Intercept Pharmaceuticals (ICPT)

Initiating at OUTPERFORM with $25 Fair Value: All Smiles for ICPT's Bile

- **We are initiating coverage of Intercept Pharmaceuticals with an OUTPERFORM rating and $25 fair value.** We believe Intercept's lead drug, Obeticholic Acid (OCA), represents a compelling investment opportunity with strong Phase 2 data and clear unmet medical need for the treatment of Primary Biliary Cirrhosis (PBC). PBC is a relatively well-defined orphan disease market, where a significant subset of patients does not adequately benefit from the current standard of care treatment.
- **Prior Phase 2 OCA studies demonstrate convincing therapeutic benefit and significantly de-risk the currently enrolling pivotal trial, in our view.** We see a high chance of success for Intercept's ongoing Phase 3 POISE study in PBC. In two well-conducted Phase 2 studies, OCA demonstrated highly statistically significant lowering of alkaline phosphatase (ALP), the key biomarker by which PBC disease activity and progression are measured. We expect these positive results to be replicated in the Phase 3 study, which is enrolling a larger number of patients and employs a longer treatment duration.
- **We estimate worldwide OCA peak sales of $350MM for PBC; development in additional indications provides the opportunity for longer-term value creation and additional catalysts.** While our fair value for ICPT is mostly reflective of PBC, OCA appears promising for a number of liver-related indications including Non-Alcoholic Steatohepatitis (NASH), portal hypertension, and bile acid diarrhea. After PBC, Intercept's most advanced OCA program is for NASH, an enormous unmet medical need with blockbuster potential due to high rates of obesity and no currently approved therapies.
- **Our fair value of $25 is calculated using a sum-of-parts analysis,** applying a 30% annual discount to our peak worldwide sales estimates for ICPT's drug candidates, incorporating a 1-10x multiple based on stage of clinical development. Our sum-of-parts valuation includes the contribution of OCA for the treatment of PBC and NASH. We currently do not incorporate the potential value of INT-767 or INT-777 in our fair value due to the early-stage status of these drugs at this time.

FYE Dec	2011A	2012E			2013E		
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	$0.0A	$0.8A		--	$0.4E		--
Q2 Jun	0.0A	0.8A		--	0.4E		--
Q3 Sep	0.0A	0.5E		--	0.4E		--
Q4 Dec	0.0A	0.4E		--	0.4E		--
Year*	**$1.8A**	**$2.5E**		**--**	**$1.6E**		**--**
Change	n/a	n/a			n/a		
	2011A	2012E			2013E		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	$0.00A	($0.25)A		--	($0.41)E		--
Q2 Jun	0.00A	(0.47)A		--	(0.41)E		--
Q3 Sep	0.00A	(0.42)E		--	(0.40)E		--
Q4 Dec	0.00A	(0.30)E		--	(0.40)E		--
Year*	**($1.19)A**	**($1.53)E**		**--**	**($1.62)E**		**--**
P/E	nm	nm			nm		
Change	n/a	n/a			n/a		

Consensus estimates are from Thomson First Call.
** Numbers may not add up due to rounding.*

November 8, 2012

Price
$20.02

Rating
OUTPERFORM

Fair Value Estimate
$25

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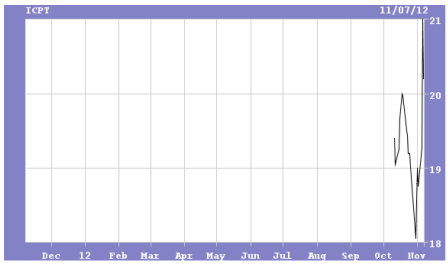
Company Information

Shares Outst (M)	18.2
Market Cap (M)	$364.3
52-Wk Range	$17.96 - $21.35
Book Value/sh	$5.02
Cash/sh	$6.07
Enterprise Value (M)	$253.8
LT Debt/Cap %	0.0%

Company Description

Intercept Pharmaceuticals is an emerging biopharmaceutical company specializing in the development of bile acid therapies. The company's lead drug, Obeticholic Acid (OCA), is currently in Phase III development for the treatment of Primary Biliary Cirrhosis (PBC).



Source: Thomson Reuters

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Investment Summary

- **Intercept Pharmaceuticals is an emerging biopharmaceutical company developing small molecule drug treatments for significant unmet medical needs in orphan and other chronic liver diseases by leveraging its expertise and intellectual property in bile acid chemistry.**
- **We believe investment in ICPT has an attractive risk/reward profile as: 1) clinical success is likely; 2) regulatory risk is reasonable; and 3) commercial risk is below average.**
- **Intercept's lead drug, OCA, has generated impressive efficacy data in two Phase 2 studies.**
    - Two Phase 2 studies demonstrated highly statistically significant benefits of OCA ($p < 0.0001$) in PBC. In short, we believe OCA possesses one of the more clinically-derisking Phase 2 datasets among biotech drugs in development.
    - We do not see any worrisome safety signals so far. OCA's main drawback is pruritus (itching) which is a tolerability issue, not a safety issue in our view, and appears minor at the 10mg dose that is being pursued in Phase 3. Pruritus-related discontinuation rates may shape the drug's total market opportunity but we expect only a modest impact which we have accounted for in our peak sales estimates.
- **Primary Biliary Cirrhosis (PBC) is a relatively well defined orphan market with a clear unmet medical need.**
    - PBC patients are predominantly adult women, and are typically discovered via abnormally high levels of a particular liver enzyme called alkaline phosphatase (ALP) during routine blood tests, or by seeking medical attention due to persistent pruritus and/or fatigue.
    - The current standard-of-care for PBC is the now-generic drug Urso (short for Ursodeoxycholic acid). Most patients diagnosed with PBC receive Urso therapy, but the drug is not sufficiently effective in about 40-50% of cases and these patients remain at high risk of eventual liver failure and death. This presents a clear, unmet medical need in a well-defined market of patients who are already being treated for this orphan disease indication.
    - Should OCA be approved, we believe the barriers to commercial adoption will be relatively low as patients are already identified and receiving treatment. Moreover, we see upside potential to our estimates of the eligible patient population, which may err on the conservative side.
- **We expect positive clarity on FDA regulatory strategy in 2013.**
    - Intercept intends to seek accelerated approval in the US based on Phase 3 results, but is still awaiting final clarity from the FDA that the primary endpoint used (ALP biomarker) will be acceptable for accelerated approval.
    - We believe that the FDA will support an accelerated approval approach following review of a pooled "supergroup" analysis demonstrating the link between ALP levels and survival in PBC.
    - While the regulatory risk is not trivial, in our view, we expect a favorable update in 2013 which should serve as an additional catalyst for ICPT shares while investors await results of the Phase 3 POISE study.
- **We estimate peak WW sales of $350MM for OCA in PBC following approval in mid-2015.**
- **OCA development in other indications provides additional upside potential.** Due to OCA's potential applicability for a number of liver related diseases, additional Phase 2 studies are being conducted in NASH, portal hypertension and bile acid diarrhea. We believe these additional pipeline opportunities represent both the potential for long-term value creation beyond PBC as well as a source of additional news flow and catalysts over the next two years. Of note, we currently do not include the potential value of OCA for indications other than PBC or NASH, and do not include preclinical candidates INT-767 and INT-777 in our fair value estimate due to their early-stage status at this time.
- **With IPO funding, we project cash runway into 2015 which covers significant value-driving catalysts. Meanwhile, we believe that Intercept has low near-term financing risk.** Following the recent $80.2 million initial public offering, we estimate that Intercept will end 2012 with approximately $110 million in cash and equivalents. We believe the recent financing provides Intercept with a cash runway into 2015, which is well beyond expected timing of Phase 3 POISE data in mid-2014. While Intercept may seek additional financing prior to launching OCA, we view the company's near-term financing risk to be minimal.
- **We calculate ICPT is trading at an attractive valuation with significant potential upside to our fair value estimate of $25/share.** Our fair value is calculated using a sum-of-parts analysis, applying a 30% annual discount to our peak worldwide sales estimates for ICPT's drug candidates, incorporating a 1-10x multiple based on stage of clinical development. Our sum-of-parts valuation includes the contribution of OCA for the treatment of PBC and NASH.
- **Risks to the attainment of our fair value.** As discussed in more detail on page 20, the investment risks associated with ICPT include (but are not limited to): risk of clinical-trial failures, regulatory risks, commercial execution risks, competitive risks, and financing risk.

Introduction

Intercept Pharmaceuticals, Inc. (ICPT, Intercept) is a biopharmaceutical company specializing in developing novel drugs that target diseases of the liver or hepatic system. The company's lead development program is the drug OCA for the treatment of Primary Biliary Cirrhosis (PBC), a potentially serious chronic disease that can lead to liver failure and death. Intercept's remaining development pipeline consists of OCA for the treatment of other liver-related indications as well as preclinical programs for the treatment of fibrosis (INT-767) and Type-2 diabetes (INT-777).

Figure 1: Intercept's drug pipeline

Drug	Mechanism	Indication	Stage	Intercept's Ownership Rights
OCA (obeticholic acid; formerly INT-747)	FXR Agonist	PBC	Phase 3	Worldwide, excluding Japan and China
		NASH	Phase 2b	Worldwide, excluding Japan and China
		Portal Hypertension	Phase 2a	Worldwide, excluding Japan and China
		Bile Acid Diarrhea	Phase 2a	Worldwide, excluding Japan and China
INT-767	Dual FXR/TGR5 Agonist	Fibrosis	Preclinical	Worldwide
INT-777	TGR5 Agonist	Type 2 diabetes	Preclinical	Worldwide

Source: Company reports, Wedbush Securities research.

Intercept's lead drug is obeticholic acid, or frequently referred to as OCA. OCA a bile acid analogue and an agonist of FXR (farnesoid X receptor), conferring potential therapeutic properties for a number of liver-related diseases. OCA was first described in 2002 by an academic laboratory at the University of Perugia in Italy, the head of which went on to co-found Intercept in the same year.

Following positive results from Phase 2 studies, Intercept recently progressed OCA into late-stage development for the treatment of PBC. PBC is a chronic liver disease resulting from an autoimmune response against the bile ducts, and can lead to cirrhosis and liver failure, causing death or the need for liver transplantation. PBC is classified as an Orphan Disease, and affects roughly 65,000 to 85,000 patients in the US. A key hallmark of PBC (especially in early stages of the disease before progression of cirrhosis), is elevated levels of the liver enzyme Alkaline Phosphatase (ALP). Phase 2 studies of OCA demonstrated highly significant reductions of ALP levels in patients with PBC.

Intercept began enrollment of a Phase 3 study of OCA in PBC, called POISE, in early 2012. We expect enrollment to be completed in the first half of 2013, followed by the release of topline data in mid-2014. Aside from PBC, Intercept is also developing OCA for other indications including NASH, Portal Hypertension and Bile Acid Diarrhea, all of which are in Phase 2.

Intercept owns worldwide rights to OCA with the exception of Japan and China, where Dainippon Sumitomo Pharma has an exclusive license from Intercept. The company has also signed a collaborative agreement with Servier for the discovery and development of bile-acid related drugs and technology.

The remainder of Intercept's clinical pipeline consists of INT-767, a dual agonist of FXR and TGR5, in early stage development for fibrosis, along with INT-777, a TGR5 agonist in early stage development for diabetes. We expect Intercept for prioritize development of INT-767 over INT-777 going forward. Moreover, we believe the potential applicability of OCA for diseases other than PBC, along with encouraging preclinical data for INT-767, provide for multiple shots-on-goal from a drug-development viewpoint and a steady stream of potential catalysts from an investment viewpoint.

Intercept is headquartered in New York City, NY, and reported having 18 employees as of August 31, 2012.

Upcoming Milestones, Cash Runway and Valuation

Near-term Milestones

We estimate the following near and longer-term milestones for Intercept:

Expected Date	Event
Q4:2012	Completion of enrollment in Phase 2 FLINT trial of OCA in NASH
H1:2013	Completion of enrollment in Phase 3 POISE trial of OCA in PBC
H1:2013	Presentation and publication of PBC biomarker supergroup analysis
Mid:2013	Topline results from OCA trial in bile acid diarrhea (OBADIAH)
H2:2013	Start of Phase 3 OCA confirmatory outcomes study in PBC
Mid:2014	**Topline data from pivotal Phase 3 POISE study of OCA in PBC**
H2:2014	Topline data from Phase 2 FLINT study of OCA in NASH
Mid:2015	Potential US Approval of OCA for the treatment of PBC

Cash Runway

Following the company's IPO, we estimate that Intercept will end 2012 with approximately $111 million in cash and equivalents.

With an anticipated cash burn between $5 and $12 million per quarter, we believe that Intercept's existing cash will be sufficient to fund the company's anticipated needs into 2015. We would expect the company to seek additional financing, if necessary, towards the start of OCA commercialization, which we currently project for H2:2015. We view the risk of a near-term financing to be minimal.

Valuation

Our ICPT fair value of $25 is calculated using a sum-of-parts analysis, applying at 30% annual discount to our peak sales estimates of OCA in PBC and NASH, and incorporating a 1-10 multiple based on stage of clinical development. Our fair value assumes peak OCA annual sales of approximately $350 million for PBC and $315 million for NASH.

We believe ICPT is trading at an attractive valuation with significant upside potential to our fair value estimate of $25 per share. With a clinical profile derisked by strong Phase 2 results, and a defined market opportunity in PBC, we believe that ICPT represents an attractive investment opportunity for investors with a 12-month time horizon.

We use multiples to account for clinical and regulatory risk at various stages of development.

NOVEL DRUGS

1: In preclinical testing	6: In Pivotal Trial
2: Passed preclinical	7: Pivotal data
3: IND filed	8: Regulatory review
4: Phase I data	9: Approved
5: Phase II data	10: Launched

Today: 11/8/12	Stock	MktCap ($000)	Upside
Wedbush Fair Value for ICPT	$24.54	$446,607	23%
Full Pipeline Value:	$25.14	$457,509	
Net Cash:	$6.07	$110,505	
ICPT Total Value:	$31.21	$568,014	
Current ICPT Stock:	$20.02	$364,310	
ICPT Diluted Shares Outstanding (000s):	18,197		

Intercept Pipeline Valuation

Product		Indication	Eligible # Annual WW Treatments Est	Pricing $ per Patient per Year Est/Actual	Peak Penetration Est	Gross WW Peak Sales Est ($000)	ICPT Net Peak Revs Est WW ($000)	Estimated Launch	Multiple	Annual Discount Rate	Wedbush MktCap Fair Value ($000)	Wedbush Stock Fair Value
FXR Agonist	OCA (INT-747)	PBC	58,200	$18,844	30%	$351,705	$351,705	7/1/2015	6	30%	$369,240	$20.29
FXR Agonist	OCA (INT-747)	NASH	7,225,000	$2,340	2%	$315,938	$315,938	7/1/2018	4	30%	$77,367	$4.25
FXR/TGR5 Agonist	INT-767	Fibrosis	2,750,000	$2,500	5%	$343,750	$343,750	1/1/2021	1	30%	$10,902	$0.60

Source: Company reports, Wedbush Securities research.

Primary Biliary Cirrhosis and Chronic Liver Disease

Primary biliary cirrhosis, or PBC, is a rare liver disease that primarily affects adult women of middle age. PBC is marked by autoimmune-mediated damage to the bile ducts that circulate bile acids out of the liver. Over time, destruction of these bile ducts causes bile acids to accumulate to toxic levels in the liver, leading to its progressive degradation caused by chronic inflammation and fibrosis. Obstruction of normal bile flow, also known by the medical term *cholestasis*, is damaging to the healthy liver. (Bile exists as a liquid and is necessary to help digest fats and fat-soluble vitamins in the small intestine). While the degree of severity of PBC exists as a spectrum across patients, over time the disease can eventually lead to liver failure and death. Indeed, before the recent emergence of diseases such as NASH, PBC was once the most frequent cause of liver transplantation in the US.

Because PBC is a progressive disease with a relatively protracted course, determinations such as diagnosis, progression, and treatment-response rely upon measuring the levels of a biomarker called alkaline phosphatase (abbreviated as ALP). ALP is an enzyme which is released by the liver in response to certain toxicities, which in the case of PBC is the build up of bile acids due to cholestasis. As discussed in later sections of this report, ALP levels are crucial to tracking disease course and determining whether a patient has adequately responded to therapy.

Patients with PBC are typically identified by either: complaints of frequent pruritus (itching or tingling) and fatigue, or findings of elevated ALP during routine blood-tests (which include a liver enzyme panel). A diagnosis of PBC following elevated ALP levels is made upon positive results from a confirmatory test for serum anti-mitochondrial-antibodies. A liver biopsy is not considered necessary for confirming a diagnosis of PBC, although biopsies may be performed at intervals throughout the disease course to check for progression and the onset of cirrhosis. Our research suggests that a diagnosis of PBC is not an especially difficult (or elusive) task for a general practitioner, although patients are usually referred to a specialist following diagnosis. Under-diagnosis of PBC exists primarily in patients with more mild disease and/or patients who do not receive routine medical exams, by our estimation.

Figure 2: Snapshot of Primary Biliary Cirrhosis (PBC)

Incidence	Up to 1:1,000 females over 40 years old. 9-10:1 female:male preponderance.
Prevalence	Orphan disease designation in US and EU. Approximately 300,000 persons with PBC in developed countries, with 60,000 diagnosed and treated.
Diagnosis	Patient typically presents as a middle-aged female with complaints of pruritus and fatigue. Diagnosis is confirmed via elevated ALP levels + positive AMA; liver biopsy not required but can be performed to measure and track the disease course.
Course	Progressive disease; severity and rate of progression are highly variable. Some patients exhibit minimal symptoms, others rapidly progress to liver failure. Median survival in untreated patients is reported to be 7.5 to 16 years.
Symptoms/ Complications	Pruritus, fatigue, jaundice, hypercholesterolemia, xanthomas, osteomalacia; in later stages of the disease: portal hypertension, hyperbilirubinemia, ascites, encephalopathy, liver failure. Pruritus and fatigue are present in up to 85% and 70% of PBC patients.
Current standard of care	Ursodiol (Urso) is only approved therapy. Immunosuppressants are sometimes used off-label.
Treatment duration	Chronic therapy is generally necessary.

Source: FDA review documents, company reports, Wedbush Securities research.

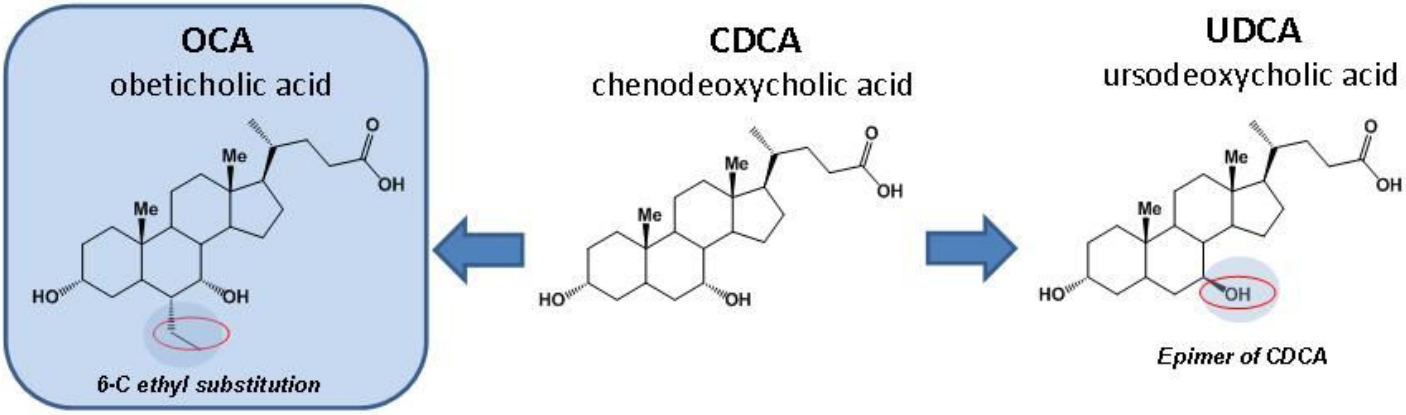
PBC is designated as an orphan disease in the US and Europe. As elaborated in sections below, while making a highly accurate determination of the disease's prevalence is difficult, Intercept estimates that there are approximately 300,000 persons with PBC in developed countries, of whom roughly 60,000 have been diagnosed and are being treated with Urso. Our own analysis of the US market size (excluding Europe and ROW) suggests the total population of diagnosed and treated PBC patients to be approximately 34,000, with approximately 14,000 of these patients being likely eligible for second-line therapy with OCA.

Urso – Current Standard of Care Falls Short in Large Subset of PBC Patients

Currently, the only approved drug for the treatment of PBC goes by the generic name ursodeoxycholic acid, abbreviated as UDCA, but often referred to as Urso for short (not to be confused with URSO in all capital letters, which refers to one branded version of Urso approved specifically for PBC in 1997, but has since gone generic). Urso is one of the naturally occurring bile acids in most mammals, but in humans it comprises only small percentage (<5%) of a person's total bile acid pool. Upon administration of synthetic Urso, the drug enters the enterohepatic circulation (a loop consisting of the liver, biliary tract and intestine) and alters the composition of the bile pool so that Urso comprises up to 50-60% of a patient's total bile acids (at therapeutic doses).

The primary mechanism of action by which Urso functions as a therapeutic for PBC is physiochemical in nature, and not through interactions with receptors or signalizing pathways. In short, Urso is less toxic to hepatocyte cell membranes than the bile acid CDCA, which is normally the largest component of the bile acid pool. Urso therapy dilutes the normally large concentration of CDCA; in cholestatic patients high levels of CDCA can have toxic effects as its accumulation in the liver damages hepatocyte membranes to the point of triggering apoptosis.

Figure 3: Chemical structures of CDCA, UDCA, and OCA



Source: Intercept Pharmaceuticals presentation.

Urso was first approved in 1987 for the treatment of gallstones and was marketed under the brand name ACTIGALL by Ciba-Geigy (now part of Novartis). Off-label use in PBC began almost simultaneously. A clinical study of a tablet formulation (able to be divided among 4 daily doses, unlike ACTIGALL, which is a capsule formulation) was undertaken to study Urso as a therapy for PBC. This drug, banded URSO by Axcan Pharmaceuticals (now Aptalis Pharma) was approved for PBC by the FDA in December 1997.

We have thoroughly examined the FDA review documents related to URSO's NDA filing and subsequent approval. In our view, the key takeaways from the URSO review include:

- (1) FDA's findings that the drug has a very clean safety profile, with very little concern for potential safety issues with chronic usage (of note, pre-malignant/cancerous lesions were observed in the urinary tract of rats treated with lifelong URSO therapy, but this did not appear to be a significant concern for the reviewer).
- (2) FDA's findings that efficacy was established in the pivotal study despite the fact that primary endpoint success was driven by the bilirubin component and statistical significance was not achieved for other components of the composite endpoint including death and liver transplant.
- (3) Acknowledgement by the FDA reviewer that demonstrating improvements in outcomes such as death and liver transplant would require a multi-year study of many hundreds of patients, which may not be practical for a PBC pivotal study.

A summary of the clinical studies used to support URSO's approval is shown in Figure 4, below.

Figure 4: Overview of pivotal and supportive study for URSO approval in PBC

Study Type	URSO Pivotal Study	URSO Supportive Study
Dates	• April 1988 – May 1992	• April 1988 – July 1992
Primary Investigator	• K.D. Lindor, Mayo Clinic	• E.J. Heathcote, Toronto Hospital
Main Trial Design Features	• Randomized, double-blind, placebo controlled, 2-year duration • Efficacy endpoint: time to treatment failure • Treatment failure defined as: death; need for liver transplant; development of varices, ascites or encephalopathy; doubling of serum bilirubin; voluntary withdrawal; or marked worsening of fatigue or pruritus.	• Randomized, double-blind, placebo controlled, 2-year duration • Efficacy endpoint was the percent change in total serum bilirubin at 2 years. Secondary outcome measures: changes in symptoms, laboratory assessments of cholestasis, serum Ig levels, histologic state change and death and/or liver transplant.
Study Population	• PBC confirmed by liver biopsy with serum ALP at least 1.5x ULN and AMA-positive • Patients stratified according to histologic stage, the presence or absence of esophageal varices, and serum bilirubin levels	• PBC confirmed by liver biopsy with elevated serum ALP and AMA-positive.
Treatment arms	• UDCA: 250 mg film-coated tablets, 13-15 mg/kg/day administered in 4 divided doses (n=89) • Placebo: 4 times daily (n=91)	• UDCA: 20 mg capsules, 14 mg/kg/day administered as a single oral dose with evening meals (n=111) • Placebo: once daily (n=111)
Comments	• Primary endpoint reached with 47% of placebo patients vs. 23% of Urso patients meeting definition of treatment failure ($p<0.01$). Of all the components of treatment failure, only bilirubin doubling showed a statistically significant difference between URSO and placebo. Positive trends observed for death (3% vs. 7%) and transplantation (3% vs. 6%).	

Source: Adapted from FDA medical officer's review of URSO NDA, citing Gastroenterology 106:1284-1290 (1994); Hepatology 19:1149-1156 (1994). Note ULN refers to the upper limit of normal levels of a liver enzyme.

Although Urso's clean safety profile and modest efficacy has led to its widespread adoption in PBC, a significant number of patients do not derive enough benefit from therapy to bring the disease under control. We believe this is like due to PBC's wide spectrum of disease severity along with Urso's non-specific mechanism of action.

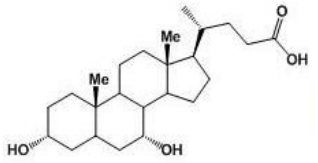
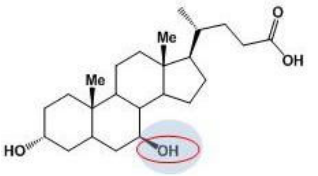
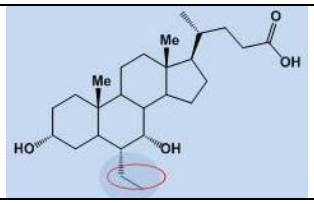
Recall that PBC disease course is measured by ALP levels in the early-to-mid stages of the disease. Patients whose ALP levels remain high despite therapy with Urso are considered to be non-responders and remain at high risk of liver failure and death. Indeed, in the pivotal Phase 3 URSO study, the average ALP level after 2-years of therapy remained 2.7 times higher than the upper limit of normal (ULN), despite a mean decline of 53% from baseline. Importantly, the consensus treatment goal for PBC therapy is a reduction in ALP to below 1.67x ULN.

The unmet medical need in PBC exists precisely in these patients whose ALP levels remain above 1.67x ULN after treatment with Urso.

OCA Addresses Unmet Medical Need in PBC

Intercept is developing OCA as a second-line therapy for PBC in patients who do not adequately respond to Urso. OCA is a bile acid analogue that does not exist as part of the normal bile acid pool in humans. As shown below, OCA is structurally similar to CDCA, with the only difference being the addition of an ethyl group at carbon position six. This substitution allows the molecule to fit tightly inside the pocket of FXR binding domain and is the driver of its activity as a potent FXR agonist, unlike Urso which has no FXR-related activity and derives its therapeutic benefit in PBC from mostly physiochemical means (displacing the more-toxic bile acid CDCA). Moreover, OCA is not converted back into CDCA under physiological conditions like Urso and can be administered at much lower doses as a therapeutic agent (10 mg/day vs. ~1,000 mg/day split over multiple doses).

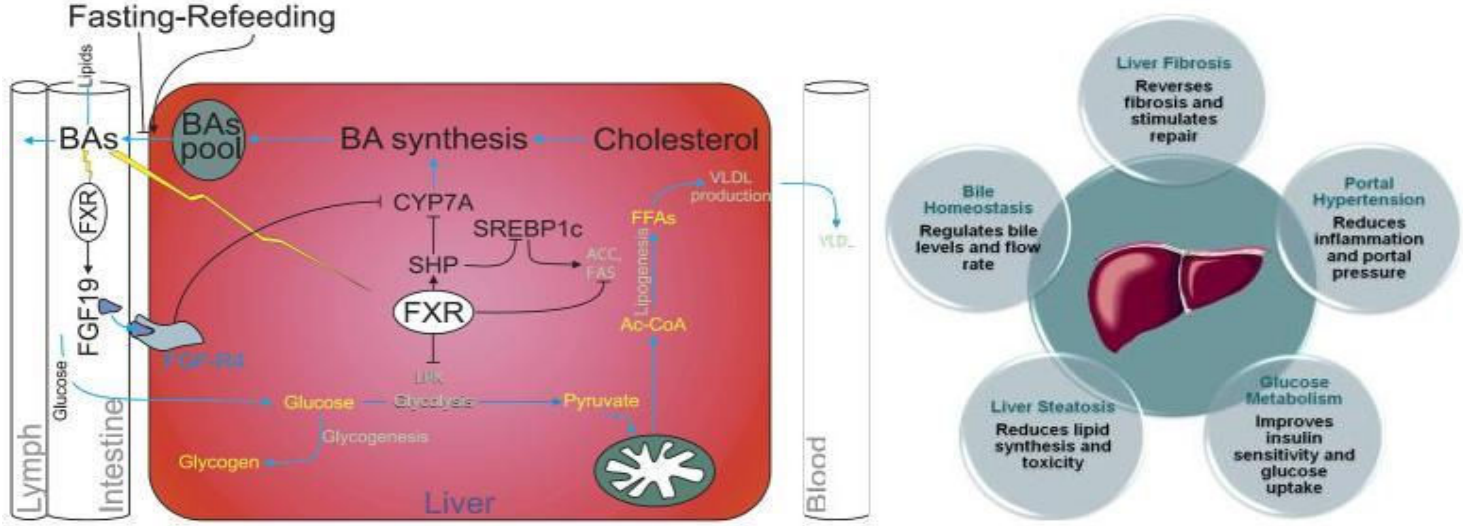
Figure 5: Chemical structure and FXR activity of CDCA, UDCA and OCA.

Bile Acid	Structure	FXR activity (EC_{50})	Comments
CDCA (chenodeoxychoilic acid)		8.66 µM	Normally comprises majority of bile acid pool. CDCA retains some FXR activity and has been used historically to treat gallstones, but severe GI side-effects preclude use in PBC and led to development of Urso (UDCA).
UDCA (ursodeoxycholic acid)		No activity	Epimer of CDCA. Normally 2-4% of bile acid pool composition. Urso therapy brings concentration to > 50%. Less toxic to hepatocyte cell membranes than CDCA.
OCA (obeticholic acid)		0.099 µM	6-ethyl substitution of CDCA (6E CDCA). Not present in normal bile acid pool and is not converted to CDCA under physiologic conditions. Mechanism of action via FXR agonism leading to improved bile flow.

Source: Intercept, Wedbush Securities research; R Pellicciari Med Chem 45(17) 2002.

FXR, short for Farnesoid X Receptor, was discovered in 1999 as a bile acid receptor. Further research elucidated FXR's function as playing an important role in regulating the flow and synthesis of bile acids. FXR has also been identified as necessary for the normal regeneration of the liver and its downstream targets encompass a myriad of liver disease related deregulations (Figure 6).

Figure 6: FXR Pathway and mechanisms of action by FXR agonists in chronic liver disease.



Source: Intercept Presentation.

Phase 2 Studies Set the Stage for Pivotal Study Success

As discussed below in more detail, our review of the cumulative clinical experience with OCA strongly suggests that the drug provides a clinically meaningful benefit for PBC patients.

In short, our optimism regarding OCA's chance of clinical success is based upon the robust efficacy demonstrated in Phase 2 studies. In both Phase 2 PBC studies, OCA demonstrated highly statistically significant reductions in ALP levels compared to placebo (p<0.0001 for primary endpoint at all doses tested). These reductions occurred when OCA was administered as monotherapy (201 trial n=59) or in combination with Urso (202 trial; n=165), and in total, 80% of OCA patients experienced a greater than 10% reduction in ALP levels (the clinically meaningful cutoff), compared to only 13% of placebo patients. Moreover, if one retrospectively applies the same responder criteria being used in the Phase 3 trial to the Phase 2 datasets, 40-45% of the OCA patients would have met the endpoint, compared to 5-9% of placebo patients. Given the general caveat in drug development that Phase 3 studies rarely perform as well as their Phase 2 counterparts, the overwhelming level of efficacy demonstrated in OCA Phase 2 studies provides a substantial buffer against the typical unforeseen clinical risks that can impact Phase 3 studies.

Figure 7: Summary of OCA Phase 2 study results in PBC.

	Prospective Primary Efficacy Endpoint Mean Δ% ALP (12 weeks)	p-value	Retrospective Analyses: Responder Endpoint (12 months)	p-value
OCA Combination with Urso (Study 202)				
10 mg (n=38)	-24%	<0.0001	--	--
25 mg (n=47)	-25%	<0.0001		
50 mg (n=39)	-21%	<0.0001		
Placebo Control (n=37)	-3%	NS	--	--
OCA Monotherapy (Study 201)				
10 mg (n=20)	-45%	<0.0001	--	--
50 mg (n=16)	-38%	<0.0001		
Placebo Control (n=23)	0%	NS	--	--
Overall OCA versus Placebo pooled across both Phase 2 trials	--	--	1) 40-45% OCA versus 5%-9% placebo achieved Δ%ALP to 1.67x ULN, ≥10% drop from baseline, & normal bilirubin (endpoint in Ph 3 PRIME) 2) 80% OCA versus 13% placebo achieved ≥10% drop in ALP	<0.0025

Source: Company reports, Wedbush Securities research, clinicaltrials.gov (NCT00550862, NCT00570765), NS = not (statistically) significant.

A more detailed analysis of the individual Phase II OCA trials is provided below.

Phase II OCA Monotherapy Study (201 Trial)

Intercept began the Phase II OCA monotherapy study in December 2007. The trial was a multi-center (US, Canada and Western Europe), double-blind, placebo controlled study in 59 PBC patients with a 12 week treatment duration and 2 week follow-up. Patients were randomized to receive oral OCA 10mg, 50mg or placebo once daily. The study's primary endpoint was the reduction in ALP, with secondary endpoints assessing levels of GGT, ALT, AST and bilirubin. To be eligible for the study, patients must have had a baseline ALP value above 1.5 ULN and have not received treatment for PBC within the prior 3 months.

The study met its primary endpoint, with both dose groups demonstrating a dramatic mean decrease in ALP levels of 45% for 10mg and 38% for 50mg, which was statistically significant (p<0.0001 for both doses) compared to the slight elevation seen in placebo patients. Because the study recruited patients not receiving treatment for PBC, starting ALP levels were high (400-475 U/L; or ~3.5-4x ULN), as would be expected. Importantly, the ALP lowering ability of OCA was replicated in a second Phase II study that tested the drug's ability to reduce ALP when given on top of Urso. Of note, patients who completed the 201 trial were given the option to enroll in an open label long-term safety and efficacy extension study. That study is currently ongoing.

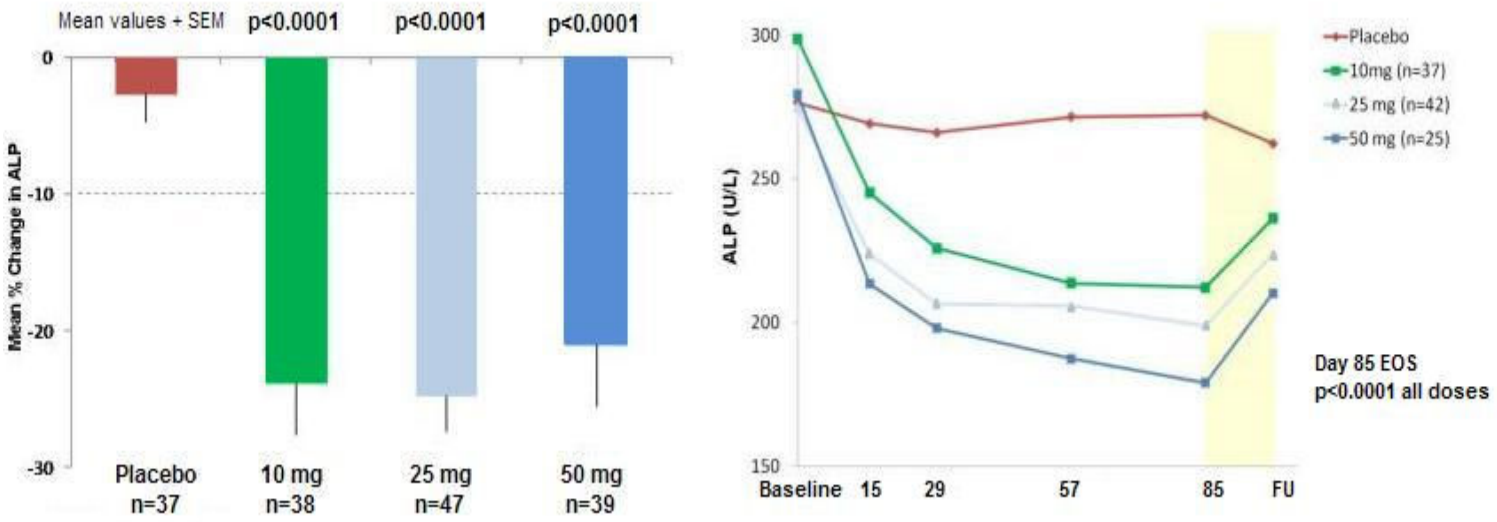
Phase II OCA Combination Study (202 Trial)

The most comprehensive of Intercept's completed clinical studies is the Phase 2 '202 Trial' which tested OCA in combination with Urso in PBC patients who had persistently elevated ALP levels despite being treated with Urso. To be eligible for the study, patients must exhibit ALP levels greater than 1.5x ULN despite stable Urso therapy for at least 6 months prior to screening. Enrollment in the study began in November 2008.

The 202 Trial enrolled a total of 165 patients in centers from the US, Canada and Western Europe. Patients were randomized to receive OCA 10mg, 25mg, 50mg or placebo once daily for 12 weeks in combination with Urso (patients also returned for a follow-up visit 2 weeks later). The study's primary endpoint was reduction in ALP, with secondary endpoints including measurements in GGT, ALT, AST and bilirubin levels.

As shown below, each OCA dose cohort exhibited a statistically significant reduction in ALP levels compared to the placebo group (i.e., Urso alone), with mean reductions of 23.7%, 24.7% and 21.0% at 10mg, 25mg and 50mg of OCA compared to no change for placebo (-2.6%).

Figure 8: Phase II efficacy data from OCA combination study



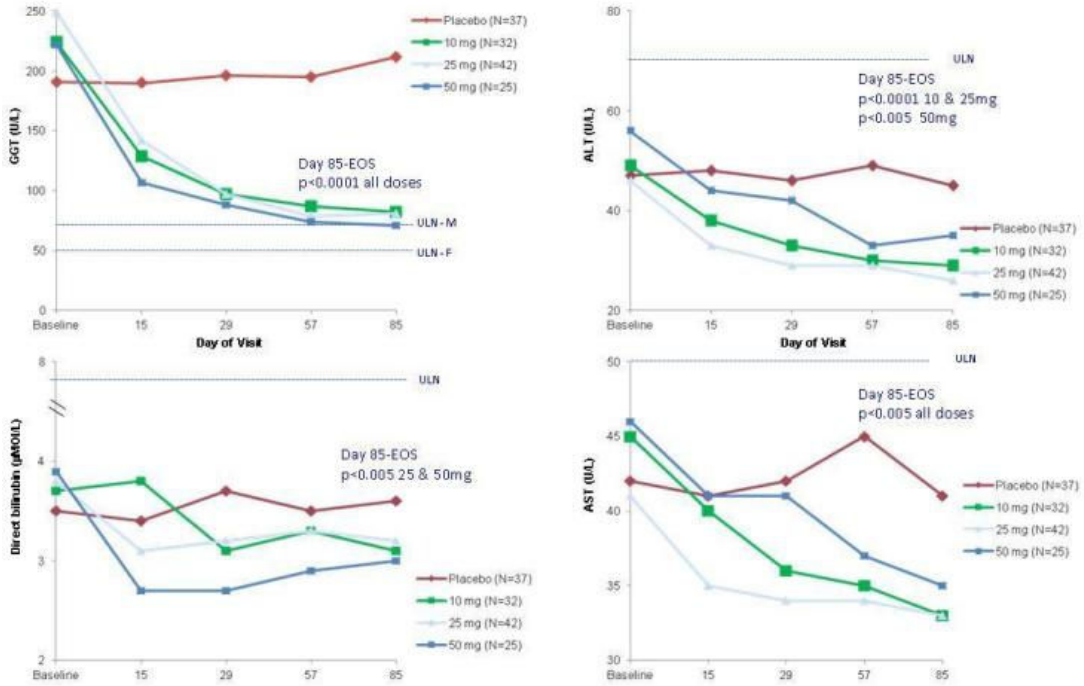
Source: Intercept presentation and Wedbush Securities

The above-left figure reflects a modified intent-to-treat analysis and includes patients who withdrew from the study, which mostly impacted the 50 mg arm due to tolerability issues (pruritus). ALP reductions in patients who completed the study are shown above on the right, where a dose-effect is more pronounced. We highlight that the ALP reductions seen at the 10 mg dose were also reflective of a very high level of efficacy. As discussed in the next section, OCA's much improved tolerability profile and strong efficacy at 10 mg prompted its selection as the dose utilized in Phase III.

In our view, the Phase 2 combination study offers clear and convincing evidence that OCA is effective at reducing ALP levels in patients who previously reached the limit of Urso benefit (see placebo+Urso arm at left of Figure 8). Intercept noted that 80% of OCA treated patients across both Phase II studies experienced a reduction in ALP levels of at least 10% (considered to be clinically relevant), compared to only 13% of placebo patients. As discussed in more detail on page 15, achieving target reductions in ALP levels strongly correlates to improved survival.

Additionally, as shown below, the 202 study also demonstrated statistically significant reductions in a number of other liver function markers, such as GGT, ALT, AST, and bilirubin, the latter of which is a co-component of the primary endpoint in the Phase 3 POISE study.

Figure 9: Secondary endpoint outcomes from Phase 2 OCA combination study in PBC

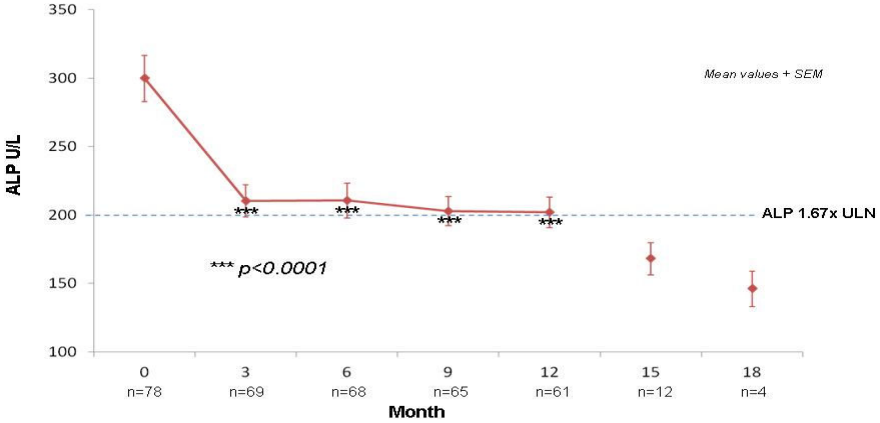


Source: Company reports, Wedbush Securities research.

Phase 2 Long-Term Safety Extension (LTSE) Trial (Continued from 202 Trial)

After the completion of the Phase 2 combination study, 78 patients went on to participate in an open-label study to examine long-term safety and efficacy (LTSE) of OCA. In the LTSE study, patients continued to receive OCA open-label, and could receive dose increases at their physician's discretion. As described by Intercept, in patients whose dose was increased, a benefit was observed from increasing the dose up to 25 mg from 10 mg (9% incremental fall in ALP) but not when the dose was increased above 25 mg. Over two-thirds of patients underwent dose increases to 20 mg or more.

Figure 10: ALP reductions observed in Phase 2 LTSE trial



Source: Intercept Pharmaceuticals.

As shown in Figure 10 above, patients receiving OCA showed an average reduction in ALP to approximately 1.67x ULN by month 3 and continuing through one year. This cutoff represents an important distinction as the primary Phase 3 POISE endpoint (reduction in ALP to below 1.67x ULN along with at least a 15% reduction in ALP). We note that while there are data from only a small number of patients beyond 12 months, OCA's effects appear to be durable for longer periods of time.

Safety and Tolerability of OCA in Phase 2 studies

In our view, the Phase 2 studies demonstrated am encouraging safety profile for OCA, with no drug-related serious adverse events observed and little difference among other safety events when compared to placebo.

Figure 11: Adverse events observed in OCA Phase 2 PBC studies

	Phase 2 Combination Study (202)					Phase 2 Monotherapy Study (201)		
	10mg	25mg	50mg	Placebo (+Urso)		10mg	50mg	Placebo
Started Trial (n=)	38	48	41	38		20	16	23
Completed Trial (n=)	37	42	25	37		16	9	23
Withdrew (n, %)	1 (3%)	6 (13%)	16 (39%)	1 (3%)		4 (20%)	7 (44%)	0 (0%)
Serious Adverse Events								
Patients with SAE	0 (0%)	1 (2%)	5 (12%)	1 (3%)		0 (0%)	0 (0%)	1 (4%)
SAE types (all SAEs deemed unrelated to study drug)		Salivary gland neoplasm	Angina pectoris, GI hemorrhage, jaundice, angioedema	Dyspnea				Rash
Other Adverse Events								
Pruritus	18 (47%)	41 (85%)	33 (80%)	19 (50%)		14 (70%)	15 (94%)	8 (35%)
Headache	3 (8%)	5 (10%)	7 (17%)	4 (11%)		4 (20%)	2 (13%)	5 (22%)
Fatigue	7 (18%)	3 (6%)	5 (12%)	5 (13%)		0 (0%)	1 (6%)	3 (13%)
Constipation	3 (8%)	4 (8%)	3 (7%)	3 (8%)		0 (0%)	0 (0%)	0 (0%)
Diarrhea	3 (8%)	4 (8%)	3 (7%)	3 (8%)		0 (0%)	2 (13%)	1 (4%)
Nausea	4 (11%)	3 (6%)	4 (10%)	1 (3%)		0 (0%)	4 (25%)	4 (17%)
Abdominal Distension	2 (5%)	0 (0%)	4 (10%)	1 (3%)		1 (5%)	2 (13%)	1 (4%)
Dry Eye	0 (0%)	3 (6%)	2 (5%)	1 (3%)		0 (0%)	0 (0%)	0 (0%)
Oropharyngeal Pain	2 (5%)	4 (8%)	0 (0%)	1 (3%)		0 (0%)	0 (0%)	0 (0%)
Epistaxis	0 (0%)	0 (0%)	5 (12%)	0 (0%)		0 (0%)	0 (0%)	0 (0%)
Vomiting	0 (0%)	3 (6%)	0 (0%)	0 (0%)		1 (5%)	1 (6%)	1 (4%)
Pyrexia	3 (8%)	0 (0%)	0 (0%)	0 (0%)		0 (0%)	1 (6%)	2 (9%)
Urinary Tract Infection	0 (0%)	0 (0%)	0 (0%)	3 (8%)		0 (0%)	0 (0%)	0 (0%)

Source: Intercept, clinicaltrials.gov, Wedbush Securities research.

Although the drug appears to have a very clean safety profile, OCA does noticeably differ from placebo in the rate of pruritus, or itching/tingling. We underscore the important distinction that pruritus is chiefly a tolerability issue and not a safety issue in PBC. As discussed previously, pruritus is a hallmark symptom of PBC and many patients are first diagnosed after presenting with persistent pruritus.

As it relates to the Phase 3 study and eventual commercial potential, pruritus becomes a factor in patients when it is serious enough to lead to discontinuation of treatment. While many patients experience relatively mild and/or temporary pruritus while receiving OCA, higher doses tested in Phase 2 did show a relatively high rate of study withdrawal (39% at 50 mg). Fortunately, the 10mg dose retains comparable levels of efficacy and demonstrated much lower rates of pruritus (47%, comparable to 50% for Urso/placebo) and drop outs (3%). Moreover, the expectation of pruritus-related drop outs was factored into the Phase 3 enrollment size to ensure appropriate powering (we do not envision that an unexpectedly higher dropout rate is likely to derail the pivotal study).

We view that some degree of patient discontinuation due to pruritus is likely, and we have incorporated a 5% treatment discontinuation rate in our market model for OCA in PBC.

Pivotal Phase 3 POISE Study

Intercept is conducting a pivotal Phase 3 study of OCA in PBC titled POISE. The study began in early 2012 and is on track to complete enrollment in early 2013. The design of the Phase 3 POISE study is summarized below.

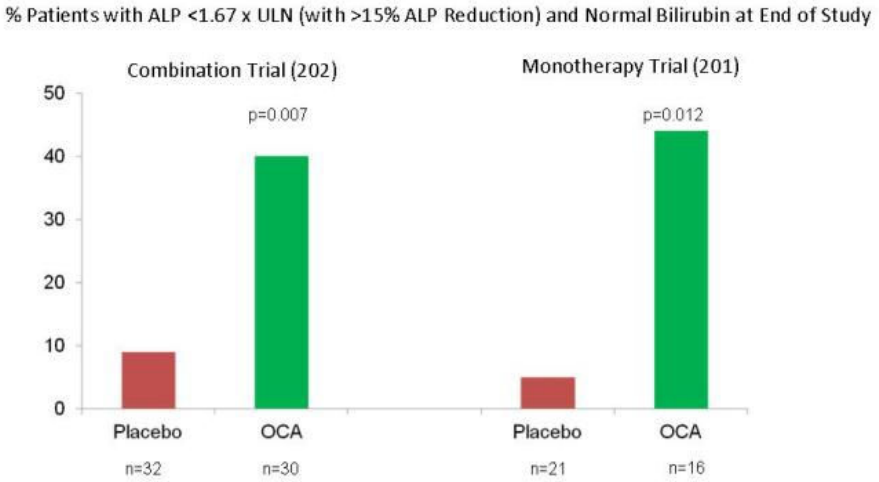
Figure 12: Features of Phase 3 POISE study

Study type	Randomized (1:1:1), double blind, multi-center (~60 sites in 13 countries)
Target enrollment	180 patients
Enrollment dates	January 2012 – Q1:2013 (our estimate)
Inclusion criteria	Definite or probable diagnosis of PBC (meeting at least 2/3 of the following criteria: (1) history of elevated ALP levels for at least 7 months; (2) positive AMA finings; (3) liver biopsy consistent with PBC). On Urso for at least 12 months or demonstrated intolerance to Urso. ALP levels ≥ 1.67x ULN and/or bilirubin levels between ULN and 2x ULN.
Exclusion criteria	History of HBV or HCV infection, primary sclerosing cholangitis, alcoholic liver disease, NASH or Gilbert's Syndrome. Presence of late-stage PBC complications including portal hypertension, cirrhosis with complications, or hepatorenal syndrome. History of severe pruritus requiring current or prior systemic treatment, or prior participation in an OCA clinical study.
Treatment arms	(1) 5mg/10mg: OCA 5mg daily for 6 months followed by titration to 10 mg for 6 months (2) 10mg: OCA 10mg daily for 12 months (3) Placebo Patients on Urso at the start will continue to receive the drug during the duration of the trial.
Primary endpoint	Proportion of patients at 12-months meeting a composite response endpoint consisting of: • Reduction in ALP to less than 1.67x ULN • Absolute reduction in ALP of at least 15% • Bilirubin within normal limits A patient must meet all three components to be considered a responder.
Secondary endpoints	GGT, ALT, AST, Bilirubin, Albumin, Prothrombin Time, INR, QoL, Pruritus, Enhanced Liver Fibrosis test, transient elastography, other biomarkers of liver fibrosis.
Powering	90% power for primary endpoint (powering assumptions not disclosed).
Data readout	Top line data expected in mid-2014.

Source: clinicaltrials.gov, company reports.

In addition to the highly statistically significant results from OCA's earlier studies, our confidence in POISE success is bolstered by a pooled retrospective analysis of the Phase 2 patients which applied the composite primary endpoint used in Phase 3.

Figure 13: Analysis of Phase 2 patient outcomes using the composite endpoint employed by the POISE study



Source: Intercept.

As shown in Figure 13, roughly 40% of OCA treated patients met the composite endpoint compared to < 10% for placebo-treated patients. This difference was statistically significant, and we highlight the smaller sample size and shorter treatment duration compared to the ongoing Phase 3 study. While retrospective analyses are not as conclusive as prospective studies, we believe these findings mitigate the risk of the Phase 3 study underperforming due to the use of a modified primary endpoint. Moreover, we believe the selection of a more clinically relevant responder endpoint in Phase 3 is necessary to secure accelerated approval by the FDA.

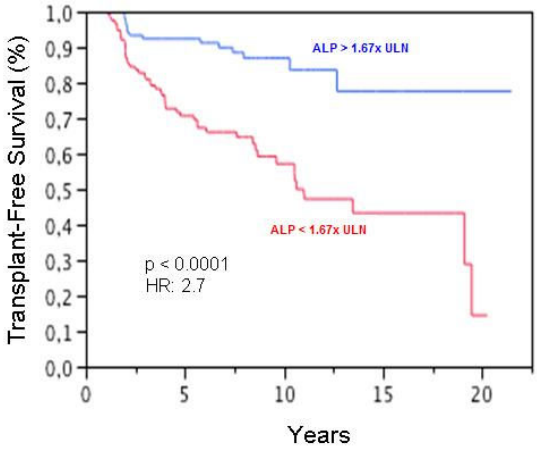
Regulatory Pathway for OCA in PBC

We believe the OCA regulatory pathway in Europe is straightforward, with the company indicating that the POISE trial has been deemed acceptable by the EMA. For US approval, Intercept intends to seek Subpart H (accelerated) approval using data from the POISE study. Under accelerated approval, the FDA can approve a drug based on a surrogate endpoint rather than a clinical outcome measurement such as survival or morbidity. For the case of OCA, the surrogate endpoint would be the ALP/bilirubin response that is the primary endpoint in the Phase 3 POISE study (ALP < 1.67x ULN and reduction ≥ 15%, along with normal bilirubin).

An accelerated approval strategy is most often used for significant unmet medical needs in which conducting an outcome-based study would be too difficult. Instead, a surrogate endpoint that is reasonably likely to predict clinical benefit is used in lieu of an outcome endpoint.

Our understanding of Intercept's current standing with FDA is that the agency has asked to see the evidence linking ALP to clinical outcomes (e.g., survival and need for liver transplant) and has indicated that it will likely be supportive of accelerated approval should there be a correlation. In response, Intercept is conducting a post-hoc study pooling data from over 10 single-center observational studies that tracked the transplant-free survival of PBC patients stratified by ALP levels (mostly using a cutoff of 1.67x ULN). Intercept refers to the pooled data analysis as the "supergroup" analysis and is expected to include data from at least 4,000 PBC patients. As many of the individual studies themselves strongly demonstrate the link between ALP and outcomes, we believe the supergroup is highly likely to be corroborative. An example of the findings from one of the larger single-site studies is shown below.

Figure 14: Transplant-free survival of PBC patients stratified by ALP above or below 1.67x ULN, single study (Paris)



Source: Intercept.

Intercept is currently compiling and analyzing the data and we expect a top-line data announcement in Q1:13. Given the time needed to schedule a meeting with the FDA and the time for data review, a response regarding POISE's approvability may not be released until around Q3:13 (although we expect this issue to remain a key topic of debate for an advisory committee). However, we are strongly optimistic about Intercept's ability to get OCA approved under Subpart H as: (1) data from an outcomes study in PBC would require a very large number of patients and a multi-year duration (as supported by the results of URSO's pivotal study and the separation of curves in Figure 14 above); (2) key opinion leaders are vocal in their support for ALP as a valid marker of survival in PBC; (3) FDA's own review of Urso noted that demonstrating a survival benefit in PBC would be onerous for a pivotal study, and Urso was approved without demonstrating a statistically significant reduction in survival; and (4) In our view, the FDA and its expert advisory panels have been increasingly willing to approve safe drugs based on surrogate endpoints for orphan indications with unmet medical need, especially for diseases with a vocal base of physician and patient-advocates such as PBC.

That said, we acknowledge that regulatory risk remains a key consideration for investors given the general inherent uncertainties surrounding any FDA action. In turn, we believe positive results from the supergroup analysis and clarity from FDA represent potential positive catalysts for Intercept during 2013 while investors wait for data from the POISE study.

Market Size Estimates and OCA Sales Potential

In reviewing the available medical literature on PBC, we found a range of prevalence estimates; however, we believe our own assumptions for OCA's market potential mostly err to the conservative.

Based on industry data, Intercept estimates approximately 60,000 diagnosed PBC patients in developed countries are receiving Urso therapy (out of 300,000 total individuals thought to have the disease). Of these 60,000 PBC patients, Intercept estimates that up to 50% do not adequately respond to Urso and would be candidates to receive OCA as a second-line treatment. In support, clinical studies of Urso have shown that approximately half of patients do not reach the important ALP < 1.67x ULN cut-off following therapy. Based on our conversations with PBC physician-specialists, we believe that while a 50% Urso failure rate is not unrealistic, a more conservative estimate may be more appropriate given the wider range of real-world opinions from physicians.

Our detailed assumptions of the US market opportunity for OCA in PBC are shown below:

Figure 15: Assumptions for US PBC market opportunity and peak revenue estimates

	WS Estimate	Comment
US Female population 40-89	73,800,000	Data from 2010 US Census
Prevalence of PBC	1 in 1,250	Literature suggests variance of estimates, up to 1 in 1,000
Females 40-89 w/ PBC	59,000	
Males and (F < 40) w/ PBC	6,556	9:1 Female preponderance
Total # Persons with PBC	**65,556**	
% Diagnosed & treated	53%	Robust safety and low cost of generic urso but some patients have very mild disease course
Total # Patients treated	**34,744**	
% of Urso failures	40%	May be conservative; ICPT estimates the failure rate to be up to 50%
Patients eligible for OCA	**13,898**	
% Peak OCA penetration	75%	High penetration estimate as patients are already under treatment for PBC
% D/C due to Pruritus	5%	Intolerable pruritus leads to discontinuation in a small number of patients
# Patients on chronic OCA therapy	**9,902**	
Pricing per year of OCA therapy	$23,000	
US Peak revenue estimate ($MM)	**$227.7**	

Source: Wedbush Securities Research

We note that our estimate of approximately 14,000 patients eligible for OCA is slightly below the low end of Intercept's 15,000-20,000 patient estimate. We model the number of eligible patients in Europe to be similar to the US, albeit with lower annual pricing potential for OCA therapy. Although we prefer to be conservative, there may be potential upside to our peak revenue estimates, as our pricing and the percentage of patients who are Urso refractory may be conservative.

With regards to competition in PBC, we note that the small number of drugs in active development is made up mostly of potent immunosuppressants which we believe would be likely relegated to third-line use due to safety concerns.

Intercept's Pipeline Beyond PBC Offers Additional Catalysts and Potential for Longer Term Value Creation

Although we view ICPT's valuation to be being driven mostly by OCA in PBC, the company is currently pursuing other indications for OCA including Non-Alcoholic Steatohepatitis (NASH), portal hypertension (a late-stage complication of liver failure that often precedes death) and bile acid diarrhea. Additionally, Intercept has disclosed preclinical compounds INT-767 (dual FXR/TGR5 agonist) and INT-777 (TGR5 agonist), targeting fibrosis and diabetes, respectively.

A summary of Intercept's currently active clinical programs is shown below:

Figure 16: Intercept's Development Programs and Active Clinical Studies

Drug	Indication	Stage	Comments / Expected Milestones	Expected Data Readout
OCA	PBC	Phase 3	Pivotal POISE trial. Expect enrollment to complete in early 2013.	Mid-2014
OCA	PBC	Phase 2	Ongoing long-term extension portion of completed Phase II trial.	Incremental data expected during 2013-2014
OCA	NASH	Phase 2b	FLINT study. NIDDK sponsored. 280 patient target enrollment. Expect enrollment completion in Q4:2012.	Q4:2014
OCA	Portal Hypertension	Phase 2a	PESTO study. Investigator sponsored (UK). 39 patient target enrollment. 7 day treatment duration measuring hepatic venous pressure gradient.	Data from first 13-patient cohort in late 2012 or early 2013
OCA	Bile Acid Diarrhea	Phase 2a	OBADIA study. Investigator sponsored (UK). 30 patient target enrollment. 14 day treatment duration.	Mid 2013
INT-767	Fibrosis	Preclinical	Dual FXR/TGR5 agonist. Potential follow-on compound to OCA.	
INT-777	Type 2 diabetes	Preclinical	Available for partnering but expect minimal development by ICPT.	

Source: Company reports; clinicaltrials.gov, Wedbush Securities research.

We note OCA's potential therapeutic ability across a range of liver-related conditions and are encouraged by the potential for OCA to turn into a viable franchise on its own, particularly if the safety profile continues to be benign. While we only include PBC and NASH in our fair value of ICPT at this time (due to the early stage nature of the rest of the pipeline), we believe these additional pipeline opportunities represent both the potential for long-term value creation beyond PBC as well as a source of additional news flow and catalysts over the coming 1-2 years.

NASH Represents Intercept's Most Advanced Program after PBC

Non-Alcoholic Steatohepatitis (NASH) has become an increasingly prevalent medical problem in recent years as the rates of obesity continue to increase. NASH has an incidence rate of approximately 25% in obese individuals, and is estimated to affect roughly 7.5 million adults in the US (increasing to 25 million by 2025) according to the NIH. If left untreated, patients with NASH can progress to liver cirrhosis, becoming susceptible to a high risk of liver failure and liver cancer. There are currently no approved drug therapies for NASH.

In 2010, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) selected OCA as the most promising new NASH treatment in development and funded a study called FLINT to examine its therapeutic ability. This Phase 2b study began enrollment in early 2011 and is expected to finish enrolling 280 patients shortly. The study has a 72-week treatment duration (25 mg OCA vs. placebo) with a primary endpoint of biopsy-determined improvement in NAFLD Activity Score. We expect results to be available in Q4:2014. Importantly, the study passed an interim futility analysis in June 2012 conducted after the first 100+ patients reached at least 24 weeks of therapy (with the earliest enrolled patients having reached up to 15 months of therapy).

Company Background

Sales, Marketing and Distribution

As a development-stage biopharmaceutical company, Intercept relies on third-party contract manufacturers to supply its drugs for clinical trials. We do not expect Intercept to pursue internal manufacturing capabilities for the foreseeable future.

Meanwhile, with OCA still several years from potential commercialization, we do not expect Intercept to invest in significant sales or marketing activities for some time. Moreover, the company may sign commercialization partnerships with larger drug companies in specific countries or territories. Alternatively, if Intercept attempts to market OCA on its own, we believe the relatively consolidated nature of PBC specialists would only require a relatively small sales force.

Recent Financing History

Prior to its initial public offering, Intercept raised approximately $100 million cumulatively since inception via the issuance and sale of common stock, convertible notes, preferred stock and warrants (and excluding payments to Intercept as part of collaborative agreements). The company also received additional non-dilutive financing in 2011 through collaboration and licensing agreements with Dainippon Sumitomo Pharma (DSP) and Les Laboratories Servier (Servier), which are amortized as revenue. Intercept's recent financing-related history is summarized below:

Figure 17: Intercept's recent financing history

Date	Financing event
October 2012	Intercept completed an initial public offering, raising $80.2 million in net proceeds through the sale of 5.75 million shares priced at $15.00. The offering included 750,000 shares which were sold to cover over-allotments.
August 2012	Intercept raised $29.8 million via a securities purchase agreement with OrbiMed and Genextra for two tranches of shares. The first tranche was issued in August 2012 and resulted in $29.8 million in net proceeds to Intercept. A second tranche would have been eligible to be issued had Intercept not completed an IPO.
March 2011	Intercept received $15.0 million from Dainippon Sumitomo Pharma (DSP) as an up-front payment for an exclusive licensing agreement for the development of OCA in Japan and China.
August 2011	Intercept received $1.4 million from Servier as an up-front payment for a collaboration agreement on the discovery and development of bile-acid related drugs and technology.

Source: Company reports, Wedbush Securities research.

Our model suggests that Intercept may need to raise additional funds before reaching OCA commercialization. We currently estimate that the company's cash balance of $110 milion post-IPO provides cash runway into 2015. We project OCA to begin commercialization for PBC in Q3:2015.

Intellectual Property and Exclusivity

We assess Intercept's patent portfolio to be particularly strong. As of August, 2012, Intercept reports the following:

- OCA US composition of matter patent expiring in November 2022 and eligible for a ~5 year extension (7,138,390)
- OCA US method of use patent for treatment of cholestasis expiring in February 2022 (7,786,102)
- OCA US manufacturing method patent expiring December 2028 (7,994,352)
- Awaiting filing of new manufacturing method and polymorph composition of matter patents (expiring ~2032)
- Awaiting filing of methods patents regarding dose claims for PBC & NASH and pruritus biomarker management (exp ~2032)

Meanwhile, Orphan Drug designation in the US and Europe provides for additional exclusivity. For example, under 21 CFR 36, the Orphan Drug designation prevents the FDA from approving a generic filed under an Abbreviated New Drug Application (ANDA) for a period of 7 years.

Management

We believe Intercept is led by an experienced management team with a valuable background in developing new therapeutics, as well as securing partnerships with leading pharmaceutical companies.

Figure 18: Management Team of Intercept Pharmaceuticals

Name	Position	Experience
Mark Pruzanski, M.D.	Chief Executive Officer and President	Dr. Pruzanski is a co-founder of Intercept and has served as chief executive officer and president, and has been a member of the board of directors, since the company's inception in 2002. He has over 15 years of experience in life sciences company management, venture capital and strategic consulting. Dr. Pruzanski was previously a venture partner at Apple Tree Partners, an early stage life sciences venture capital firm he co-founded in 1999. Prior to that, he was an entrepreneur-in-residence at Oak Investment Partners. Dr. Pruzanski received his M.D. from McMaster University in Ontario, a M.A. degree in International Affairs from the Johns Hopkins University School of Advanced International Studies in Bologna, Italy and Washington, D.C., and a bachelor's degree from McGill University in Montreal, Canada.
Barbara Duncan	Chief Financial Officer and Secretary	Ms. Duncan has served as chief financial officer and secretary since May 2009 and as treasurer since 2010. She has over 14 years experience in the life sciences industry. From 2001 through April 2009, Ms. Duncan served as chief financial officer and then chief executive officer at DOV Pharmaceutical, Inc., a biopharmaceutical company focused on central nervous system disorders, which was sold to Euthymics Bioscience, Inc. in 2010. Prior to joining DOV, Ms. Duncan served as a vice president of Lehman Brothers Inc. in its corporate finance division from August 1998 to August 2001, where she provided financial advisory services primarily to companies in the life sciences and general industrial industries. Ms. Duncan received her B.S. from Louisiana State University in 1985 and her M.B.A. from the Wharton School, University of Pennsylvania, in 1994. She previously served as a director of DOV and currently serves on the board of directors at Edgemont Pharmaceuticals, LLC, a privately held, specialty pharmaceutical company with a primary focus in the field of neuroscience.
David Shapiro, M.D.	Chief Medical Officer and EVP, Development	Dr. Shapiro joined Intercept in 2008. He has over 25 years of clinical development experience in the pharmaceutical industry. Dr. Shapiro founded a consulting company, Integrated Quality Resources, that focused on development stage biopharmaceutical companies and was active in this role from 2005 to 2008. From 2000 to 2005, Dr. Shapiro was executive vice president, medical affairs and chief medical officer of Idun Pharmaceuticals, Inc., prior to its acquisition by Pfizer. From 1995 to 1998, he was president of the Scripps Medical Research Center at Scripps Clinic. He also served as vice president, clinical research at Gensia and as director and group leader, hypertension clinical research at Merck Research Laboratories from 1985 to 1990. He is an elected Fellow of both the Royal College of Physicians of London and the Faculty of Pharmaceutical Physicians of the United Kingdom.
Luciano Adorini, M.D.	Chief Scientific Officer	Dr. Adorini has served as Intercept's chief scientific officer since 2008. Dr. Adorini has over 20 years of industry experience. From Jan 2002 through Dec 2007, Dr. Adorini served as chief scientific officer at BioXell S.p.A. From January 1993 to December 2001, he served as associate director of Roche Milano Richerche, where he contributed to the development of several drugs. He is a board member of a number of peer-reviewed publications and has served as president of the Italian Society of Immunology, Clinical Immunology and Allergology. Dr. Adorini received his M.D. degree from the Medical School of Padova University and conducted postdoctoral studies at the University of California at Los Angeles.

Source: Company reports, Wedbush Securities research.

Risks to the Attainment of Our Fair Value Estimate

Clinical Risk. Intercept's drugs will be required to demonstrate satisfactory efficacy and safety in clinical trials before such drugs can be approved. The complicated nature of large clinical trials increases the risk that endpoints may not be met, even if the drug is active in its studied population. For example, even though Phase 2 studies of OCA showed statistically significant positive results, differences in the design of Phase 3 studies (e.g., altered primary endpoint, treatment duration) may lead to failure in unforeseen ways. Moreover, serious safety problems often only become evident when a drug is administered to a large group of patients, such as a Phase 3 trial. If an unexpected safety problem were to arise in the POISE study, Intercept may be required to halt further development of OCA, which would be a significant setback to company's future prospects.

Regulatory Risk. Intercept has not yet received approval in the US for any of its drugs, and may face difficulties in doing so which could postpone commercialization. The required regulatory process for drug candidates is complex, and requires the collection and production of extensive amounts of data from time-consuming and expensive clinical trials. Moreover, decisions on approval are at the sole discretion of the regulatory agencies, which may be unpredictable at times. Intercept will likely to pursue accelerated approval for PBC based on the Phase 3 POISE study. If the FDA does not agree with accelerated approval suitability, Intercept may have to conduct additional clinical studies, which may delay our projected approval timelines significantly. Finally, even after drugs are approved for marketing, regulatory agencies retain jurisdiction and the right to remove these drugs from the market if they are viewed to present sufficient danger.

Commercialization Risk. Although Intercept may succeed in securing regulatory approval of its compounds, the company may face unpredictable challenges in commercializing its drugs. These risks include the presence of a competing drug with a more favorable efficacy and/or safety profile, lower cost, stronger physician preference and greater ease of reimbursement. Moreover, Intercept may be dependent on partnerships to commercialize its drugs if it signs such agreements with third parties. Should these partnerships derail, the company may face significant challenges or delays to successfully commercializing its drugs.

Intellectual Property Risk. Although we believe that Intercept holds a relatively strong intellectual property position, there is inherent uncertainty in both the interpretation of patent claims and the application of patent law. Moreover, when the company's licensed patents expire, Intercept may be unable to prevent third-parties from copying its products. Furthermore, competitors might challenge the validity or scope of Intercept's patents in court, or simply find ways around them. Finally, third-party patents that are not licensed to Intercept and which could prevent the company from commercializing its product candidates, or continue to do so, could be granted in the future or even already exist.

Manufacturing Risk. Intercept does not possess its own manufacturing capabilities to clinically or commercially supply sufficient quantities of its drugs and/or other pharmaceutical preparations in development. Any disruption or contaminant problems could result in delays to clinical studies or future commercialization until such problems are resolved.

Competition Risk. The indications being targeted by Intercept are also being targeted by several competitors, some with superior resources. Intercept may be unable to compete for market share as effectively as these larger companies, even if Intercept's products have superior clinical profiles.

Financing Risk. While we believe Intercept is sufficiently capitalized to reach significant value inflection points, unexpected setbacks may require additional investment before Intercept is able to generate sufficient revenues from the commercialization of its drugs. Such financing may to be dilutive and may be on terms unfavorable to investors. If Intercept is unable to complete a necessary financing, the company may be forced to curtail or even cease operations.

Intercept Pharmaceuticals (NASDAQ: ICPT)

Historical and Projected Income Statement

(In thousands except per share data)

(Fiscal Year Ends on December 31)

Wedbush PacGrow LifeSciences

Akiva Felt

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	2011A	2012					2013E	2014E	2015E
	FY:11A	Q1A	Q2A	Q3	Q4	FY:12E	FY:13E	FY:14E	FY:15E
Revenues:									
Revenues/Royalties on Product Sales	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 15,632
OCA for Primary Biliary Cirrhosis	-	-	-	-	-	-	-	-	*15,632*
OCA for NASH	-	-	-	-	-	-	-	-	-
Collaboration Revenue	$ 1,805	$ 759	$ 759	$ 540	$ 400	$ 2,458	$ 1,600	$ 1,600	$ 1,600
Licensing revenue and Milestones	*1,805*	*759*	*759*	*540*	*400*	*2,458*	*1,600*	*1,600*	*1,600*
Total Revenues	**$ 1,805**	**$ 759**	**$ 759**	**$ 540**	**$ 400**	**$ 2,458**	**$ 1,600**	**$ 1,600**	**$ 17,232**
Operating Expenses									
Research and Development	11,426	3,060	5,018	3,500	3,500	15,078	20,800	22,000	17,000
Sales, General and Administrative	4,209	1,059	944	1,500	1,800	5,303	8,000	14,000	24,000
Other	-	-	-	-	-	-	-	-	-
Total Operating Expenses	**15,636**	**4,119**	**5,962**	**5,000**	**5,300**	**20,381**	**28,800**	**36,000**	**41,938**
Operating Income (Loss)	(13,830)	(3,360)	(5,203)	(4,460)	(4,900)	(17,923)	(27,200)	(34,400)	(24,706)
Interest and dividend income	61	10	7	1	6	24	93	72	28
Interest (expense)	(13)	(7)	(0)	(0)	(0)	(8)	(1)	(1)	-
Revaluation of warrants	1,045	678	302	-	-	979	-	-	-
Other income (expense)	-	-	(192)	-	-	(192)	-	-	-
Income Before Income Taxes	**(12,738)**	**(2,680)**	**(5,086)**	**(4,459)**	**(4,894)**	**(17,119)**	**(27,107)**	**(34,329)**	**(24,677)**
Other comprehensive income (loss)	(3,000)	(750)	(750)	-	-	(1,500)	-	-	-
Provision for Income Taxes (benefit)	-	-	-	-	-	-	-	-	27
Net Income (Loss)	**$ (15,738)**	**$ (3,430)**	**$ (5,836)**	**$ (4,459)**	**$ (4,894)**	**$ (18,619)**	**$ (27,107)**	**$ (34,329)**	**$ (24,704)**
EPS (Basic & Diluted; Pro forma)	(1.19)	(0.25)	(0.47)	(0.42)	(0.30)	(1.53)	(1.62)	(2.00)	(1.38)
Shares Outstanding (Basic)	**10,733**	10,733	10,733	10,733	16,483	**12,171**	**16,733**	**17,133**	**17,908**
Fully Diluted Shares Outstanding		12,066	12,066	12,066	18,197	**13,599**	**18,447**	**18,847**	**19,247**
Net Cash	**$17,908**		$10,026	$35,898	$110,584	**$110,584**	**$81,533**	**$39,572**	**$10,364**
Change in Cash (Burn)	**$2,412**					**$92,676**	**($29,051)**	**($41,961)**	**($29,209)**

Source: Company reports, Wedbush Securities research.

Analyst Biography

Mr. Felt is a Research Analyst covering Biopharmaceutical and Medical Technology companies. He previously served as a senior associate on the healthcare team at Wedbush PacGrow Lifesciences from 2009-2012. Prior to joining Wedbush, Mr. Felt worked for two years as an associate analyst covering the biotechnology sector and one year in industry as a clinical research assistant.

Mr. Felt holds a B.S. in Biomedical Engineering from Washington University and a Master's degree in Biotechnology from Columbia University.

Analyst Certification
I, Akiva Felt, Liana Moussatos, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

Disclosure information regarding historical ratings and price targets is available at http://www.wedbush.com/ResearchDisclosure/DisclosureQ312.pdf

Investment Rating System:
Outperform: Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.
Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.
Underperform: Expect the total return of the stock to underperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).*

Rating Distribution (as of September 30, 2012)	**Investment Banking Relationships (as of September 30, 2012)**
Outperform:54% Neutral: 42% Underperform: 4%	Outperform:13% Neutral: 0% Underperform: 0%

The Distribution of Ratings is required by FINRA rules; however, WS' stock ratings of Outperform, Neutral, and Underperform most closely conform to Buy, Hold, and Sell, respectively. Please note, however, the definitions are not the same as WS' stock ratings are on a relative basis.

The analysts responsible for preparing research reports do not receive compensation based on specific investment banking activity. The analysts receive compensation that is based upon various factors including WS' total revenues, a portion of which are generated by WS' investment banking activities.

Wedbush Equity Research Disclosures as of November 8, 2012

Company	Disclosure
Intercept Pharmaceuticals	1,3,4,5,7

Research Disclosure Legend
1. WS makes a market in the securities of the subject company.
2. WS managed a public offering of securities within the last 12 months.
3. WS co-managed a public offering of securities within the last 12 months.
4. WS has received compensation for investment banking services within the last 12 months.
5. WS provided investment banking services within the last 12 months.
6. WS is acting as financial advisor.
7. WS expects to receive compensation for investment banking services within the next 3 months.
8. WS provided non-investment banking securities-related services within the past 12 months.
9. WS has received compensation for products and services other than investment banking services within the past 12 months.
10. The research analyst, a member of the research analyst's household, any associate of the research analyst, or any individual directly involved in the preparation of this report has a long position in the common stocks.
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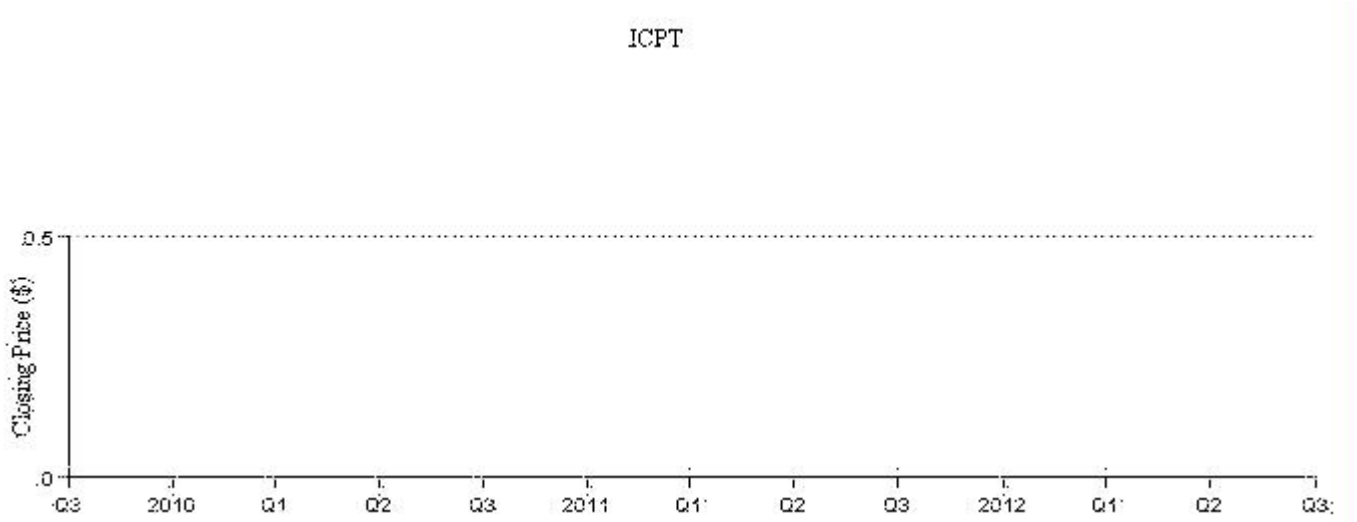
Wedbush disclosure price charts are updated within the first fifteen days of each new calendar quarter per FINRA regulations. Price charts for companies initiated upon in the current quarter, and rating and target price changes occurring in the current quarter, will not be displayed until the following quarter. Additional information on recommended securities is available on request.



* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.
Please access the attached hyperlink for WS' Coverage Universe: http://www.wedbush.com/services/cmg/equities-division/research/equity-research Applicable disclosure information is also available upon request by contacting Ellen Kang in the Research Department at (213) 688-4529, by email to ellen.kang@wedbush.com, or the Business Conduct Department at (213) 688-8090. You may also submit a written request to the following: Business Conduct Department, 1000 Wilshire Blvd., Los Angeles, CA 90017.

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