

Intercept Pharmaceuticals (ICPT - \$163.83)

Healthcare / Biotechnology

17-0 approval vote presages FDA approval at May 29 PDUFA

ICPT received a tremendous endorsement yesterday with the 17-0 “Yes” vote in favor of approval of OCA for treating PBC, with no abstentions on the vote. Obviously this is as good an outcome as could be looked for at the AdCom and reflects ICPT’s robust clinical trial package submission and the significant unmet medical need for Urso failures in PBC. The one voting question was “Taking into account the risks and benefit of OCA in the population studied, is there substantial evidence to support accelerated approval of OCA for the proposed indication, based on its effect on alkaline phosphatase?” This was based on the demonstrated success of PBC in reducing alkaline phosphatase (ALP) – a key surrogate marker for PBC – and the dearth of other options for Urso failures, which is the current standard of care. We reiterate our Buy rating, \$515 price target.

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

Trading Data:

Last Price (04/07/2016)	\$163.83
52-Week High (05/18/2015)	\$314.88
52-Week Low (02/11/2016)	\$89.76
Market Cap. (MM)	\$4,000
Shares Out. (MM)	24.41

- **PBC PDUFA date May 29th.** Following the positive AdCom vote we believe it is highly likely that the FDA approves OCA for treating PBC on the May 29th PDUFA date, with launch in 2H16.
- **Sales estimates & pricing post approval.** We currently project 2016E-2019E PBC sales of \$15.9M, \$147.9M, \$276.6M, and \$202.8M respectively. We model in a \$50K annual cost of therapy for PBC in the US, with sales dropping off 2019E as we anticipate OCA for NASH approval & launch and a subsequent reduction in annual cost of therapy to the ~\$15K range.
- **ICPT ready for June launch if approved.** On the post-vote call management indicated that they have commercial scale product ready to go, and would expect to launch as early as June 2016 should they receive approval in May.
- **Dosing duration in refractory patients a key question.** There was some discussion in the AdCom on the duration of continued treatment for patients showing no effect on ALP at 3 months, and from ICPT’s conversations this patient population will likely be continued at least 9-months to 1 year before stopping treatment – similar to current Urso practice.
- **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
FY17E	NA	NA	NA	NA	(\$7.50)	NA
FY16E	(\$3.11)	(\$3.44)	(\$3.67)	(\$4.14)	(\$14.40)	NA
FY15	(\$1.21)	(\$1.54)	(\$1.69)	(\$2.95)	(\$8.04)	NA
FY14	(\$0.58)	(\$0.84)	(\$1.44)	(\$1.46)	(\$4.36)	NA

Analyst

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Source: Laidlaw & Company estimates

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European approval anticipated in 2H16. We model in a \$35K annual cost of therapy in the EU, with 2017E-2019E sales of \$53.4M, \$137.2M, and \$138.9M respectively.

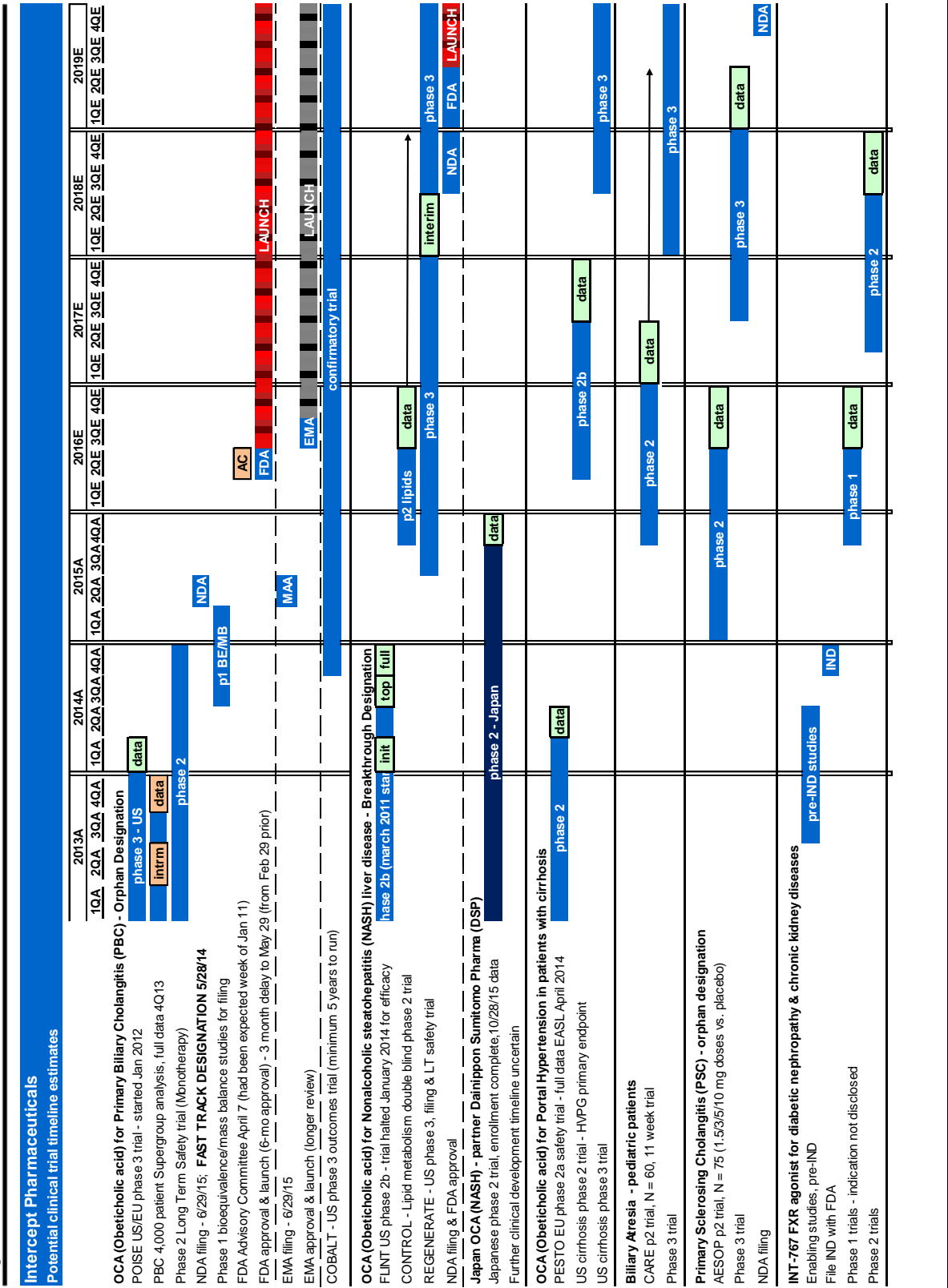
NASH lipid data next. We anticipate the CONTROL lipid trial to read out in 2H16, with the interim look at the REGENERATE phase 3 trial to follow in 1H18.

Figure 1: 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	\$515
2016 fully diluted shares out		27,664

Source: Company Reports; Laidlaw & Company estimates

Figure 2: Clinical trial timeline estimates



Source: Company Reports; Laidlaw & Company estimates

Figure 3: Quarterly Income Statement

Intercept Pharmaceuticals										
Quarterly income statement										
(\$000's except per share)	2014A				2014A Year	2015A				2015A Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QA	
Revenues										
License fees	\$405	\$445	\$445	\$445	\$1,742	\$1,445	\$445	\$445	\$447	\$2,782
Total Revenues	\$405	\$445	\$445	\$445	\$1,742	\$1,445	\$445	\$445	\$447	\$2,782
Expenses										
Cost of Goods Sold	0	0	0	0	0	0	0	0	0	0
Gross Margin	405	445	445	445	1,742	1,445	445	445	447	2,782
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
Total Op Expenses	11,844	18,174	31,316	31,877	93,212	30,203	40,569	44,229	76,562	196,057
Inc (loss) from Ops	(11,439)	(17,729)	(30,871)	(31,432)	(91,470)	(28,758)	(40,124)	(43,784)	(76,115)	(193,275)
Other income (exp)	136	104	228	308	776	272	929	889	637	2,727
Int exp					0					0
Pretax Inc (Loss)	(11,303)	(17,625)	(30,643)	(31,124)	(90,694)	(28,486)	(39,195)	(42,895)	(75,478)	(190,548)
Div. pref stock, not declared					0					0
Adjusted Net Income/(loss)	(11,303)	(17,625)	(30,643)	(31,124)	(90,694)	(28,486)	(39,195)	(42,895)	(75,478)	(190,548)
Total non-cash expenses	(234,726)	51,095	(5,200)	(3,700)	(192,532)	(10,900)	(8,700)	(8,000)	(12,774)	(35,881)
Net income as reported	(246,029)	33,470	(35,843)	(34,824)	(283,226)	(39,386)	(47,895)	(50,895)	(88,252)	(226,429)
Adj-EPS ex-1x	(\$0.58)	(\$0.84)	(\$1.44)	(\$1.46)	(\$4.36)	(\$1.21)	(\$1.54)	(\$1.69)	(\$2.95)	(\$8.04)
EPS as reported	(\$12.61)	\$1.51	(\$1.69)	(\$1.63)	(\$13.63)	(\$1.78)	(\$1.99)	(\$2.10)	(\$3.62)	(\$9.56)
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 & Laidlaw estimates

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Figure 4: Annual Income Statement

Intercept Pharmaceuticals							
Annual income statement							
(\$000's except per share)	2014A	2015A	2016E	2017E	2018E	2019E	Comments
Revenues							
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	
Total Revenues	\$1,742	\$2,782	\$17,884	\$149,985	\$278,642	\$439,222	
Expenses							
Cost of Goods Sold	-	-	2,646	22,198	33,197	24,335	
Gross Margin	1,742	2,782	15,238	127,787	245,445	414,887	
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	
Total Op Expense	93,212	196,057	394,000	371,000	326,500	309,500	2016 OpEx guide: \$360M-\$400M
Inc (loss) from Ops	(91,470)	(193,275)	(378,762)	(243,213)	(81,055)	105,387	
Interest & dividend inc	776	2,727	2,000	2,000	2,000	2,000	
Pretax Inc (Loss)	(90,694)	(190,548)	(376,762)	(241,213)	(79,055)	107,387	
Taxes	-	-	-	(36,182)	(23,282)	34,364	
Div. pref stock	-	-	-	-	-	-	
Adjusted Net Income/(loss)	(90,694)	(190,548)	(376,762)	(205,031)	(55,773)	73,023	
Total non-cash expenses							
Net income as reported	(283,226)	(226,429)					
Adj-EPS ex-1x	(\$4.36)	(\$8.04)	(\$14.40)	(\$7.50)	(\$1.95)	\$2.30	
EPS as reported	(\$4.36)						
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	
Margin & expense analysis							
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%	
Year-over-year change							
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 & Laidlaw estimates

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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.

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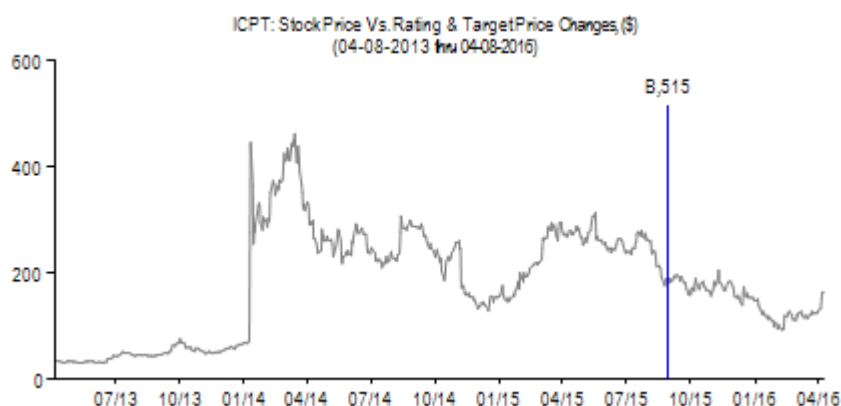
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3 Year Rating Change History

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

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	65.71%	25.71%	2.86%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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