

July 11, 2013

HEALTHCARE/BIO AND SPECIALTY PHARMACEUTICALS

Stock Rating:

OUTPERFORM

12-18 mo. Price Target \$64.00
ICPT - NASDAQ \$49.90

3-5 Yr. EPS Gr. Rate NA
52-Wk Range \$50.00-\$15.00
Shares Outstanding 20.7M
Float 7.0M
Market Capitalization \$928.2M
Avg. Daily Trading Volume 80,368
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	(0.86)	(0.38)	(0.39)	(2.24)	NM
Prior (E)	--	(0.42)	(0.39)	(0.40)	(1.83)	NM
2014E	--	--	--	--	(1.90)	NM
Prior (E)	--	--	--	--	(1.92)	NM
2015E	--	--	--	--	(0.43)	NM

Intercept Pharmaceuticals

FDA Guidance on Accelerated Approval Supports Our Thesis; PT to \$64 from \$60

SUMMARY

We believe the recent FDA draft guidance entitled "Expedited Programs for Serious Conditions" ([FDA Draft Guidance](#)) corroborates our expectations that OCA will qualify for accelerated approval in PBC. Although in draft form, the guidance provides a clear indication of FDA's current thinking regarding the criteria necessary for accelerated approval. Specifically, the FDA clarifies what constitutes: (1) a serious condition, (2) an improvement over available therapies and (3) a surrogate endpoint that is reasonably likely to predict clinical benefit. We provide a detailed review of the updated guidance in this note. We view the update as particularly important as regulatory uncertainty represents the greatest risk to OCA's US approval, as well as upcoming (4Q13) catalyst potential.

KEY POINTS

- **Several areas appear to be of interest to ICPT.** Higher profile updates include breakthrough therapy designation and accelerated approval using "intermediate clinical endpoints," neither of which is directly applicable to the POISE study. However, important updates regarding surrogate endpoints and accelerated approval suitability provide support for our bullish thesis.
- **Key issue is whether ALP is an acceptable surrogate endpoint.** Recall that ICPT's Phase 3 POISE study of OCA utilizes a surrogate endpoint of alkaline phosphatase (ALP) and bilirubin, which we believe can be convincingly linked to improved outcomes by the "supergroup" analysis of ~4,000 PBC patients.
- **We do not identify any new areas of concern regarding OCA's candidacy for accelerated approval.**
- **Confirmatory study initiation in 4Q13 represents an important de-risking catalyst, in our view.** If ICPT moves forward with a confirmatory outcomes study in 4Q13 as expected, we believe this would signal that the company has reached a tentative understanding with the FDA regarding accelerated approval.
- **Raising PT to \$64 from \$60 on model adjustments.** Of note, our new 2Q EPS estimate of (\$0.86) is due to non-cash warrant revaluation expense as a result of ICPT's higher share price at the end of the quarter.

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.

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ICPT & Accelerated Approval—Background

As previously highlighted in our initiation report on 6/20/2013, Intercept intends to seek accelerated approval for OCA based on the upcoming results (expected in 2Q14) of the Phase 3 POISE study in primary biliary cirrhosis (PBC).

By way of background, accelerated approval refers to a special pathway established in 1992 by which the FDA can approve a drug based on a surrogate endpoint (e.g., laboratory biomarker measurement) instead of an outcomes-based endpoint (e.g., survival) that is typically required for approval. The granting of accelerated approval is also contingent upon the sponsor agreeing to conduct an additional post-approval (Phase 4) confirmatory study to assess clinical benefit using a traditional outcomes endpoint. The results of the confirmatory study are not required for accelerated approval to be granted, but approval can be subsequently revoked if the confirmatory study fails to show benefit.

Recall that the POISE study's primary endpoint is a surrogate endpoint consisting of ALP and bilirubin response (ALP below 1.67x ULN and a reduction of at least 15%, along with normal bilirubin levels). In comparison, the future confirmatory study would most likely utilize a primary endpoint of transplant-free survival. As discussed in more detail below, we believe the FDA will be amenable to accelerated approval for OCA via the POISE surrogate endpoint due to the nature of the disease as well as strong evidence provided by the large "supergroup" study of ~4,000 PBC patients, demonstrating the link between ALP/bilirubin response and transplant-free survival.

Recent Guidance on Accelerated Approval Appears to Support Our Positive Outlook

On June 26th, the FDA published new draft guidance ([link](#)) on the topics of fast-track designation, breakthrough designation and accelerated approval. Although the guidelines are in draft form, we believe they provide important insight into the FDA's current thinking on accelerated approval. Of note, the FDA's last formal guidance regarding these topics was issued in January 2006.

The updated guidance seeks to better define the terms (in bold below) used to describe the accelerated approval criteria outlined in section 506(c) of the FDASIA act, which was signed into law in 2012:

"...a product for a **serious or life-threatening condition** ... upon a determination that the product has an effect on a **surrogate endpoint that is reasonably likely to predict clinical benefit**, or an effect on a **clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality**, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the **availability or lack of alternative treatment**" (emphasis in original).

In the sections below, we examine the FDA's comments on the relevant definitions and provide our thoughts regarding the specific applicability to Intercept's pursuit of accelerated approval for OCA in primary biliary cirrhosis.

(1) Serious Condition. The FDA states that it will continue to interpret the term as it has done so in the past. Specifically, a disease is considered serious based on clinical judgment of “such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.” Although the accelerated approval pathway is most commonly employed for cancer indications, we believe PBC satisfies the “serious condition” criteria as a progressive disease that leads to liver failure and death, with a median survival of less than 10 years.

(2) Provides meaningful advantage over available therapies. Recall that the only currently approved therapy for PBC is ursodeoxycholic acid (Urso). For diseases with an existing approved therapy, the FDA outlines several circumstances where a new treatment would be considered to address an unmet medical need and provide a meaningful advantage over available therapies. We believe the circumstance most relevant to ICPT is described as follows, “[a new treatment that] has a benefit for patients who are unable to tolerate available therapy *or whose disease has failed to respond to available therapy*, or the treatment can be used effectively with other critical agents that cannot be combined with available therapy” (emphasis added).

The new guidelines provide additional flexibility for the FDA to qualify a drug as addressing an unmet medical need in situations where the drug has not fully demonstrated an advantage over existing therapy but works via a novel mechanism of action that has a “well-understood relationship to the disease pathophysiology.”

(3) Surrogate endpoint that is reasonably likely to predict clinical benefit. We see this is as the “make-or-break” issue for ICPT. Fortunately, in our view, the updated guidelines appear to specifically enable the FDA to utilize the types of studies like ICPT’s supergroup analysis in order to support the assertion that a particular biomarker is reasonably likely to predict clinical benefit. Moreover, we would not be surprised if ICPT’s supergroup study was discussed internally at FDA as a specific example of what the new guidelines are seeking to address.

That said, the key question remains whether the results of the supergroup analysis are sufficient to conclude that the ALP/bilirubin-responder endpoint is “reasonably likely to predict clinical benefit.” Section VII.C.1 of the FDA’s draft guidance outlines the agency’s approach to evaluating this question. To start, the agency will make, on a case-by-case basis, an informed judgment using both internal and external expertise. Next, the FDA discusses the importance of understanding the relationship between the drug’s effect and the disease process:

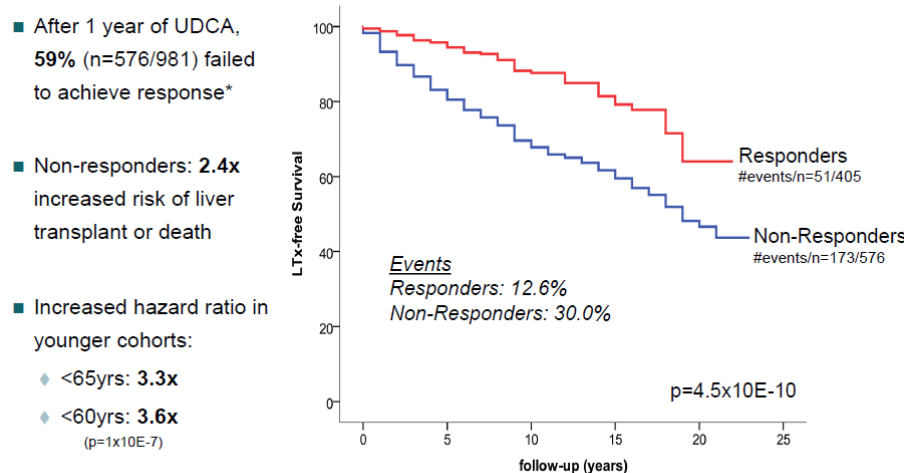
- “The extent to which a drug’s effect on the surrogate endpoint is known to predict an effect on the disease is critical. Sometimes this relationship can be assessed epidemiologically but it is most persuasively established by knowing that a drug that affects the surrogate also affects a clinical outcome.”

The FDA then lists several examples of factors to consider when assessing a surrogate endpoint. We focus on the following two examples as being most relevant to ICPT:

- “Whether there is reliable and consistent epidemiologic evidence supporting the relationship between the endpoint and the intended clinical benefit.”
- “Whether the effect on the endpoint has been shown to predict clinical benefit with other drugs in the class for the disease being treated.”

We believe that the numerous single-center studies that have measured PBC disease outcomes as a function of ALP serve to demonstrate consistent and reliable evidence. Next, we believe ICPT’s supergroup analysis directly addresses the FDA’s second example above. Recall that the supergroup study looked at whether patients who achieved the ALP/bilirubin response on Urso therapy were associated with improved transplant-free survival compared to those patients who did not meet the criteria. As shown in Exhibit 1 below, the results were highly statistically significant.

Exhibit 1: Initial Top-Line Results of PBC Supergroup Analysis



Intercept pharmaceuticals

*Response: ALP <1.67xULN (with ≥15% reduction from baseline) & normal bilirubin, among patients with initial ALP >1.67x ULN and/or abnormal bilirubin (n=981 at t=0)

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Source: Company presentation; UDCA = Urso.

Of course, it remains possible that ALP levels are nothing more than a correlative measurement of underlying disease activity, and are an artifact of Urso treatment (i.e., patients with less-serious disease are more likely to demonstrate a drop in ALP when given Urso). Hence the need for our discussion above, as the *raison d'être* of accelerated approval is to provide a pathway for drugs to reach the market via surrogate endpoints that are not yet fully validated.

Exhibit 2: Selected Quotes Regarding FDA Qualifying Criteria for Accelerated Approval

FDA Qualifying Criteria	Citations From New FDA Draft Guidance Relevant to ICPT
Serious Condition	<ul style="list-style-type: none"> • A disease/condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but morbidity need not be irreversible if it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.
Provides meaningful advantage over available therapies (unmet medical need)	<ul style="list-style-type: none"> • An unmet medical need is a condition whose treatment or diagnosis is not addressed adequately by available therapies. • When available therapy exists for a condition, a new treatment generally would be considered to address an unmet medical need if treatment: <ul style="list-style-type: none"> ○ Has a benefit for patients who are unable to tolerate available therapy or whose disease has failed to respond to available therapy, or the treatment can be used effectively with other critical agents that cannot be combined with available therapy. • For example, in a condition for which there are approved therapies that have a modest response rate or significant heterogeneity in response, a drug with a novel mechanism of action (but comparable safety and effectiveness) could have the potential to provide an advantage over available therapy. In such a case, the novel mechanism of action should have a well-understood relationship to the disease pathophysiology. In addition, there should be reasonable basis for concluding that a significant number of patients may respond differently to the new drug compared to available therapy. • Accordingly, FDA intends to consider a range of potential advantages over available therapy beyond those shown in head-to-head comparisons.
Demonstrates an effect on surrogate endpoint that is reasonably likely to predict clinical benefit.	<ul style="list-style-type: none"> • For purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. • The empirical evidence may include "epidemiological, pathophysiological, therapeutic, pharmacologic, or other evidence developed using biomarkers, for example, or other scientific methods or tools." • Clinical data should be provided to support the assertion that a relationship of the surrogate or intermediate clinical endpoint to the outcome is reasonably likely, and should be relevant to the relationship between the specific endpoint to be used and the specific intended clinical benefit of the drug. • Whether a drug effect on a given endpoint is reasonably likely to predict clinical benefit is a matter of judgment. FDA considers all relevant evidence and weighs the uncertainty against the severity of the disease to be treated and the lack of available therapy. On a case-by-case basis, FDA will make informed judgments using both internal and external expertise. • The extent to which a drug's effect on the surrogate endpoint is known to predict an effect on the disease is critical. Sometimes this relationship can be assessed epidemiologically but it is most persuasively established by knowing that a drug that affects the surrogate also affects a clinical outcome.

	<ul style="list-style-type: none"> Following are examples of factors to consider in identifying and assessing a surrogate endpoint: <ul style="list-style-type: none"> Whether there is reliable and consistent epidemiologic evidence supporting relationship between the endpoint and the intended clinical benefit. Whether the effect on the endpoint has been shown to predict clinical benefit with other drugs in the class for the disease being treated.
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Source: June 2013 FDA Draft Guidance on Expedited Programs for Serious Conditions.

Exhibit 3: Comparison of FDA Expedited Programs for Serious Conditions

	Fast Track	Breakthrough Therapy	Accelerated Approval	Priority Review
Nature of program	Designation	Designation	Approval Pathway	Designation
Reference	<ul style="list-style-type: none"> Section 506(b) of the FD&C Act, as added by section 112 of the Food and Drug Administration Modernization Act of 1997 (FDAMA), and amended by section 901 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) 	<ul style="list-style-type: none"> Section 506(a) of the FD&C Act, as added by section 902 of FDASIA 	<ul style="list-style-type: none"> 21 CFR part 314, subpart H 21 CFR part 601, subpart E Section 506(c) of the FD&C Act, as amended by section 901 of FDASIA 	<ul style="list-style-type: none"> Prescription Drug User Fee Act of 1992
Qualifying criteria	<ul style="list-style-type: none"> A drug that is intended to treat a serious condition AND nonclinical or clinical data demonstrate the potential to address unmet medical need^a OR A drug that has been designated as a qualified infectious disease product^b 	<ul style="list-style-type: none"> A drug that is intended to treat a serious condition AND preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies^a 	<ul style="list-style-type: none"> A drug that treats a serious condition AND generally provides meaningful advantage over available therapies AND demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit (i.e., an intermediate clinical endpoint) 	<ul style="list-style-type: none"> An application (original or efficacy supplement) for a drug that treats a serious condition AND if approved, would provide a significant improvement in safety or effectiveness OR Any supplement that proposes a labeling change pursuant to a report on a pediatric study under 505A^c OR An application for a drug that has been designated as a qualified infectious disease product^d OR Any application or supplement for a drug submitted with a priority review voucher^e

Source: June 2013 FDA Draft Guidance on Expedited Programs for Serious Conditions

Exhibit 4: Comparison of FDA Expedited Programs for Serious Conditions (Cont'd)

	Fast Track	Breakthrough Therapy	Accelerated Approval	Priority Review
Nature of program	Designation	Designation	Approval Pathway	Designation
When to submit	<ul style="list-style-type: none"> • With IND or after • Ideally, no later than the pre-BLA or pre-NDA meeting 	<ul style="list-style-type: none"> • With IND or after • Ideally, no later than the end-of-Phase 2 meeting 	<ul style="list-style-type: none"> • The sponsor should ordinarily discuss the possibility of accelerated approval with the review division during development, supporting, for example, the use of the planned endpoint as a basis for approval and discussing the confirmatory trials. 	<ul style="list-style-type: none"> • With original BLA, NDA, or efficacy supplement
Timelines for FDA response	<ul style="list-style-type: none"> • Within 60 calendar days of receipt of request 	<ul style="list-style-type: none"> • Within 60 calendar days of receipt of request 	<ul style="list-style-type: none"> • Not specified 	<ul style="list-style-type: none"> • Within 60 calendar days of receipt of original BLA, NDA, or efficacy supplement
Features	<ul style="list-style-type: none"> • Actions to expedite development and review • Rolling review 	<ul style="list-style-type: none"> • All fast track designation features • Intensive guidance on efficient drug development during IND, beginning as early as Phase 1 • Organizational commitment involving senior managers 	<ul style="list-style-type: none"> • Approval based on an effect on a surrogate or intermediate clinical endpoint that is reasonably likely to predict a drug's clinical benefit 	<ul style="list-style-type: none"> • Shorter clock for review of marketing application (6 months compared to the 10-month standard review)
Additional considerations	<ul style="list-style-type: none"> • Designation may be withdrawn if it no longer meets fast track qualifying criteria 	<ul style="list-style-type: none"> • Designation may be withdrawn if it no longer meets breakthrough therapy qualifying criteria 	<ul style="list-style-type: none"> • Submission of copies of promotional materials for review • Conduct any required postapproval trials to verify and describe the anticipated clinical benefit or effect on IMM • Subject to expedited withdrawal 	<ul style="list-style-type: none"> • Designation will be assigned at the time of original BLA, NDA or efficacy supplement filing

^a Designation applies to a combination of a drug (either alone or in combination with other drugs) and the specific use for which it is being studied. Where appropriate, designation may be granted to development of a new use of an FDA-approved drug.

^b Title VIII of FDASIA entitled "Generating Antibiotic Incentives Now (GAIN)" provides incentives for the development of antibacterial and antifungal drugs for human use intended to treat serious and life threatening infections. Under GAIN, a drug may be designated as a *qualified infectious disease product (QIDP)* if it meets the criteria outlined in the statute. A drug that receives QIDP designation is eligible under the statute for fast track designation and priority review. However, QIDP designation is beyond the scope of this guidance.

^c Any supplement to an application under section 505 of the FD&C Act that proposes a labeling change pursuant to a report on a pediatric study under this section shall be considered to be a priority review supplement per section 505A of the FD&C Act as amended by section 5(b) of the Best Pharmaceuticals for Children Act.

^d See footnote b above.

Source: June 2013 FDA Draft Guidance on Expedited Programs for Serious Conditions

Exhibit 5: ICPT Potential Upcoming Milestones

Expected Date	Event Description
2H13	Additional presentations of PBC "supergroup" data
2H13	Update data from Phase 2a trial of OCA in portal hypertension (PESTO study)
2H13	Update data from Phase 2a trial of OCA in bile-acid diarrhea (OBADIAH 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.

Valuation Update

We are increasing our price target to \$64/share (from \$60/share) after adjusting our model to reflect our increased comfort with the Phase 3 POISE surrogate endpoint. Specifically, the contribution from OCA in PBC to our sum-of-parts valuation has increased to \$44/share from \$40/share, which now reflects a 76% probability of approval (from 74%).

Exhibit 6: ICPT Valuation Analysis

	Expected	Peak Sales	Est.		
Drug/Indication	Launch	Estimate (\$MM)	Probability of Success	P-Adj NPV (\$MM)	P-Adj Value / Share
OCA - Primary Biliary Cirrhosis	2015	\$716	76%	\$956	\$44
OCA/INT-767 - Portal Hypertension	2018	\$637	28%	\$232	\$11
OCA/INT-767 - Bile Acid Diarrhea	2018	\$541	33%	\$191	\$9
Pipeline Value				\$1,378	\$64
Net Cash				\$146	\$7
Total Equity Value				\$1,378	\$64

Diluted Shares Outstanding Used for Valuation (MM) 21.6

Source: Oppenheimer & Co.

Intercept Pharma. (ICPT)

(\$000's) (FY - DEC)

Oppenheimer & Co.

	2011A	2012A	2013E				2014E	2015E	
	FY:11A	FY:12A	Q1A	Q2E	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	2,446	405	400	400	400	1,605	1,600	1,600
Total revenues	\$ 1,805	\$ 2,446	\$ 405	\$ 400	\$ 400	\$ 400	\$ 1,605	\$ 1,600	\$ 39,320
Cost of Goods	-	-	-	-	-	-	-	-	3,539
Gross profit	1,805	2,446	405	400	400	400	1,605	1,600	35,781
Operating expenses									
Research and development	11,426	16,183	4,833	4,929	5,028	5,128	19,918	22,906	23,364
Selling, general and administrative	4,209	5,177	2,397	2,541	2,617	2,695	10,250	15,375	24,000
Other	-	-	-	-	-	-	-	-	-
Total expenses	15,636	21,360	7,229	7,470	7,645	7,824	30,168	38,280	47,364
Operating income	(13,830)	(18,914)	(6,824)	(7,070)	(7,245)	(7,424)	(28,562)	(36,680)	(11,582)
Revaluation of warrants	1,045	(24,625)	(3,683)	(7,500)	-	-	(11,183)	-	-
Other income (expense)	0	(2,822)	296	21	31	31	(11,183)	114	103
Pre-tax income	(12,738)	(46,274)	(10,210)	(14,549)	(7,214)	(7,393)	(39,745)	(36,567)	(11,479)
Income tax expense (benefit)	3,000	-	-	-	-	-	-	-	(1,722)
Net income	(\$15,738)	(\$46,274)	(\$10,210)	(\$14,549)	(\$7,214)	(\$7,393)	(\$39,745)	(\$36,567)	(\$9,757)
Basic shares outstanding	3,330	6,283	16,558	16,917	18,747	18,897	17,780	19,272	19,887
Diluted shares outstanding			19,423	19,782	21,612	21,762	20,645	22,137	22,809
GAAP EPS (basic and diluted)	(\$4.73)	(\$7.36)	(\$0.62)	(\$0.86)	(\$0.38)	(\$0.39)	(\$2.24)	(\$1.90)	(\$0.43)
Cash and Equivalents	\$ 17,707	\$ 110,194	\$ 104,220	\$ 156,529	\$ 153,635	\$ 150,564	\$ 150,564	\$ 130,438	\$ 132,583

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.

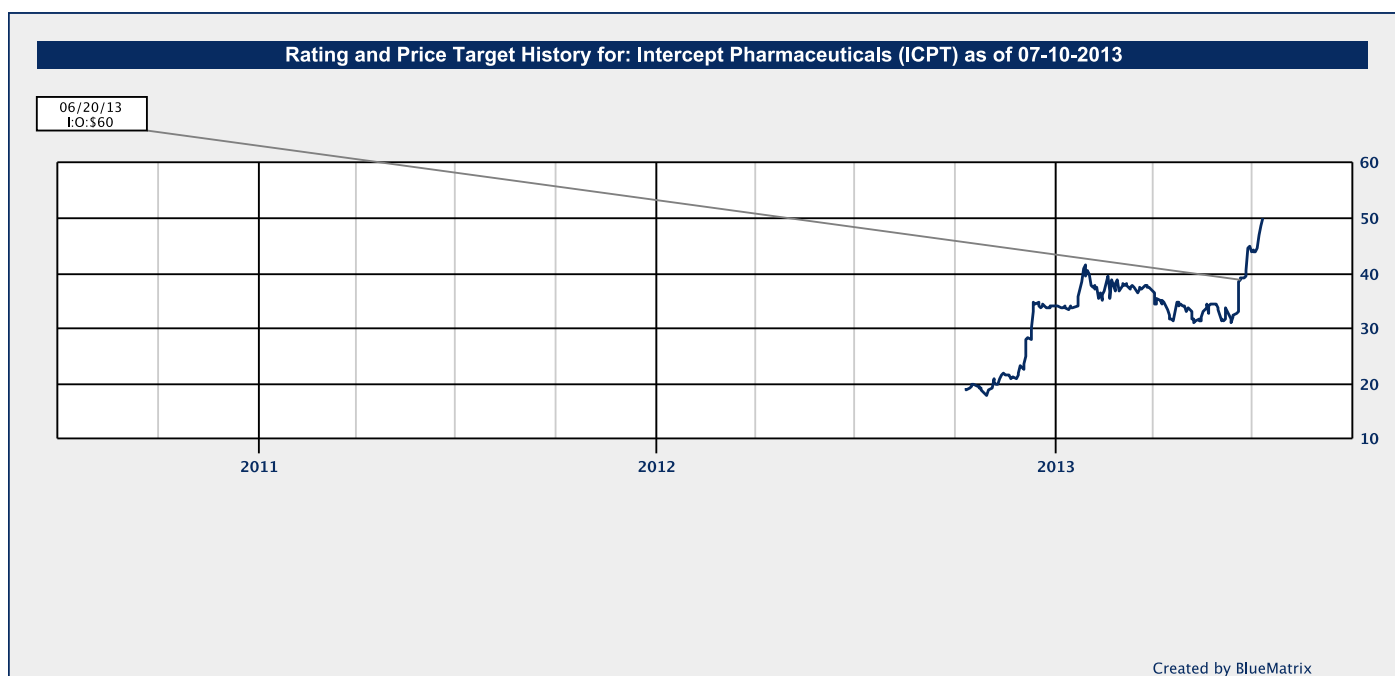
Financing Risk. While we believe ICPT is sufficiently capitalized to reach significant value inflection points, any unexpected clinical or regulatory setbacks may prompt capital raising before ICPT is able to generate sufficient revenues from the commercial activities.

Important Disclosures and Certifications

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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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Underperform (U) - Stock expected to underperform the S&P 500 within the next 12-18 months.

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Buy - anticipates appreciation of 10% or more within the next 12 months, and/or a total return of 10% including dividend payments, and/or the ability of the shares to perform better than the leading stock market averages or stocks within its particular industry sector.

Neutral - anticipates that the shares will trade at or near their current price and generally in line with the leading market averages due to a perceived absence of strong dynamics that would cause volatility either to the upside or downside, and/or will perform less well than higher rated companies within its peer group. Our readers should be aware that when a rating change occurs to Neutral from Buy, aggressive trading accounts might decide to liquidate their positions to employ the funds elsewhere.

Sell - anticipates that the shares will depreciate 10% or more in price within the next 12 months, due to fundamental weakness perceived in the company or for valuation reasons, or are expected to perform significantly worse than equities within the peer group.

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Rating	Count	IB Serv/Past 12 Mos.		Count	Percent
		Percent			
OUTPERFORM [O]	299	50.94		140	46.82
PERFORM [P]	279	47.53		96	34.41
UNDERPERFORM [U]	9	1.53		3	33.33

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