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EQUITY RESEARCH
Company Report

February 10, 2017

Intercept Pharmaceuticals (ICPT - $120.55)

Healthcare / Biotechnology

Changing Clinical Trials Mid-stream Typically a Negative Sign

Ticker:	ICPT
Rating:	**Sell**
Price Target:	**$95.00**

This AM before the open ICPT announced that they have made what we believe is a fairly significant change to their Phase 3 REGENERATE trial design of obeticholic acid (OCA) in NASH. Specifically ICPT is no longer planning to enroll 1,400 patients (by 1H17) for their interim look but are instead now targeting 750 patients (by mid-17). ICPT has also changed the primary endpoint from the combined endpoint of fibrosis improvement with no worsening of NASH ***and*** NASH resolution with no worsening of fibrosis to ***either*** fibrosis improvement with no worsening of NASH ***or*** NASH resolution with no worsening of fibrosis, an endpoint that ICPT believes is superior and should be make-able with a smaller patient population (see Figure 2 & 3 next page). Given the dramatically reduced enrollment guidance for the interim look, we wonder how much the endpoint change (from *both* to *either/or*) was driven by the fact that the new endpoint is easier to hit or by the fact that they have faced a much more daunting enrollment task than they had initially expected and would have needed up to four years to hit 1,400 patients to hit the old, harder endpoint. Absent commentary from the FDA we may never know. What we do know is that this constitutes a real change in the Phase 3 trial as it is ongoing, which isn't the mark of a prospectively well-designed trial. We do not see today's announcement as a positive for ICPT and we are reiterating our Sell rating and our $95 price target.

- **An easier endpoint but ICPT picked the first one for a reason.** We agree that the new *either/or* endpoint is an easier target to hit, but the prior more difficult *and* endpoint was specifically chosen by ICPT based on the FLINT data chosen to "raise the bar" for the field. We believe the new endpoints will no longer as fully separate OCA from other treatments in development.
- **Interim look still in 2019.** ICPT continues to guide to interim REGENERATE data in 2019 (we're mid-19), and if positive they remain on-track for a potential 1H20 NDA filing, 2H21 launch.
- **Reiterate our Sell rating $95 PT.** OCA for NASH: $62/share, Ocaliva: $19/share, other indications, cash (end '17, net debt) & tech: $14/share.

Trading Data:

Last Price (02/10/2017)	$120.55
52–Week High (07/29/2016)	$177.93
52–Week Low (02/11/2016)	$91.50
Market Cap. (MM)	$2,920.0
Shares Out. (MM)	24.81

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

Source: Laidlaw & Company estimates

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Figure 1: 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 2: Current REGENERATE trial design

Phase 3: REGENERATE - OCA for NASH with fibrosis	
Aim	Safety & efficacy of OCA in treating NASH with fibrosis
Design	Double blind, global, ~350 sites (up from 300 prev.), 3 arm (10mg, 25mg, placebo; 1:1:1), interim look at 72 weeks; then patients continue in trial until a # of pre-specified adverse liver related clinical events occur
Dosing	10mg or 25mg OCA orally daily for duration of study enrollment (interim look at 72 weeks)
Endpoints	Interim 72 week hitology look on 750 patients, 1': **EITHER** Fibrosis improvement with no worsening of NASH - **OR** - NASH resolution with no worsening of fibrosis; 2': various histological & non-invasive endpoints (undefined 8/4/15); Final study endpoints will include progression to cirrhosis mortality, transplant, Hepatocellular carcinoma, other events
Patients	N = 2,000 (full study) with biopsy confirmed NASH & fibrosis Stage 2 or 3; N = 750 for interim analysis
Results	Interim enroll copletion mid-17, interim look expected 2019 (72 weeks post enroll complete, trial started 3Q15)

Source: Company Reports: Laidlaw & Company estimates

Figure 3: Prior REGENERATE trial design

Phase 3: REGENERATE - OCA for NASH with fibrosis	
Aim	Safety & efficacy of OCA in treating NASH with fibrosis
Design	Double blind, global, ~350 sites (up from 300 prev.), 3 arm (10mg, 25mg, placebo; 1:1:1), interim look at 72 weeks; then patients continue in trial until a # of pre-specified adverse liver related clinical events occur
Dosing	10mg or 25mg OCA orally daily for duration of study enrollment (interim look at 72 weeks)
Endpoints	Interim 72 week hitology look on 1,400 patients, 1': Fibrosis improvement with no worsening of NASH & NASH resolution with no worsening of fibrosis; 2': various histological & non-invasive endpoints (undefined 8/4/15); Final study endpoints will include progression to cirrhosis mortality, transplant, Hepatocellular carcinoma, other events
Patients	N = 1,400 with biopsy confirmed NASH & fibrosis Stage 2 or 3 for interim analysis, up to 2,500 patients in extension trial
Results	Interim look expected mid-19 (~4 yrs post initiation, started 3Q15)

Source: Company Reports: Laidlaw & Company estimates

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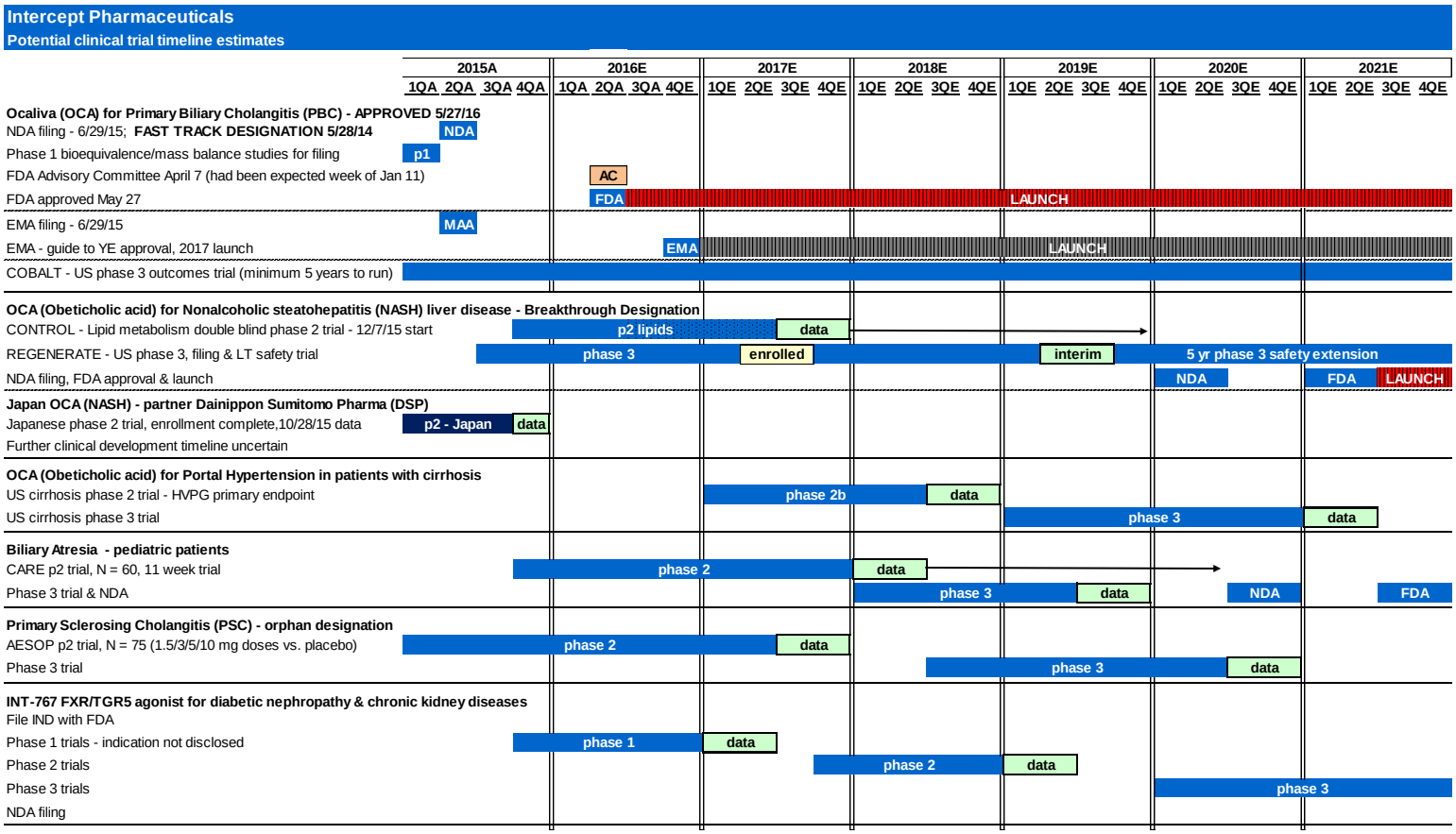
Figure 4: Clinical Trial Timeline Estimates



Source: Laidlaw & Company estimates

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Figure 5: 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 2QA	2016E 3QA	2016E 4QE	2016E Year
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

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Figure 6: Annual Income Statement

Intercept Pharmaceuticals
Annual income statement

($000's except per share)	2015A	2016E	2017E	2018E	2019E	Comments
Revenues						
Ocaliva US PBC sales		$7,461	$51,320	$141,531	$120,940	**US launch 2Q16**
Ocaliva EU PBC sales			5,714	35,335	69,474	**EU launch 2Q17**
US NASH royalties for OCA				0	0	**Launch 2H 2021**
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

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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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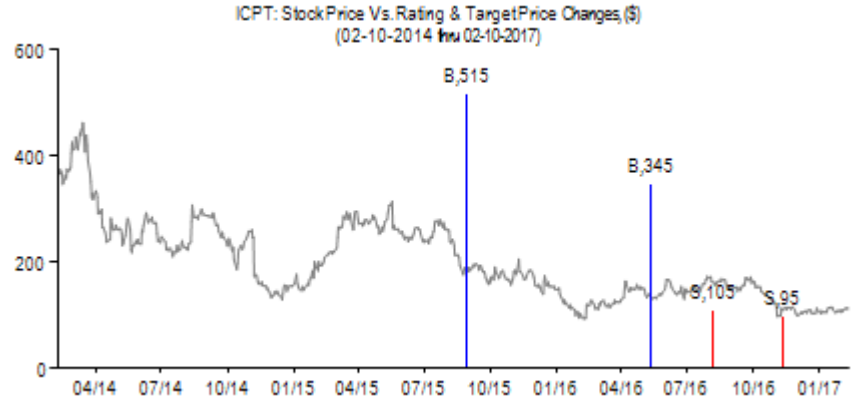
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
08/31/2015	Buy (B)	189.76
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 **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.	2.44%	2.44%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	60.98%	26.83%	2.44%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.44%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

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