

## Intercept Pharmaceuticals (ICPT - \$73.70)

### A Letter to Healthcare Providers Followed by an FDA Warning, OCA's Risk Profile Increases

Recently, the FDA issued a warning that OCA is being inappropriately dosed in certain patients with moderate to severe decreases in liver function and thus leading to increased risk of serious liver injury and death. As a reminder, this news from the FDA is coming on the heels of ICPT's "Dear Health Care Provider" letter submitted on 9/8/17. ICPT's initial letter wasn't too concerning, in our opinion, as liver failure and death were reported in Child-Pugh B and C (only in ~3% of PBC population) that were dosed more frequently than recommended in the label. However, we believe yesterday's FDA warning adds to the risk profile of OCA since some correctly dosed patients with mild liver disease may also have suffered adverse events. Additionally, we believe it is noteworthy that the FDA's Adverse Event Reporting System (FAERS) includes only the cases submitted to them, which means there might be more cases than accounted for. Seven of eight fatal cases received 5mg daily vs. maximum of 10mg 2X/week as recommended by the label. While at a high level, most of the information in the FDA warning had been discussed in the previous ICPT prior "Dear Healthcare Provider" letter, we do believe this warning adds a layer of risk to OCA that could potentially translate to NASH down the road, which is still the main reason to own ICPT, in our opinion. We have also slightly lowered our PBC sales launch to reflect potential lower adoption and usage from the medical community. Higher risk of OCA in both PBC and NASH has led to us to lower our price target from \$119/share to \$90/share as we maintain our Hold rating.

- **"Dear Healthcare Provider" letter and now an FDA warning for OCA, long September at ICPT.** Although most of the information in the FDA issued warning was mentioned in the previous letter from ICPT, we view adverse events potentially suffered by well-dosed patients with mild liver disease as adding to OCA's risk profile.
- **With more caution required, PBC and NASH adoption rates could be hindered.** We have slightly pulled back our PBC adoption rate and believe heightened caution could ultimately add risk to NASH adoption.
- **Reiterating our Hold rating, lowering price target to \$90.** We value OCA for NASH (US & EU) at \$51/share, Ocaliva at \$25/share, other indications, cash (end '18, net debt) & tech value at \$14/share.

#### Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY18E</b>	(\$3.00)	(\$3.11)	(\$2.63)	(\$2.93)	(\$11.63)	NA
<b>FY17E</b>	(\$3.01)A	(\$2.84)A	(\$3.20)	(\$3.39)	(\$12.45)	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

Source: Laidlaw & Company estimates

#### Healthcare / Biotechnology

Ticker:	ICPT
Rating:	Hold
Price Target:	↓ \$90.00

#### Trading Data:

Last Price (09/21/2017)	\$73.70
52-Week High (09/28/2016)	\$172.75
52-Week Low (09/21/2017)	\$73.50
Market Cap. (MM)	\$1,850
Shares Out. (MM)	25.1

#### Analyst

Francois Brisebois, MSc  
(857)317-5362  
fbrisebois@laidlawltd.com

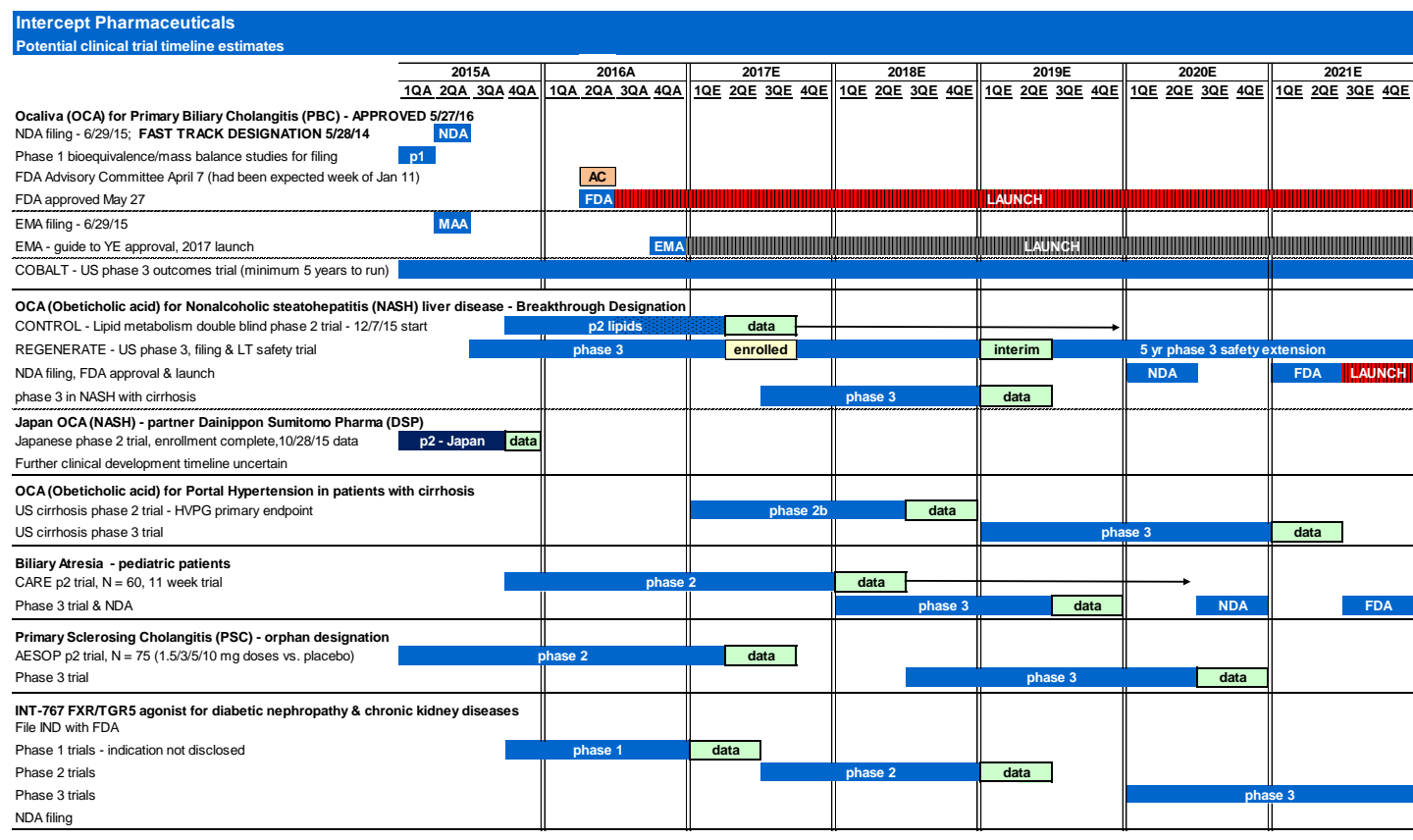
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**Figure 1: Valuation**

<b>Sum-of-the-parts valuation</b>		
Segment	Valuation (000's)	Per share value
OCA for NASH in the US	\$1,425,898	\$47
Ocaliva for PBC US & EU	\$726,565	\$25
OCA for NASH EU royalty	\$124,160	\$4
OCA for other indications	\$180,222	\$6
Cash (end of '18E) & tech	\$254,216	\$8
	\$2,711,060	<b>\$90</b>
2018 fully diluted shares out		30,138

Source: Company Reports: Laidlaw & Company estimates

Figure 2: Clinical Trial Timeline Estimates



Source: Laidlaw & Company estimates

Figure 3: Quarterly Income Statement

Intercept Pharmaceuticals										
Quarterly income statement										
(\$000's except per share)	2016A				2016A Year	2017E				2017E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QE	4QE	
<b>Revenues</b>										
Ocaliva US PBC sales		\$75	\$4,732	\$13,364	\$18,171	\$19,800	\$27,876	\$31,349	\$35,891	\$114,915
Ocaliva EU PBC sales						800	2,565	3,800	4,785	11,950
License fees	\$445	\$5,445	445	445	6,780	445	446	500	500	1,891
<b>Total Revenues</b>	<b>\$445</b>	<b>\$5,520</b>	<b>\$5,177</b>	<b>\$13,809</b>	<b>\$24,951</b>	<b>\$21,048</b>	<b>\$30,887</b>	<b>\$35,648</b>	<b>\$41,176</b>	<b>\$128,756</b>
<b>Expenses</b>										
Cost of Goods Sold	0	0	0	0	0	97	279	300	4,474	5,150
<b>Gross Margin</b>	<b>445</b>	<b>5,520</b>	<b>5,177</b>	<b>13,809</b>	<b>24,951</b>	<b>20,951</b>	<b>30,608</b>	<b>35,348</b>	<b>36,702</b>	<b>123,606</b>
R&D	31,607	38,354	36,923	42,595	149,479	36,000	35,977	41,485	45,935	159,397
SG&A	40,310	40,149	38,103	64,413	182,975	54,052	59,782	67,735	69,785	251,354
<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>90,051</b>	<b>95,759</b>	<b>109,220</b>	<b>115,720</b>	<b>410,750</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>(69,100)</b>	<b>(65,151)</b>	<b>(73,872)</b>	<b>(79,018)</b>	<b>(287,141)</b>
Other income (exp)	726	796	(7,065)	1,096	3,904	1,240	1,224	750	750	3,964
Interest expense			1,286	(7,131)	(14,196)	(7,207)	(7,279)	(7,500)	(7,500)	(29,486)
<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>(75,067)</b>	<b>(71,206)</b>	<b>(80,622)</b>	<b>(85,768)</b>	<b>(312,663)</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>(75,067)</b>	<b>(71,206)</b>	<b>(80,622)</b>	<b>(85,768)</b>	<b>(312,663)</b>
Total non-cash expenses	(55,928)	(5,113)	(13,187)	(20,808)	(95,036)	(14,863)	(15,358)			
<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>(89,930)</b>	<b>(86,564)</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>(\$3.01)</b>	<b>(\$2.84)</b>	<b>(\$3.20)</b>	<b>(\$3.39)</b>	<b>(\$12.45)</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>	<b>(\$3.61)</b>	<b>(\$3.46)</b>			
Shares out (000)	24,495	24,612	24,738	24,812	24,683	24,931	25,029	25,179	25,329	25,117
Fully diluted shares (000)	26,510	26,635	26,720	26,608	26,618	29,688	29,712	29,862	30,012	29,819

Source: Company Reports: Laidlaw &amp; Company estimates

Figure 4: Annual Income Statement

Intercept Pharmaceuticals						
Annual income statement						
(\$000's except per share)	2016A	2017E	2018E	2019E	2020E	Comments
<b>Revenues</b>						
Ocaliva US PBC sales	\$18,171	\$114,915	\$181,360	\$239,270	\$258,856	US launch 2Q16
Ocaliva EU PBC sales		11,950	33,378	43,526	44,392	EU launch 2Q17
License fees	6,780	1,891	2,000	2,000	2,000	
<b>Total Revenues</b>	<b>\$24,951</b>	<b>\$128,756</b>	<b>\$216,738</b>	<b>\$284,796</b>	<b>\$305,248</b>	
<b>Expenses</b>						
Cost of Goods Sold	-	5,150	23,621	31,108	33,357	
<b>Gross Margin</b>	<b>24,951</b>	<b>123,606</b>	<b>193,117</b>	<b>253,689</b>	<b>271,891</b>	
R&D	149,479	159,397	212,160	215,540	230,970	
SG&A	182,975	251,354	293,200	319,190	321,460	
<b>Total Op Expense</b>	<b>332,453</b>	<b>410,750</b>	<b>505,360</b>	<b>534,730</b>	<b>552,430</b>	2017 non-GAAP guide: \$380M-\$420M
<b>Inc (loss) from Ops</b>	<b>(307,502)</b>	<b>(287,141)</b>	<b>(312,243)</b>	<b>(281,041)</b>	<b>(280,539)</b>	
Interest & dividend inc	3,904	3,964	3,000	3,000	3,000	
<b>Pretax Inc (Loss)</b>	<b>(317,794)</b>	<b>(312,663)</b>	<b>(324,243)</b>	<b>(293,041)</b>	<b>(292,539)</b>	
Taxes	-	-	-	-	-	Sig. tax loss carryforwards
<b>Adjusted Net Income/(loss)</b>	<b>(317,794)</b>	<b>(312,663)</b>	<b>(324,243)</b>	<b>(293,041)</b>	<b>(292,539)</b>	
Total non-cash expenses	(95,036)					
<b>Net income as reported</b>	<b>(412,830)</b>					
<b>Adj-EPS ex-1x</b>	<b>(\$12.88)</b>	<b>(\$12.45)</b>	<b>(\$11.63)</b>	<b>(\$8.77)</b>	<b>(\$8.09)</b>	
<b>EPS as reported</b>	<b>(\$16.73)</b>					
Shares out (000)	24,683	25,117	27,888	33,410	36,172	
Fully diluted shares (000)	26,618	29,819	30,138	36,160	39,172	

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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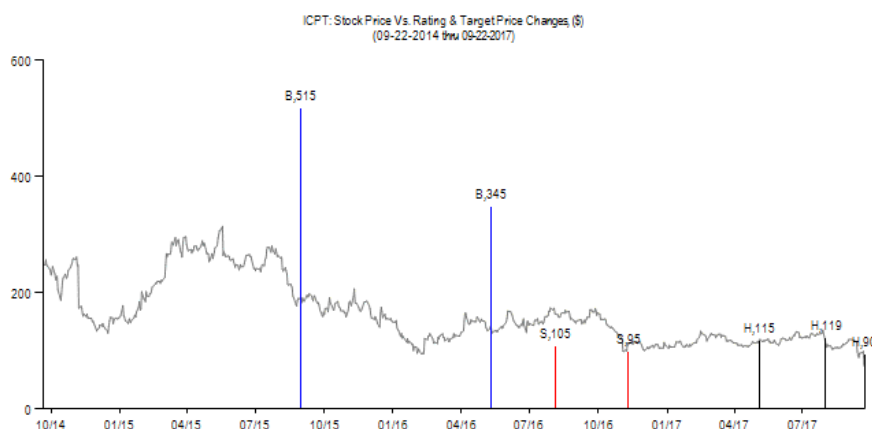
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#### Rating and Price Target Change History



#### 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)	118.74

#### 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	118.74
08/01/2...	119.00	110.76
09/22/2...	90.00	73.70*

\* Previous Close 9/21/2017

Source: Laidlaw & Company

Created by: Blue-Compass.net

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			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	64.58%	31.25%	2.08%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	4.17%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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