April 8, 2013

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Intercept Pharmaceuticals (ICPT - OUTPERFORM): Upcoming EASL Presentation Confirms Clinical Relevance of Phase 3 Primary Endpoint; Reiterate OUTPERFORM and $46 FV

Price: $35.58 **Fair Value Estimate: $46**

- **Data from a PBC Supergroup analysis supports the use of the Phase 3 (POISE) ALP/bilirubin endpoint as a surrogate for clinical outcomes.** More specifically, ALP < 1.67x upper limit of normal (ULN) and normal bilirubin levels was highly statistically predictive of liver-transplant free survival in Primary Biliary Cirrhosis (PBC) patients. The risk of adverse clinical outcomes increases from 2-10x in patients with ALP ≥ 1.67x ULN and/or abnormal bilirubin levels compared to patients with biochemical values below them ($p < 0.001$). Furthermore, independent assessments of ALP and bilirubin were each predictive of adverse outcomes. The analysis was conducted by the Global PBC Study Group (PBC Supergroup) and reflects pooled data from about 2,100 patients across 15 academic medical centers in eight countries. Although expected, we believe these data are important as they confirm the validity of the primary endpoint (ALP < 1.67x upper limit of normal and normal bilirubin) being used in the ongoing Phase 3 POISE trial. In our view, the positive results provide solid data that the FDA can use to justify acceptance of using ALP/bilirubin response as a surrogate endpoint for clinical outcomes. We note that, the EMA has already deemed the Phase 3 POISE trial design as acceptable.

- **The PBC Supergroup analysis will be presented at the European Association for the Study of the Liver (EASL; April 24-28; Amsterdam).** The abstract (Abstract 941) is titled "Alkaline Phosphatase Values are a Surrogate Marker in Prediction of Transplant Free Survival in Patients with Primary Biliary Cirrhosis – an International, Collaborative Analysis" and will be presented during the *Autoimmune and Chronic Cholestatic Liver Diseases* poster session (P02-12) on April 26th. The abstract is available via Intercept's website (www.interceptpharma.com) under "Upcoming Events."

- **We estimate the following near and longer-term milestones for Intercept:**

Expected Date	Event
April 25-28	Presentation of initial PBC biomarker "supergroup" analysis at EASL (Amsterdam)
May 17-19	Topline results from Phase 2a OCA trial in bile acid diarrhea (OBADIAH) at DDW (Orlando, FL)
H2:2013	Additional data presented on complete 4,000+ patient "supergroup" analysis of PBC biomarkers
H2:2013	Start of Phase 3 OCA confirmatory outcomes study in PBC
FY:2013	Additional data from OCA Phase 2a study in portal hypertension (PESTO)
Q2:2014	**Topline data from pivotal Phase 3 POISE study of OCA in PBC**
Q4:2014	Topline data from Phase 2 FLINT study of OCA in NASH
Mid:2015	Potential US Approval of OCA for the treatment of PBC

- **Reiterate OUPTERFORM rating and $46 fair value.** Our fair value is calculated by applying a 30% annual discount to out peak worldwide sales estimates for ICPT's drug candidates, incorporating a 1-10x multiple based on stage of clinical development. Our sum-of-parts valuation includes the contribution of OCA in PBC, portal hypertension, and NASH. Given the evolving outlook regarding key variables such as pricing, target patient population and market size, and clinical profile of OCA in the different indications, we see room for additional upside beyond our fair value.

INVESTMENT THESIS

Intercept Pharmaceuticals is an emerging biopharmaceutical company developing small molecule drug treatments for significant unmet medical needs in orphan and other chronic liver diseases by leveraging its expertise and intellectual property in bile acid chemistry. We maintain an optimistic outlook for ICPT's attractive risk/reward profile as: 1) clinical success is likely; 2) regulatory risk is reasonable and continues to decline; and 3) commercial risk is below average.

Intercept's lead drug, obeticholic acid or OCA, has generated impressive efficacy data in two Phase 2 studies for the treatment of Primary Biliary Cirrhosis (PBC). In short, we believe OCA possesses one of the more clinically-derisked Phase 2 datasets among biotech drugs in development. PBC is a relatively well defined orphan market with a clear unmet medical need. Should OCA be approved, we believe the barriers to commercial adoption will be relatively low as patients are already identified and receiving treatment. Moreover, we see upside potential to our estimates of the eligible patient population as well as pricing, which may err on the conservative side. We see a high chance of success for Intercept's ongoing Phase 3 POISE study in PBC, with data expected in Q2:2014. Meanwhile, we see significant upside potential beyond PBC from follow-on indications such as portal hypertension, NASH and bile-acid diarrhea.

VALUATION AND RISKS

Our fair value of $46 is calculated using a sum-of-parts analysis, applying a 30% annual discount to our peak worldwide sales estimates for ICPT's drug candidates, incorporating a 1-10x multiple based on stage of clinical development. Our sum-of-parts valuation includes the contribution of OCA for the treatment of PBC, portal hypertension and NASH. Given the evolving outlook regarding key variables such as pricing, market size and clinical profile of OCA in the different indications, we see room for additional upside beyond our fair value.

Risks to the attainment of our fair value include: Intercept's products obtain disappointing clinical trial results and/or fail to gain regulatory approval; Intercept is unable to pursue accelerated approval for OCA in the US or faces lengthy regulatory delays; Intercept or a partner fails to effectively commercialize its drug products due to unenthusiastic physician response or superior clinical results are obtained by a third-party competitor; unexpected safety problems emerge with Intercept's drug products; Intercept is unable to raise additional capital, if necessary, at terms favorable to shareholders.

We use multiples to account for clinical and regulatory risk at various stages of development.		Today: 4/8/13	Stock	MktCap ($000)	Upside
NOVEL DRUGS		Wedbush Fair Value for ICPT	$46.38	$856,902	30%
1: In preclinical testing	6: In Pivotal Trial	Full Pipeline Value:	$47.76	$869,054	
2: Passed preclinical	7: Pivotal data	Net Cash:	$6.06	$110,194	
3: IND filed	8: Regulatory review	ICPT Total Value:	$53.81	$979,248	
4: Phase I data	9: Approved	Current ICPT Stock:	$35.58	$647,460	
5: Phase II data	10: Launched	ICPT Diluted Shares Outstanding (000s):	18,197		

Intercept Pipeline Valuation

Product		Indication	Eligible # Annual WW Treatments Est	Pricing $ per Patient per Year Est/Actual	Peak Penetration Est	Gross WW Peak Sales Est ($000)	ICPT Net Peak Revs Est WW ($000)	Estimated Launch	Multiple	Annual Discount Rate	Wedbush MktCap Fair Value ($000)	Wedbush Stock Fair Value
FXR Agonist	OCA (INT-747)	PBC	58,200	$18,844	32%	$391,323	$391,323	4/1/2015	6	30%	$488,890	$26.87
FXR Agonist	OCA (INT-747)	Portal Hypertension	800,000	$4,625	17%	$632,000	$632,000	7/1/2017	5	30%	$280,325	$15.40
FXR Agonist	OCA (INT-747)	NASH	7,225,000	$2,340	2%	$321,250	$321,250	7/1/2018	4	30%	$87,687	$4.82
FXR/TGR5 Agonist	INT-767	Fibrosis	2,750,000	$2,500	5%	$343,750	$343,750	1/1/2021	1	30%	$12,152	$0.67

Source: Company reports, Wedbush Securities research

Analyst Certification
I, Liana Moussatos, Ph.D., Richard Lau, certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).*

Rating Distribution (as of December 31, 2012)	**Investment Banking Relationships (as of December 31, 2012)**
Outperform:53% Neutral: 42% Underperform: 5%	Outperform:14% Neutral: 2% Underperform: 0%

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Wedbush Equity Research Disclosures as of April 8, 2013

Company	Disclosure
Intercept Pharmaceuticals	1,3,4,5,7

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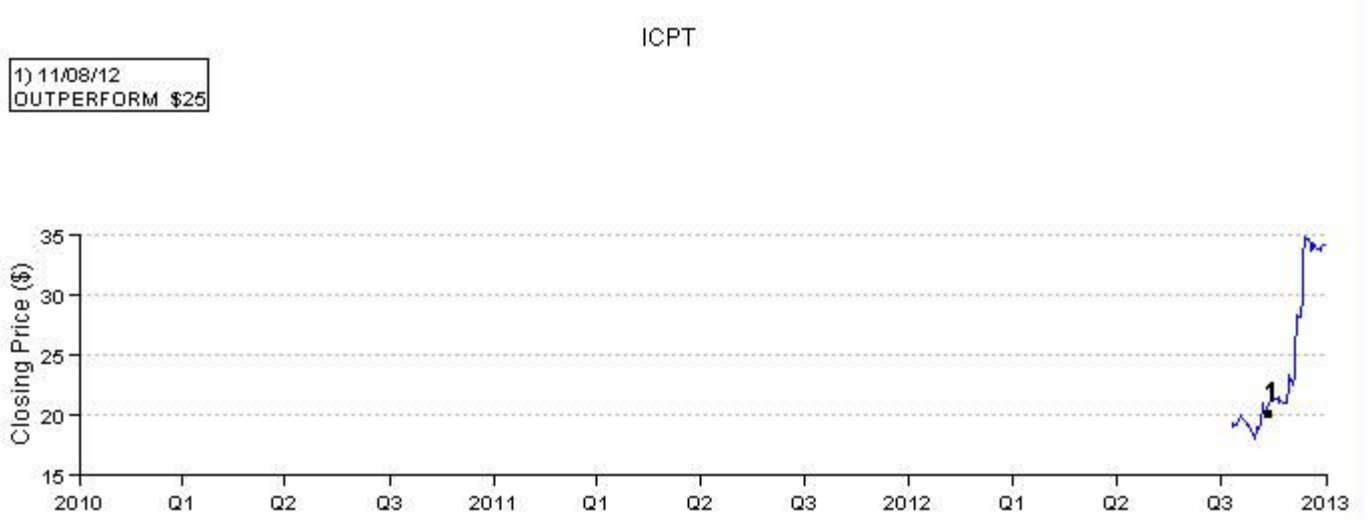

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