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EQUITY RESEARCH
Company Report

June 1, 2016

Intercept Pharmaceuticals (ICPT - $148.36)

Healthcare / Biotechnology

Ocaliva Approval a Real and Significant Milestone for ICPT

Ticker:	ICPT
Rating:	**Buy**
Price Target:	**$345.00**

ICPT reported that the FDA has approved Ocaliva (obeticholic acid) for the treatment of Primary Biliary Cholangitis (PBC) either in combo with Urso or for Urso intolerant patients. While this had been anticipated following the 17-0 AdCom vote in April, it is nevertheless a significant milestone for ICPT as they have now demonstrated their ability to get a product through the FDA's accelerated approval process utilizing a surrogate marker endpoint. We believe this bodes well for the ability of ICPT to get OCA for NASH through the same accelerated approval process in 2H18. Bears on the name quickly highlighted the known concern that the dyslipidemia issues which appeared in the FLINT trial will potentially derail an FDA approval of OCA for NASH or severely limit OCA's usage following approval. We believe this is looking at the second derivative effect too strongly, especially in light of the benign label for Ocaliva which has no black box warning. We continue to expect FDA approval for OCA in NASH in 2H18 and broad uptake of the drug subsequent to approval. We reiterate our Buy rating, $345 price target.

- **Pricing likely in-line with our estimate.** While the headline annual cost of therapy announced yesterday was above our estimate ($69.4K vs. LL: $50K) we believe that after gross/net adjustments our $50K/year number is in the ballpark.
- **Ocaliva projected sales ramp unchanged.** We continue to project 2016E-2019E PBC sales of $15.9M, $147.9M, $276.6M, and $202.8M respectively. Our $50K annual cost of therapy for PBC in the US drops off in 2019 as we anticipate OCA for NASH approval & launch and a subsequent reduction in annual cost of therapy to the ~$15K range for this larger patient population.
- **Patient access program - Interconnect.** Like most orphan drug sellers, ICPT will institute a patient access service called Interconnect to help patients & physicians' offices walk through the inevitable prior-authorization or insurance company rejections that inevitably follow an orphan drug introduction.
- **Reiterate Buy rating and $345 PT.** Our price target is based on a sum-of-the-parts analysis, with NASH at $266/share, PBC at $36/share, and the remaining pipeline and cash (end 2016) at $43/share.

Trading Data:

Last Price (05/31/2016)	$148.36
52–Week High (07/24/2015)	$285.00
52–Week Low (02/11/2016)	$89.76
Market Cap. (MM)	$3,650
Shares Out. (MM)	24.60

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY17E	($2.27)	($1.97)	($1.67)	($1.41)	($7.30)	NA
FY16E	($2.89)A	($3.55)	($3.58)	($4.01)	($14.10)	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

Source: Laidlaw & Company estimates

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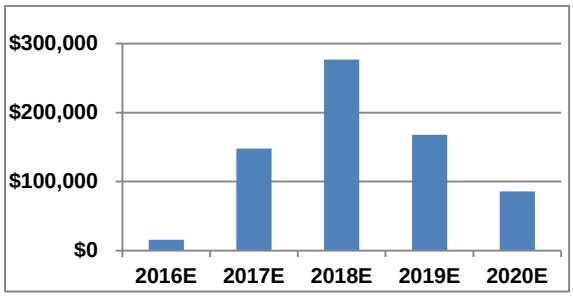
Figure 1: Valuation

Sum-of-the-parts valuation: ICPT		
Segment	Valuation (000's)	Per share value
OCA for NASH in the US	$5,595,815	$198
OCA for NASH EU royalty	$1,599,170	$57
OCA for PBC US & EU	$1,007,594	$36
OCA for other indications	$475,825	$17
Cash (end of '16E) & tech	$1,049,021	$37
	$9,727,425	**$345**
2016 fully diluted shares out		28,249

Source: Company Reports: Laidlaw & Company estimates

Figure 2: Ocaliva sales projections



Source: Laidlaw & Company estimates

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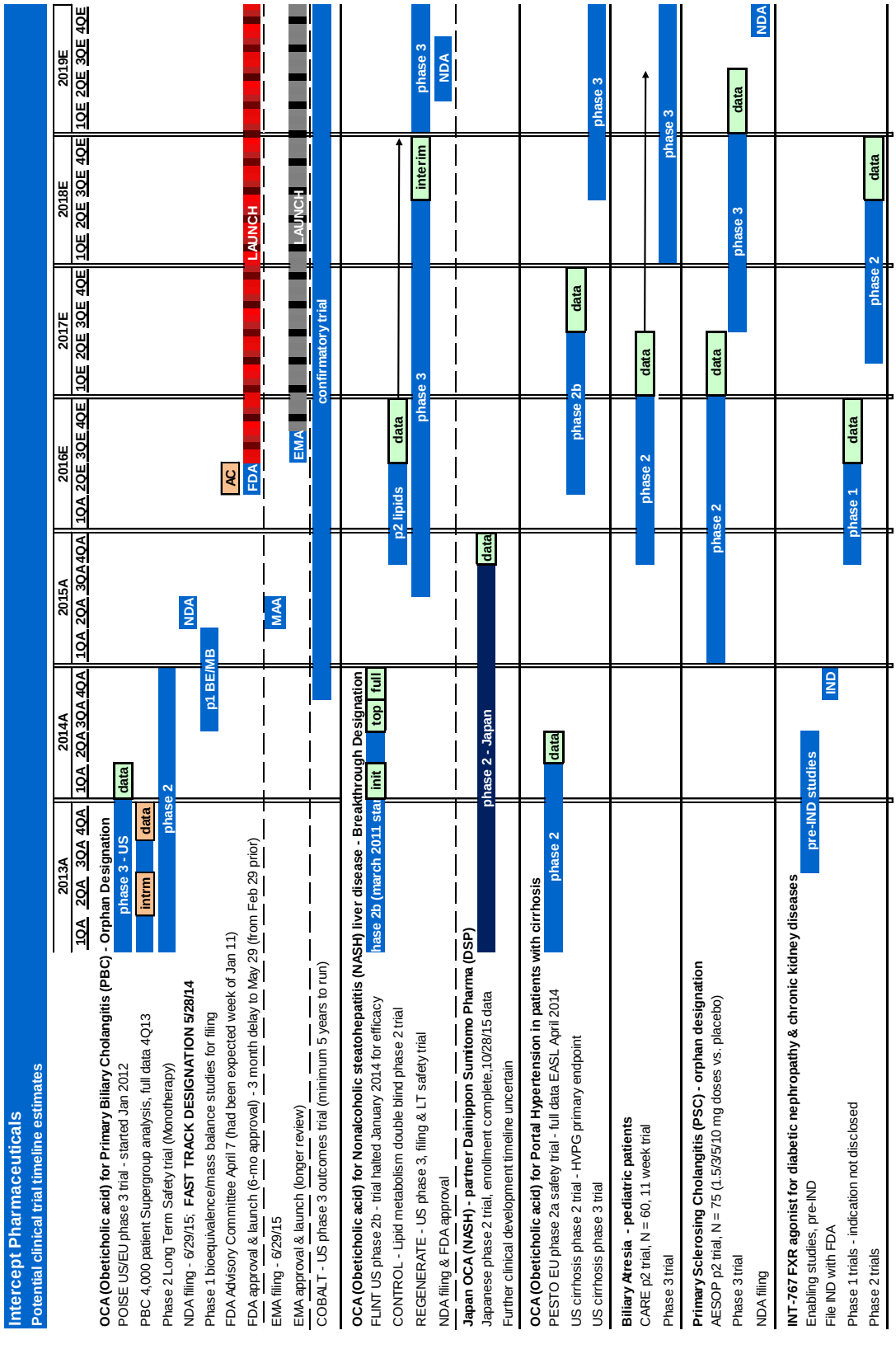
Figure 3: Clinical trial timeline estimates



Source: Company Reports; Laidlaw & Company estimates

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Figure 4: Quarterly Income Statement

Intercept Pharmaceuticals
Quarterly income statement

($000's except per share)	2015A 1QA	2015A 2QA	2015A 3QA	2015A 4QA	2015A Year	2016E 1QA	2016E 2QE	2016E 3QE	2016E 4QE	2016E Year
Revenues										
License fees	$1,445	$445	$445	$447	$2,782	$445	$445	445	445	1,780
Total Revenues	**$1,445**	**$445**	**$445**	**$447**	**$2,782**	**$445**	**$445**	**$5,713**	**$11,061**	**$17,664**
Expenses										
Cost of Goods Sold	0	0	0	0	0	0	0	1,054	1,592	2,646
Gross Margin	**1,445**	**445**	**445**	**447**	**2,782**	**445**	**445**	**4,660**	**9,469**	**15,018**
R&D	21,916	22,895	22,337	37,747	104,894	31,607	45,000	50,000	60,000	186,607
SG&A	8,288	17,674	21,892	38,816	91,163	40,310	45,500	52,750	62,250	200,810
Total Op Expenses	**30,203**	**40,569**	**44,229**	**76,562**	**196,057**	**71,917**	**90,500**	**102,750**	**122,250**	**387,417**
Inc (loss) from Ops	**(28,758)**	**(40,124)**	**(43,784)**	**(76,115)**	**(193,275)**	**(71,472)**	**(90,055)**	**(98,090)**	**(112,781)**	**(372,399)**
Other income (exp)	272	929	889	637	2,727	726	500	500	500	2,226
Int exp					0					
Pretax Inc (Loss)	**(28,486)**	**(39,195)**	**(42,895)**	**(75,478)**	**(190,548)**	**(70,746)**	**(89,555)**	**(97,590)**	**(112,281)**	**(370,173)**
Div. pref stock, not declared					0					0
Adjusted Net Income/(loss)	**(28,486)**	**(39,195)**	**(42,895)**	**(75,478)**	**(190,548)**	**(70,746)**	**(89,555)**	**(97,590)**	**(112,281)**	**(370,173)**
Total non-cash expenses	(10,900)	(8,700)	(8,000)	(12,774)	(35,881)	(55,928)				(55,928)
Net income as reported	**(39,386)**	**(47,895)**	**(50,895)**	**(88,252)**	**(226,429)**	**(126,674)**				**(426,101)**
Adj-EPS ex-1x	**($1.21)**	**($1.54)**	**($1.69)**	**($2.95)**	**($8.04)**	**($2.89)**	**($3.55)**	**($3.58)**	**($4.01)**	**($14.10)**
EPS as reported	**($1.78)**	**($1.99)**	**($2.10)**	**($3.62)**	**($9.56)**	**($5.17)**				**($16.24)**
Shares out (000)	22,172	24,014	24,215	24,351	23,694	24,495	25,245	27,245	27,995	26,245
Fully diluted shares (000)	23,581	25,514	25,443	25,601	25,035	26,510	27,245	29,245	29,995	28,249

Source: Company Reports: Laidlaw & Company estimates

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Figure 5: Annual Income Statement

Intercept Pharmaceuticals
Annual income statement

($000's except per share)	2015A	2016E	2017E	2018E	2019E	Comments
Revenues						
US PBC sales for OCA		$15,884	$147,985	$276,642	$167,972	**US launch 2H16**
EU PBC sales for OCA			53,355	137,177	138,948	**EU launch 1H17**
US NASH royalties for OCA				0	0	**Launch 2020**
License fees	$2,782	1,780	2,000	2,000	2,000	
Total Revenues	**$2,782**	**$17,664**	**$203,340**	**$415,819**	**$308,920**	
Expenses						
Cost of Goods Sold	-	2,646	30,201	33,197	20,157	
Gross Margin	**2,782**	**15,018**	**173,139**	**382,622**	**288,763**	
R&D	104,894	186,607	195,000	224,500	200,000	
SG&A	91,163	200,810	193,560	206,000	216,000	
Total Op Expense	**196,057**	**387,417**	**388,560**	**430,500**	**416,000**	**2016 OpEx guide: $360M-$400M**
Inc (loss) from Ops	**(193,275)**	**(372,399)**	**(215,421)**	**(47,878)**	**(127,237)**	
Interest & dividend inc	2,727	2,226	2,000	2,000	2,000	
Pretax Inc (Loss)	**(190,548)**	**(370,173)**	**(213,421)**	**(45,878)**	**(125,237)**	
Taxes	-	-	-	-	-	
Div. pref stock	-	-	-	-	-	
Adjusted Net Income/(loss)	**(190,548)**	**(370,173)**	**(213,421)**	**(45,878)**	**(125,237)**	
Total non-cash expenses	(35,881)	(55,928)				
Net income as reported	**(226,429)**	**(426,101)**				
Adj-EPS ex-1x	**($8.04)**	**($14.10)**	**($7.30)**	**($1.50)**	**($3.95)**	
EPS as reported						
Shares out (000)	23,694	26,245	29,245	30,495	31,695	
Fully diluted shares (000)	25,035	28,249	30,745	32,495	33,695	

Source: Company Reports: Laidlaw & Company estimates

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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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Additional information available upon request.

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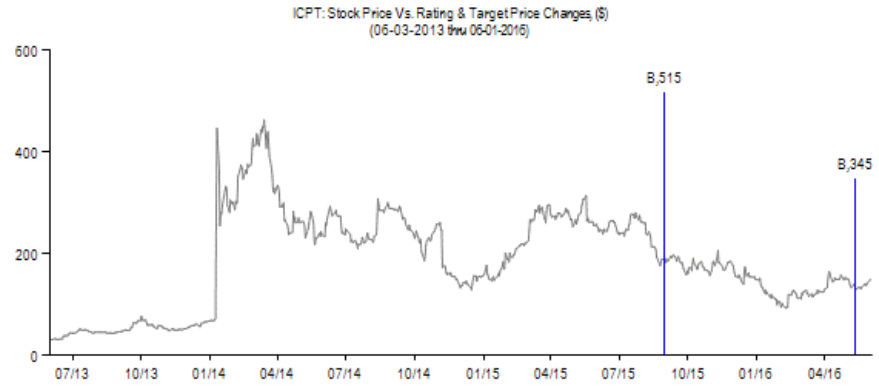
Rating and Price Target Change History



3 Year Rating Change History

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

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
08/31/2015	515.00	189.76
05/11/2016	345.00	137.28

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
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.	66.67%	27.78%	2.78%
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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