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Intercept Pharmaceuticals (ICPT)

Q2 Financials: Cash Runway Through Early 2016 Includes Multiple Milestones; Reiterating OUTPERFORM; Increasing FV To \$67 For Time

- Q2 financials were roughly in line with our estimates. Intercept reported \$405,000 in revenues from the amortization of the \$15 million upfront payment from Dainippon Sumitomo Pharma, R&D of \$5.1 million, G&A of about \$0.9 million, and GAAP EPS loss of \$0.79. These were roughly in line with our \$400,000, \$5.1 million, \$2.5 million, and loss of \$0.55, respectively; however, we underestimated the revaluation of warrants (\$(5.6)MM vs. our \$(2.5)MM). We do not view this as material given the developmental stage of the company. The company ended Q2 with about \$161.8 million in cash, cash equivalents, and investments, which the company projected will last through early 2016. We have incorporated Q2 results and made minor changes to our projections.
- Next in Q4: Milestones include an August 25th satellite symposium on the genetics, pathogenesis and therapy of PBC held during the International Congress of Immunology (ICI August 22-027, 2013, Milan, IT), release of full "supergroup" data correlating alkaline phosphatase with clinical outcomes and YE full Phase 2a release for OCA treatment of portal hypertension (PESTO). We also anticipate YE initiation of the confirmatory OCA/PBC Phase 3 trial (indicating FDA acceptance of ALP endpoint).
- We see cash runway through early 2016 covering additional transforming milestones. In addition to the four Q4 2013 events, we see four potential value drivers in 2014 and 2015 including: Q2:14: initial results from the pivotal Phase 3 testing OCA treatment of PBC (NCT01473524); Q4:14: initial results from FLINT Phase 2 trial testing OCA treatment of NASH; Q4:14: NDA and MAA filings for OCA/PBC; mid-2015: potential approval and launch of OCA/PBC.
- Reiterate OUTPERFORM rating and increasing our fair value to \$67 for time.
 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.

August 13, 2013

Price

\$46.30

Rating

OUTPERFORM

Fair Value Estimate \$67 (from \$65)

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Company Information					
Shares Outst (M)	18.7				
Market Cap (M)	\$866.3				
52-Wk Range	\$17.96 - \$52.47				
Book Value/sh	\$6.21				
Cash/sh	\$5.89				
Enterprise Value (M)	\$756.1				
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	2012A		2013E			2014E	
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	\$0.8A	\$0.4A			\$0.4E		\$0.4E
Q2 Jun	0.8A	0.4E		0.4E	0.4E		0.4E
Q3 Sep	0.5A	0.4E		0.4E	0.4E		0.4E
Q4 Dec	0.4A	0.4E		0.4E	0.4E		0.4E
Year*	\$2.4A	\$1.6E		\$3.3E	\$1.6E		\$5.1E
Change	n/a	n/a			n/a		
	2012A		2013E			2014E	
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
EPS Q1 Mar		CURR. (\$0.62)A		CONS.	CURR. (\$0.50)E	PREV. (\$0.45)E	CONS. (\$0.45)E
-	ACTUAL			CONS. (0.51)E			
Q1 Mar	ACTUAL (\$1.03)A	(\$0.62)A	PREV.		(\$0.50)E	(\$0.45)E	(\$0.45)E
Q1 Mar Q2 Jun	ACTUAL (\$1.03)A (1.75)A	(\$0.62)A (0.79)E	PREV. (0.55)E	 (0.51)E	(\$0.50)E (0.54)E	(\$0.45)E (0.49)E	(\$0.45)E (0.49)E
Q1 Mar Q2 Jun Q3 Sep	ACTUAL (\$1.03)A (1.75)A (1.86)A	(\$0.62)A (0.79)E (0.58)E	PREV. (0.55)E (0.52)E	 (0.51)E (0.47)E	(\$0.50)E (0.54)E (0.57)E	(\$0.45)E (0.49)E (0.51)E	(\$0.45)E (0.49)E (0.51)E
Q1 Mar Q2 Jun Q3 Sep Q4 Dec	(\$1.03)A (1.75)A (1.86)A (2.02)A	(\$0.62)A (0.79)E (0.58)E (0.60)E	(0.55)E (0.52)E (0.55)E	 (0.51)E (0.47)E (0.51)E	(\$0.50)E (0.54)E (0.57)E (0.59)E	(\$0.45)E (0.49)E (0.51)E (0.54)E	(\$0.45)E (0.49)E (0.51)E (0.54)E



Source: Thomson Reuters

Consensus estimates are from Thomson First Call.

* Numbers may not add up due to rounding.

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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.

Figure 1: MODEL UPDATE

Intercept Pharmaceuticals (NASDAQ: ICPT)

Historical and Projected Income Statement (In thousands except per share data) Wedbush PacGrow LifeSciences
Liana Moussatos, Ph.D.
Richard Lau

(Fiscal Year Ends on December 31)									Т	
	2012A	2012A 2013E				2014E	2015E	2016E	2017E	
	FY:12A	Q1A	Q2A	Q3	Q4	FY:13E	FY:14E	FY:15E	FY:16E	FY:17E
Gross Product Sale	s:									
OCA (INT-747)									
PB	ć							30,314	105,097	221,472
Portal Hypertensio	1							-	-	6,696
Bile Acid Diarrhe								-	-	14,062
Revenues/Royalties on Product Sale	s \$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 30,314	\$ 104,236	\$ 224,671
OCA (INT-747)									
PB	c -	-	-	-	-	-	-	30,314	104,236	214,037
Licensing Revenu		\$ 405	\$ 405	\$ 405		\$ 1,620				
Total Revenues	\$ 2,446	\$ 405	\$ 405	\$ 405	\$ 405	\$ 1,620	\$ 1,600	\$ 31,914	\$ 105,836	\$ 226,271
Operating Expenses										
Cost of Goods	_							1,819		13,125
Research and Development	16,183	4,833	5,133	5,492	5,932	21,390	28,204	33,355		45,648
Sales, General and Administrative	5,177	2,397	2,891	3,036	3,187	11,511	14,789	33,692	52,098	60,947
Other				-	-		-		-	
Total Operating Expenses	21,360	7,229	8,024	8,528	9,119	32,900		68,866	, ,	119,721
Operating Income (Loss)	(18,914)	(6,824)	(7,619)	(8,123)	(8,714)	(31,280)	(41,393)	(36,952)	8,478	106,550
Interest and dividend income	82	-	-	24	40	64	135	89	73	73
Interest (expense)	3	-	-	-	-	-	-	-	-	-
Revaluation of warrants	(24,625)	(3,683)		(2,500)	(2,500)		-	-	-	-
Other income (expense)	(189)	296	(287)	(287)	(287)	(565)	(1,148)			(1,148)
Income Before Income Taxes	(43,644)	(10,210)	(13,478)	(10,886)	(11,461)	(46,035)	(42,407)	(38,011)	7,403	105,475
Other comprehensive income (loss)	(2,630)	-		-	-	-	-	-	-	-
Provision for Income Taxes (benefit)	-	-	-	-	-	-	-	-	1,958	23,277
Net Income (Loss)	\$ (46,274)	\$ (10,210)	\$ (13,477)	\$ (10,886)	\$ (11,461)	\$ (46,035)	\$ (42,407)	\$ (38,011)	\$ 5,445	\$ 82,198
EPS (Basic & Diluted; Pro forma)	(7.36)	(0.62)	(0.79)	(0.58)	(0.60)	(2.58)	(2.20)	(1.90)	0.25	3.71
Shares Outstanding (Basic)	6,283	16,558		18.895		17,855				
Fully Diluted Shares Outstanding	0,200	18,297		20,634						22,184
Net Cas	h \$110,272	\$ 104,220	\$161,799	\$155,597	\$146,552	\$146,552	\$100,680	\$61,086	\$65,535	\$146,942
Change in Cash (Burn	\$92,363					\$36,280	(\$45,872)	(\$39,593)	\$4,449	\$81,407

Source: Company data, Wedbush Securities, Inc.

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Next in Q4: Milestones include an August 25th satellite symposium on the genetics, pathogenesis and therapy of PBC held during the International Congress of Immunology (ICI August 22-027, 2013, Milan, IT), release of full "supergroup" data correlating alkaline phosphatase with clinical outcomes and YE full Phase 2a release for OCA treatment of portal hypertension (PESTO). We also anticipate YE initiation of the confirmatory OCA/PBC Phase 3 trial (indicating FDA acceptance of ALP endpoint).



Figure 2: MILESTONES

Expected Date	Event
Q3 2013	Satellite symposium on genetics, pathogenesis & therapy of PBC (ICI 8/22-25/2013 Milan, IT) (Aug 25)
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
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Source: Company data, Wedbush Securities, Inc.

We see cash runway through early 2016 covering additional transforming milestones. In addition to the four Q4 2013 events, we see four potential value drivers in 2014 and 2015 including: Q2:14: initial results from the pivotal Phase 3 testing OCA treatment of PBC (NCT01473524); Q4:14: initial results from FLINT Phase 2 trial testing OCA treatment of NASH; Q4:14: NDA and MAA filings for OCA/PBC; mid-2015: potential approval and launch of OCA/PBC.

Figure 3: VALUATION

· -		t for clinical and	•					Today:	8/13/13	Stock	MktCap (\$000)	Upside
risk a	it various stage	es of developme	nt.				Wedbush	Fair Value 1	or ICPT	\$67.45	\$1,262,005	46%
1: In preclinical 2: Passed precl	•	6: Phase III testing 7: Phase III data (p	ositive)			ļ		Full Pipeli	ne Value: Net Cash:	\$59.54 \$5.89	\$1,113,984 \$110,194	
3: IND filed 4: Phase I data	(positive)	8: Regulatory revi 9: Approved	ew					ICPT To Current IC	tal Value: PT Stock:	\$65.43 \$46.30	\$1,224,178 \$866,251	
5: Phase II data	(positive)	10: Launched					ICPT Shar	es Outstandi	ng (000s):	18,710	. ,	
			lı	ntercep	t Pipeli	ne Valu	uation					
Pro	duct	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%	\$802,829	\$42.91
FXR Agonist	OCA (INT-747)	Portal Hypertension	432,000	\$12,008	11%	\$684,000	\$422,100	7/1/2017	5	30%	\$205,119	\$10.96
FXR Agonist	OCA (INT-747)	NASH	10,440,000	\$2,047	2%	\$360,000	\$318,995	7/1/2018	4	30%	\$95,394	\$5.10
FXR Agonist	OCA (INT-747)	Bile Acid Diarrhea	3,960,000	\$1,915	12%	\$697,500	\$326,500	7/1/2017	5	30%	\$158,663	\$8.48
TGR5 Agonist	INT-777	Type II Diabetes	34,400,000	\$3,844	1%	\$2,437,000	\$181,850	6/1/2019	1	30%	\$10,686	\$0.57
FXR/TGR5 Agonist	INT-767	Fibrosis	13,200,000	\$1,915	1%	\$421,953	\$181,098	6/1/2019	1	30%	\$10,642	\$0.57

Source: Company data, Wedbush Securities, Inc.

Reiterate OUTPERFORM rating and increasing our fair value to \$67 for time 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.



Risks to Attainment of 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.



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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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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Outperform:54%	Outperform:15%
Neutral: 41%	Neutral: 1%
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Company	Disclosure
Intercept Pharmaceuticals	1,3,4,5,7

Research Disclosure Legend

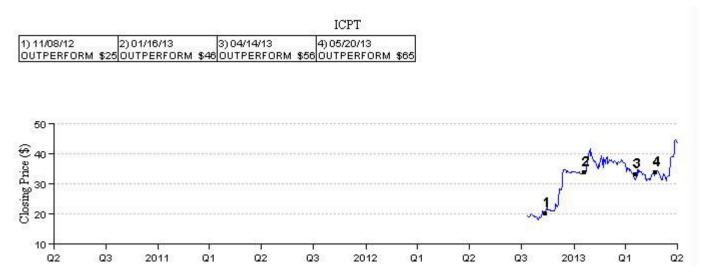
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