

## Intercept Pharmaceuticals (ICPT - \$168.45)

### ICPT at AASLD – You Shook Me All Night Long

ICPT recently held an analyst/investor event late into the evening at the annual American Association for the Study of Liver Diseases (AASLD) in San Francisco. Our highlights are below, but it remains clear that ICPT is focused on remaining the leader in the NASH space, with a variety of trials underway or expected to start over the next few quarters including a cirrhosis trial, a pediatric NASH trial, a lipid study, and the ongoing REGENERATE trial. We continue to like ICPT here, and we are reiterating our Buy rating and our \$515 price target.

- **Deep pipeline getting deeper.** While the REGENERATE Phase 3 trial has been underway since September 2015, ICPT is looking at using OCA for a variety of indications such as portal hypertension, primary and secondary bile acid diarrhea, primary sclerosing cholangitis, and now pediatric NASH. ICPT also will create a “NASH Registry” program to track patients over time. ICPT will start a Phase 3 cirrhosis study with hepatic venous pressure gradient (HVPG) as the primary endpoint starting in 2016. The NASH CONTROL lipid study remains on track for a 4Q15 start. See Figure 1 below.
- **Non-invasive diagnostic tools, a priority for ICPT.** Amongst all non-invasive measurement techniques, Fibrosis-4 (FIB-4) seems like an inexpensive and leading method with a negative outcome accuracy of 95% and positive accuracy ~80%. These numbers suggests that FIB-4 could be used as a valid diagnosis tool for NASH. ICPT also demonstrated that NASH resolution was proportional to biopsy length, >20mm being ideal.
- **Additional PBC launch details likely on December analyst day.** With the PDUFA on 2/29/16 and a likely advisory committee in mid-January, we continue to expect OCA approval for PBC. ICPT plans to give additional OCA launch details on their 12/1/15 analyst day in NYC. We model in FY16 PBC sales of \$34M in the US in 2016.
- **Reiterate Buy rating and \$515 PT.** Our price target is based on a sum-of-the-parts analysis, with NASH at \$437/share, PBC at \$36/share, and the remaining pipeline and cash (end 2016) at \$42/share.

*Healthcare / Biotechnology*

Ticker: ICPT  
Rating: **Buy**  
Price Target: **\$515.00**

#### Trading Data:

Last Price (11/17/2015)	\$168.45
52-Week High (05/18/2015)	\$314.88
52-Week Low (12/03/2015)	\$128.50
Market Cap. (MM)	\$4,100
Shares Out. (MM)	24.33

#### Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY16E</b>	(\$3.08)	(\$2.79)	(\$2.94)	(\$2.81)	(\$11.60)	NA
<b>FY15E</b>	(\$1.21)A	(\$1.54)A	(\$1.69)A	(\$3.50)	(\$8.47)	NA
<b>FY14</b>	(\$0.58)	(\$0.84)	(\$1.44)	(\$1.46)	(\$4.36)	NA
<b>FY13</b>	(\$0.39)	(\$0.47)	(\$0.57)	(\$0.44)	(\$1.87)	NA

#### Analyst

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Source: Laidlaw & Company estimates

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Figure 1: Covering the NASH landscape

Broad and Comprehensive NASH clinical plan for OCA			
	Trial	Description	Status
Phase 3	REGENERATE	Efficacy & Safety in NASH w/ Fibrosis	Initiated September 2015
Phase 2 Planned	CONTROL	OCA & Statin Effects on LDL and Lipid Metabolism	Initiate 4Q 2015
	Cirrhosis Program	Efficacy & Safety in NASH w/ Cirrhosis & Portal Hypertension	Initiate 2016
	Non-Invasive	Dedicated Non-Invasive Technology Evaluation in NASH	In planning
	Pediatric NASH	Efficacy & Safety in Pediatric NASH Patients	In planning
Phase 2 completed		NASH Registry	In planning
	FLINT	Efficacy & Safety in Non-Cirrhotic NASH	<i>Tetri et al. The Lancet 2015; 385: 956-65</i>
	Diabetes/NAFLD	Diabetes + NAFLD Euglycemic Clamp	<i>Mudaliar et al. Gastroenterology 2013; 145:574-82</i>

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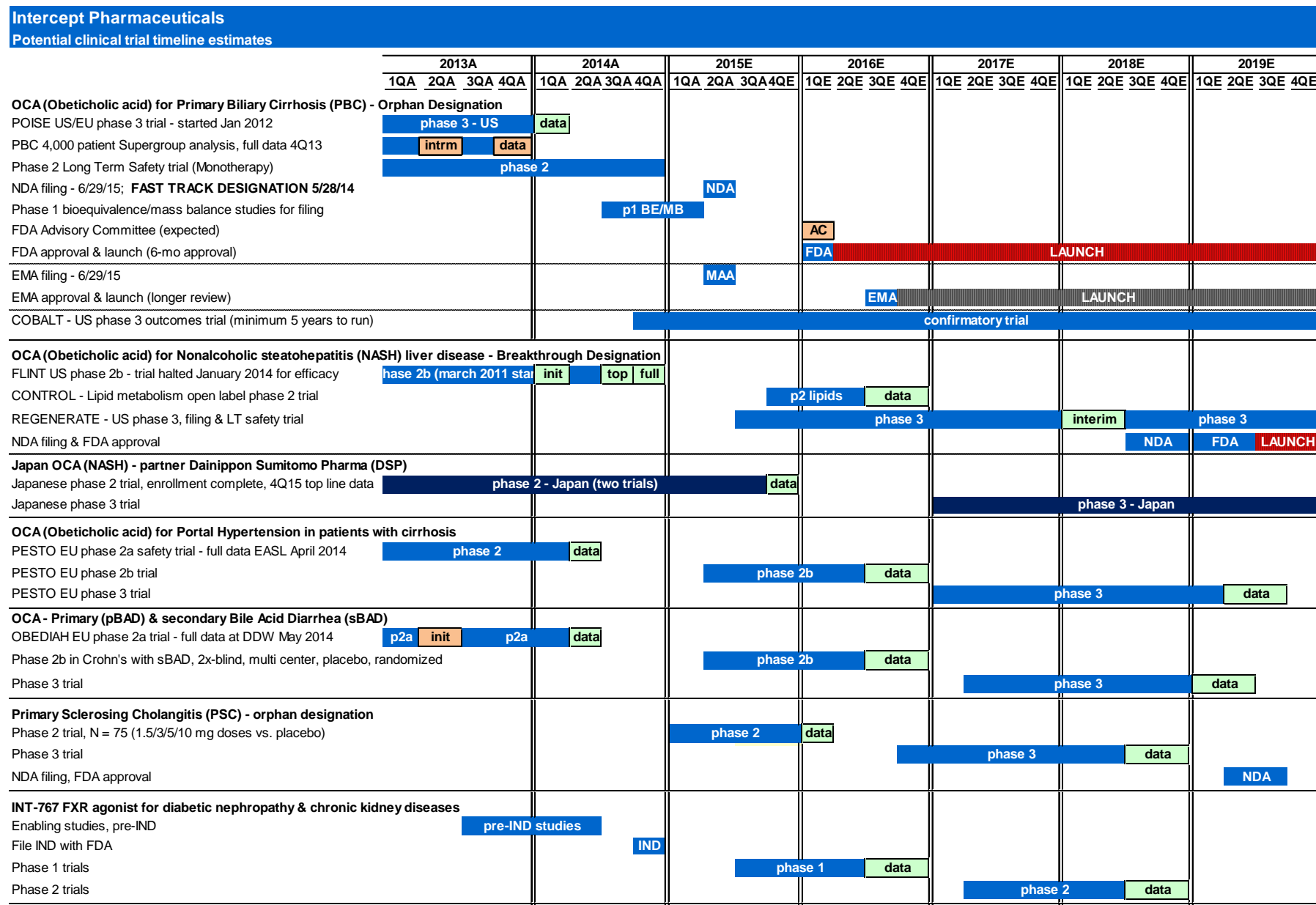
Source: Company Reports; Laidlaw & Company estimates

Figure 2: Valuation

Sum-of-the-parts valuation: ICPT		
Segment	Valuation (000's)	Per share value
OCA for NASH in the US	\$9,032,921	\$322
OCA for NASH EU royalty	\$3,218,379	\$115
OCA for PBC US & EU	\$1,007,594	\$36
OCA for other indications	\$475,825	\$17
Cash (end of '16E) & tech	\$702,427	\$25
	\$14,437,145	<b>\$515</b>
2016 fully diluted shares out		28,027

Source: Company Reports; Laidlaw & Company estimates

Figure 3: Clinical trial timeline estimates



Source: Company Reports; Laidlaw & Company estimates

Figure 4: Quarterly Income Statement

Intercept Pharmaceuticals										
Quarterly income statement										
(\$000's except per share)	2014A				2014A Year	2015E				2015E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE	
<b>Revenues</b>										
License fees	\$405	\$445	\$445	\$445	\$1,742	\$1,445	\$445	\$445	\$445	\$2,780
<b>Total Revenues</b>	<b>\$405</b>	<b>\$445</b>	<b>\$445</b>	<b>\$445</b>	<b>\$1,742</b>	<b>\$1,445</b>	<b>\$445</b>	<b>\$445</b>	<b>\$445</b>	<b>\$2,780</b>
<b>Expenses</b>										
Cost of Goods Sold	0	0	0	0	0	0	0	0	0	0
<b>Gross Margin</b>	<b>405</b>	<b>445</b>	<b>445</b>	<b>445</b>	<b>1,742</b>	<b>1,445</b>	<b>445</b>	<b>445</b>	<b>445</b>	<b>2,780</b>
R&D	9,893	12,119	24,780	21,868	68,661	21,916	22,895	22,337	40,000	107,148
SG&A	1,951	6,055	6,536	10,009	24,551	8,288	17,674	21,892	51,500	99,354
<b>Total Op Expenses</b>	<b>11,844</b>	<b>18,174</b>	<b>31,316</b>	<b>31,877</b>	<b>93,212</b>	<b>30,203</b>	<b>40,569</b>	<b>44,229</b>	<b>91,500</b>	<b>206,501</b>
<b>Inc (loss) from Ops</b>	<b>(11,439)</b>	<b>(17,729)</b>	<b>(30,871)</b>	<b>(31,432)</b>	<b>(91,470)</b>	<b>(28,758)</b>	<b>(40,124)</b>	<b>(43,784)</b>	<b>(91,055)</b>	<b>(203,721)</b>
Other income (exp)	136	104	228	308	776	272	929	889	150	2,240
Int exp					0					0
<b>Pretax Inc (Loss)</b>	<b>(11,303)</b>	<b>(17,625)</b>	<b>(30,643)</b>	<b>(31,124)</b>	<b>(90,694)</b>	<b>(28,486)</b>	<b>(39,195)</b>	<b>(42,895)</b>	<b>(90,905)</b>	<b>(201,481)</b>
Div. pref stock, not declared					0					0
<b>Adjusted Net Income/(loss)</b>	<b>(11,303)</b>	<b>(17,625)</b>	<b>(30,643)</b>	<b>(31,124)</b>	<b>(90,694)</b>	<b>(28,486)</b>	<b>(39,195)</b>	<b>(42,895)</b>	<b>(90,905)</b>	<b>(201,481)</b>
Total non-cash expenses	(234,726)	51,095	(5,200)	(3,700)	(192,532)	(10,900)	(8,700)	(8,000)	(10,250)	(37,850)
<b>Net income as reported</b>	<b>(246,029)</b>	<b>33,470</b>	<b>(35,843)</b>	<b>(34,824)</b>	<b>(283,226)</b>	<b>(39,386)</b>	<b>(47,895)</b>	<b>(50,895)</b>	<b>(101,155)</b>	<b>(239,331)</b>
<b>Adj-EPS ex-1x</b>	<b>(\$0.58)</b>	<b>(\$0.84)</b>	<b>(\$1.44)</b>	<b>(\$1.46)</b>	<b>(\$4.36)</b>	<b>(\$1.21)</b>	<b>(\$1.54)</b>	<b>(\$1.69)</b>	<b>(\$3.50)</b>	<b>(\$8.47)</b>
<b>EPS as reported</b>	<b>(\$12.61)</b>	<b>\$1.51</b>	<b>(\$1.69)</b>	<b>(\$1.63)</b>	<b>(\$13.63)</b>	<b>(\$1.78)</b>	<b>(\$1.99)</b>	<b>(\$2.10)</b>	<b>(\$4.09)</b>	<b>(\$10.06)</b>
Shares out (000)	19,505	20,965	21,260	21,382	20,784	22,172	24,014	24,215	24,715	23,779
Fully diluted shares (000)	21,958	22,205	22,674	22,494	22,333	23,581	25,514	25,443	25,965	25,126

Specialty Pharmaceuticals

Source: Company Reports &amp; Laidlaw estimates

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**Figure 5: Annual Income Statement****Intercept Pharmaceuticals****Annual income statement**

(\$000's except per share)	2014A	2015E	2016E	2017E	2018E	2019E	Comments
<b>Revenues</b>							
US PBC sales for OCA			\$34,344	\$153,600	\$276,642	\$202,796	US launch 2Q16
EU PBC sales for OCA				53,355	137,177	138,948	EU launch 1Q17
US NASH royalties for OCA					-	234,426	US launch 2H19
License fees	\$1,742	\$2,780	2,000	2,000	2,000	2,000	
<b>Total Revenues</b>	<b>\$1,742</b>	<b>\$2,780</b>	<b>\$36,344</b>	<b>\$155,600</b>	<b>\$278,642</b>	<b>\$439,222</b>	
<b>Expenses</b>							
Cost of Goods Sold	-	-	6,201	23,040	33,197	24,335	
<b>Gross Margin</b>	<b>1,742</b>	<b>2,780</b>	<b>30,143</b>	<b>132,560</b>	<b>245,445</b>	<b>414,887</b>	
R&D	68,661	107,148	245,000	275,000	201,000	181,000	
SG&A	24,551	99,354	93,250	122,000	124,750	125,500	
<b>Total Op Expense</b>	<b>93,212</b>	<b>206,501</b>	<b>338,250</b>	<b>397,000</b>	<b>325,750</b>	<b>306,500</b>	2015 OpEx guide: under \$240M
<b>Inc (loss) from Ops</b>	<b>(91,470)</b>	<b>(203,721)</b>	<b>(308,107)</b>	<b>(264,440)</b>	<b>(80,305)</b>	<b>108,387</b>	
Interest & dividend inc	776	2,240	400	400	400	400	
<b>Pretax Inc (Loss)</b>	<b>(90,694)</b>	<b>(201,481)</b>	<b>(307,707)</b>	<b>(264,040)</b>	<b>(79,905)</b>	<b>108,787</b>	
Taxes	-	-	-	(39,606)	(23,532)	34,812	
Div. pref stock	-	-	-	-	-	-	
<b>Adjusted Net Income/(loss)</b>	<b>(90,694)</b>	<b>(201,481)</b>	<b>(307,707)</b>	<b>(224,434)</b>	<b>(56,373)</b>	<b>73,975</b>	
Total non-cash expenses							
<b>Net income as reported</b>	<b>(283,226)</b>	<b>(239,331)</b>					
<b>Adj-EPS ex-1x</b>	<b>(\$4.36)</b>	<b>(\$8.47)</b>	<b>(\$11.60)</b>	<b>(\$8.10)</b>	<b>(\$1.95)</b>	<b>\$2.30</b>	
<b>EPS as reported</b>	<b>(\$4.36)</b>						
Shares out (000)	20,784	23,779	26,527	27,702	28,902	30,102	
Fully diluted shares (000)	22,333	25,126	28,027	29,152	30,902	32,102	

Source: Company Reports &amp; Laidlaw estimates

Specialty Pharmaceuticals  
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## Major Risks

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Exogenous events could impact our outlook. We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often, our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

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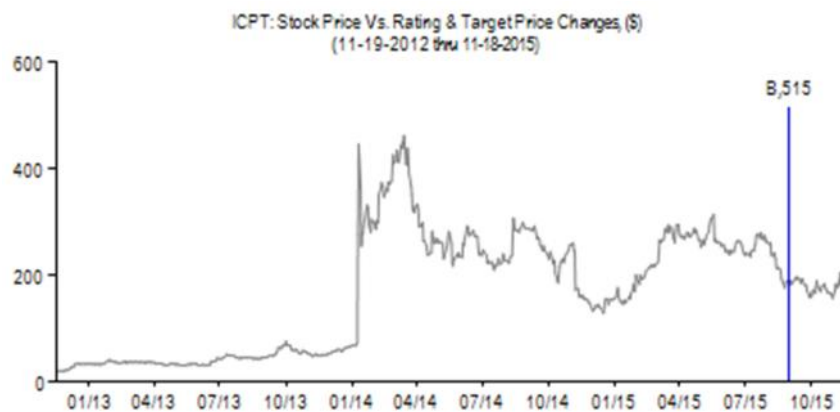
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Date	Rating	Closing Price (\$)
08/31/2015	Buy (B)	189.76

**3 Year Price Change History**

Date	Target Price (\$)	Closing Price, (\$)
08/31/2015	515.00	189.76

Source: Laidlaw & Company

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Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	71.88%	25.00%	6.25%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	3.13%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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