

## Intercept Pharmaceuticals (ICPT - \$205.97)

### PBC Moving to the Forefront as February PDUFA Looms

ICPT reported 3Q15 with a bottom line beat mainly due to lower than anticipated operating expenses in 2H15. That said ICPT is not an earnings story at this point. On the conference call management highlighted the upcoming FDA PDUFA date for obeticholic acid (OCA) for primary biliary cirrhosis (PBC) on 2/29/16. The company is gearing up for the expected approval and launch in the US in mid-2016. ICPT is expecting an Advisory Committee (AdCom) meeting for the PBC indication, likely in the mid-January timeframe. ICPT has already hired 45 territory managers in the US and we expect additional details on the PBC launch strategy at ICPT's upcoming investor/analyst day on 12/1/15 in NYC. We anticipate a heavy ICPT presence at the upcoming AASLD with 28 NASH abstracts for OCA and the initiation of the Control lipid study before year end. We reiterate our Buy rating and \$515 price target.

- **Preparations for PBC launch underway.** With the PDUFA (2/29/16) and tentative AdCom (mid-January), we continue to expect OCA approval for PBC. ICPT plans to give more launch details on their 12/1/15 analyst day in NYC. We model in FY16 PBC sales of \$34M in the US in 2016.
- **Deep pipeline of additional follow-on indications.** The regenerate Phase 3 has been underway since September 2015, and ICPT is looking at using OCA for a variety of other liver-related indications, including portal hypertension, primary and secondary bile acid diarrhea, and primary sclerosing cholangitis. See Figure 3: Clinical trial timeline estimates, later in this report for our trial projections.
- **Lower operating expenses drive bottom-line beat.** ICPT reported 3Q15 yesterday before the open with net loss/share of (\$2.10) vs Laidlaw (\$2.34) and consensus of (\$2.73). ICPT is not an earnings story at this point, but the lower expenses were due to hiring personnel, clinical trials, and manufacturing expenses. ICPT now anticipates FY15 operating expenses will be below previous guidance of \$240M.
- **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.

### 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

Source: Laidlaw & Company estimates

Healthcare / Biotechnology

Ticker:	ICPT
Rating:	<b>Buy</b>
Price Target:	<b>\$515.00</b>

### Trading Data:

Last Price (11/10/2015)	\$205.97
52-Week High (05/18/2015)	\$314.88
52-Week Low (12/03/2015)	\$128.50
Market Cap. (MM)	\$5,010
Shares Out. (MM)	24.33

### Analyst

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Figure 1: Variance analysis

<b>Intercept Pharmaceuticals</b>					
<b>Quarterly variance analysis</b>					
(\$000's except per share)	3Q14A	3Q15A	3Q15E	Var	% Y/Y
License revenues	\$445	\$445	\$445	\$0	0%
<b>Total Revenue</b>	<b>\$445</b>	<b>\$445</b>	<b>\$445</b>	<b>\$0</b>	<b>0%</b>
COGS	-	-	-	0	NM
<b>Gross Profit</b>	<b>445</b>	<b>445</b>	<b>445</b>	<b>0</b>	<b>0%</b>
R&D Expense	24,780	22,337	40,000	(17,663)	-10%
SG&A Expense	6,536	21,892	21,500	392	235%
<b>Operating Inc (loss)</b>	<b>(30,871)</b>	<b>(43,784)</b>	<b>(61,055)</b>	<b>17,271</b>	<b>42%</b>
Interest & dividend income	228	889	150	739	290%
<b>Pretax Inc (loss)</b>	<b>(30,643)</b>	<b>(42,895)</b>	<b>(60,905)</b>	<b>18,010</b>	<b>40%</b>
Income Taxes	0	0	0	0	NM
Dividend pref. stock	0	0	0	0	NM
<b>Net Income - ex-1x items</b>	<b>(30,643)</b>	<b>(42,895)</b>	<b>(60,905)</b>	<b>18,010</b>	<b>40%</b>
Average Shares (000)	21,260	24,215	24,514	(299)	14%
<b>EPS ex-1x items</b>	<b>(\$1.44)</b>	<b>(\$1.69)</b>	<b>(\$2.34)</b>	<b>\$0.66</b>	<b>17%</b>

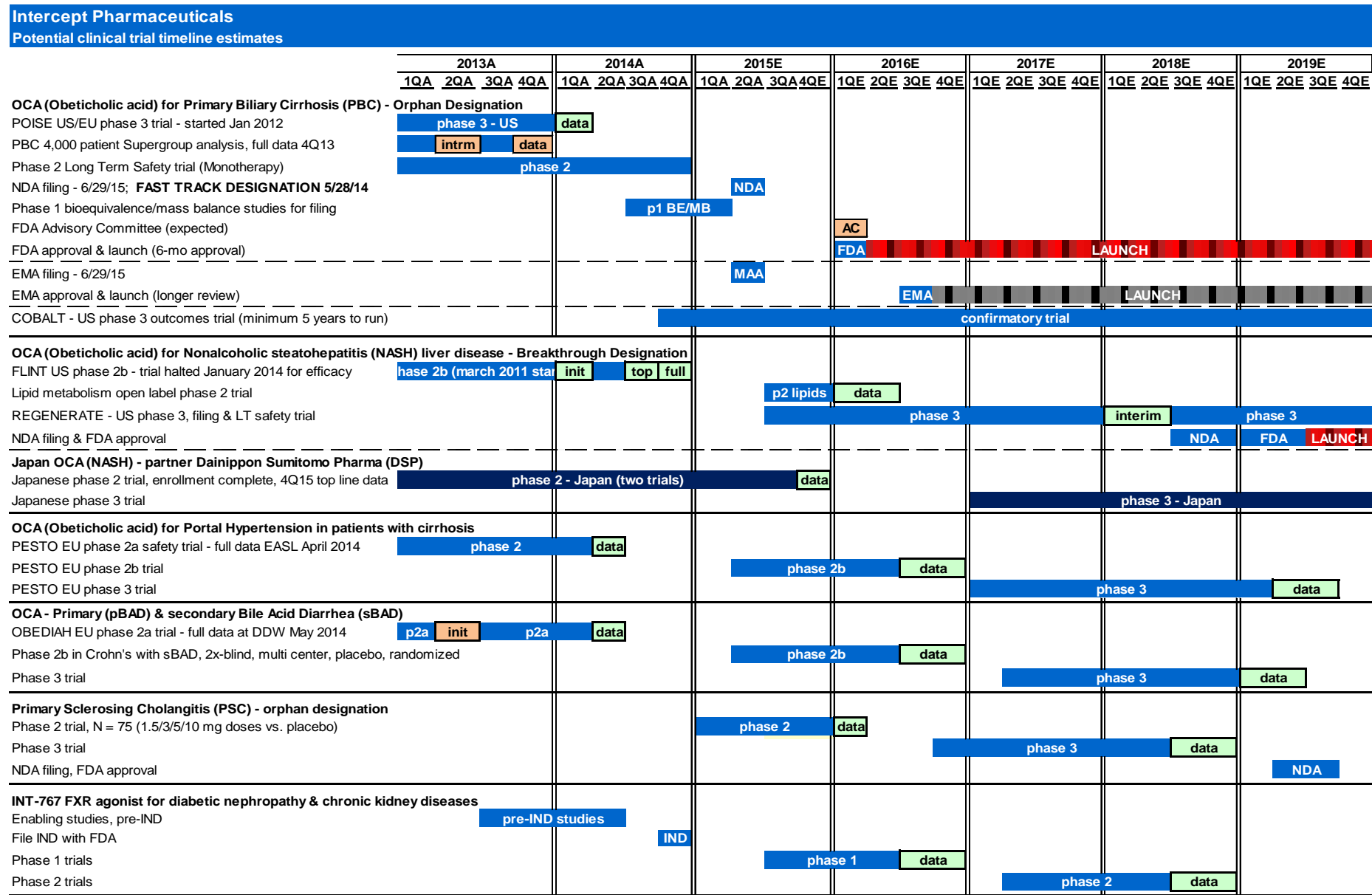
Source: Company Reports: Laidlaw &amp; Company estimates

Figure 2: Valuation

<b>Sum-of-the-parts valuation: ICPT</b>		
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 &amp; Company estimates

Figure 3: Clinical trial timeline estimates



Source: Company Reports; Laidlaw & Company estimates

Figure 4: Quarterly Income Statement

<b>Intercept Pharmaceuticals</b>										
<b>Quarterly income statement</b>										
(\$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

Source: Company Reports &amp; Laidlaw estimates

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Figure 5: Annual Income Statement

<b>Intercept Pharmaceuticals</b>							
<b>Annual income statement</b>							
(\$000's except per share)	<b>2014A</b>	<b>2015E</b>	<b>2016E</b>	<b>2017E</b>	<b>2018E</b>	<b>2019E</b>	<b>Comments</b>
<b>Revenues</b>							
US PBC sales for OCA			\$34,344	\$153,600	\$276,642	\$202,796	<b>US launch 2Q16</b>
EU PBC sales for OCA				53,355	137,177	138,948	<b>EU launch 1Q17</b>
US NASH royalties for OCA					-	234,426	<b>US launch 2H19</b>
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>	<b>2015 OpEx guide: under \$240M</b>
<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

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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.

Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

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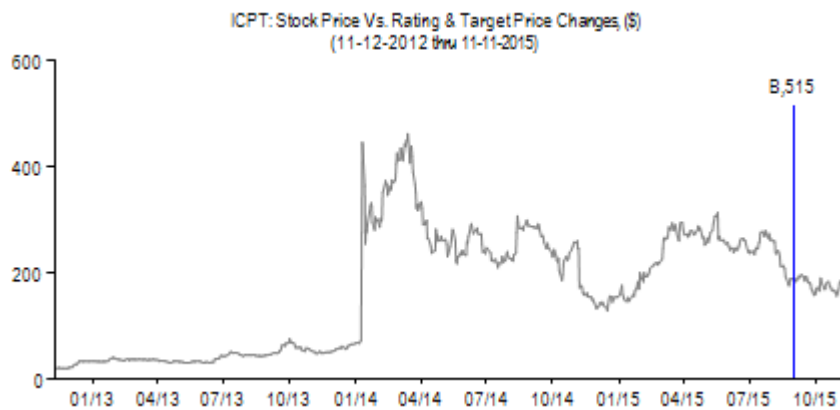
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3 Year Rating Change History		
Date	Rating	Closing Price (\$)
08/31/2015	Buy (B)	189.76

3 Year Price Change History		
Date	Target Price (\$)	Closing Price, (\$)
08/31/2015	515.00	189.76

Source: Laidlaw & Company

Created by: Blue-Compass.net

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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