September 9, 2013

HEALTHCARE/BIO AND SPECIALTY PHARMACEUTICALS

Stock Rating:

OUTPERFORM

12-18 mo. Price Target	$64.00
ICPT - NASDAQ	$48.14

3-5 Yr. EPS Gr. Rate	NA
52-Wk Range	$52.47-$15.00
Shares Outstanding	20.7M
Float	7.0M
Market Capitalization	$923.4M
Avg. Daily Trading Volume	92,113
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	--	--	--	--	(0.78)	NM

Intercept Pharmaceuticals

FDA Workshop Highlights Challenges, Some Progress for NASH Drug Development

SUMMARY

Last Thursday and Friday (9/5-6), AASLD and the FDA held a workshop to discuss issues related to clinical trial design for nonalcoholic steatohepatitis (NASH) (link). The event featured numerous discussions by KOLs and industry participants in the NASH space, with the goal of providing the FDA with important feedback on how to think about acceptable registrational studies. From our vantage point it appeared that the workshop did more to detail the challenges, of which there are many, inherent in drug development for NASH and was less successful at generating a consensus view on pivotal study design. That said, we did find several causes for optimism.

KEY POINTS

- **We have not included the NASH opportunity in our valuation for ICPT due to uncertainties regarding path-to-market.** Recall that ICPT's OCA is being tested in a Phase 2b study in NASH, with data expected in 4Q14. We view any NASH-related progress as upside potential to our price target.
- **Leading minds in NASH join together for AASLD/FDA workshop.** We found the two-day event to be highly informative and productive. KOLs (key opinion leaders) presented updates on the key aspects of drug development in NASH, and were joined in discussions by industry participants from companies in the space, including Intercept's Chief Medical Officer David Shapiro.
- **Existing hurdles remain front and center.** Discussions mainly centered on NASH's unique challenges, including: 1) patient identification and stratification; 2) impracticality of survival-based endpoints; (3) lack of acceptable surrogate endpoints; and 4) continued reliance on liver biopsies.
- **Emerging research offers some optimism.** As research in the field intensifies, several KOLs appear optimistic that acceptable surrogate endpoints are on the horizon, although timing is likely 2+ years away.
- **We maintain cautious optimism for OCA in NASH; long-term potential remains substantial.** Although the current challenges may take several years to overcome, we think ICPT is well positioned to be the leading drug developer in the space. For now, we remain focused on OCA's development in PBC (Ph3), Portal Hypertension (Ph2) and BAD (Ph2).

Stock Price Performance

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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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 Valuation (MM)					21.6

Source: Oppenheimer & Co.

Exhibit 2: ICPT Upcoming Catalysts

Expected Date	Event Description
2H13	Additional presentations of PBC "supergroup" data
4Q13	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
mid-2015	Potential approval of OCA for PBC

Source: Company Documents and Oppenheimer & Co.

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.

Important Disclosures and Certifications

Analyst Certification - The author certifies that this research report accurately states his/her personal views about the subject securities, which are reflected in the ratings as well as in the substance of this report. The author certifies that no part of his/her compensation was, is, or will be directly or indirectly related to the specific recommendations or views contained in this research report.

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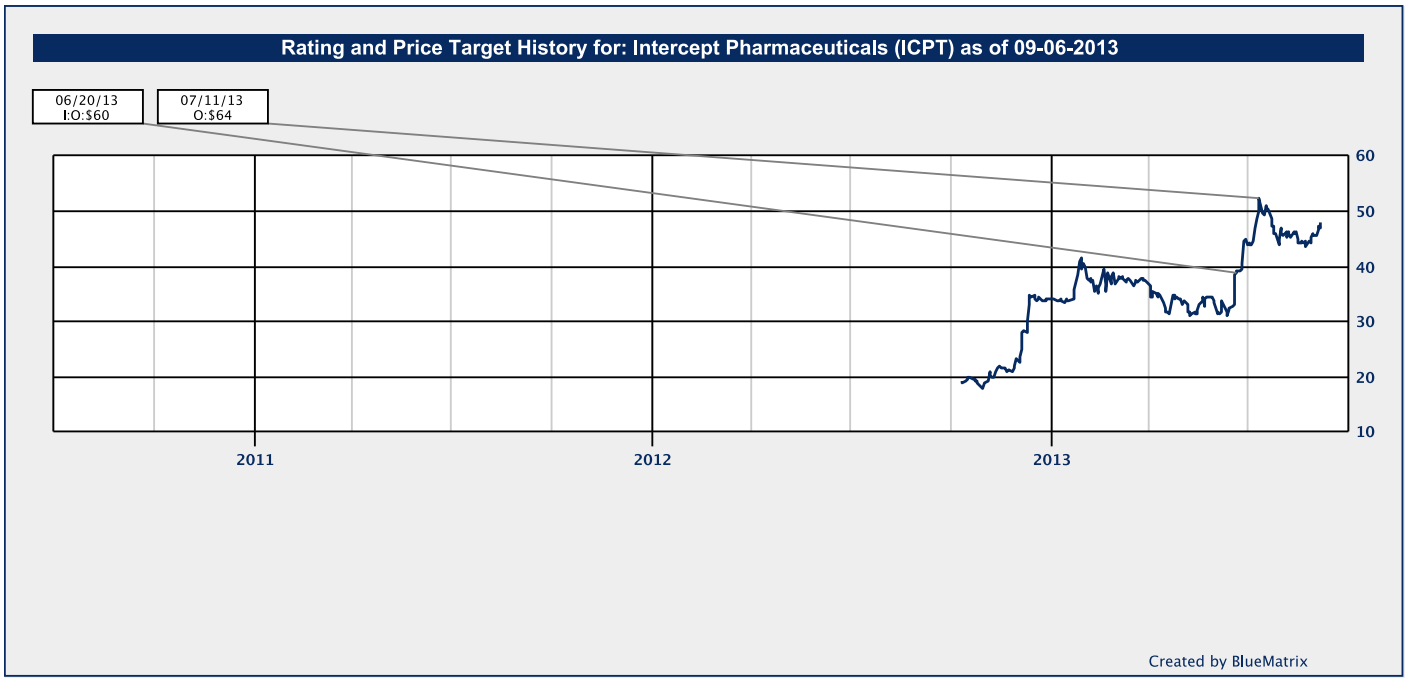

All price targets displayed in the chart above are for a 12- to- 18-month period. Prior to March 30, 2004, Oppenheimer & Co. Inc. used 6-, 12-, 12- to 18-, and 12- to 24-month price targets and ranges. For more information about target price histories, please write to Oppenheimer & Co. Inc., 85 Broad Street, New York, NY 10004, Attention: Equity Research Department, Business Manager.

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			IB Serv/Past 12 Mos.	
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PERFORM [P]	280	48.03	98	35.00
UNDERPERFORM [U]	8	1.37	3	37.50

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