

### **COMPANY UPDATE**

October 23, 2013

HEALTHCARE/BIO AND SPECIALTY PHARMACEUTICALS

# Stock Rating:

## OUTPERFORM

12-18 mo. Price Target	\$94.00
ICPT - NASDAQ	\$54.96

3-5 Yr. EPS Gr. Rate	NA
52-Wk Range	\$77.53-\$17.96
Shares Outstanding	20.7M
Float	7.0M
Market Capitalization	\$1,081.7M
Avg. Daily Trading Volume	129,817
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
2014E					(2.04)	NM
2015E					(0.13)	NM

# **Intercept Pharmaceuticals**

# Positive Takeaways From Recent Mgmt Meetings

#### SUMMARY

We spent two days with ICPT management this week. We affirm our optimism ahead of Phase 3 PBC data in 2Q14 and believe the recent pull-back represents a buying opportunity. Compared to our last series of meetings with ICPT back in February, we noted a marked increase in investor familiarity with the story. Discussions focused on several areas including: (1) recent stock weakness and S-1 filing; (2) handicapping the POISE data; (3) accelerated approval pathway for PBC; and (4) follow-on indications such as PH, BAD, and NASH. We believe the increased focus on the follow-on indications bodes well as these opportunities are not reflected in ICPT's share price, in our view. ICPT remains our top pick among development-stage biopharma.

#### **KEY POINTS**

- Confusion over S-1 filing and Form 4 selling may be contributing to weakness. ICPT did not offer new shares, and the selling by two early-stage investors was for the amount of their initial investments. Both retain large positions in ICPT (Genextra 34% holder & Orbimed 9% holder, post-offering).
- Approaching follow-on indications milestones. ICPT expects to press-release data from additional cohorts in Phase 2a PH (PESTO) and BAD (OBADIAH) by year-end, and present full data at subsequent medical meetings (EASL & DDW potentially). The company also expects to start a Phase 2 primary sclerosing cholangitis study (PSC) in 2014.
- Optimistic body language regarding PBC data and NDA. The majority of patients have completed dosing in POISE and the last patient will reach 12 months of therapy around year-end. ICPT will submit the final "supergroup" data to FDA in the coming months and believes it will be able to reach an agreement over confirmatory study design.
- Symposium at AASLD to drive awareness of PBC. ICPT is sponsoring a symposium on PBC, PSC and NASH on 11/3 (link) with talks from KOLs. We expect the session to be informative and the timing appears good because Hep C (historically the key draw at AASLD) interest is likely becoming saturated.
- Reiterate Outperform and \$94 PT. We continue to see upside in ICPT from current levels on PBC success and progress in follow-on indications.

#### Stock Price Performance

# 1 Year Price History for ICPT 80 60 40 20 32013 Q1 Q2 Q3 2014 Created by Blankfarix

#### **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).

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#### **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 (PH), bile acid diarrhea (BAD) and nonalcoholic steatohepatitis (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 \$94 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 \$73/share valuation for OCA in PBC assuming a 76% chance of success and peak sales of ~\$1,100M; \$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 its 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.

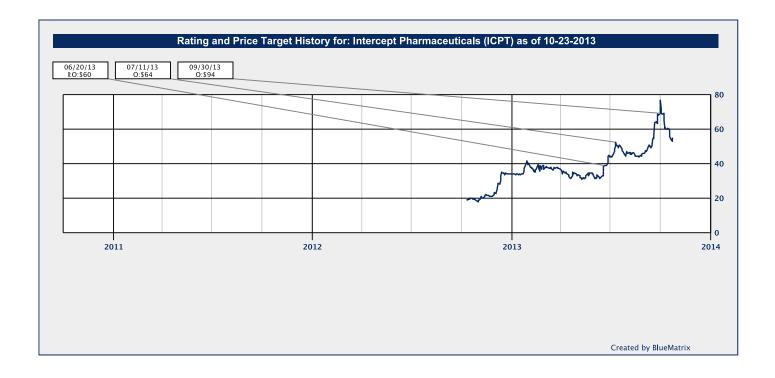
**Competitive Risk.** The indications being targeted by ICPT are also being targeted by several competitors, some with superior resources. **Financing Risk.** While we believe ICPT is sufficiently capitalized to reach significant value inflection points, any unexpected clinical or regulatory setbacks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

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Distribution of Rating				
		IB Serv/Past 12 Mos.		
Rating	Count	Percent	Count	Percent
OUTPERFORM [O]	296	49.75	139	46.96
PERFORM [P]	290	48.74	99	34.14
UNDERPERFORM [U]	9	1.51	4	44.44

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