

## Intercept Pharmaceuticals (ICPT - \$119.29)

### 4Q15 Tracks in-line, April AdCom the next key catalyst

ICPT reported FY15 earnings yesterday, roughly in-line with our adjusted estimates. ICPT remains very much a development story not an earnings story at this point, with their first real revenues from OCA not anticipated until 2H16 (assuming FDA approval on the May 29<sup>th</sup> PDUFA date). Most notably ICPT's deep pipeline remains on track, with enrollment progressing in the Phase 3 REGENERATE trial for NASH as well as the P2 trials in primary sclerosing cholangitis and the biliary atresia programs. The next key catalyst remains the upcoming April 7<sup>th</sup> Advisory Committee (AdCom) for OCA for primary biliary cholangitis (PBC). We continue to expect a favorable AdCom and a vote for approval, given the demonstrated success in treating key surrogate markers for PBC, the dearth of treatments for Urso (current standard of care) failures, and the clean safety profile in clinical trials. We reiterate our Buy rating, \$515 price target.

- **NASH lipid & REGENERATE studies underway.** With a long way to go until they enroll 1,400 patients (much less follow them for 72 weeks) ICPT declined to update the enrollment status for REGENERATE but did reiterate it was successfully underway. We continue to estimate a 1H18 interim look. We forecast 2H16 top line data for the CONTROL lipid metabolism study data.
- **Non-invasive diagnostic tools remain a priority for ICPT.** Amongst all noninvasive measurement techniques, Fibrosis-4 (FIB-4) seems like an inexpensive and leading method with a negative outcome accuracy of 95% and positive accuracy ~80%, which suggests that FIB-4 could be used as a valid diagnosis tool for NASH at some point.
- **2016 guidance indicates a significant spending ramp.** ICPT guided to \$360M-\$400M in operating expenses in 2016, loaded to 2H16 consisting of the continued build out of ICPT's European infrastructure in preparation for the launch of PBC in Europe. With approval anticipated in the US on or about May 29<sup>th</sup> ICPT has substantially completed the US build-out.
- **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>	(\$3.11)	(\$3.44)	(\$3.67)	(\$4.14)	(\$14.40)	NA
<b>FY15</b>	(\$1.21)	(\$1.54)	(\$1.69)	(\$2.95)	(\$8.04)	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 (02/23/2016)	\$119.29
52-Week High (05/18/2015)	\$314.88
52-Week Low (02/11/2016)	\$89.76
Market Cap. (MM)	\$2,090
Shares Out. (MM)	24.33

### Analyst

Jim Molloy Specialty Pharma & Biotechnology  
(617) 283-5521  
jmolloy@laidlawltd.com

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Figure 1: Variance analysis

Intercept Pharmaceuticals										
Quarterly variance analysis										
(\$000's)	4Q14A	4Q15A	4Q15E	Var	% Y/Y	FY14A	FY15A	FY15E	Var	% Y/Y
License revenues	\$445	\$447	\$445	\$2	0%	\$1,742	\$2,782	\$2,780	\$2	60%
<b>Total Revenue</b>	<b>\$445</b>	<b>\$447</b>	<b>\$445</b>	<b>\$2</b>	<b>0%</b>	<b>\$1,742</b>	<b>\$2,782</b>	<b>\$2,780</b>	<b>\$2</b>	<b>60%</b>
COGS	-	-	-	0	NM	-	-	-	0	NM
<b>Gross Profit</b>	<b>445</b>	<b>447</b>	<b>445</b>	<b>2</b>	<b>0%</b>	<b>1,742</b>	<b>2,782</b>	<b>2,780</b>	<b>2</b>	<b>60%</b>
R&D Expense	21,868	37,747	40,000	(2,254)	73%	68,661	104,894	107,148	(2,254)	53%
SG&A Expense	10,009	38,816	51,500	(12,685)	288%	24,551	91,163	99,354	(8,191)	271%
<b>Operating Inc (loss)</b>	<b>(31,432)</b>	<b>(76,115)</b>	<b>(91,055)</b>	<b>14,940</b>	<b>142%</b>	<b>(91,470)</b>	<b>(193,275)</b>	<b>(203,721)</b>	<b>10,446</b>	<b>111%</b>
Int & div income	308	637	150	487	107%	776	2,727	2,240	487	251%
<b>Pretax Inc (loss)</b>	<b>(31,124)</b>	<b>(75,478)</b>	<b>(90,905)</b>	<b>15,427</b>	<b>143%</b>	<b>(90,694)</b>	<b>(190,548)</b>	<b>(201,481)</b>	<b>10,933</b>	<b>110%</b>
Income Taxes	0	0	0	0	NM	0	0	0	0	NM
Div pref. stock	0	0	0	0	NM	0	0	0	0	NM
<b>NI - ex-1x items</b>	<b>(31,124)</b>	<b>(75,478)</b>	<b>(90,905)</b>	<b>15,427</b>	<b>143%</b>	<b>(90,694)</b>	<b>(190,548)</b>	<b>(201,481)</b>	<b>10,933</b>	<b>110%</b>
Avg Shares (000)	21,382	24,351	24,715	(364)	14%	20,784	23,694	23,779	(85)	14%
<b>EPS ex-1x items</b>	<b>(\$1.46)</b>	<b>(\$2.95)</b>	<b>(\$3.50)</b>	<b>\$0.55</b>	<b>103%</b>	<b>(\$4.36)</b>	<b>(\$8.04)</b>	<b>(\$8.47)</b>	<b>\$0.43</b>	<b>84%</b>

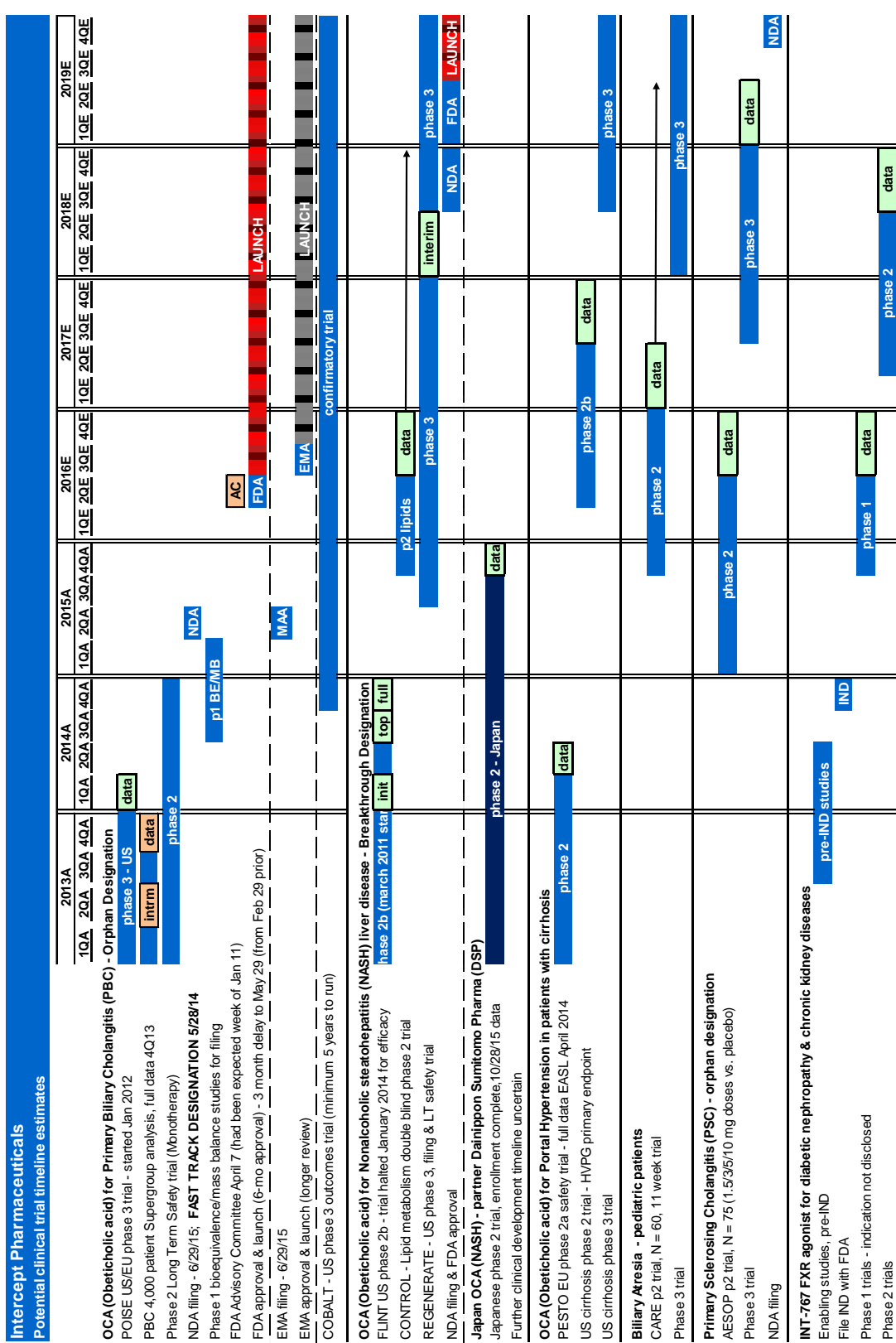
Source: Company Reports: Laidlaw &amp; Company estimates

Figure 2: Valuation

Sum-of-the-parts valuation: ICPT		
Segment	Valuation (000's)	Per share value
OCA for NASH in the US	\$8,896,352	\$322
OCA for NASH EU royalty	\$3,178,350	\$115
OCA for PBC US & EU	\$1,007,594	\$36
OCA for other indications	\$475,825	\$17
Cash (end of '16E) & tech	\$702,418	\$25
	\$14,260,539	<b>\$515</b>
2016 fully diluted shares out		27,664

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	2015A				2015A Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QA	
<b>Revenues</b>										
License fees	\$405	\$445	\$445	\$445	\$1,742	\$1,445	\$445	\$445	\$447	\$2,782
<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>\$447</b>	<b>\$2,782</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>447</b>	<b>2,782</b>
R&D	9,893	12,119	24,780	21,868	68,661	21,916	22,895	22,337	37,747	104,894
SG&A	1,951	6,055	6,536	10,009	24,551	8,288	17,674	21,892	38,816	91,163
<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>76,562</b>	<b>196,057</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>(76,115)</b>	<b>(193,275)</b>
Other income (exp)	136	104	228	308	776	272	929	889	637	2,727
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>(75,478)</b>	<b>(190,548)</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>(75,478)</b>	<b>(190,548)</b>
Total non-cash expenses	(234,726)	51,095	(5,200)	(3,700)	(192,532)	(10,900)	(8,700)	(8,000)	(12,774)	(35,881)
<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>(88,252)</b>	<b>(226,429)</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>(\$2.95)</b>	<b>(\$8.04)</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>(\$3.62)</b>	<b>(\$9.56)</b>
Shares out (000)	19,505	20,965	21,260	21,382	20,784	22,172	24,014	24,215	24,351	23,694
Fully diluted shares (000)	21,958	22,205	22,674	22,494	22,333	23,581	25,514	25,443	25,601	25,035

Source: Company Reports &amp; Laidlaw estimates

Specialty Pharmaceuticals  
Jim Molloy (857) 317-5061 jmolloy@laidlawltd.com

Figure 5: Annual Income Statement

<b>Intercept Pharmaceuticals</b>							
<b>Annual income statement</b>							
(\$000's except per share)	2014A	2015A	2016E	2017E	2018E	2019E	Comments
<b>Revenues</b>							
US PBC sales for OCA			\$15,884	\$147,985	\$276,642	\$202,796	US launch 2H16
EU PBC sales for OCA				53,355	137,177	138,948	EU launch 1H17
US NASH royalties for OCA					-	234,426	US launch 2H19
License fees	\$1,742	\$2,782	2,000	2,000	2,000	2,000	
<b>Total Revenues</b>	<b>\$1,742</b>	<b>\$2,782</b>	<b>\$17,884</b>	<b>\$149,985</b>	<b>\$278,642</b>	<b>\$439,222</b>	
<b>Expenses</b>							
Cost of Goods Sold	-	-	2,646	22,198	33,197	24,335	
<b>Gross Margin</b>	<b>1,742</b>	<b>2,782</b>	<b>15,238</b>	<b>127,787</b>	<b>245,445</b>	<b>414,887</b>	
R&D	68,661	104,894	195,000	225,000	201,000	188,000	
SG&A	24,551	91,163	199,000	146,000	125,500	121,500	
<b>Total Op Expense</b>	<b>93,212</b>	<b>196,057</b>	<b>394,000</b>	<b>371,000</b>	<b>326,500</b>	<b>309,500</b>	2016 OpEx guide: \$360M-\$400M
<b>Inc (loss) from Ops</b>	<b>(91,470)</b>	<b>(193,275)</b>	<b>(378,762)</b>	<b>(243,213)</b>	<b>(81,055)</b>	<b>105,387</b>	
Interest & dividend inc	776	2,727	2,000	2,000	2,000	2,000	
<b>Pretax Inc (Loss)</b>	<b>(90,694)</b>	<b>(190,548)</b>	<b>(376,762)</b>	<b>(241,213)</b>	<b>(79,055)</b>	<b>107,387</b>	
Taxes	-	-	-	(36,182)	(23,282)	34,364	
Div. pref stock	-	-	-	-	-	-	
<b>Adjusted Net Income/(loss)</b>	<b>(90,694)</b>	<b>(190,548)</b>	<b>(376,762)</b>	<b>(205,031)</b>	<b>(55,773)</b>	<b>73,023</b>	
Total non-cash expenses							
<b>Net income as reported</b>	<b>(283,226)</b>	<b>(226,429)</b>					
<b>Adj-EPS ex-1x</b>	<b>(\$4.36)</b>	<b>(\$8.04)</b>	<b>(\$14.40)</b>	<b>(\$7.50)</b>	<b>(\$1.95)</b>	<b>\$2.30</b>	
<b>EPS as reported</b>	<b>(\$4.36)</b>						
Shares out (000)	20,784	23,694	26,164	27,339	28,539	29,739	
Fully diluted shares (000)	22,333	25,035	27,664	28,789	30,539	31,739	
<b>Margin &amp; expense analysis</b>							
COGS as % prod sales	NA	NA	17%	15%	12%	12%	
R&D	NA	NA	1090%	150%	72%	43%	
SG&A	NA	NA	1113%	97%	45%	28%	
Op. margin cont. ops	NA	NA	-2118%	-162%	-29%	24%	
Taxes	NA	NA	NA	15%	29%	32%	
Net margin	NA	NA	-2107%	-137%	-20%	17%	
<b>Year-over-year change</b>							
Net revenue	NA		543%	739%	86%	58%	
R&D	183%	53%	86%	15%	-11%	-6%	
SG&A	159%	271%	118%	-27%	-14%	-3%	
Operating income	NA	NA	NA	-36%	-67%	-230%	
Net income	NA	NA	NA	-46%	-73%	-231%	

Source: Company Reports &amp; Laidlaw estimates

Specialty Pharmaceuticals  
Jim Molloy (857) 317-5061 jmolloy@laidlawltd.com

## 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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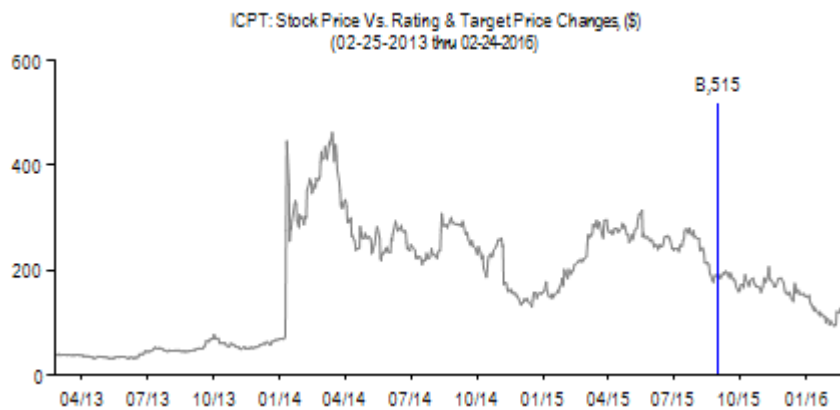
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**Rating and Price Target Change History**



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

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.	64.71%	26.47%	2.94%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	0.00%	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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