

April 21, 2013

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Intercept Pharmaceuticals (ICPT - OUTPERFORM): Bear Thesis Oversights Result In No Change To Our Estimates Or Fair Value; Reiterate OUTPERFORM And \$56 FV

Price: \$31.34

Fair Value Estimate: \$56

- **Recent bear arguments may have caused recent unwarranted weakness in ICPT value, in our view.** Bear arguments have focused on the use of generic fibrates as a second line (off-label) treatment for PBC on top of Urso and that their use suggests consensus estimates and valuations are too high. While we accept that some PBC physicians may be using fibrates off-label, the data cited is from pilot studies, which are insufficient to characterize the fibrate clinical profile in PBC patients.
- **The durability of fibrates in PBC may also limit use.** Because the cited data was limited to small pilot studies, we do not know how durable the combination of Urso and a fibrate would be—leaving open the use of a branded OCA as third line when efficacy fails or when safety issues arise.
- **Fibrates are contraindicated in PBC.** There are reports that fibrates may be contraindicated in PBC patients as they may ELEVATE liver enzymes—including the fibrate (bezafibrate) being tested in the ongoing French Phase 3 trial (NCT01654731). In fact, the drug label for bezafibrate (http://ams.body1.com/stellartribute/pdf_docs/Bezaliip%20Prescribing%20Info%20Combined%20Summary.pdf) states that the drug is CONTRAINDICATED in PBC patients. Another common fibrate has also been observed to cause elevations in liver enzymes (fenofibrate: <http://www.rxabbvie.com/pdf/tricorpi.pdf>; http://www.rxabbvie.com/pdf/trilipix_pi.pdf). So we believe the potential impact of fibrates over OCA due to increased pruritus affecting tolerability is likely to be tempered by fibrate safety issues counteracting their potential efficacy.
- **Fibrate use will also be limited to off-label.** Use of fibrates will also be limited by lack of marketing since it is unlikely that a generic company will complete the necessary clinical program to obtain approval for a fibrate to treat PBC.
- **Finally, there was a criticism that analysts' have not incorporated potential use of fibrates in their estimates and valuations.** We remind investors that for orphan diseases, high prices for drugs only require a small number of patients in order to achieve multi-hundred millions in sales. We refer investors to BioMarin's (BMRN:Nasdaq; NEUTRAL,) Naglazyme which achieved sales of about \$257 million in 2012 for an orphan disease in which there are only about 1100 patients worldwide. We disagree that off-label use of a generic fibrate would make it impossible for Intercept to charge orphan drug prices for OCA (especially since elevations in liver enzymes could counteract Urso's efficacy over time). We remind investors that another orphan disease, pulmonary arterial hypertension (PAH), first tests newly diagnosed patients to see whether they respond to generic calcium channel blockers and we have seen little impact of a generic Flolan on branded parenteral PAH drug sales. As we have seen in PAH, we believe there is room for generic Urso, generic fibrates and branded OCA for PBC. Our recently revised estimates and increased valuation is based on OCA achieving peak penetration in about 7,180 PBC patients worldwide with a weighted average price of about \$67,400 per patient per year—and we believe there is upside to this pricing for an orphan drug. This translates to about \$500 million in gross peak annual worldwide sales—which we remain comfortable even with potential off-label use of generic fibrates—especially given their safety profile.
- **Reiterate OUTPERFORM rating and \$56 fair value.** Our fair value is calculated by applying a 30% annual discount to our net peak WW revenues for each drug/indication and applying a 1-10x multiple depending on stage of development to reflect risk. Each combination is added in a sum-of-parts to calculate fair value for ICPT.

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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 26	Presentation of initial PBC biomarker "supergroup" analysis (Abs941 EASL 4/24-28 Amsterdam)
May 18-21	Topline results from Phase 2a OCA trial in bile acid diarrhea (OBADIAH) (DDW 5/18-21 Orlando)
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

VALUATION AND RISKS

Our fair value of \$56 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: 4/19/13 Stock MktCap (\$000) Upside								
				Wedbush Fair Value for ICPT \$55.78 \$1,015,075 78%								
1: In preclinical testing		6: Phase III testing 7: Phase III data (positive) 8: Regulatory review 9: Approved 10: Launched		Full Pipeline Value:				\$56.32	\$1,024,865			
2: Passed preclinical				Net Cash:				\$6.06	\$110,194			
3: IND filed				ICPT Total Value:				\$62.38	\$1,135,059			
4: Phase I data (positive)				Current ICPT Stock:				\$31.34	\$570,303			
5: Phase II data (positive)				ICPT Diluted Shares Outstanding (000s):				18,197				
Intercept Pipeline Valuation												
Product		Indication	Eligible # Annual WW Treatable 2nd Line Patients Est	Pricing (WW Wtd Avg \$USD / Patient / Year)	WW Wtd Avg Peak Penetration Est	Gross WW Peak Sales Est (\$000)	ICPT Net Peak Revs Est WW + Upfront & Miles (\$000)	1st Estimated Launch	Multiple	Annual Discount Rate	Wedbush MktCap Fair Value (\$000)	Wedbush Stock Fair Value
FXR Agonist	OCA (INT-747)	PBC	18,040	\$67,400	40%	\$517,440	\$586,544	4/1/2015	6	30%	\$738,603	\$40.59
FXR Agonist	OCA (INT-747)	Portal Hypertension	432,000	\$12,008	11%	\$684,000	\$422,100	7/1/2017	5	30%	\$188,710	\$10.37
FXR Agonist	OCA (INT-747)	NASH	10,440,000	\$2,047	2%	\$360,000	\$318,995	7/1/2018	4	30%	\$87,763	\$4.82
FXR Agonist	OCA (INT-747)	Bile Acid Diarrhea	3,960,000	\$1,915	12%	\$697,500	\$326,500	7/1/2017	3	30%	\$87,582	\$4.81
TGR5 Agonist	INT-777	Type II Diabetes	34,400,000	\$3,844	1%	\$2,437,000	\$181,850	6/1/2019	1	30%	\$9,831	\$0.54
FXR/TGR5 Agonist	INT-767	Fibrosis	13,200,000	\$1,915	1%	\$421,953	\$181,098	6/1/2019	1	30%	\$9,790	\$0.54

Source: Wedbush Securities

Covered Companies Mentioned in this Report

Company	Ticker	Current Price	Rating	Fair Value
BioMarin Pharmaceuticals	BMRN	65.44	NEUTRAL	\$54

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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	2012A	2013E					2014E	2015E	2016E	2017E
	FY:12A	Q1	Q2	Q3	Q4	FY:13E	FY:14E	FY:15E	FY:16E	FY:17E
Gross Product Sales:										
OCA (INT-747)								30,314	105,097	221,472
PBC								-	-	6,696
Portal Hypertension								-	-	14,062
Bile Acid Diarrhea								-	-	-
Revenues/Royalties on Product Sales	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 30,314	\$ 104,236	\$ 224,671
OCA (INT-747)								30,314	104,236	214,037
PBC	-	-	-	-	-	-	-	-	-	6,696
Portal Hypertension	-	-	-	-	-	-	-	-	-	3,937
Bile Acid Diarrhea										
Collaboration Revenue	\$ 2,446	\$ 400	\$ 400	\$ 400	\$ 400	\$ 1,600	\$ 1,600	\$ 1,600	\$ 1,600	\$ 1,600
Total Revenues	\$ 2,446	\$ 400	\$ 400	\$ 400	\$ 400	\$ 1,600	\$ 1,600	\$ 31,914	\$ 105,836	\$ 226,271
Operating Expenses										
Cost of Goods								1,819	6,240	13,125
Research and Development	16,183	4,978	5,277	5,647	6,098	22,001	28,996	34,292	40,116	46,930
Sales, General and Administrative	5,177	2,292	2,407	2,527	2,653	9,879	12,312	28,049	43,372	50,739
Other	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	21,360	7,271	7,684	8,174	8,752	31,880	41,308	64,159	89,728	110,794
Operating Income (Loss)	(18,914)	(6,871)	(7,284)	(7,774)	(8,352)	(30,280)	(39,708)	(32,245)	16,108	115,476
Interest and dividend income	92	18	27	25	23	93	68	26	12	12
Interest (expense)	(4)	-	-	-	-	-	-	-	-	-
Revaluation of warrants	(24,625)	(2,500)	(2,500)	(2,500)	(2,500)	(10,000)	-	-	-	-
Other income (expense)	(192)	-	-	-	-	-	-	-	-	-
Income Before Income Taxes	(43,644)	(9,352)	(9,757)	(10,249)	(10,829)	(40,187)	(39,640)	(32,219)	16,120	115,488
Other comprehensive income (loss)	(2,630)	-	-	-	-	-	-	-	-	-
Provision for Income Taxes (benefit)	-	-	-	-	-	-	-	-	2,819	25,280
Net Income (Loss)	\$ (46,274)	\$ (9,352)	\$ (9,757)	\$ (10,249)	\$ (10,829)	\$ (40,187)	\$ (39,640)	\$ (32,219)	\$ 13,301	\$ 90,209
EPS (Basic & Diluted; Pro forma)	(7.36)	(0.61)	(0.63)	(0.66)	(0.69)	(2.60)	(2.50)	(1.94)	0.68	4.50
Shares Outstanding (Basic)	6,283	15,323	15,423	15,523	15,623	15,473	15,873	16,648	17,648	18,648
Fully Diluted Shares Outstanding		18,297	18,397	18,497	18,597	18,447	18,847	19,247	19,647	20,047
Net Cash	\$110,272	\$103,448	\$95,998	\$88,105	\$79,689	\$79,689	\$36,641	\$2,610	\$14,844	\$104,179
Change in Cash (Burn)	\$92,363					(\$30,583)	(\$43,048)	(\$34,031)	\$12,235	\$89,334

Margins:	FY:12A	FY:13E	FY:14E	FY:15E	FY:16E	FY:17E
COGs %	N/A	N/A	N/A	6%	6%	6%
Gross Margin	N/A	N/A	N/A	94%	94%	94%
Operating Margin	-773%	-1718%	-1821%	-101%	15%	51%
Net Income	-1892%	-2338%	-2439%	-101%	13%	40%

Growth Rates (y/y):										
Revenue	135%	53%	53%	76%	99%	65%	100%	1995%	332%	214%
Operating Income	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	717%
Income Before Taxes	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	716%
Net Income	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	N/M	678%

Source: Company reports, Wedbush Securities research.

Analyst Certification

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Neutral: Expect the total return of the stock to perform in-line with 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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Outperform: 51%	Outperform: 18%
Neutral: 44%	Neutral: 2%
Underperform: 5%	Underperform: 0%

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

Research Disclosure Legend

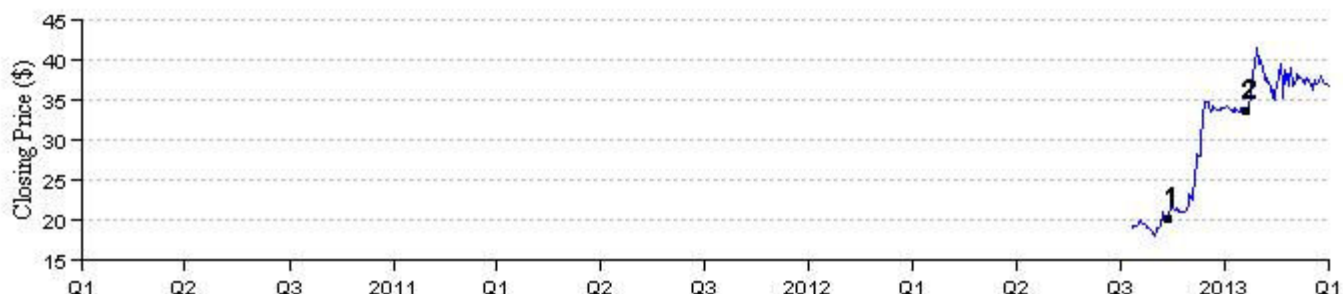
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ICPT

1) 11/08/12	2) 01/16/13
OUTPERFORM \$25	OUTPERFORM \$46



BMRN

1) 04/30/10	2) 07/22/10	3) 10/25/10	4) 11/05/10	5) 11/19/10	6) 11/24/10	7) 01/07/11	8) 02/16/11	9) 07/31/11
NEUTRAL \$24	NEUTRAL \$26	NEUTRAL \$27	NEUTRAL \$26	NEUTRAL \$27	NEUTRAL	NEUTRAL \$27	NEUTRAL \$30	NEUTRAL \$31
10) 10/25/11	11) 10/31/11	12) 01/04/12	13) 04/27/12	14) 06/08/12	15) 07/29/12	16) 09/26/12	17) 10/22/12	
NEUTRAL \$33	NEUTRAL \$34	NEUTRAL \$35	NEUTRAL \$36	NEUTRAL \$35	NEUTRAL \$37	NEUTRAL \$39	NEUTRAL \$41	
18) 11/05/12	19) 02/19/13	20) 03/19/13						
NEUTRAL \$46	NEUTRAL \$50	NEUTRAL \$53						



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