

# **First Read**

# Concert Pharmaceuticals

# CTP-354 Looks Like a Drug, Moving to Phase-2

# Conclusion: CTP-354 progresses with new data of multiple ascending dose

The final ph1 data for CTP-354 reported at the American Neurological Association's Annual Meeting suggest that CTP-354 is differentiated from benzodiazepines by having high and sustained brain GABA-A receptor occupancy levels at doses that were non-sedating. With these data in hand, Concert will initiate phase-2 studies with 3 dose groups in spinal cord injury (SCI) by YE14, and later in multiple sclerosis (early 2015). We think these data strongly support the rationale for '354 in spasticity (and later in other anxiety-related indications). Together with CTP-499 (starting phase-3), we see significant upside in CNCE shares via proprietary pipeline development.

# Key points from the data and ph2 plan

The new data from multiple ascending dose (MAD) study show CTP-354 was generally well tolerated with no dose-limiting toxicities across all dose cohorts, and no treatment discontinuations were reported in ph1. [1] PET scan receptor occupancy data showed multiple doses of 6mg confers ~50% occupancy rate without sedation and significant side effects, which was discussed on the last quarterly call in August. Recall sedation is dose-limiting for benzo's at about 25% occupancy. [2] While doses up to 12mg were tested in MAD, the ph2 studies will evaluate 2, 4 and 8 mg, because the CNS-related side effects increased at 12mg. At 8mg, the company expect to achieve about 70% occupancy based on a modelling using plasma concentration level. [3] The company is on track to advance '354 into ph2 testing by YE14, initially targeting spasticity in SCI followed by an additional ph2 in MS in early 2015. [4] The company previously said that 25-30% improvement in the Modified Ashworth Scale (MAS) as the bar for ph2.

#### Implications: Significant upside remains as CTP-354 progresses to ph2

We currently model a 15% probability of success for CTP-354 in MS and SCI and, in our view, the market ascribes minimal value for the proprietary pipeline ('345 and '499). As a result, we see significant upside from pipeline development.

# Valuation: Buy with \$25 PT by sum-of-the-parts

We estimate that '354 is worth \$8 with revenues from the program beginning in 2019.

Equities		
Americas Biotechnology	y	
12-month ratio	ng	Buy
12m price targ	jet	US\$25.00
Price		US\$12.42
RIC: CNCE.O B	BG: CNCE US	
Trading data a	nd key metrics	
52-wk range		US\$15.08-0.00
Market cap.	US\$0.22bn	
Shares o/s	17.9m (COM)	
Free float		35%
Avg. daily volu	me ('000)	187
Avg. daily valu	e (m)	US\$2.0
Common s/h e	quity (12/14E)	US\$0.05bn
P/BV (12/14E)		3.9x
Net debt / EBIT	DA (12/14E)	1.7x
EPS (UBS, dilute	ed) (US\$)	
	12/14E	
	UBS	Cons.
Q1	-	(0.76)
Q2	-	(0.45)
Q3E	-	(0.49)
Q4E	-	(0.50)
12/14E	(2.02)	(1.94)

12/15E

12/16E

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Highlights (US\$m)	12/11	12/12	12/13	12/14E	12/15E	12/16E	12/17E	12/18E
Revenues	19	13	25	8	30	56	78	124
EBIT (UBS)	(11)	(19)	(4)	(30)	(21)	(23)	(31)	(18)
Net earnings (UBS)	(12)	(21)	(6)	(32)	(23)	(25)	(33)	(20)
EPS (UBS, diluted) (US\$)	(9.66)	(16.15)	(4.99)	(2.02)	(1.25)	(1.05)	(1.38)	(0.82)
DPS (US\$)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Net (debt) / cash	23	7	10	48	29	138	118	113
Profitability/valuation	12/11	12/12	12/13	12/14E	12/15E	12/16E	12/17E	12/18E
EBIT margin %	-58.3	-144.8	-17.4	-403.4	-70.7	-41.4	-40.5	-14.5
ROIC (EBIT) %	-	>500	74.6	>500	<-500	(389.9)	<-500	(485.8)
EV/EBITDA (core) x	-	-	-	-6.7	-9.3	-6.5	-3.2	-6.8
P/E (UBS, diluted) x	-	-	-	(6.1)	(9.9)	(11.8)	(9.0)	(15.2)
Equity FCF (UBS) yield %	-	-	-	(14.7)	(8.1)	(7.8)	(11.2)	(4.7)
Net dividend vield %	_	_	-	0.0	0.0	0.0	0.0	0.0

Source: Company accounts, Thomson Reuters, UBS estimates. Metrics marked as (UBS) have had analyst adjustments applied. Valuations: based on an average share price that year, (E): based on a share price of US\$12.42 on 13 Oct 2014 08:11 EDT

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## **Forecast returns**

Forecast price appreciation	+101.3%
Forecast dividend yield	0.0%
Forecast stock return	+101.3%
Market return assumption	5.4%
Forecast excess return	+95.9%

## **Statement of Risk**

We see several risks to CNCE shares, including clinical, regulatory, and commercial. Clinical risks include if CTP-354 or CTP-499 result in unforeseen safety, tolerability, or toxicity signals, or fails to yield positive clinical results. Regulatory risks include the regulatory agencies not approving the drug candidates after completing clinical trials. Commercial risks include Concert not being the only company developing deuterated analogues or compounds for the specific indications of interest, resulting in competition that may or may not materialize. In addition, generic competitors could challenge the Concert's patent estate after the company brings its products to the market.

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12-Month Rating	Definition	Coverage <sup>1</sup>	IB Services <sup>2</sup>
Buy	FSR is > 6% above the MRA.	47%	34%
Neutral	FSR is between -6% and 6% of the MRA.	42%	28%
Sell	FSR is > 6% below the MRA.	11%	21%
Short-Term Rating	Definition	Coverage <sup>3</sup>	IB Services <sup>4</sup>
Buy	Stock price expected to rise within three months from the time the rating was assigned because of a specific catalyst or event.	less than 1%	less than 1%
Sell	Stock price expected to fall within three months from the time the rating was assigned because of a specific catalyst or event.	less than 1%	less than 1%

Source: UBS. Rating allocations are as of 30 September 2014.

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**UBS Securities LLC:** Matthew Roden, PhD; Jeffrey Hung; Charles Shi, PhD.

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Company Name	Reuters	12-month rating	Short-term rating	Price	Price date
Concert Pharmaceuticals <sup>2, 4, 6, 13, 16</sup>	CNCE.O	Buy	N/A	US\$12.42	10 Oct 2014

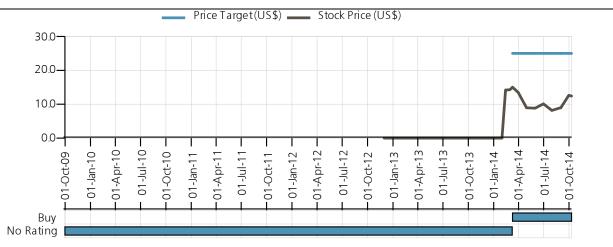
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# **Concert Pharmaceuticals (US\$)**



Source: UBS; as of 10 Oct 2014

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