

## Intercept Pharmaceuticals (ICPT - \$116.79)

Healthcare / Biotechnology

### NASH Remains the Reason to Own ICPT, but It Remains Distant

ICPT reported their 4Q16 and FY16 results this morning before the open beating on top-line as US Ocaliva for Primary Biliary Cholangitis (PBC) sales led the way with 4Q16 sales of ~\$13.4M (vs \$11.5M consensus high). The launch of PBC is certainly exceeding expectations, but ICPT continues to burn significant amounts of cash as they build out their worldwide infrastructure for Ocaliva (an orphan drug). ICPT set 2017 adjusted operating expense guidance at \$380M-\$420M, which will chew up a significant chunk of the \$689M in cash they ended 2016 with. We have modelled in another ~\$500M raise in 2018, but ICPT could easily reach out to the capital markets in 2H17 if they remain leery of getting within one year of available cash at current cash burn rates (\$80M-\$85M/Q). We continue to see the recent changes to ICPT's REGENERATE trial as coming from a position of weakness (inability to enroll the initial trial) rather than strength (an easier endpoint to hit). Recall that no one forced ICPT to have the initial endpoint of both fibrosis improvement and NASH resolution, the company chose this endpoint as a way to "close the door" to additional competition after they were approved. Now the either/or endpoint may be easier to hit, but still it is a fairly significant change to a Phase 3 endpoint in the mid-point of a trial. We maintain our Sell rating, \$95 PT.

Ticker:	ICPT
Rating:	<b>Sell</b>
Price Target:	↓ <b>\$95.00</b>

#### Trading Data:

Last Price (02/23/2017)	\$116.79
52-Week High (08/01/2016)	\$177.93
52-Week Low (11/04/2016)	\$96.63
Market Cap. (MM)	\$2,897.4
Shares Out. (MM)	24.8

- **OCA for PBC beat consensus high, guided expenses still concern us.** While 4Q16 of ~\$13.8M beat consensus high of \$11.5M, PBC, in our view, is still disproportionately small relative to their 2017 guidance for adj. operating expenses of \$380M-\$420M (ex non-cash charges). We estimate 2017 PBC sales of \$71M with n OpEx burn of >\$410M. With cash of \$689.4M we believe ICPT could come back to the market in late 2017/early 2018 for up to ~\$500M.
- **Easier REGENERATE endpoint could raise competitive risks.** While the lowering of patients (n=1,400 to n=750) for their Phase 3 interim look (mid-19) and the changing of primary endpoints increase chances of hitting stat. sig, we believe this lowers the competitive edge and barrier to entry of competitors in this crowded space.
- **Reiterate our Sell rating, \$95 PT.** We value OCA for NASH (US & EU) at \$60/share, Ocaliva at \$16/share, other indications, cash (end '17, net debt) & tech value at \$19/share.

#### Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY18E</b>	(\$3.08)	(\$3.25)	(\$2.88)	(\$3.30)	(\$12.50)	NA
<b>FY17E</b>	(\$3.20)	(\$3.24)	(\$3.28)	(\$3.23)	(\$12.95)	NA
<b>FY16</b>	(\$2.89)	(\$2.93)	(\$3.06)	(\$4.00)	(\$12.88)	NA
<b>FY15</b>	(\$1.21)	(\$1.55)	(\$1.69)	(\$2.95)	(\$8.04)	NA

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Source: Laidlaw & Company estimates

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Figure 1: Variance Analysis

Intercept Pharmaceuticals Quarterly variance analysis										
(\$000's)	4Q15A	4Q16A	4Q16E	Variance	% Y/Y	FY15A	FY16A	FY16E	Variance	% Y/Y
US PBC sales		\$13,364	\$2,654	\$10,710	NM		\$18,171	\$7,461	\$10,710	NM
License revenues	\$445	445	445	0	0%	\$2,782	6,780	6,780	0	144%
<b>Total Revenue</b>	<b>\$445</b>	<b>\$13,809</b>	<b>\$3,099</b>	<b>\$10,710</b>	<b>3003%</b>	<b>\$2,782</b>	<b>\$24,951</b>	<b>\$14,241</b>	<b>\$10,710</b>	<b>797%</b>
COGS	-	-	530.80	(531)	NM	-	-	530.80	(531)	NM
<b>Gross Profit</b>	<b>445</b>	<b>13,809</b>	<b>2,568</b>	<b>11,241</b>	<b>3003%</b>	<b>2,780</b>	<b>24,951</b>	<b>13,710</b>	<b>11,241</b>	<b>798%</b>
R&D Expense	37,738	42,595	50,000	(7,405)	13%	109,407	149,479	156,884	(7,405)	37%
SG&A Expense	38,816	64,413	53,250	11,163	66%	91,163	182,975	171,812	11,163	101%
<b>Operating Inc (loss)</b>	<b>(76,108)</b>	<b>(93,199)</b>	<b>(100,682)</b>	<b>7,483</b>	<b>22%</b>	<b>(197,790)</b>	<b>(307,502)</b>	<b>(314,985)</b>	<b>7,483</b>	<b>55%</b>
Int & div income	637	1,096	500	596	72%	2,727	(4,447)	(5,043)	596	-263%
<b>Pretax Inc (loss)</b>	<b>(75,471)</b>	<b>(99,234)</b>	<b>(100,182)</b>	<b>948</b>	<b>31%</b>	<b>(195,063)</b>	<b>(317,794)</b>	<b>(318,742)</b>	<b>948</b>	<b>63%</b>
<b>NI - ex-1x items</b>	<b>(75,471)</b>	<b>(99,234)</b>	<b>(100,182)</b>	<b>948</b>	<b>31%</b>	<b>(195,063)</b>	<b>(317,794)</b>	<b>(318,742)</b>	<b>948</b>	<b>63%</b>
Avg Shares (000)	24,351	24,812	25,488	(676)	2%	23,694	24,683	24,833	(150)	4%
<b>EPS ex-1x items</b>	<b>(\$2.95)</b>	<b>(\$4.00)</b>	<b>(\$3.93)</b>	<b>(\$0.07)</b>	<b>36%</b>	<b>(\$8.23)</b>	<b>(\$12.88)</b>	<b>(\$12.84)</b>	<b>(\$0.04)</b>	<b>56%</b>
<b>EPS as reported</b>	<b>(\$3.62)</b>					<b>(\$9.75)</b>				

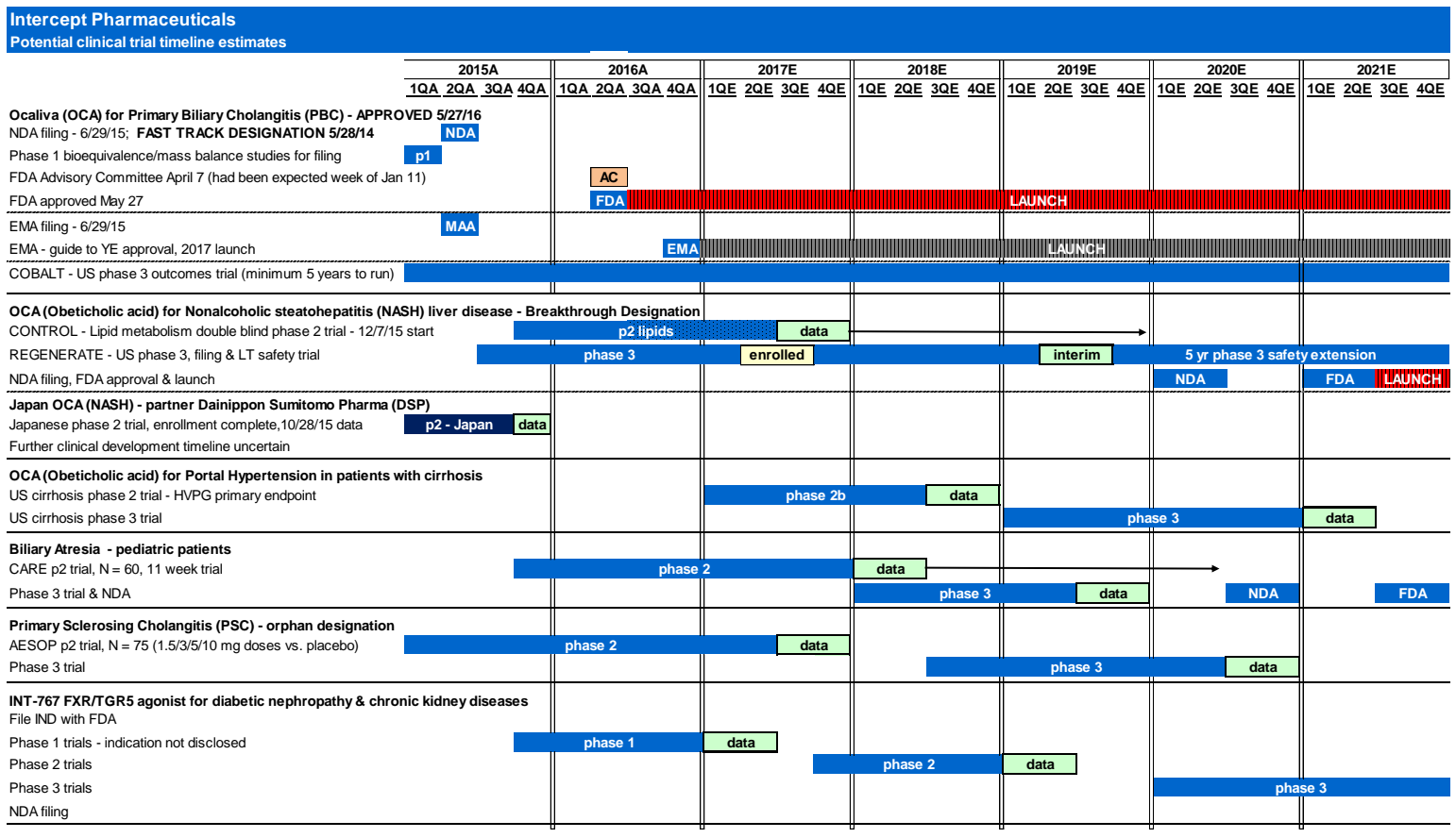
Source: Company reports; Laidlaw &amp; Company estimates

Figure 2: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
OCA for NASH in the US	\$1,525,826	\$55
Ocaliva for PBC US & EU	\$439,999	\$16
OCA for NASH EU royalty	\$155,005	\$5
OCA for other indications	\$130,826	\$4
Cash (end of '17E) & tech	\$465,642	\$15
	\$2,717,299	<b>\$95</b>
2017 fully diluted shares out		28,162

Source: Company Reports; Laidlaw &amp; 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)	2016A				2016A Year	2017E				2017E Year
	1QA	2QA	3QA	4QA		1QE	2QE	3QE	4QE	
<b>Revenues</b>										
Ocaliva US PBC sales		\$75	\$4,732	\$13,364	\$18,171	\$14,038	\$14,143	\$19,949	\$22,970	\$71,100
Ocaliva EU PBC sales							943	1,900	2,871	5,714
License fees	\$445	\$5,445	445	445	6,780	500	500	500	500	2,000
<b>Total Revenues</b>	<b>\$445</b>	<b>\$5,520</b>	<b>\$5,177</b>	<b>\$13,809</b>	<b>\$24,951</b>	<b>\$14,538</b>	<b>\$15,586</b>	<b>\$22,349</b>	<b>\$26,341</b>	<b>\$78,814</b>
<b>Expenses</b>										
Cost of Goods Sold	0	0	0	0	0	842	1,509	2,403	2,843	7,597
<b>Gross Margin</b>	<b>445</b>	<b>5,520</b>	<b>5,177</b>	<b>13,809</b>	<b>24,951</b>	<b>13,696</b>	<b>14,078</b>	<b>19,946</b>	<b>23,499</b>	<b>71,218</b>
R&D	31,607	38,354	36,923	42,595	149,479	42,445	47,135	48,985	50,200	188,765
SG&A	40,310	40,149	38,103	64,413	182,975	52,695	50,985	57,885	60,380	221,945
<b>Total Op Expenses</b>	<b>71,917</b>	<b>78,502</b>	<b>75,026</b>	<b>107,008</b>	<b>332,453</b>	<b>95,140</b>	<b>98,120</b>	<b>106,870</b>	<b>110,580</b>	<b>410,710</b>
<b>Inc (loss) from Ops</b>	<b>(71,472)</b>	<b>(72,982)</b>	<b>(69,849)</b>	<b>(93,199)</b>	<b>(307,502)</b>	<b>(81,444)</b>	<b>(84,042)</b>	<b>(86,924)</b>	<b>(87,081)</b>	<b>(339,492)</b>
Other income (exp)	726	796	(7,065)	1,096	(4,447)	500	500	500	500	2,000
Int exp			1,286	(7,131)						
<b>Pretax Inc (Loss)</b>	<b>(70,746)</b>	<b>(72,186)</b>	<b>(75,628)</b>	<b>(99,234)</b>	<b>(317,794)</b>	<b>(80,944)</b>	<b>(83,542)</b>	<b>(86,424)</b>	<b>(86,581)</b>	<b>(337,492)</b>
Div. pref stock, not declared					0					0
<b>Adjusted Net Income/(loss)</b>	<b>(70,746)</b>	<b>(72,186)</b>	<b>(75,628)</b>	<b>(99,234)</b>	<b>(317,794)</b>	<b>(80,944)</b>	<b>(83,542)</b>	<b>(86,424)</b>	<b>(86,581)</b>	<b>(337,492)</b>
Total non-cash expenses	(55,928)	(5,113)	(13,187)	(20,808)	(95,036)					
<b>Net income as reported</b>	<b>(126,674)</b>	<b>(77,299)</b>	<b>(88,815)</b>	<b>(120,042)</b>	<b>(412,830)</b>					
<b>Adj-EPS ex-1x</b>	<b>(\$2.89)</b>	<b>(\$2.93)</b>	<b>(\$3.06)</b>	<b>(\$4.00)</b>	<b>(\$12.88)</b>	<b>(\$3.20)</b>	<b>(\$3.24)</b>	<b>(\$3.28)</b>	<b>(\$3.23)</b>	<b>(\$12.95)</b>
<b>EPS as reported</b>	<b>(\$5.17)</b>	<b>(\$3.14)</b>	<b>(\$3.59)</b>	<b>(\$4.84)</b>	<b>(\$16.73)</b>					
Shares out (000)	24,495	24,612	24,738	24,812	24,683	25,312	25,812	26,312	26,812	26,062
Fully diluted shares (000)	26,510	26,635	26,720	26,862	26,682	27,412	27,912	28,412	28,912	28,162

Source: Company Reports: Laidlaw &amp; Company estimates

Figure 5: Annual Income Statement

Intercept Pharmaceuticals							
Annual income statement							
(\$000's except per share)	2015A	2016A	2017E	2018E	2019E	2020E	Comments
<b>Revenues</b>							
Ocaliva US PBC sales		\$18,171	\$71,100	\$104,486	\$126,331	\$151,053	US launch 2Q16
Ocaliva EU PBC sales			5,714	27,854	39,926	44,392	EU launch 2Q17
License fees	\$2,782	6,780	2,000	2,000	2,000	2,000	
<b>Total Revenues</b>	<b>\$2,782</b>	<b>\$24,951</b>	<b>\$78,814</b>	<b>\$134,340</b>	<b>\$168,257</b>	<b>\$197,445</b>	
<b>Expenses</b>							
Cost of Goods Sold	-	-	7,597	14,557	18,288	21,499	
<b>Gross Margin</b>	<b>2,780</b>	<b>24,951</b>	<b>71,218</b>	<b>119,783</b>	<b>149,969</b>	<b>175,946</b>	
R&D	109,407	149,479	188,765	212,775	216,050	231,600	
SG&A	91,163	182,975	221,945	283,565	311,200	311,590	
<b>Total Op Expense</b>	<b>200,570</b>	<b>332,453</b>	<b>410,710</b>	<b>496,340</b>	<b>527,250</b>	<b>543,190</b>	2017 non-GAAP guide: \$380M-\$420M
<b>Inc (loss) from Ops</b>	<b>(197,790)</b>	<b>(307,502)</b>	<b>(339,492)</b>	<b>(376,557)</b>	<b>(377,281)</b>	<b>(367,244)</b>	
Interest & dividend inc	2,727	(4,447)	2,000	2,000	2,000	2,000	
<b>Pretax Inc (Loss)</b>	<b>(195,063)</b>	<b>(317,794)</b>	<b>(337,492)</b>	<b>(374,557)</b>	<b>(375,281)</b>	<b>(365,244)</b>	
Taxes	-	-	-	-	-	-	Sig. tax loss carryforwards
<b>Adjusted Net Income/(loss)</b>	<b>(195,063)</b>	<b>(317,794)</b>	<b>(337,492)</b>	<b>(374,557)</b>	<b>(375,281)</b>	<b>(365,244)</b>	
Total non-cash expenses	(35,881)	(95,036)					
<b>Net income as reported</b>	<b>(230,944)</b>	<b>(412,830)</b>					
<b>Adj-EPS ex-1x</b>	<b>(\$8.23)</b>	<b>(\$12.88)</b>	<b>(\$12.95)</b>	<b>(\$12.50)</b>	<b>(\$10.40)</b>	<b>(\$9.40)</b>	
<b>EPS as reported</b>	<b>(\$9.75)</b>	<b>(\$16.73)</b>					
Shares out (000)	23,694	24,683	26,062	29,962	36,075	38,837	
Fully diluted shares (000)	24,977	26,682	28,162	32,212	38,825	41,837	
Cash position	\$628,055	\$689,385	\$440,642	\$560,460	\$525,679	\$208,435	assume 2018 fund raise

Source: Company Reports: Laidlaw &amp; Company estimates

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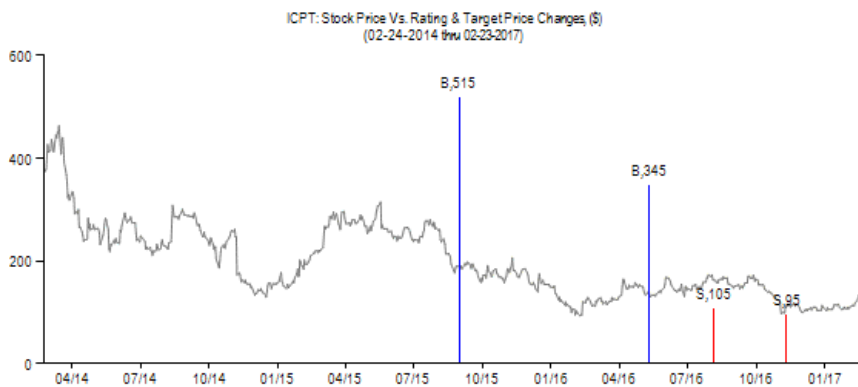
#### Rating and Price Target Change History

#### 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	109.00



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.	2.44%	2.44%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	60.98%	26.83%	2.44%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	2.44%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

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