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Intercept Pharmaceuticals, Inc.

**ICPT - BUY** 

**August 13, 2013** 

#### Specialty Pharmaceuticals

## Intercept Pharmaceuticals, Inc.

(ICPT) - BUY

(-0)					
Price: Fair Value Esti 52-Week Rang Market Cap (M. Shr.O/S-Dilute Average Daily Dividend: Book Value:	e: IM): ed (mm):	\$46.30 \$55.00 \$15.00-\$52.47 \$912 19.7 1,505,259 NA \$3.34			
FYE: Dec Revenue (M):	2012A \$2.4A	2013E \$1.6E	2014E \$1.6E		
Quarterly Reve Q1 Q2 Q3 Q4	so.8A \$0.8A \$0.5A \$0.4A	\$0.4A \$0.4A \$0.4E \$0.4E	\$0.4E \$0.4E \$0.4E \$0.4E		
FYE: Dec EPS: Prior EPS:		2013E \$(2.36)E \$(2.09)	2014E \$(2.20)E \$(2.31)		
Quarterly EPS: Q1 Q2 Q3 Q4	\$(1.03)A \$(1.75)A \$(1.86)A	\$(0.62)A \$(0.79)A \$(0.45)E \$(0.50)E	\$(0.54)E \$(0.56)E		



Equity Research
Note

# ICPT 2Q In-line, Raising Fair Value to \$55 from \$48

#### INVESTMENT CONCLUSION:

ICPT released its 2Q13 figures this morning before the opening which were roughly in line with our expectations, ex-warrant revaluation of (\$5.5M). ICPT is not an earnings story at this point. We continue to have positive expectations on the outcome of the P3 POISE trial on obeticholic acid (OBC) for primary biliary cirrhosis (PBC), which should read out 2Q14. More near term, ICPT is expected to release the full PBC "supergroup" data in 4Q13 which we expect should further validate ICPT's surrogate endpoints as appropriate and predictive of clinical outcomes for the P3 POISE trial. We continue to like ICPT here and it is one of our top small cap picks in the specialty pharma space. Reiterate Buy rating, raising our fair value to \$55 from \$48 on increased confidence on the P3 POISE trial results.

#### **KEY POINTS:**

- Financials look fine. ICPT reported 2Q13 with revenues of \$405K (JMS: \$400K & cons: \$400K) and EPS of (\$0.79) vs JMS (\$0.48) & cons (\$0.51). Both R&D and SG&A expense were slightly lower than we had expected. In June, ICPT raised \$61.4M from a secondary offering, supplementing their cash position which ended the quarter at \$161.8M which should take the company through to early 2016 & OCA launch (assuming approval). The EPS miss was due to the non-cash revaluation of warrants in the Q, which is linked to the share price. The revaluation expense this quarter of \$5.5M was primarily due to the ~20% run up in ICPT's share price in 2Q13.
- Full PBC "supergroup" analysis 4Q13. Though ICPT released interim data on the retrospective 2,100 "supergroup" study of patients with PBC in April, the full data is expected to be presented 4Q13, which we expect should further substantiate that the primary endpoint of lowering serum liver makers used in their P3 POISE trail will be predictive of clinical outcomes. With the European Medicines Agency (EMA) already on board, we believe that this analysis may help tip the scales for the FDA.
- POISE trial data remains on track for 2Q14. We believe that the P3 POISE trail is designed for success as it closely mimics the successful P2 trial and historically we've found that P3 trials which closely resemble successful P2 trails tend to have the best chance for success. Applying the P3 endpoints to the 10mg cohort of the P2 trial shows 40% of patients hitting the P3 trial primary endpoint (p=0.012). See our table "Potential clinical trial timeline estimates" later in this report for more details.
- **PESTO & OBEDIAH top line 4Q13.** We continue to anticipate the P2 data for portal hypertension (PESTO) and bile acid diarrhea (OBEDIAH) in 4Q13. While smaller markets than the anticipated 8M patient indication in non-alcoholic steatohepatitis (NASH), these could provide good validation of the efficacy of OCA in helping to repair liver function.
- Maintain Buy rating, \$55 Fair Value: Our \$55/share sum-of-the-parts is based on OCA for PBC at \$41/share, OCA for NASH at \$9/share, and \$5/share for cash (end 2014) and technology value.

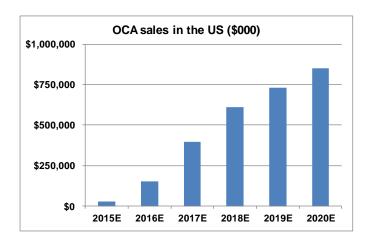
Research Analyst Certifications and Important Disclosures are on pages 6 - 7 of this report

### **EXHIBIT 1:**

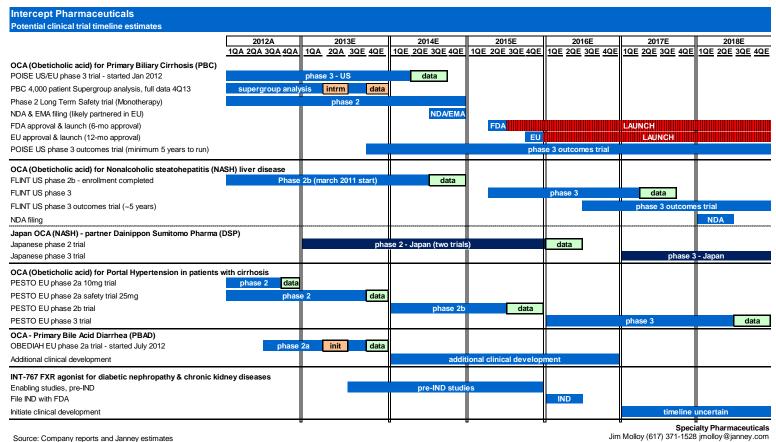
Sum-of-the-parts valuation: ICPT								
Segment	Valuation	Per share						
	(000's)	value						
OCA for PBC in the US	\$832,492	\$41						
OCA for NASH in the US	\$206,017	\$9						
Cash (end of '14E) & tech value	\$109,358	\$5						
	\$1,268,904	\$55						
2014 fully diluted shares out		23,085						

Source: Janney estimates

### **EXHIBIT 2:**



#### **EXHIBIT 3:**



Source: Company reports and Janney estimates

# Intercept Pharmaceuticals Quarterly income statement

	2012A				2012A	2013E			2013E	
(\$000's except per share)	1QA	2QA	3QA	4QA	<u>Year</u>	<u>1QA</u>	2QA	3QE	4QE	<u>Year</u>
Revenues										
License fees	\$759	\$759	\$523	\$405	\$2,446	\$405	\$405	\$400	\$400	\$1,610
Total Revenues	\$759	\$759	\$523	\$405	\$2,446	\$405	\$405	\$400	\$400	\$1,610
Expenses										
Cost of Goods Sold	0	0	0	0	0	0	0	0	0	0
Gross Margin	759	759	523	405	2,446	405	405	400	400	1,610
Research and Development	3,060	5,018	3,318	4,787	16,183	4,833	5,133	5,800	6,250	22,016
SG&A	1,059	<u>944</u>	<u>991</u>	2,183	<u>5,177</u>	2,397	2,891	3,250	3,900	12,438
<b>Total Operating Expenses</b>	4,119	5,962	4,309	6,970	21,360	7,229	8,024	9,050	10,150	34,453
Income (loss) from Ops	(3,360)	(5,203)	(3,786)	(6,565)	(18,914)	(6,824)	(7,619)	(8,650)	(9,750)	(32,843)
Warrant Revaluation income	678	301	(1,418)	(24,187)	(24,626)	(3,683)	(5,572)			(9,255)
FOREX loss on liquidation		(198)								
Interest & dividend income	10	7	13	61	(100)	296	(287)	10	10	29
Interest expense	(7)	0	3	0	(4)					0
QTP grant	(0.000)	(5.000)	(5.407)	(00.004)	0	(40.040)	(40, 470)	(0.040)	(0.740)	0
Pretax Income (Loss)	(2,680)	(5,092)	(5,187)	(30,691)	(43,644)	(10,210)	(13,478)	(8,640)	(9,740)	(42,068)
Div. pref stock, not declared	(750)	(750)	(1,000)	(130)	(2,630)	0				0
Net income/(loss)	(3,430)	(5,842)	(6,187)	(30,821)	(46,274)	(10,210)	(13,478)	(8,640)	(9,740)	(42,068)
EPS as reported	(\$1.03)	(\$1.75)	(\$1.86)	(\$2.02)	(\$7.36)	(\$0.62)	(\$0.79)	(\$0.45)	(\$0.50)	(\$2.36)
•		•	•			•	•			,
Shares out (000)	3,330	3,330	3,330	15,223	6,283	16,558	16,970	19,210	19,460	18,049
Fully diluted shares (000)	11,725	14,326	14,326	19,238	19,238	19,423	19,742	21,960	22,210	20,834

Specialty Pharmaceuticals
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Source: Company reports and Janney estimates

Intercept Pharmaceuticals								
Annual income statement								
(\$000's except per share)	2012A	2013E	2014E	2015E	2016E	2017E	2018E	
Revenues				•				
OCA sales	-	-	-	\$27,799	\$150,913	\$396,849	\$609,266	
OCA royalties (EU & Japan)	-	-	-	-	6,849	35,454	60,236	
License fees	\$2,446	\$1,610	\$1,600	1,600	1,800	2,000	2,000	
Total Revenues	\$2,446	\$1,610	\$1,600	\$29,399	\$159,562	\$434,303	\$671,502	
Expenses								
Cost of Goods Sold	-	-	-	6,745	22,637	59,527	91,390	
Gross Margin	2,446	1,610	1,600	22,654	136,925	374,776	580,112	
Research and Development	16,183	22,016	28,000	30,250	34,000	45,000	65,000	
SG&A	5,177	12,438	17,750	25,000	39,250	101,500	150,500	
<b>Total Operating Expenses</b>	21,360	34,453	45,750	55,250	73,250	146,500	215,500	
Income (loss) from Ops	(18,914)	(32,843)	(44,150)	(32,596)	63,675	228,276	364,612	
Warrant Revaluation income	(24,626)	(9,255)	-	-	-	-	-	
FOREX loss on liquidation	-	-	-	-	-	-	-	
Interest & dividend income	(100)	29	40	60	75	100	100	
Interest expense Pretax Income (Loss)	(4) (43,644)	(42,068)	(44,110)	(32,536)	63,750	228,376	364,712	
Taxes	(43,044 <i>)</i> -	-	-	(32,330)	-	34,256	91,178	
Div. pref stock, not declared	(2,630)	-	-	-	-	-	-	
Net income/(loss)	(46,274)	(42,068)	(44,110)	(32,536)	63,750	194,119	273,534	
EPS as reported	(\$7.36)	(\$2.36)	(\$2.20)	(\$1.55)	\$2.65	\$6.80	\$9.20	
Shares out (000)	6,283	18,049	20,085	21,210	22,360	23,535	24,735	
Fully diluted shares (000)	19,238	20,834	23,085	24,710	24,060	28,535	29,735	
Margin & expense analysis								
COGS as % prod sales	NA	NA	NA	24%	14%	14%	14%	
R&D	NA	NA	NA	103%	21%	10%	10%	
SG&A	NA	NA	NA	85%	25%	23%	22%	
Op. margin cont. ops	NA	NA	NA	-111%	40%	53%	54%	
Taxes	NA	NA	NA	0%	0%	15%	25%	
Net margin	NA	NA	NA	-111%	40%	45%	41%	
Year-over-year change								
Net revenue	NA	NA	NA		443%	172%	55%	
R&D	42%	36%	27%	8%	12%	32%	44%	
SG&A	23%	140%	43%	41%	57%	159%	48%	
Operating income	NA	NA	NA	NA	NA		60%	
Net income	NA	NA	NA	NA	NA	205%	41%	

Source: Company reports and Janney estimates

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#### **Company Description**

Intercept Pharmaceuticals is a development stage biopharmaceutical company that is developing therapeutics to treat chronic liver diseases utilizing proprietary bile acid chemistry. The lead candidate is obeticholic acid (OCA), a bile acid analog and farnesoid X receptor (FXR) agonist that is in phase 3 trials for the treatment of primary biliary cirrhosis. ICPT is also conducting phase 2a clinical trials with OCA to treat portal hypertension; phase 2b clinical trials for the nonalcoholic steatohepatitis treatment (NASH) in sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases; and phase 2a trials for the treatment of bile acid diarrhea.

#### IMPORTANT DISCLOSURES

#### **Research Analyst Certification**

I, Jim Molloy, the Primarily Responsible Analyst for this research report, hereby certify that all of the views expressed in this research report accurately reflect my personal views about any and all of the subject securities or issuers. No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views I expressed in this research report.

#### Janney Montgomery Scott LLC ("Janney") Equity Research Disclosure Legend

Intercept Pharmaceuticals, Inc. currently is, or during the past 12 months was, a Janney Montgomery Scott LLC client. Janney Montgomery Scott LLC, provided investment banking related services.

Janney Montgomery Scott LLC managed or co-managed a public offering of securities for Intercept Pharmaceuticals, Inc. in the past 12 months.

Janney Montgomery Scott LLC received compensation for investment banking services from Intercept Pharmaceuticals, Inc. in the past 12 months.

Janney Montgomery Scott LLC intends to seek or expects to receive compensation for investment banking services from Intercept Pharmaceuticals, Inc. in the next three months.

The research analyst is compensated based on, in part, Janney Montgomery Scott's profitability, which includes its investment banking revenues.

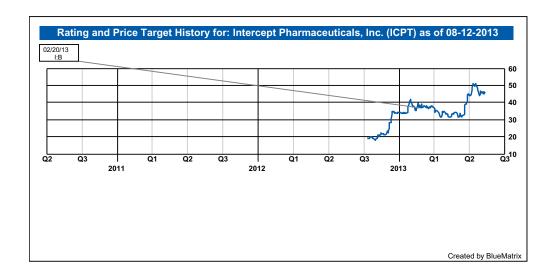
#### **Definition of Ratings**

**BUY:** Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

**NEUTRAL:** Janney believes that the subject company is fairly valued and will perform in line with comparable companies within its sector. Investors may add to current positions on short-term weakness and sell on strength as the valuations or fundamentals become more or less attractive.

**SELL:** Janney expects that the subject company will likely decline in value and will underperform comparable companies within its sector.

#### **Price Charts**



#### Janney Montgomery Scott Ratings Distribution as of 6/30/13

IB Serv./Past 12 Mos.

Rating	Count	Percent	Count	Percent
BUY [B]	218	51.90	34	15.60
NEUTRAL [N]	198	47.14	21	10.61
SELL [S]	4	0.95	0	0.00

### \*Percentages of each rating category where Janney has performed Investment Banking services over the past 12 months.

#### **Other Disclosures**

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