

Intercept Pharmaceuticals (ICPT - \$163.21)

A Worldwide Launch on a Single Orphan Drug – What Could Go Wrong? Lowering Rating to Sell, PT to \$105

We are lowering our price target and rating on ICPT this morning following the company's reported 2Q16 EPS last night. The company indicated that FY17 operating expenses are likely to be higher than the \$360M-\$400M spend for FY16, and that the uptake of Ocaliva for PBC in the US and the EU should be expected to proceed at a rather moderated pace. The company has ~\$850M in cash (pro-forma) following the July convertible debt offering (which netted ~\$409M), which at ICPT's current prolific spending means they will be down to a year of cash in 2017 (again). While the company has been adept at raising prodigious amounts of capital to date, a key architect of that fund raising ability – former CFO Duncan – has stepped aside for new CFO Kapadia. ICPT's key asset, OCA for NASH, remains the main reason to own the stock but the pivotal REGENERATE Phase 3 trial data is now a 2019 event (from 2H18 previously), and the important CONTROL lipid study is now a 2H17 event (from 4Q16 previously). ICPT is currently rolling out an expensive worldwide infrastructure to launch a single orphan drug – Ocaliva – which can mean years of slogging to profitability unless additional products can be found to add to the reps' bags to help more fully utilize the sales force. Our new price target incorporates what we believe are more conservative rollout expectations for Ocaliva for PBC and OCA for NASH, and also incorporates the now extended launch timelines. We are lowering our PT to \$105, which is ~40% lower than ICPT's current trading level, which drives our new Sell rating.

- **NASH timelines slippage & lowered expectations.** Most of our lowered PT comes from somewhat more conservative launch expectations for OCA for NASH, and also from our expectations for the launch to be pushed out at least another year to 2H20 (from 2019 previously).
- **Single product launches are challenging.** ICPT doesn't dispute this, and guides to a moderated launch. With quarterly Ocaliva sales a key focus until 2019 we expect the sales ramp could disappoint Street expectations.
- **Lowering rating to Sell, \$105 PT.** Our price target is based on a sum-of-the-parts analysis, with NASH at \$66/share, PBC at \$36/share, and the remaining pipeline and cash (end 2016) at \$43/share.

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY17E	(\$2.78)	(\$2.76)	(\$2.92)	(\$3.02)	(\$11.50)	NA
FY16E	(\$2.89)A	(\$3.14)A	(\$3.64)	(\$4.19)	(\$13.79)	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

Healthcare / Biotechnology

Ticker:		ICPT
Rating:	↓	Sell
Price Target:	↓	\$105.00

Trading Data:

Last Price (08/04/2016)	\$163.21
52-Week High (08/05/2015)	\$266.30
52-Week Low (02/11/2016)	\$89.76
Market Cap. (MM)	\$4,105
Shares Out. (MM)	24.60

Analyst

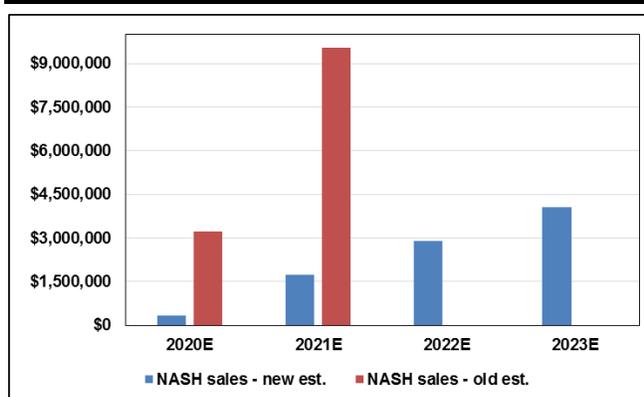
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Revising NASH launch for a more moderated rollout. We have revised our expectations for the OCA for NASH uptake projections (see Figure 1 below) as well as extending our projections out to 2023 (from 2021 previously). While we still see OCA for NASH as a potential “blockbuster” drug (ie: sales over \$1B) we believe a more moderated ramp might be warranted given the slow moving nature of the disease and the multiple co-morbidities typically associated with a NASH diagnosis including obesity and heart disease. The very real potential dyslipidemia issues could limit usage among some patients and moderate the initial roll out. That said, we still project sales over \$4B by year 4 of launch, which would be considered a winner in most people’s books.

Figure 1: OCA for NASH sales revisions



Source: Company reports; Laidlaw & Company estimates

Figure 2: Variance Analysis

Intercept Pharmaceuticals					
Quarterly variance analysis					
(\$000's)	2Q15A	2Q16A	2Q16E	Variance	% Y/Y
US PBC sales		\$75	0	\$75	NM
License revenues	\$445	5,445	\$445	\$5,000	1124%
Total Revenue	\$445	\$5,520	\$520	\$5,000	1140%
COGS	-	-	-	0	NM
Gross Profit	445	5,520	520	5,000	1140%
R&D Expense	22,895	38,354	45,000	(6,647)	68%
SG&A Expense	17,674	40,149	45,500	(5,352)	127%
Operating Inc (loss)	(40,124)	(72,982)	(89,980)	16,998	82%
Int & div income	929	796	500	296	-14%
Pretax Inc (loss)	(39,195)	(72,186)	(89,480)	17,294	84%
Income Taxes	0	0	0	0	NM
Div pref. stock	0	0	0	0	NM
NI - ex-1x items	(39,195)	(72,186)	(89,480)	17,294	84%
Avg Shares (000)	24,014	24,612	25,245	(633)	2%
EPS ex-1x items	(\$1.54)	(\$2.93)	(\$3.54)	\$0.61	91%
EPS as reported	(\$1.99)	(\$3.14)	\$0.00		

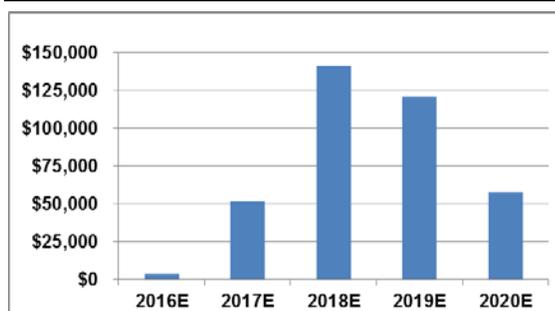
Source: Company reports; Laidlaw & Company estimates

Figure 3: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
OCA for NASH in the US	\$1,841,231	\$58
OCA for NASH EU royalty	\$257,665	\$8
Ocaliva for PBC US & EU	\$478,015	\$15
OCA for other indications	\$140,171	\$4
Cash (end of '17E) & tech	\$645,538	\$20
	\$3,362,620	\$105
2017 fully diluted shares out		31,928

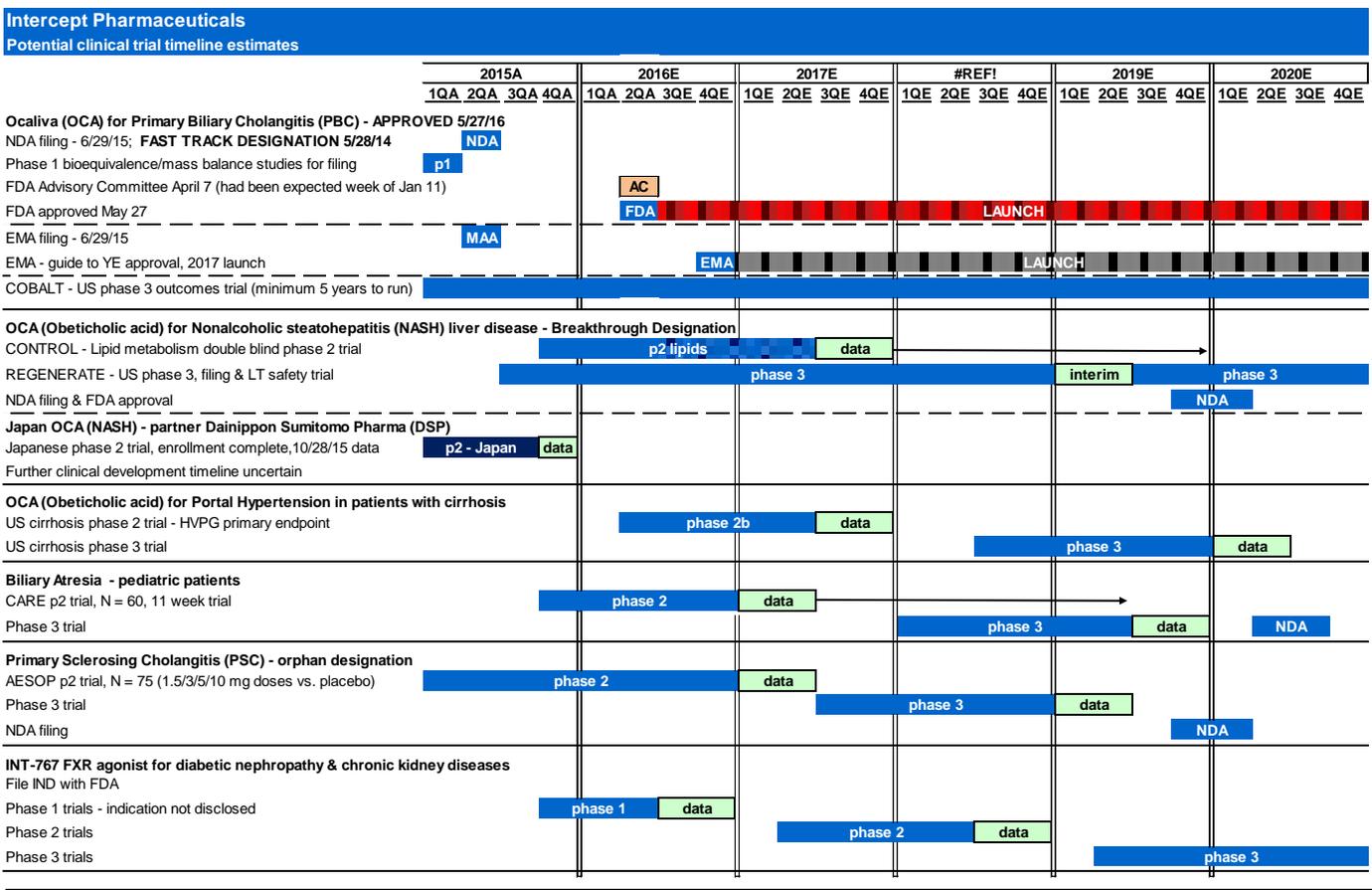
Source: Company Reports; Laidlaw & Company estimates

Figure 4: Ocaliva sales projections



Source: Laidlaw & Company estimates

Figure 5: Clinical Trial Timeline Estimates



Source: Laidlaw & Company estimates

Figure 6: Quarterly Income Statement

Intercept Pharmaceuticals										
Quarterly income statement										
(\$000's except per share)	2015A				2015A Year	2016E				2016E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QE	4QE	
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	\$1,762	\$3,099	\$10,826
Expenses										
Cost of Goods Sold	0	0	0	0	0	0	0	263	398	662
Gross Margin	1,445	445	445	447	2,782	445	5,520	1,499	2,701	10,165
R&D	21,916	22,895	22,337	37,747	104,894	31,607	38,354	50,000	60,000	179,961
SG&A	8,288	17,674	21,892	38,816	91,163	40,310	40,149	52,750	62,250	195,459
Total Op Expenses	30,203	40,569	44,229	76,562	196,057	71,917	78,502	102,750	122,250	375,419
Inc (loss) from Ops	(28,758)	(40,124)	(43,784)	(76,115)	(193,275)	(71,472)	(72,982)	(101,251)	(119,549)	(365,254)
Other income (exp)	272	929	889	637	2,727	726	796	500	500	2,522
Int exp					0					
Pretax Inc (Loss)	(28,486)	(39,195)	(42,895)	(75,478)	(190,548)	(70,746)	(72,186)	(100,751)	(119,049)	(362,732)
Div. pref stock, not declared					0					0
Adjusted Net Income/(loss)	(28,486)	(39,195)	(42,895)	(75,478)	(190,548)	(70,746)	(72,186)	(100,751)	(119,049)	(362,732)
Total non-cash expenses	(10,900)	(8,700)	(8,000)	(12,774)	(35,881)	(55,928)	(5,113)			(61,041)
Net income as reported	(39,386)	(47,895)	(50,895)	(88,252)	(226,429)	(126,674)	(77,299)			(423,773)
Adj-EPS ex-1x	(\$1.21)	(\$1.54)	(\$1.69)	(\$2.95)	(\$8.04)	(\$2.89)	(\$2.93)	(\$3.64)	(\$4.19)	(\$13.79)
EPS as reported	(\$1.78)	(\$1.99)	(\$2.10)	(\$3.62)	(\$9.56)	(\$5.17)	(\$3.14)			(\$16.11)
Shares out (000)	22,172	24,014	24,215	24,351	23,694	24,495	24,612	27,678	28,428	26,303
Fully diluted shares (000)	23,581	25,514	25,443	25,601	25,035	26,510	26,612	29,678	30,428	28,307

Source: Company Reports: Laidlaw & Company estimates

Figure 7: Annual Income Statement

Intercept Pharmaceuticals						
Annual income statement						
(\$000's except per share)	2015A	2016E	2017E	2018E	2019E	Comments
Revenues						
Ocaliva US PBC sales		\$4,046	\$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 2H20
License fees	\$2,782	6,780	2,000	2,000	2,000	
Total Revenues	\$2,782	\$10,826	\$59,034	\$178,865	\$192,414	
Expenses						
Cost of Goods Sold	-	662	8,555	19,455	14,513	
Gross Margin	2,782	10,165	50,479	159,410	177,901	
R&D	104,894	179,961	195,000	215,000	200,000	
SG&A	91,163	195,459	198,810	206,250	216,000	
Total Op Expense	196,057	375,419	393,810	421,250	416,000	guide: "low end" of \$360M-\$400M
Inc (loss) from Ops	(193,275)	(365,254)	(343,331)	(261,840)	(238,099)	
Interest & dividend inc	2,727	2,522	2,000	2,000	2,000	
Pretax Inc (Loss)	(190,548)	(362,732)	(341,331)	(259,840)	(236,099)	
Taxes	-	-	-	-	-	
Div. pref stock	-	-	-	-	-	
Adjusted Net Income/(loss)	(190,548)	(362,732)	(341,331)	(259,840)	(236,099)	
Total non-cash expenses	(35,881)	(61,041)				
Net income as reported	(226,429)	(423,773)				
Adj-EPS ex-1x	(\$8.04)	(\$13.79)	(\$11.50)	(\$8.40)	(\$7.35)	
EPS as reported	(\$9.56)	(\$16.11)				
Shares out (000)	23,694	26,303	29,678	30,928	32,128	
Fully diluted shares (000)	25,035	28,307	31,928	33,428	34,878	

Source: Company Reports: Laidlaw & Company estimates

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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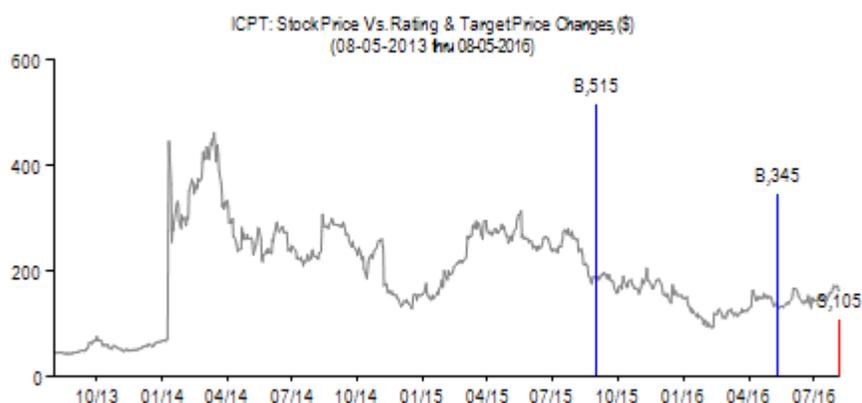
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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
08/31/2015	Buy (B)	189.76
08/05/2016	Sell (S)	163.21*

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	163.21*

* Previous Close 8/4/2016

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
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.	62.16%	27.03%	2.70%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.70%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.70%	0.00%	0.00%

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