

### **QUARTERLY UPDATE**

August 13, 2013

Stock Rating:

## **OUTPERFORM**

12-18 mo. Price Target	\$64.00
ICPT - NASDAQ	\$46.30

3-5 Yr. FPS Gr. Rate	NA
52-Wk Range	\$52.47-\$15.00
Shares Outstanding	20.7M
Float	7.0M
Market Capitalization	\$861.2M
Avg. Daily Trading Volume	83,848
Dividend/Div Yield	NA/NM
Book Value	\$3.66
Fiscal Year Ends	Dec
2013E ROE	NA
LT Debt	NA
Preferred	NA
Common Equity	\$66M
Convertible Available	No

EPS Diluted	Q1	Q2	Q3	Q4	Year	Mult.
2011A					(4.73)	NM
2012A	(1.03)	(1.75)	(1.86)	(2.02)	(7.36)	NM
2013E	(0.62)A	(0.79)A	(0.41)	(0.42)	(2.22)	NM
Prior (E)		(0.86)	(0.38)	(0.39)	(2.24)	NM
2014E					(2.04)	NM
Prior (E)					(1.90)	NM
2015E					(0.78)	NM
Prior (F)					(0.43)	NM

HEALTHCARE/BIO AND SPECIALTY PHARMACEUTICALS

# **Intercept Pharmaceuticals**

# 2Q13 Model Update

### **SUMMARY**

Intercept reported 2Q13 financial results in a press release this morning. The company did not hold a conference call (consistent with prior intra-year quarterly updates). Reported 2Q operating loss of (\$7.6M) was greater than our (\$7.1M) estimate due to slightly higher R&D and S&A expenses. Reported GAAP EPS of (\$0.79) included a \$5.6M non-cash charge related to revaluation of warrants, which is essentially an accounting artifact. Intercept ended the quarter with \$161.8M in cash, including \$61.4M raised in the June secondary offering. We are adjusting our model to reflect the 2Q13 results. Reiterate Outperform and \$64 price target.

### **KEY POINTS**

- We are updating our model to reflect Intercept's reported 2Q13 results. Of note, our model suggests that the company's current cash position of \$161.8M is sufficient to fund the company beyond the anticipated launch of OCA for Primary Biliary Cirrhosis (PBC) in 2015.
- Key upcoming catalysts include updated data from Phase 2a studies of OCA in portal hypertension (PESO study) and bile-acid diarrhea (OBADIAH study) in 2H13, followed by the results of the pivotal Phase 3 POISE study in PBC.
- Reiterate Outperform and \$64 Price Target. Our \$64 price target is derived from a sum-of-parts, probability-adjusted NPV calculation. We continue to see upside potential to our \$64 price target from continued positive progress in both PBC and non-PBC indications.



# 1 Year Price History for ICPT 60 50 40 40 20 31 2013 Created by BlueMatrix

### **Company Description**

Intercept is a biopharmaceutical company focused on the development of novel treatments for liver diseases. Lead drug OCA is in Phase 3 for the treatment of Primary Biliary Cirrhosis (PBC).

Akiva Felt 415-399-5728 Akiva.Felt@opco.com Angad Verma 212-667-8165 Angad.Verma@opco.com Oppenheimer & Co. Inc. does and seeks to do business with companies covered in its research reports. As a result, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision. See "Important Disclosures and Certifications" section at the end of this report for important disclosures, including potential conflicts of interest. See "Price Target Calculation" and "Key Risks to Price Target" sections at the end of this report, where applicable.

Exhibit 1: ICPT Probability-Weighted Valuation Analysis

Drug/Indication	Expected Launch	Peak Sales Estimate (\$MM)	Est. Probability of Success	P-Adj NPV (\$MM)	P-Adj Value / Share
OCA - Primary Biliary Cirrhosis	2015	\$716	76%	\$965	\$45
OCA/INT-767 - Portal Hypertension	2018	\$637	28%	\$234	\$11
OCA/INT-767 - Bile Acid Diarrhea	2018	\$541	33%	\$193	\$9
Pipeline Value				\$1,392	\$64
Net Cash				\$148	\$7
Total Equity Value				\$1,392	\$64
Diluted Shares Outstanding Used for V	/aluation (MM)				21.6

Source: Oppenheimer & Co.

**Exhibit 2: ICPT Upcoming Catalysts** 

Expected Date	Event Description
8/25/2013	Satellite symposium at International Congress of Immunology (PBC focused)
2H13	Additional presentations of PBC "supergroup" data
2H13	Update data from Phase 2a trial of OCA in bile-acid diarrhea (OBADIAH study)
4Q13	Update data from Phase 2a trial of OCA in portal hypertension (PESTO study)
4Q13	Initiation of Phase 3 OCA confirmatory outcomes study in PBC
2Q14	Topline data from pivotal Phase 3 POISE study of OCA in PBC
4Q14	Topline data from Phase 2 study of OCA in NASH (FLINT study)
4Q14	FDA and EMA regulatory filings for OCA in PBC
2014	Potential updates regarding clinical development plans for PH/BAD
mi d-2015	Potential approval of OCA for PBC

Source: Company Documents and Oppenheimer & Co.

### Intercept Pharma. (ICPT) (\$000's) [FY-DEC] Oppenheimer & Co.

	2011A			2012A					2013E			2014E	2015E
	FY:11A	Q1A	Q2A	Q3A	Q4A	FY:12A	Q1A	Q2A	Q3E	Q4E	FY:13E	FY:14E	FY:15E
Revenues/Royalties on Product Sales			-	-	-			-					37,720
OCA - Primary Biliary Cirrhosis	-					-		-	-		-	-	37,720
OCA or INT-767 - Portal Hypertension	-					-		-	-	-	-	-	0
OCA or INT-767 PBAD						-		-			-	-	0
Licensing revenue and Milestones	1,805		759	523	405	2,446	405	405	405	405	1,620	1,620	1,620
Total revenues	\$ 1,805	\$ 759 \$	759 \$	523 \$	405	\$ 2,446	\$ 405 \$	405	\$ 405 \$	405	\$ 1,620	\$ 1,620	\$ 39,340
Cost of Goods													3,541
Gross profit	1.805	759	759	523	405	2,446	405	405	405	405	1.620	1.620	35,799
Operating expenses	.,					3,					.,	.,	,
Research and development	11.426	3.060	5.018	3.318	4.787	16.183	4.833	5.133	5.236	5,340	20.542	24.650	32.045
Selling, general and administrative	4,209	1.059	944	991	2.183	5.177	2.397	2.891	2.978	3,067	11.333	16.432	24,649
Other	4,205	1,000	344	331	2,100	3,177	2,351	2,031	2,310	3,007	11,303	10,432	24,043
Total expenses	15.636	4.119	5.962	4.309	6.970	21.360	7.229	8.024	8.213	8.407	31.874	41.082	56,693
Operating income	(13.830)	(3,360)	(5,203)	(3,786)	(6,565)	(18,914)	(6.824)	(7,619)	(7,808)	(8,002)	(30,254)	(39,462)	(20,894)
operating mount	(10,000)	(0,000)	(0,200)	(0,100)	(0,000)	(10,014)	(0,024)	(1,010)	(1,000)	(0,002)	(00,201)	(00,102)	(20,001)
Revaluation of warrants	1.045	678	302	(1,418)	(24, 187)	(24,625)	(3,683)	(5,572)	-		(9,255)	-	
Other income (expense)	0	(750)	(942)	(1,000)	(130)	(2.822)	296	(287)	25	24	58	87	75
Pre-tax income	(12,738)	(3,430)	(5,836)	(6,187)	(30,821)	(46,274)	(10,210)	(13,478)	(7,783)	(7,978)	(39,450)	(39,375)	(20,743)
Income tax expense (benefit)	3,000	i i		-	-	-		-	-	-			(3,111)
Net income	(\$15,738)	(\$3,430)	(\$5,836)	(\$6,187)	(\$30,821)	(\$46,274)	(\$10,210)	(\$13,478)	(\$7,783)	(\$7,978)	(\$39,450)	(\$39,375)	(\$17,632)
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Basic shares outstanding	3,330	3,330	3,330	3,330	15,223	6,283	16,558	16,971	18,781	18,931	17,810	19,306	19,922
Diluted shares outstanding					18,197		19,423	19,693	21,504	21,654	20,568	22,029	22,699
GAAP EPS (basic and diluted)	(\$4.73)	(\$1.03)	(\$1.75)	(\$1.86)	(\$2.02)	(\$7.36)	(\$0.62)	(\$0.79)	(\$0.41)	(\$0.42)	(\$2.22)	(\$2.04)	(\$0.78)
Cash and Equivalents	\$ 17,707	S - S	- S	36,049 \$	110,194	\$ 110,194	\$ 104,220 \$	161,799	\$ 157,924 \$	154.276	\$ 154,276	\$ 94,244	
Source: Oppenheimer & Co. Inc., Company Reports	,	. ,	•	,	-,	,		,	, +	,=			,



### **Investment Thesis**

We believe ICPT's lead asset, obeticholic acid (OCA), which is in a Phase 3 trial for the treatment of primary biliary cirrhosis (PBC), and in earlier stages of development for the treatment of portal hypertension, bile acid diarrhea and NASH, has well-defined commercial potential and an overall risk/reward profile that appears highly favorable at the current share price. Specifically, we believe OCA will be able fill a much-needed role as a second-line therapy in PBC, as the current standard of care, Urso, is ineffective in up to 40%-50% of patients. We also believe OCA's development in other liver diseases represents significant upside potential for ICPT.

### **Price Target Calculation**

Our \$64 price target is based on a sum-of-the-parts analysis for ICPT's lead asset, OCA, being developed for the treatment of PBC, portal hypertension, and bile acid diarrhea. We value ICPT using a probability-adjusted net present value (pNPV) approach, calculating anticipated profits from OCA (or the follow-on drug INT-767) through 2026, discounted at 10.5% with no terminal value. We then adjust for clinical and regulatory risk by assigning an estimated probability of success (i.e., reaching commercialization), based on stage of clinical development and our assessment of the available clinical data and characteristics of the proposed indication. Specifically, we estimate a \$44/share valuation for OCA in PBC assuming a 76% chance of success and peak sales of ~\$716M; \$11/share for OCA/INT-767 in portal hypertension assuming a 28% chance of success and peak sales of ~\$640M; and \$9/share for OCA/INT-767 in bile acid diarrhea assuming a 33% chance of success and peak sales of \$540M.

### **Key Risks to Price Target**

Clinical Risk. Intercept's drugs will be required to demonstrate efficacy and safety in clinical trials before they can be approved by regulatory agencies.

**Regulatory Risk**. ICPT has yet to submit for or receive approval for any of its drugs in the US, and may face difficulties in doing so, potentially delaying commercialization. The company intends to seek accelerated approval in the US for OCA in PBC, which carries additional risks compared to traditional approval.

**Commercialization Risk**. Despite ICPT's ability to potentially attain approval of their development candidates, the company may face unpredictable commercialization challenges.

**Intellectual Property Risk.** There is inherent uncertainty in both the interpretation of patent claims and the application of patent law, regardless of the apparent strength of ICPT's patent portfolio.

Manufacturing Risk. ICPT does not possess its own manufacturing capabilities to clinically or commercially supply sufficient quantities of its drugs.

**Competitive Risk.** The indications being targeted by ICPT are also being targeted by several competitors, some with superior resources. **Financing Risk.** While we believe ICPT is sufficiently capitalized to reach significant value inflection points, any unexpected clinical or regulatory setbacks may prompt capital raising before ICPT is able to generate sufficient revenues from the commercial activities.

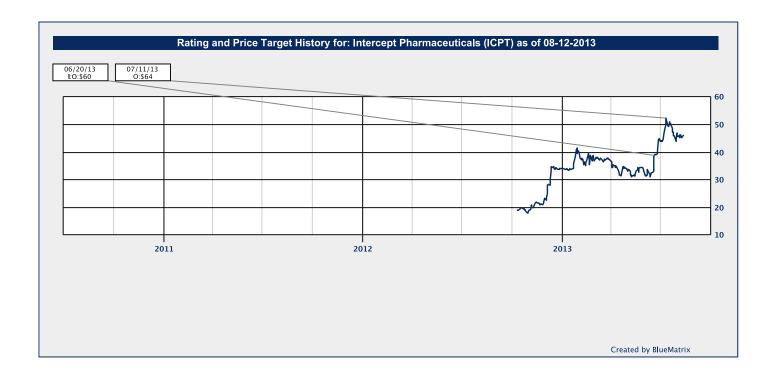
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	Dis	tribution	of Rating
		IB Serv/Pa	st 12 Mos.
Count	Percent	Count	Percent
292	50.87	135	46.23
273	47.56	95	34.80
9	1.57	3	33.33
	292 273	Count         Percent           292         50.87           273         47.56	292 50.87 135 273 47.56 95

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