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EQUITY RESEARCH
Company Report

May 05, 2017

Intercept Pharmaceuticals (ICPT - $117.29)

Healthcare / Biotechnology

PBC Off to a Strong Start, NASH Still the Real Value Driver

Ticker:	ICPT
Rating:	Hold
Price Target:	**$115.00**

ICPT reported their 1Q17 results yesterday before the open beating once again on top-line as US Ocaliva for Primary Biliary Cholangitis (PBC) started the year strong (despite seasonality) with 1Q17 sales of ~$21.1M (vs $18.3M consensus high). ICPT noted strong execution and education of the medical community as well as increase in demand as the main reasons for their impressive launch. While ICPT announced the completion of enrollment of their interim analysis cohort, we still see recent changes in the REGENERATE trial (n=1,400 to n=750) and easier endpoint (NASH resolution *or* fibrosis improvement) as lowering the barrier to entry for competition in a crowded space. In terms of catalysts, we now expect read outs from both the Phase 2 CONTROL lipid study (assessing combination statin therapy in NASH patients) and Phase 2 AESOP in primary sclerosing cholangitis (PSC) to read out mid-2017. In light of the impressive launch, we have re-adjusted our PBC sales and now expect 2017 sales to increase from our prior ~$71M to ~$111M and have upgraded our Sell rating to a Hold and $115 price target.

Trading Data:

Last Price (05/04/2017)	$117.29
52–Week High (08/01/2016)	$177.93
52–Week Low (11/04/2016)	$90.63
Market Cap. (MM)	$2,910
Shares Out. (MM)	438.5

- **OCA for PBC starts the year with real momentum, guided expenses still high.** OCA for PBC started 2017 strong as top line ~$21.1M beat consensus high of ~$18.3M. While we have re-adjusted our PBC estimates due to better than expected launch and now expect 2017 sales of $111M vs our prior $71M, we still view this as relatively small in comparison to their reiterated 2017 guidance for adjusted operating expenses of $380M-$420M (ex non-cash charges). With an OpEx burn of >$400M and cash of $608M we still believe ICPT could come back to the market in late 2017/early 2018 for up to ~$500M.

- **REGENERATE is enrolled, a few adjustments later.** ICPT announced that their Phase 3 REGENERATE trial has completed enrollment of their interim analysis cohort, which is mostly in-line with expectations. As a reminder, ICPT lowered the amount of patients necessary from n=1,400 to n=750 and changed the primary endpoints. This increases the chances of hitting statistical significance but lowers the barrier to entry of competitors in an increasingly crowded space, in our opinion.

- **Upgrade our Sell rating to a Hold, $115 PT.** We value OCA for NASH (US & EU) at $80/share, Ocaliva at $28/share, other indications, cash (end '17, net debt) & tech value at $8/share.

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY18E	($2.73)	($3.19)	($2.61)	($2.89)	($11.39)	NA
FY17E	($3.01)A	($3.09)	($3.14)	($3.18)	($12.43)	NA
FY16	($2.89)	($2.93)	($3.06)	($4.00)	($12.88)	NA
FY15	($1.21)	($1.55)	($1.69)	($2.95)	($8.04)	NA

Source: Laidlaw & Company estimates

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Figure 1: Variance Analysis

Intercept Pharmaceuticals
Quarterly variance analysis

($000's)	1Q16A	1Q17A	1Q17E	Variance	% Y/Y
US PBC sales		$19,800	$14,038	$5,762	NM
License revenues	$445	445	500	(55)	0%
Total Revenue	**$445**	**$21,048**	**$14,538**	**$6,510**	**4630%**
COGS	-	97.00	842.28	(745)	NM
Gross Profit	**445**	**20,951**	**13,696**	**7,255**	**4608%**
R&D Expense	31,607	36,000	42,445	(6,446)	14%
SG&A Expense	40,310	54,052	52,695	1,357	34%
Operating Inc (loss)	**(71,472)**	**(69,100)**	**(81,444)**	**12,344**	**-3%**
Int & div income	726	1,240	500	740	71%
Pretax Inc (loss)	**(70,746)**	**(75,067)**	**(84,694)**	**9,627**	**6%**
NI - ex-1x items	**(70,746)**	**(75,067)**	**(84,694)**	**9,627**	**6%**
Avg Shares (000)	24,495	24,931	25,312	(381)	2%
EPS ex-1x items	**($2.89)**	**($3.01)**	**($3.35)**	**$0.34**	**4%**
EPS as reported	**($5.17)**	**($3.61)**			

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	$2,024,756	$73
Ocaliva for PBC US & EU	$757,577	$28
OCA for NASH EU royalty	$176,305	$7
OCA for other indications	$130,826	$5
Cash (end of '17E) & tech	$82,535	$3
	$3,172,000	**$115**
2017 fully diluted shares out		28,162

Source: Company Reports: Laidlaw & Company estimates

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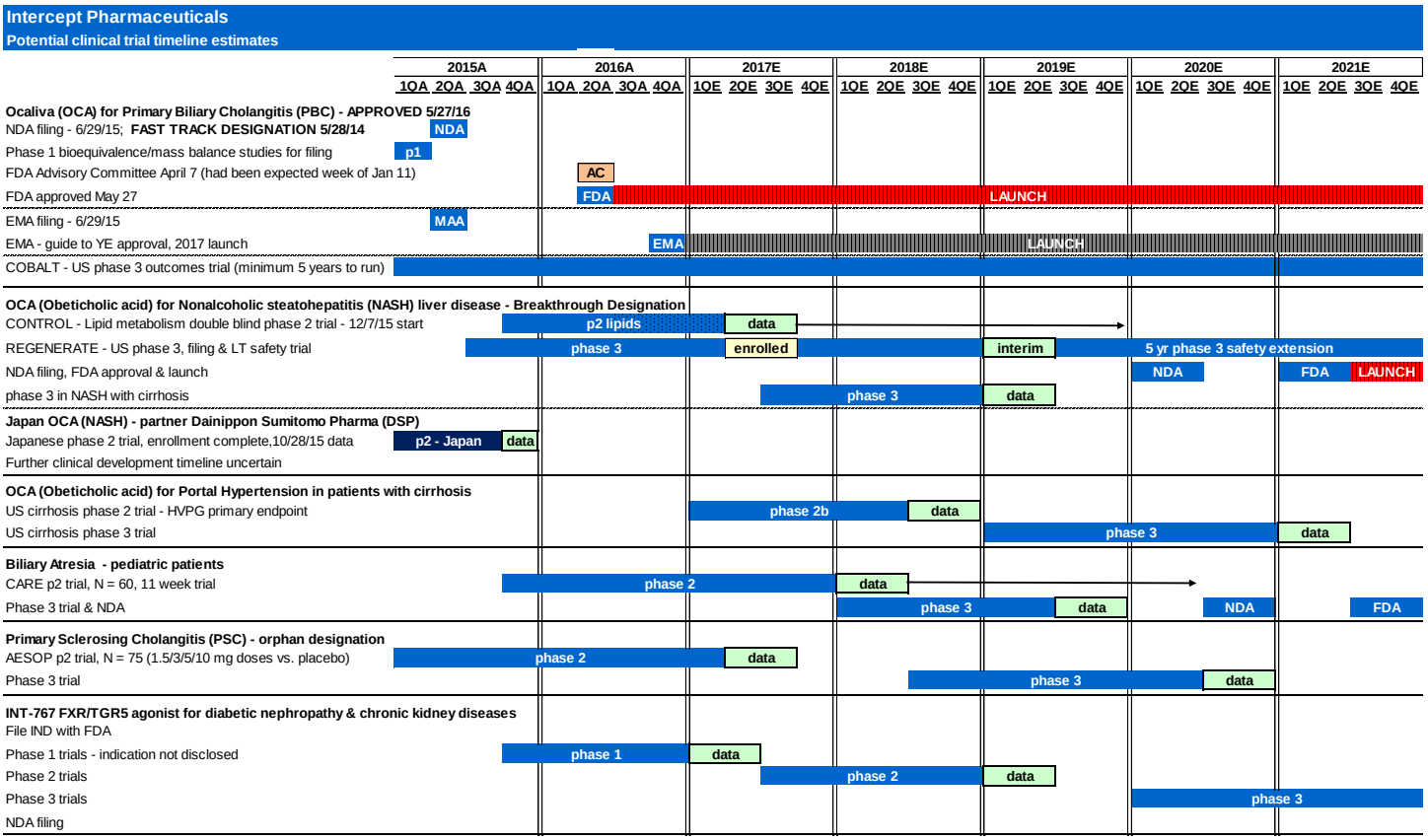
Figure 3: Clinical Trial Timeline Estimates



Source: Laidlaw & Company estimates

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Figure 4: Quarterly Income Statement

Intercept Pharmaceuticals
Quarterly income statement

($000's except per share)	2016A 1QA	2016A 2QA	2016A 3QA	2016A 4QA	2016A Year	2017E 1QA	2017E 2QE	2017E 3QE	2017E 4QE	2017E Year
Revenues										
Ocaliva US PBC sales		$75	$4,732	$13,364	$18,171	$19,800	$22,629	$28,499	$28,712	$99,640
Ocaliva EU PBC sales						800	1,886	2,850	3,828	9,364
License fees	$445	$5,445	445	445	6,780	445	500	500	500	1,945
Total Revenues	**$445**	**$5,520**	**$5,177**	**$13,809**	**$24,951**	**$21,048**	**$25,015**	**$31,849**	**$33,041**	**$110,949**
Expenses										
Cost of Goods Sold	0	0	0	0	0	97	2,452	3,448	3,579	9,576
Gross Margin	**445**	**5,520**	**5,177**	**13,809**	**24,951**	**20,951**	**22,564**	**28,400**	**29,461**	**101,373**
R&D	31,607	38,354	36,923	42,595	149,479	36,000	47,135	48,985	50,200	182,320
SG&A	40,310	40,149	38,103	64,413	182,975	54,052	50,985	57,885	60,380	223,302
Total Op Expenses	**71,917**	**78,502**	**75,026**	**107,008**	**332,453**	**90,051**	**98,120**	**106,870**	**110,580**	**405,621**
Inc (loss) from Ops	**(71,472)**	**(72,982)**	**(69,849)**	**(93,199)**	**(307,502)**	**(69,100)**	**(75,556)**	**(78,470)**	**(81,119)**	**(304,245)**
Other income (exp)	726	796	(7,065)	1,096	3,904	1,240	750	750	750	3,490
Interest expense			1,286	(7,131)	(14,196)	(7,207)	(3,750)	(3,750)	(3,750)	(18,457)
Pretax Inc (Loss)	**(70,746)**	**(72,186)**	**(75,628)**	**(99,234)**	**(317,794)**	**(75,067)**	**(78,556)**	**(81,470)**	**(84,119)**	**(319,212)**
Div. pref stock, not declared					0					0
Adjusted Net Income/(loss)	**(70,746)**	**(72,186)**	**(75,628)**	**(99,234)**	**(317,794)**	**(75,067)**	**(78,556)**	**(81,470)**	**(84,119)**	**(319,212)**
Total non-cash expenses	(55,928)	(5,113)	(13,187)	(20,808)	(95,036)	(14,863)				
Net income as reported	**(126,674)**	**(77,299)**	**(88,815)**	**(120,042)**	**(412,830)**	**(89,930)**				
Adj-EPS ex-1x	**($2.89)**	**($2.93)**	**($3.06)**	**($4.00)**	**($12.88)**	**($3.01)**	**($3.09)**	**($3.14)**	**($3.18)**	**($12.43)**
EPS as reported	**($5.17)**	**($3.14)**	**($3.59)**	**($4.84)**	**($16.73)**	**($3.61)**				
Shares out (000)	24,495	24,612	24,738	24,812	24,683	24,931	25,431	25,931	26,431	25,681
Fully diluted shares (000)	26,510	26,635	26,720	26,608	26,618	27,031	27,531	28,031	28,531	27,781

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)	2016A	2017E	2018E	2019E	2020E	Comments
Revenues						
Ocaliva US PBC sales	$18,171	$99,640	$159,823	$199,491	$230,094	**US launch 2Q16**
Ocaliva EU PBC sales		9,364	33,378	43,526	44,392	**EU launch 2Q17**
License fees	6,780	1,945	2,000	2,000	2,000	
Total Revenues	**$24,951**	**$110,949**	**$195,201**	**$245,017**	**$276,487**	
Expenses						
Cost of Goods Sold	-	9,576	21,252	26,732	30,194	
Gross Margin	**24,951**	**101,373**	**173,949**	**218,285**	**246,293**	
R&D	149,479	182,320	212,610	215,540	230,970	
SG&A	182,975	223,302	286,150	319,190	321,460	
Total Op Expense	**332,453**	**405,621**	**498,760**	**534,730**	**552,430**	**2017 non-GAAP guide: $380M-$420M**
Inc (loss) from Ops	**(307,502)**	**(304,245)**	**(324,811)**	**(316,445)**	**(306,137)**	
Interest & dividend inc	3,904	3,490	3,000	3,000	3,000	
Pretax Inc (Loss)	**(317,794)**	**(319,212)**	**(336,811)**	**(328,445)**	**(318,137)**	
Taxes	-	-	-	-	-	Sig. tax loss carryfrowards
Adjusted Net Income/(loss)	**(317,794)**	**(319,212)**	**(336,811)**	**(328,445)**	**(318,137)**	
Total non-cash expenses	(95,036)					
Net income as reported	**(412,830)**					
Adj-EPS ex-1x	**($12.88)**	**($12.43)**	**($11.39)**	**($9.20)**	**($8.27)**	
EPS as reported	**($16.73)**					
Shares out (000)	24,683	25,681	29,581	35,694	38,456	
Fully diluted shares (000)	26,618	27,781	31,831	38,444	41,456	
Cash position	$698,511	$398,891	$556,455	$568,510	$298,374	assume 2018 fund raise

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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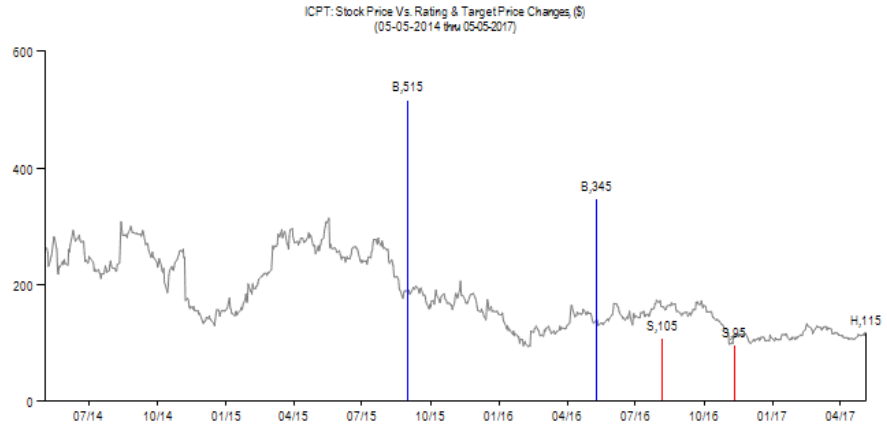
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
08/31/2...	Buy (B)	189.76
08/05/2...	Sell (S)	162.27
05/05/2...	Hold (H)	117.29*

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
08/31/2...	515.00	189.76
05/11/2...	345.00	137.28
08/05/2...	105.00	162.27
11/10/2...	95.00	109.00
05/05/2...	115.00	117.29*

** Previous Close5/4/2017*

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.	2.27%	2.27%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	61.36%	29.55%	2.27%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.27%	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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