24.9)	(4.4)	0.0	N/A	N/A
06/18e	25.8	(32.4)	(6.0)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments. \*\*18-month reporting period, 12 months thereafter.

### Share price performance



%	1m	3m	12m
Abs	(10.6)	(31.7)	(56.3)
Rel (local)	(8.3)	(31.8)	(61.0)
52-week high/low		50.9p	22.1p

### 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 projects. Its primary focus is on commercialising Tuzistra XR in the US.

### Next events

Tuzistra XR: end 2016/17 season update	June/July
CCP-08: PDUFA date	4 August
FY17 prelims	September
CCP-07: NDA resubmission	2017

### Analysts

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## CRL: Outstanding items but no major concerns

Positively, the CRL raised no concerns related to the formulation or pharmacokinetic profile of CCP-07. However, there are outstanding questions that must be resolved prior to NDA resubmission and an FDA approval decision. We continue to expect CCP-07 to be ultimately approved, but as both the nature of the FDA questions and the length of time to address them is undisclosed, we conservatively assume a one-year delay to CCP-07 approval and launch. This timeline could be brought forward once there is clarity on: (i) timing, and (ii) classification of the NDA resubmission. A Class 1 classification indicates a two-month review cycle; Class 2 would be six months.

## Limited impact on cough cold franchise

Updating our near-term assumptions to reflect the delayed CCP-07 launch lowers forecast cough cold revenues in FY18 (2017/18 season), and more modestly for FY19 as sales ramp up. Our assumptions for the other cough cold programmes are unchanged. At this stage, we anticipate limited read-through to CCP-08 (PDUFA date: 4 August) from the CCP-07 NDA CRL; however, a delay to CCP-08 approval could result if resolution of CRL issues/CCP-07 NDA resubmission is protracted.

## Valuation: DCF valuation of £399m (76p per share)

Updating our model and financial forecasts for new CCP-07 expectations, the \$2m milestone receipt and the prevailing FX rate (now \$1.28/£ from \$1.24/£) lowers our valuation to £399m or 76p/share (from £427m or 81p/share). In our view, this valuation reflects the downside scenario for CCP-07 approval timelines. Clarity on CCP-07 NDA resubmission, portfolio progress, launches and sales upgrades would unlock upside. Our valuation continues to consist of US cough cold and NCE pipeline rNPV, explicit cost modelling and inclusion of cash; we assume zero NPV for the research business.

**Exhibit 1: Financial summary**

	£'000s	2013	2015**	2016	2017e	2018e
Year end 30 June (from 2015); previously December		IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>						
Revenue		14,084	19,882	12,034	17,515	25,802
of which:						
Cough/cold portfolio & Moxatag		0	0	1,100	1,953	16,113
Frova royalties		6,684	6,648	2,894	3,500	1,389
Collaborative income (R&D funding and milestones)		7,150	13,022	8,035	11,763	8,000
Other		250	212	5	300	300
Cost of Sales		(2,244)	(1,373)	(2,004)	(2,528)	(6,496)
Gross Profit		11,840	18,509	10,030	14,988	19,306
Sales, General & Admin		(3,299)	(8,635)	(25,717)	(35,141)	(42,662)
Research & Development		(14,416)	(22,563)	(10,932)	(10,995)	(11,105)
Other		180	611	396	233	0
Operating Profit reported		(5,695)	(11,835)	(23,572)	(30,915)	(34,461)
Intangible Amortisation		(1,349)	(571)	(713)	(1,016)	(1,523)
Exceptionals		1,608	243	2,651	0	0
Share-based payment		(876)	(1,855)	(984)	(247)	(247)
EBITDA		(4,652)	(8,855)	(23,919)	(29,352)	(32,381)
Operating Profit (norm)		(5,078)	(9,652)	(24,526)	(29,653)	(32,691)
Net Interest		420	2,733	8,315	4,757	283
Other financial income		(999)	(157)	(42)	(57)	0
Profit Before Tax (norm)		(4,658)	(6,919)	(16,211)	(24,896)	(32,408)
Profit Before Tax (as reported)		(6,274)	(9,259)	(15,299)	(26,215)	(34,178)
Tax		2,273	2,858	804	2,013	844
Profit from discontinued operations		0	0	0	0	0
Profit After Tax (norm)		(2,385)	(4,061)	(15,407)	(22,883)	(31,564)
Profit After Tax (as reported)		(4,001)	(6,401)	(14,495)	(24,203)	(33,335)
Average Number of Shares Outstanding (m)		442.1	442.3	449.9	526.4	526.4
EPS - normalised (p)		(0.8)	(1.0)	(3.4)	(4.4)	(6.0)
Dividend per share (p)		0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		84.1%	93.1%	83.3%	85.6%	74.8%
EBITDA Margin (%)		-33.0%	-44.5%	-198.8%	-167.6%	-125.5%
Operating Margin (before GW and except.) (%)		-36.1%	-48.5%	-203.8%	-169.3%	-126.7%
<b>BALANCE SHEET</b>						
Fixed Assets		7,730	15,066	19,949	23,155	40,177
Intangible Assets		6,292	12,895	17,645	21,317	38,262
Tangible Assets		1,438	1,637	1,673	1,722	1,799
Other		0	534	631	116	116
Current Assets		83,298	71,509	92,541	68,721	22,894
Stocks		130	0	233	1,385	1,780
Debtors		4,443	7,017	7,225	8,638	5,655
Cash		76,918	61,258	84,018	56,633	13,394
Other (tax and derivatives)		1,807	3,234	1,065	2,065	2,065
Current Liabilities		(4,501)	(5,215)	(7,711)	(11,577)	(15,860)
Creditors		(3,384)	(3,373)	(5,175)	(5,758)	(4,241)
Other creditors		0	(5)	(80)	0	0
Short term borrowings		0	0	0	0	0
Deferred income		(962)	(1,688)	(922)	(657)	(657)
Provisions and other current liabilities		(155)	(154)	(1,614)	(5,162)	(10,962)
Long Term Liabilities		(4,283)	(4,254)	(2,048)	(1,986)	(1,986)
Long term borrowings		0	0	0	0	0
Deferred income		(156)	(744)	(1,459)	(1,408)	(1,408)
Provisions and other long-term liabilities		(4,127)	(3,510)	(589)	(578)	(578)
Net Assets		82,244	77,106	102,731	78,312	45,225
<b>CASH FLOW</b>						
Operating Cash Flow		(3,486)	(12,135)	(23,682)	(28,119)	(25,510)
Net Interest		446	353	230	4,757	283
Tax		1,929	1,887	2,912	1,013	844
Capex		(646)	(1,005)	(212)	(350)	(387)
Purchase of intangibles		(1,976)	(7,474)	(71)	(4,688)	(18,469)
Acquisitions/disposals		0	0	(3,677)	0	0
Financing		0	13	39,236	2	0
Dividends		0	0	0	0	0
Other		0	1,644	0	0	0
Net Cash Flow		(3,733)	(16,717)	14,736	(27,385)	(43,239)
Opening net debt/(cash)		(81,555)	(76,918)	(61,258)	(84,018)	(56,633)
HP finance leases initiated		0	0	0	0	0
Exchange rate movements		(904)	1,057	8,024	0	0
Other		0	0	0	0	0
Closing net debt/(cash)		(76,918)	(61,258)	(84,018)	(56,633)	(13,394)

Source: Edison Investment Research, Vernalis accounts. Note: \*\*18-month reporting period, thereafter 12-month reporting.

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