

## Intercept Pharmaceuticals (ICPT)

### Q4:12 Recap; OCA Clinical Progress Flowing Along Nicely; Reiterate OUTPERFORM

March 18, 2013

Price  
**\$36.48**

Rating  
**OUTPERFORM**

Fair Value Estimate  
**\$46**

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- **Q4 financials uneventful, impacted by non-cash item.** Intercept reported Q4:12 revenue and EPS of \$0.4MM and (\$2.02), compared to our estimates of \$0.4MM and (\$0.33) and consensus of \$1.1MM and (\$0.34). The greater-than-expected EPS loss was primarily due to an accounting artifact concerning the revaluation of warrants (no cash impact). Given the company's developmental status, we view the quarterly financial results to be of secondary importance to investors. More importantly, Intercept ended 2012 with \$110.2MM in cash and equivalents, which we believe provides cash runway well beyond key inflection points for OCA expected in 2014.
- **Positive updates on clinical and regulatory fronts for PBC.** During the call, management highlighted two key updates regarding the Phase 3 program of OCA in PBC: (1) the initial ~2,100 patient data set from the "supergroup" analysis positively supports the use of the Phase 3 ALP/bilirubin endpoint as a surrogate for clinical outcomes (to be presented at EASL in late April), and (2) in the ongoing POISE study, the current (blinded) dropout rate due to pruritus is significantly lower than what was seen in Phase 2, with all patients now having reached at least 3 months on study.
- **Expect a growing appreciation for potential indications beyond PBC.** The company continues to increase the spotlight on follow-on indications, providing an in-depth review of OCA's clinical progress in portal hypertension, NASH, and bile-acid diarrhea during the call. From our end, we have noticed increasing attention being paid to these indications by investors in recent weeks, and believe their potential contributions to valuation are not yet fully realized in ICPT's current share price.
- **Reiterate OUTPERFORM rating and \$46 fair value.** Our fair value is calculated by 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 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.

#### Company Information

Shares Outst (M)	18.2
Market Cap (M)	\$663.8
52-Wk Range	\$17.96 - \$42.67
Book Value/sh	\$3.62
Cash/sh	\$6.06
Enterprise Value (M)	\$553.6
LT Debt/Cap %	0.0%

#### Company Description

Intercept Pharmaceuticals is an emerging biopharmaceutical company specializing in the development of bile acid therapies. The company's lead drug, Obeticholic Acid (OCA), is currently in Phase III development for the treatment of Primary Biliary Cirrhosis (PBC).

FYE Dec	2011A	2012A			2013E		
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	\$0.0A	\$0.8A		--	\$0.4E		--
Q2 Jun	0.0A	0.8A		--	0.4E		--
Q3 Sep	0.0A	0.5A		--	0.4E		--
Q4 Dec	0.0A	0.4A		1.1A	0.4E		--
Year*	<b>\$1.8A</b>	<b>\$2.4A</b>		<b>\$4.0A</b>	<b>\$1.6E</b>		<b>\$4.8E</b>
Change	n/a	n/a			n/a		
	2011A	2012A			2013E		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	\$0.00A	(\$1.03)A		--	(\$0.65)E	(\$0.40)E	--
Q2 Jun	0.00A	(1.75)A		--	(0.65)E	(0.39)E	--
Q3 Sep	0.00A	(1.86)A		--	(0.65)E	(0.39)E	--
Q4 Dec	0.00A	(2.02)A	(0.33)A	(0.34)A	(0.64)E	(0.39)E	--
Year*	<b>(\$4.73)A</b>	<b>(\$7.36)A</b>	<b>(\$3.15)A</b>	<b>(\$3.17)A</b>	<b>(\$2.59)E</b>	<b>(\$1.57)E</b>	<b>(\$1.56)E</b>
P/E		nm			nm		
Change	n/a	n/a			n/a		

Consensus estimates are from Thomson First Call.

\* Numbers may not add up due to rounding.



Source: Thomson Reuters

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## 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.

## NEAR-TERM MILESTONES

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)
<b>Q2:2014</b>	<b>Topline data from pivotal Phase 3 POISE study of OCA in PBC</b>
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

## 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: 3/18/13 Stock MktCap (\$000) Upside								
NOVEL DRUGS				Wedbush Fair Value for ICPT \$46.38 \$844,064 27%								
1: In preclinical testing		6: In Pivotal Trial		Full Pipeline Value: \$31.87 \$579,909								
2: Passed preclinical		7: Pivotal data		Net Cash: \$6.06 \$110,194								
3: IND filed		8: Regulatory review		ICPT Total Value: \$37.92 \$690,103								
4: Phase I data		9: Approved		Current ICPT Stock: \$36.48 \$663,838								
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%	\$481,566	\$26.46
FXR Agonist	OCA (INT-747)	Portal Hypertension	800,000	\$4,625	17%	\$632,000	\$632,000	7/1/2017	5	30%	\$276,125	\$15.17
FXR Agonist	OCA (INT-747)	NASH	7,225,000	\$2,340	2%	\$321,250	\$321,250	7/1/2018	4	30%	\$86,373	\$4.75
FXR/TGR5 Agonist	INT-767	Fibrosis	2,750,000	\$2,500	5%	\$343,750	\$343,750	1/1/2021	1	30%	\$11,970	\$0.66

Source: Company reports, Wedbush Securities research

**Intercept Pharmaceuticals (NASDAQ: ICPT)**

**Historical and Projected Income Statement**

(In thousands except per share data)

(Fiscal Year Ends on December 31)

Wedbush PacGrow LifeSciences

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	2011A	2012A					2013E					2014E	2015E
	FY:11A	Q1A	Q2A	Q3A	Q4A	FY:12A	Q1	Q2	Q3	Q4	FY:13E	FY:14E	FY:15E
<b>Revenues:</b>													
Revenues/Royalties on Product Sales	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 26,775
OCA for Primary Biliary Cirrhosis	-	-	-	-	-	-	-	-	-	-	-	-	26,775
OCA for NASH	-	-	-	-	-	-	-	-	-	-	-	-	-
Collaboration Revenue	\$ 1,805	\$ 759	\$ 759	\$ 523	\$ 405	\$ 2,446	\$ 400	\$ 400	\$ 400	\$ 400	\$ 1,600	\$ 1,600	\$ 1,600
Licensing revenue and Milestones	1,805	759	759	523	405	2,446	400	400	400	400	1,600	1,600	1,600
<b>Total Revenues</b>	<b>\$ 1,805</b>	<b>\$ 759</b>	<b>\$ 759</b>	<b>\$ 523</b>	<b>\$ 405</b>	<b>\$ 2,446</b>	<b>\$ 400</b>	<b>\$ 400</b>	<b>\$ 400</b>	<b>\$ 400</b>	<b>\$ 1,600</b>	<b>\$ 1,600</b>	<b>\$ 28,375</b>
<b>Operating Expenses</b>													
Research and Development	11,426	3,060	5,018	3,318	4,787	16,183	5,500	5,500	5,500	5,500	22,000	26,000	20,000
Sales, General and Administrative	4,209	1,059	944	991	2,183	5,177	2,450	2,450	2,450	2,450	9,800	14,000	24,000
Other	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Operating Expenses</b>	<b>15,636</b>	<b>4,119</b>	<b>5,962</b>	<b>4,309</b>	<b>6,970</b>	<b>21,360</b>	<b>7,950</b>	<b>7,950</b>	<b>7,950</b>	<b>7,950</b>	<b>31,800</b>	<b>40,000</b>	<b>45,787</b>
Operating Income (Loss)	(13,830)	(3,360)	(5,203)	(3,786)	(6,565)	(18,914)	(7,550)	(7,550)	(7,550)	(7,550)	(30,200)	(38,400)	(17,411)
Interest and dividend income	61	10	7	13	61	92	18	27	25	23	93	68	27
Interest (expense)	(13)	(7)	(0)	3	-	(4)	-	-	-	-	-	-	-
Revaluation of warrants	1,045	678	302	(1,418)	(24,187)	(24,625)	(2,500)	(2,500)	(2,500)	(2,500)	(10,000)	-	-
Other income (expense)	-	-	(192)	-	-	(192)	-	-	-	-	-	-	-
<b>Income Before Income Taxes</b>	<b>(12,738)</b>	<b>(2,680)</b>	<b>(5,086)</b>	<b>(5,187)</b>	<b>(30,691)</b>	<b>(43,644)</b>	<b>(10,032)</b>	<b>(10,023)</b>	<b>(10,025)</b>	<b>(10,027)</b>	<b>(40,107)</b>	<b>(38,332)</b>	<b>(17,384)</b>
Other comprehensive income (loss)	(3,000)	(750)	(750)	(1,000)	(130)	(2,630)	-	-	-	-	-	-	-
Provision for Income Taxes (benefit)	-	-	-	-	-	-	-	-	-	-	-	-	484
<b>Net Income (Loss)</b>	<b>\$ (15,738)</b>	<b>\$ (3,430)</b>	<b>\$ (5,836)</b>	<b>\$ (6,187)</b>	<b>\$ (30,821)</b>	<b>\$ (46,274)</b>	<b>\$ (10,032)</b>	<b>\$ (10,023)</b>	<b>\$ (10,025)</b>	<b>\$ (10,027)</b>	<b>\$ (40,107)</b>	<b>\$ (38,332)</b>	<b>\$ (17,868)</b>
EPS ( Basic & Diluted; Pro forma)	(4.73)	(1.03)	(1.75)	(1.86)	(2.02)	(7.36)	(0.65)	(0.65)	(0.65)	(0.64)	(2.59)	(2.41)	(1.07)
Shares Outstanding (Basic)	3,330	3,330	3,330	3,330	15,223	6,283	15,323	15,423	15,523	15,623	15,473	15,873	16,648
Fully Diluted Shares Outstanding					18,197		18,297	18,397	18,497	18,597	18,447	18,847	19,247
Net Cash	\$17,908		\$10,026	\$36,049	\$110,272	\$110,272	\$103,234	\$95,235	\$87,230	\$79,219	\$79,219	\$38,161	\$16,148
Change in Cash (Burn)	\$2,412					\$92,363					(\$31,053)	(\$41,058)	(\$22,013)

Source: Company reports, Wedbush Securities research.

## Analyst Biography

Mr. Felt is a Research Analyst covering Biopharmaceutical and Medical Technology companies. He previously served as a senior associate on the healthcare team at Wedbush PacGrow Lifesciences from 2009-2012. Prior to joining Wedbush, Mr. Felt worked for two years as an associate analyst covering the biotechnology sector and one year in industry as a clinical research assistant.

Mr. Felt holds a B.S. in Biomedical Engineering from Washington University and a Master's degree in Biotechnology from Columbia University.

## Analyst Certification

I, Akiva Felt, Liana Moussatos, Ph.D., 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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Outperform: Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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## Wedbush Equity Research Disclosures as of March 18, 2013

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

## Research Disclosure Legend

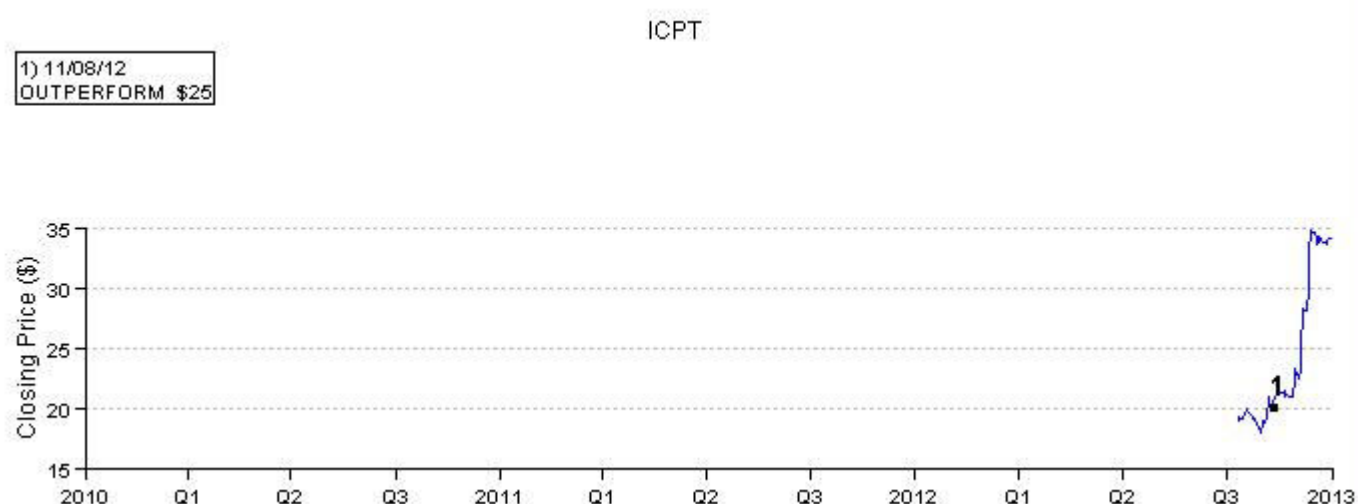
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