

Intercept Pharmaceuticals (ICPT - \$110.44)

Healthcare / Biotechnology

REGENERATE Enrollment Challenges, and a Slow PBC Launch

ICPT recently reported their 3Q16 beating on top-line as US Ocaliva for Primary Biliary Cholangitis (PBC) sales of \$4.7M exceeded our estimated \$1.3M. Management noted that due to reimbursement concerns the US PBC launch is expected to flatten in the coming quarters, which is in-line with our expectations for a moderated launch for this orphan indication. In REGENERATE, the Phase 3 pivotal trial for NASH, which remains the main reason to own ICPT in our opinion, management noted that to date enrollment has been slower than expected due to the need for serial biopsies, which can be a pain for trial participants. Management plans to remain on track for a 2019 interim look for this trial by adding more trial sites, and we have moved the interim look to mid-2019 (from 1H19 previously). See our clinical trial timeline chart later in this report for more detail. This is in-line the part of our Sell thesis - that the large, complex REGENERATE trial may well slip on timelines past our prior 1H19 expectations due to the issues management discussed on the call, among others. We also remain concerned that the spend rate at ICPT to build out a global infrastructure to launch a single orphan drug might be higher than prudent for the return expected from Ocaliva. We are reiterating our Sell rating, and lowering out PT from \$105 to \$95.

Ticker:	ICPT
Rating:	Sell
Price Target:	↓ \$95.00

Trading Data:

Last Price (11/10/2016)	\$110.44
52-Week High (11/10/2015)	\$217.99
52-Week Low (02/11/2016)	\$89.76
Market Cap. (MM)	\$2,737.8
Shares Out. (MM)	24.8

- **Slow enrollment could presage more timeline slippage.** Management insisted that they should hit their previous guidance the interim cohort enrollment completion by 1H17. We remain cautious about adding 50 sites to the 300 currently as this could lead to additional variability in data, and an even higher R&D spend in 2017-2018, when we anticipate that ICPT will need to raise additional funding yet again.
- **An orphan product with reimbursement challenges.** US PBC sales beat our expectations, but management noted they are meeting reimbursement push-back with the transition of reimbursement from medical exception to prior authorization and required criteria. Single product launches can be challenging, and orphan launches all the more so.
- **Reiterate our Sell rating, lowering PT to \$95.** We value OCA for NASH (US & EU) at \$62/share, Ocaliva at \$19/share, other indications, cash (end '17, net debt) & tech value at \$14/share.

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY17E	(\$3.31)	(\$3.28)	(\$3.35)	(\$3.31)	(\$13.25)	NA
FY16E	(\$2.89)A	(\$2.93)A	(\$3.06)A	(\$3.93)	(\$12.84)	NA
FY15	(\$1.21)	(\$1.55)	(\$1.69)	(\$2.95)	(\$8.04)	NA
FY14	(\$0.58)	(\$0.84)	(\$1.44)	(\$1.46)	(\$4.36)	NA

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Source: Laidlaw & Company estimates

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Figure 1: Variance Analysis

Intercept Pharmaceuticals					
Quarterly variance analysis					
(\$000's)	3Q15A	3Q16A	3Q16E	Variance	% Y/Y
US PBC sales		\$4,732	\$1,317	\$3,415	NM
License revenues	\$445	445	445	\$0	0%
Total Revenue	\$445	\$5,177	\$1,762	\$3,415	1063%
COGS	-	-	263	(263)	NM
Gross Profit	445	5,177	1,499	3,678	1063%
R&D Expense	22,353	36,923	50,000	(13,077)	65%
SG&A Expense	21,908	38,103	52,750	(14,647)	74%
Operating Inc (loss)	(43,815)	(69,849)	(101,251)	31,402	59%
Int & div income	889	(7,065)	500	(7,565)	-895%
Pretax Inc (loss)	(42,926)	(75,628)	(100,751)	25,123	76%
Income Taxes	0	0	0	0	NM
Div pref. stock	0	0	0	0	NM
NI - ex-1x items	(42,926)	(75,628)	(100,751)	25,123	76%
Avg Shares (000)	24,215	24,738	28,431	(3,693)	2%
EPS ex-1x items	(\$1.69)	(\$3.06)	(\$3.54)	\$0.49	81%
EPS as reported	(\$2.10)				

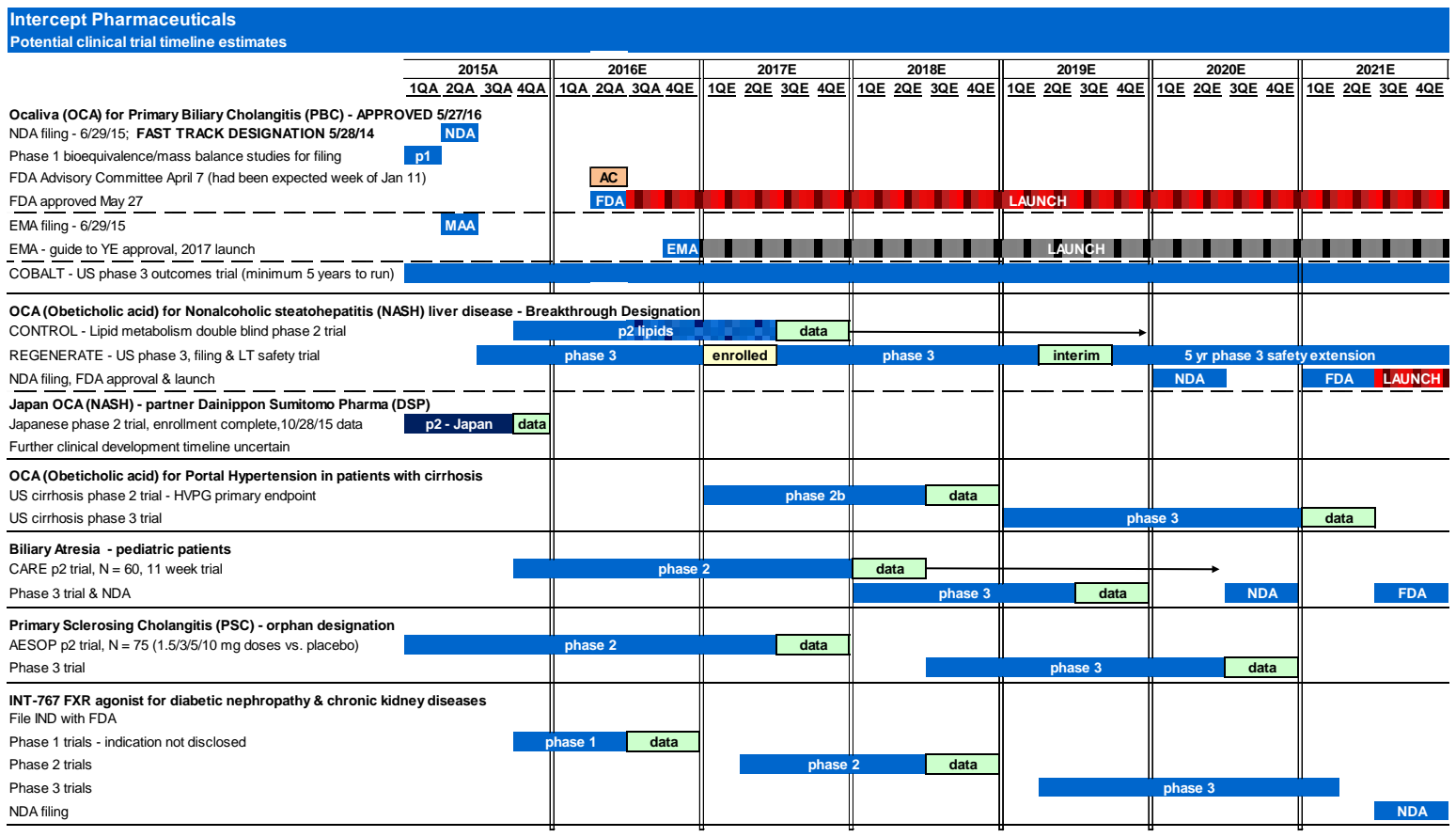
Source: Company reports; Laidlaw & Company estimates

Figure 2: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
OCA for NASH in the US	\$1,636,649	\$57
Ocaliva for PBC US & EU	\$557,684	\$19
OCA for NASH EU royalty	\$142,511	\$5
OCA for other indications	\$130,826	\$4
Cash (end of '17E) & tech	\$282,049	\$10
	\$2,749,720	\$95
2017 fully diluted shares out		28,838

Source: Company Reports; Laidlaw & Company estimates

Figure 3: Clinical Trial Timeline Estimates



Source: Laidlaw & Company estimates

Figure 4: Quarterly Income Statement

Intercept Pharmaceuticals Quarterly income statement										
(\$000's except per share)	2015A				2015A Year	2016E				2016E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE	
Revenues										
License fees	\$1,445	\$445	\$445	\$447	\$2,782	\$445	\$5,445	445	445	6,780
Total Revenues	\$1,445	\$445	\$445	\$447	\$2,782	\$445	\$5,520	\$5,177	\$3,099	\$14,241
Expenses										
Cost of Goods Sold	0	0	0	0	0	0	0	0	531	531
Gross Margin	1,445	445	445	447	2,782	445	5,520	5,177	2,568	13,710
R&D	21,916	22,895	22,353	37,747	104,910	31,607	38,354	36,923	50,000	156,884
SG&A	8,288	17,674	21,908	38,816	91,163	40,310	40,149	38,103	53,250	171,812
Total Op Expenses	30,203	40,569	44,260	76,562	196,073	71,917	78,502	75,026	103,250	328,695
Inc (loss) from Ops	(28,758)	(40,124)	(43,815)	(76,115)	(193,291)	(71,472)	(72,982)	(69,849)	(100,682)	(314,985)
Other income (exp)	272	929	889	637	2,727	726	796	(7,065)	500	(5,043)
Int exp					0			1,286		
Pretax Inc (Loss)	(28,486)	(39,195)	(42,926)	(75,478)	(190,564)	(70,746)	(72,186)	(75,628)	(100,182)	(318,742)
Div. pref stock, not declared					0					0
Adjusted Net Income/(loss)	(28,486)	(39,195)	(42,926)	(75,478)	(190,564)	(70,746)	(72,186)	(75,628)	(100,182)	(318,742)
Total non-cash expenses	(10,900)	(8,700)	(8,000)	(12,774)	(35,881)	(55,928)	(5,113)	(13,187)		(74,228)
Net income as reported	(39,386)	(47,895)	(50,926)	(88,252)	(226,444)	(126,674)	(77,299)	(88,815)		(392,970)
Adj-EPS ex-1x	(\$1.21)	(\$1.55)	(\$1.69)	(\$2.95)	(\$8.04)	(\$2.89)	(\$2.93)	(\$3.06)	(\$3.93)	(\$12.84)
EPS as reported	(\$1.78)	(\$1.99)	(\$2.10)	(\$3.62)	(\$9.56)	(\$5.17)	(\$3.14)	(\$3.59)		(\$15.82)
Shares out (000)	22,172	24,014	24,215	24,351	23,694	24,495	24,612	24,738	25,488	24,833
Fully diluted shares (000)	23,581	25,283	25,443	25,601	24,977	26,510	26,635	26,720	27,538	26,851

Source: Company Reports: Laidlaw & Company estimates

Figure 5: Annual Income Statement

Intercept Pharmaceuticals						
Annual income statement						
(<i>'000's except per share</i>)	2015A	2016E	2017E	2018E	2019E	Comments
Revenues						
Ocaliva US PBC sales		\$7,461	\$51,320	\$141,531	\$120,940	US launch 2Q16 EU launch 2Q17 Launch 2H 2021
Ocaliva EU PBC sales			5,714	35,335	69,474	
US NASH royalties for OCA				0	0	
License fees	\$2,782	6,780	2,000	2,000	2,000	
Total Revenues	\$2,782	\$14,241	\$59,034	\$178,865	\$192,414	
Expenses						
Cost of Goods Sold	-	531	8,555	19,455	14,513	
Gross Margin	2,782	13,710	50,479	159,410	177,901	
R&D	104,910	156,884	195,000	219,000	200,000	
SG&A	91,163	171,812	211,850	250,250	271,750	
Total Op Expense	196,073	328,695	406,850	469,250	471,750	2016 guide: \$320M-\$340M
Inc (loss) from Ops	(193,291)	(314,985)	(356,371)	(309,840)	(293,849)	
Interest & dividend inc	2,727	(5,043)	2,000	2,000	2,000	
Pretax Inc (Loss)	(190,564)	(318,742)	(354,371)	(307,840)	(291,849)	
Taxes	-	-	-	-	-	
Div. pref stock	-	-	-	-	-	
Adjusted Net Income/(loss)	(190,564)	(318,742)	(354,371)	(307,840)	(291,849)	
Total non-cash expenses	(35,881)	(74,228)				
Net income as reported	(226,444)	(392,970)				
Adj-EPS ex-1x	(\$8.04)	(\$12.84)	(\$13.25)	(\$11.00)	(\$10.00)	
EPS as reported	(\$9.56)	(\$15.82)				
Shares out (000)	23,694	24,833	26,738	27,988	29,188	
Fully diluted shares (000)	24,977	26,851	28,838	30,238	31,688	
Cash position	\$628,055	\$866,018	\$559,947	\$746,483	\$511,635	assume 2018 fund raise

Source: Company Reports: Laidlaw & Company estimates

Major Risks

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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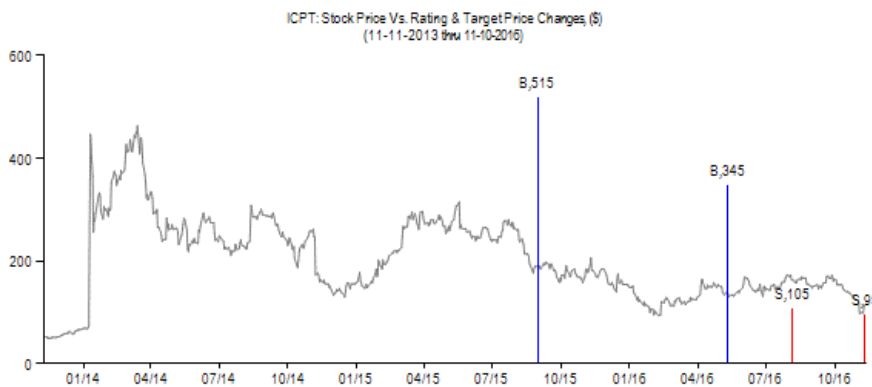
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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
08/31/2015	Buy (B)	189.76
08/05/2016	Sell (S)	162.27

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
08/31/2015	515.00	189.76
05/11/2016	345.00	137.28
08/05/2016	105.00	162.27
11/10/2016	95.00	113.00*

* Previous Close 11/9/2016

Source: Laidlaw & Company

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.56%	2.56%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

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