Intercept Pharmaceuticals (ICPT)

OCA Successful In Initial Phase 2a For Primary Bile Acid Diarrhea; Reiterate OUTPERFORM And Increase FV to $65

- **Obeticholic acid (OCA) treatment achieved a statistically significant (p=0.007) increase in fibroblast growth factor 19 (FGF19) and improvement in clinical symptoms.** Primary Bile Acid Diarrhea (PBAD) is a chronic diarrhea caused by excessive bile acid production and is estimated to affect over 3 million patients in the US. Low levels of FGF19 cause excess bile acids to enter the gut and overstimulate intestinal secretions, leading to diarrhea. The Phase 2a OBADIAH trial tested 25 mg OCA once daily. OCA increased FGF19 from 133 to 237 pg/ml at two weeks, which was associated with improved stool type (p=0.05), stool frequency (p=0.03), and stool index (p=0.005). Abdominal pain, urgency and bloating also trended in favor of OCA treatment. There were no adverse events of concern. If approved, we project gross peak sales in the U.S. could reach over $390 million and over $690 million worldwide.
- **We see cash runway to mid-2015 covering six transforming milestones.** Intercept ended Q1 with about $110.2 million in cash, cash equivalents, and short-term investments, which the company previously projected to last into mid-2015. Key milestones include: (1) Q4: full "supergroup" data; (2) YE: full Phase 2a release for OCA treatment of portal hypertension (PESTO); (3) YE: initiation of the confirmatory OCA/PBC Phase 3 trial (indicating FDA acceptance of ALP endpoint); (4) Q2:14: initial results from the pivotal Phase 3 testing OCA treatment of PBC (NCT01473524); (5) Q4:14: Initial results from FLINT Phase 2 trial testing OCA treatment of NASH as well as (6) NDA and MAA filings for OCA/PBC.
- **Next (Q4):** full supergroup data, full Phase 2a results for OCA treatment of portal hypertension, and initiation of confirmatory trial testing OCA treatment of PBC.
- **Reiterating OUTPERFORM rating, but increasing fair value to $65 due to successful clinical proof-of-concept for bile acid diarrhea.** Due to the success in Phase 2a using OCA to treat bile acid diarrhea, we have included an additional $8 per share into our fair value for ICPT. This plus time value and rounding increased our fair value to $65 from $56. 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.

FYE Dec	2012A	2013E			2014E		
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	$0.8A	$0.4E		$0.5E	$0.4E		$0.4E
Q2 Jun	0.8A	0.4E		0.5E	0.4E		0.4E
Q3 Sep	0.5A	0.4E		0.5E	0.4E		0.4E
Q4 Dec	0.4A	0.4E		0.5E	0.4E		0.4E
Year*	**$2.4A**	**$1.6E**		**$2.0E**	**$1.6E**		**$2.4E**
Change	n/a	n/a			n/a		
	2012A	2013E			2014E		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	($1.03)A	($0.62)E		($0.44)E	($0.50)E		($0.50)E
Q2 Jun	(1.75)A	(0.56)E		(0.44)E	(0.54)E		(0.54)E
Q3 Sep	(1.86)A	(0.59)E		(0.54)E	(0.57)E		(0.57)E
Q4 Dec	(2.02)A	(0.62)E		(0.59)E	(0.60)E		(0.60)E
Year*	**($7.36)A**	**($2.38)E**		**($2.03)E**	**($2.21)E**		**($2.30)E**
P/E	NM	NM			NM		
Change	NA	NA			NA		

Consensus estimates are from Thomson First Call.
** Numbers may not add up due to rounding.*

May 20, 2013

Price
$33.22

Rating
OUTPERFORM

Fair Value Estimate
$65 **(from $56)**

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Company Information

Shares Outst (M)	18.2
Market Cap (M)	$604.5
52-Wk Range	$17.96 - $42.67
Book Value/sh	$3.60
Cash/sh	$6.06
Enterprise Value (M)	$494.3
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).

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 many patients have been identified and are receiving treatment. Moreover, we see upside potential to our estimates of the eligible patient population as well as pricing. 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.

Obeticholic acid (OCA) treatment achieved a statistically significant (p=0.007) increase in fibroblast growth factor 19 (FGF19) and improvement in clinical symptoms. Primary Bile Acid Diarrhea (PBAD) is a chronic diarrhea caused by excessive bile acid production and estimated to affect over 3 million patients in the US. Low levels of FGF19 cause excess bile acids to enter the gut and overstimulate intestinal secretions, leading to diarrhea. Current treatments with bile acid sequestrants (colestyramine, colesevelam) have limited long-term compliance and may cause undesirable side effects such as bloating and may bind other drugs and vitamins. OCA mechanism of action as a FXR agonist also stimulates FGF19 to inhibit excessive bile acid synthesis in the liver and reduce GI secretions.

The Phase 2a OBADIAH trial tested 25 mg OCA once daily in an uncontrolled, open label proof-of-concept design in patients with chronic diarrhea, type 1 bile acid malabsorption and type 2 bile acid malabsorption. The primary endpoint is fasting FGF19 levels and secondary endpoints include changes in FGF19 during the day, levels of 7α-hydroxy-4-cholesten-3-one, total bile acids, symptom response, and tolerability.

OCA increased FGF19 from 133 to 237 pg/ml at two weeks which was associated with improved stool type (p=0.05), stool frequency (p=0.03), and stool index (p=0.005). Abdominal pain, urgency and bloating also trended in favor of OCA treatment. There were no adverse events of concern. If approved, we project gross peak sales in the US could reach over $390 million and over $690 million worldwide.

FIGURE 1 MODEL

Intercept Pharmaceuticals (NASDAQ: ICPT)

Historical and Projected Income Statement

(In thousands except per share data)

(Fiscal Year Ends on December 31)

Wedbush PacGrow LifeSciences

Liana Moussatos, Ph.D.

Richard Lau

	2012A	2013E					2014E	2015E	2016E	2017E
	FY:12A	Q1A	Q2	Q3	Q4	FY:13E	FY:14E	FY:15E	FY:16E	FY:17E
Gross Product Sales:										
OCA (INT-747)										
PBC								*30,314*	*105,097*	*221,472*
Portal Hypertension								-	-	*6,696*
Bile Acid Diarrhea								-	-	*14,062*
Revenues/Royalties on Product Sales	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 30,314	$ 104,236	$ 224,671
OCA (INT-747)										
PBC	-	-	-	-	-	-	-	*30,314*	*104,236*	*214,037*
Portal Hypertension	-	-	-	-	-	-	-	-	-	*6,696*
Bile Acid Diarrhea								-	-	*3,937*
Licensing Revenue	$ 2,446	$ 405	$ 400	$ 400	$ 400	$ 1,605	$ 1,600	$ 1,600	$ 1,600	$ 1,600
Total Revenues	**$ 2,446**	**$ 405**	**$ 400**	**$ 400**	**$ 400**	**$ 1,605**	**$ 1,600**	**$ 31,914**	**$ 105,836**	**$ 226,271**
Operating Expenses										
Cost of Goods								1,819	6,240	13,125
Research and Development	16,183	4,833	5,123	5,481	5,920	21,356	28,146	33,286	38,940	45,555
Sales, General and Administrative	5,177	2,397	2,517	2,643	2,775	10,331	12,875	29,330	45,353	53,056
Other	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	**21,360**	**7,229**	**7,639**	**8,124**	**8,694**	**31,686**	**41,021**	**64,435**	**90,534**	**111,737**
Operating Income (Loss)	(18,914)	(6,824)	(7,239)	(7,724)	(8,294)	(30,081)	(39,421)	(32,521)	15,303	114,534
Interest and dividend income	82	-	19	19	25	63	78	37	23	23
Interest (expense)	3	-	-	-	-	-	-	-	-	-
Revaluation of warrants	(24,625)	(3,683)	(2,500)	(2,500)	(2,500)	(11,183)	-	-	-	-
Other income (expense)	(189)	296	296	296	296	1,185	1,185	1,185	1,185	1,185
Income Before Income Taxes	**(43,644)**	**(10,210)**	**(9,423)**	**(9,909)**	**(10,473)**	**(40,015)**	**(38,157)**	**(31,299)**	**16,512**	**115,743**
Other comprehensive income (loss)	(2,630)	-	-	-	-	-	-	-	-	-
Provision for Income Taxes (benefit)	-	-	-	-	-	-	-	-	2,861	25,327
Net Income (Loss)	**$ (46,274)**	**$ (10,210)**	**$ (9,423)**	**$ (9,909)**	**$ (10,473)**	**$ (40,015)**	**$ (38,157)**	**$ (31,299)**	**$ 13,650**	**$ 90,416**
EPS (Basic & Diluted; Pro forma)	(7.36)	(0.62)	(0.56)	(0.59)	(0.62)	(2.38)	(2.21)	(1.74)	0.69	4.48
Shares Outstanding (Basic)	**6,283**	16,558	16,805	16,905	17,005	**16,818**	**17,255**	**18,030**	**19,030**	**20,030**
Fully Diluted Shares Outstanding		18,297	18,544	18,644	18,744	**18,557**	**18,994**	**19,394**	**19,794**	**20,194**
Net Cash	**$110,272**	$ 110,194	$104,332	$96,775	$88,709	**$88,709**	**$47,149**	**$14,107**	**$26,692**	**$116,235**
Change in Cash (Burn)	**$92,363**					**($21,563)**	**($41,560)**	**($33,042)**	**$12,585**	**$89,543**

Sources: Intercept Pharmaceuticals and Wedbush Pacgrow Life Sciences

The company ended Q1 with about $110.2 million in cash, cash equivalents, and short-term investments which the company previously projected to last into mid-2015.

We see cash runway to mid-2015 covering six transforming milestones. Key milestones include: (1) Q4: full "supergroup" data; (2) YE: full Phase 2a release for OCA treatment of portal hypertension (PESTO); (3) YE: initiation of the confirmatory OCA/PBC Phase 3 trial (indicating FDA acceptance of ALP endpoint); (4) Q2:14: initial results from the pivotal Phase 3 testing OCA treatment of PBC (NCT01473524); (5) Q4:14: Initial results from FLINT Phase 2 trial testing OCA treatment of NASH as well as (6) NDA and MAA filings for OCA/PBC.

FIGURE 2. MILESTONES

Expected Date	Event
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

Sources: Intercept Pharmaceuticals and Wedbush Pacgrow Life Sciences

Next (Q4): full supergroup data, full Phase 2a results for OCA treatment of portal hypertension (PESTO), and initiation of confirmatory Phase 3 trial testing OCA treatment of PBC.

FIGURE 3. VALUATION

We use multiples to account for clinical and regulatory risk at various stages of development.	
1: In preclinical testing	6: Phase III testing
2: Passed preclinical	7: Phase III data (positive)
3: IND filed	8: Regulatory review
4: Phase I data (positive)	9: Approved
5: Phase II data (positive)	10: Launched

Today:	5/20/13	Stock	MktCap ($000)	Upside
Wedbush Fair Value for ICPT		**$65.24**	**$1,187,206**	**96%**
Full Pipeline Value:		$57.59	$1,047,959	
Net Cash:		$6.06	$110,194	
ICPT Total Value:		$63.64	$1,158,153	
Current ICPT Stock:		$33.22	$604,514	
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%	$755,246	$41.50
FXR Agonist	OCA (INT-747)	Portal Hypertension	432,000	$12,008	11%	$684,000	$422,100	7/1/2017	5	30%	$192,962	$10.60
FXR Agonist	OCA (INT-747)	NASH	10,440,000	$2,047	2%	$360,000	$318,995	7/1/2018	4	30%	$89,740	$4.93
FXR Agonist	OCA (INT-747)	Bile Acid Diarrhea	3,960,000	$1,915	12%	$697,500	$326,500	7/1/2017	5	30%	$149,259	$8.20
TGR5 Agonist	INT-777	Type II Diabetes	34,400,000	$3,844	1%	$2,437,000	$181,850	6/1/2019	1	30%	$10,053	$0.55
FXR/TGR5 Agonist	INT-767	Fibrosis	13,200,000	$1,915	1%	$421,953	$181,098	6/1/2019	1	30%	$10,011	$0.55

Sources: Intercept Pharmaceuticals and Wedbush Pacgrow Life Sciences

Reiterating OUTPERFORM rating, but increasing fair value to $65 due to successful clinical proof-of-concept for bile acid diarrhea. Due to the success in Phase 2a using OCA as a treatment candidate for bile acid diarrhea, we have included our fair value of about $8 into our fair value for ICPT. This plus time value and rounding increased our fair value to $65 from $56. 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.

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.

Analyst Biography

Ms. Moussatos is a Managing Director, Equity Research responsible for the coverage of stocks in the Emerging Pharmaceuticals sector. Liana joined Wedbush from Pacific Growth Equities where she was a Senior Research Analyst. Prior to that she came from UBS Global Asset Management where she was Director and Portfolio Manager of the UBS Global Biotech Funds for five years. Previously Liana was with Bristol-Meyers Squibb where she was a manager in University and Government Licensing External Science and Technology and she also worked with Sloan-Kettering Cancer Institute in the Office of Industrial Affairs and the National Cancer Institute in the Office of Technology Development.

Liana received a B.S. in Entomology and a M.S. in Zoology and Biochemistry from Clemson University and a Ph.D. in Plant Pathology from the University of California Davis and completed a postdoctoral research fellowship in Cellular and Molecular Physiology at the Yale School of Medicine.

Liana's Edge: Liana's industry and buy-side experience provide depth in her understanding of what investors need to know along with her 13 years experience in following healthcare stocks. Her pipeline valuation includes all drug candidates / disease indications in active development and provides investors with a stock value for each program.

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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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.
Underperform: Expect the total return of the stock to underperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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).*

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Outperform:51% Neutral: 44% Underperform: 5%	Outperform:18% Neutral: 2% Underperform: 0%

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

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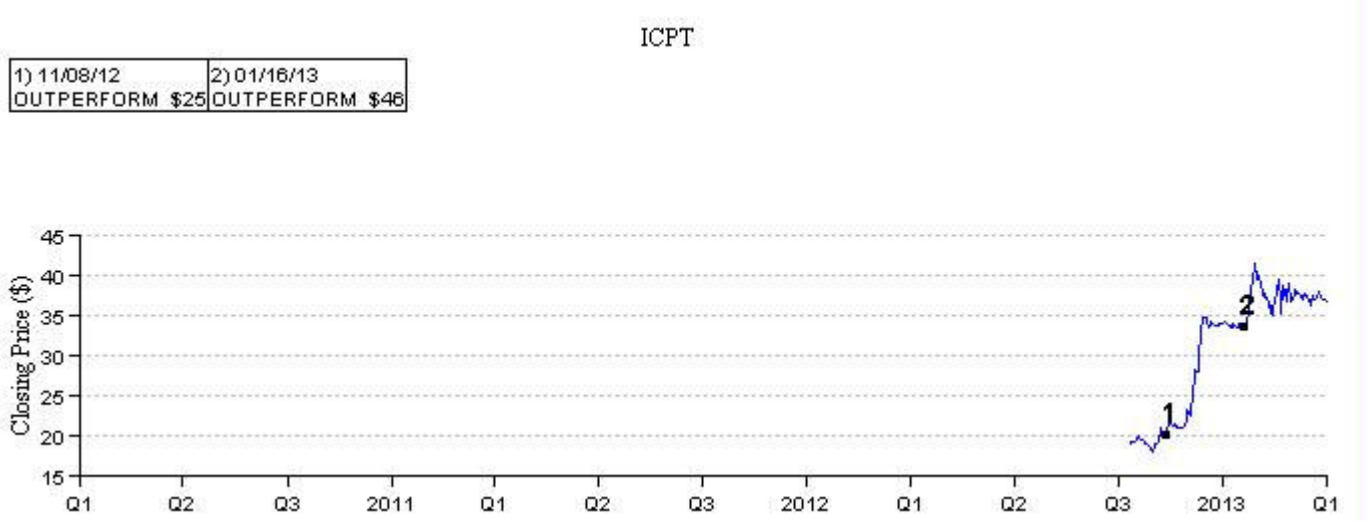

* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.
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