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Equity Research
Biotechnology

Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH, US$8.39; TSX:AUP, C$11.13)

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Bloom Burton Securities Inc.

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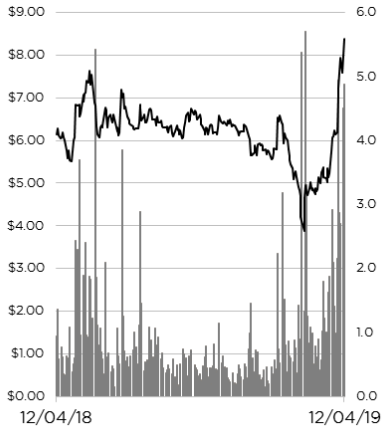
Rating:	BUY
Risk:	Speculative
12 month Price Target:	US$21.00 (was $16.00)

Price	$8.39
Implied Return	90.7%
Fiscal Year End	31-Dec
52 Week Range	$3.52-$8.54
Shares Outstanding (MM)	94.3
Market Cap. (MM)	$791.1
Float (MM Shares)	65.1
Avg. Daily Volume (MM)	1.52

	2018A	2019E	2020E
EPS	($0.76)	($0.72)	($0.32)
cash (MM, end period)	$125.9	$100.0	$75.0



This report is priced as of last trading day close. All values in US$ unless otherwise noted.

AURORA Borealis!

Yesterday, Aurinia announced positive top line results for its pivotal phase 3 study of voclosporin (VCS) in lupus nephritis (AURORA). VCS in combination with standard of care (SOC - background mycophenolate (MMF) and low-dose corticosteroids), achieved statistical superiority on the primary endpoint, renal response rate (VCS + SOC (active): 40.8% vs placebo + SOC (control): 22.5%, at 52 weeks, p<0.001; 18.3% delta).

VCS also achieved superiority in all pre-specified secondary endpoints including partial response which, along with complete response, is linked to improved long term renal outcome (link).

	Measure	Result	Odds Ratio [95% CI]	p-value
Primary Endpoint	Renal Response at 52 weeks	Voclosporin 40.8% Control 22.5%	2.65 [1.64, 4.27]	p < 0.001
Secondary Endpoints	Renal Response at 24 weeks	Voclosporin 32.4% Control 19.7%	2.23 [1.34, 3.72]	p = 0.002
	Partial Renal Response at 24 weeks	Voclosporin 70.4% Control 50.0%	2.43 [1.56, 3.79]	p < 0.001
	Partial Renal Response at 52 weeks	Voclosporin 69.8% Control 51.7%	2.26 [1.45, 3.51]	p < 0.001
	Time to UPCR ≤ 0.5	Voclosporin faster than Control	2.02 [1.51, 2.70] Hazard Ratio	p < 0.001
	Time to 50% reduction in UPCR	Voclosporin faster than Control	2.05 [1.62, 2.60] Hazard Ratio	p < 0.001

Source: Aurinia

In Aurinia's phase 2b AURA-LV study which reported in March 2017 (link), the drug-placebo delta at 48 weeks was a bit higher: 25% (VCS remission: 49% vs SOC: 24%), however, we believe that more patients in AURORA were already on SOC (and failing) at baseline, making the phase 3 patient population more difficult to treat.

Importantly, the safety profile of VCS was comparable to SOC. SAEs were reported in 20.8% of VCS patients vs 21.3% with SOC, with only 1 death being reported with VCS treatment vs 5 deaths with SOC. Estimated glomerular filtration rate (eGFR) was not significantly affected at 52 weeks, nor were blood pressure, lipids or glucose, which are commonly perturbed by other calcineurin inhibitors (CNis).

Furthermore, the response rate and time to response with VCS continue to appear favorable vs Roche's (SW:ROG; unrated) Gazyva, which reported phase 2 NOBILITY results last month (link). In NOBILITY, the drug-placebo delta at 52 weeks was 12.3% (Gazyva remission: 34.9% vs SOC: 22.6%) compared with the 18.3% delta in AURORA, and there was no drug-placebo delta (benefit) for Gazyva at 24 weeks vs the 12.7% delta for VCS at the same time point in AURORA (VCS: 32.4% vs SOC: 19.7%).

Impact

We believe investors will breathe a sigh of relief that efficacy was repeated in AURORA (a high number of international sites in AURA-LV led to some uncertainty), and a bigger sigh of relief that the mortality imbalance in AURA-LV was not repeated in AURORA. Despite the phase 2 imbalance attributed to a randomization artifact at the time (link), and more than 1,000 patients safely treated with VCS previously in other clinical trials, this VCS safety risk could not be solidly put to bed until AURORA came clean.

Due to the positive top line AURORA results, we are increasing the probability of approval of VCS in our model to 90% (was 80%). We are also increasing the probability that VCS will be class-leading in the indication, and tweaking up the probability of success of Aurinia's dry eye syndrome (DES) program to 50% from 40%. As a result, our target price for AUPH shares increases to $21.00 from $16.00. Maintaining BUY rating (Speculative risk).

With the initial AURORA safety results now positive, we now look forward to additional signs of VCS differentiation within the CNi drug class as: 1) more details emerge from AURORA, 2) ongoing pre-clinical mechanistic studies report data, and 3) results are reported for the AURORA 2-year extension study. We continue to believe that AUPH could be a $40.00+ stock with >$1 billion peak sales if signs of differentiation continue to bear out. Separately, competitor in the DES space, Aldeyra Therapeutics (NASDAQ:ALDX; unrated) earlier this week reported mixed phase 3 results which we believe fell behind Aurinia's VOS results reported earlier this year (link) with respect to both symptom improvement and fluorescein staining.

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Rating	Number	Percentage
BUY	14	78%
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HOLD	3	17%
SELL	0	0%
Total	18	100%