September 20, 2013

Intercept Pharmaceuticals

(ICPT-NASDAQ)

Stock Rating: **Outperform**
Industry Rating: **Outperform**

Biotechnology

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Roadshow Highlights Wealth of Opportunities

Event

The BMO Capital Markets US biotechnology team hosted Intercept management in meetings with investors in Toronto and Montreal this week. Meetings with CEO Dr. Mark Pruzanski focused on progress with the phase 3 POISE study for OCA in primary biliary cirrhosis (PBC) as well as expanded indications of primary sclerosing cholangitis (PSC), portal hypertension, NASH and bile acid diarrhea (BAD). Incremental points included increasing FDA interest on surrogate endpoints in liver disease following the recent FDA/AASLD workshop, multiple orphan liver disease opportunities for OCA reporting data between YE13/YE14 in PBC, PSC, portal hypertension, a potential subset of NASH and a subset of bile acid diarrhea with Crohn's and bowel resection. Guidance for OCA pricing in PBC has not been provided but a range from $50,000 to $100,000 was viewed as reasonable. Market research is ongoing and suggests potential opportunity for OCA in patients with lower ALP levels.

Impact

We are reiterating our Outperform rating on ICPT and increasing our price target to $107 following our meetings with management. With increasing support for the value proposition around ALP reduction in PBC we believe that regulatory risk is lower and pricing flexibility is greater and are adjusting our estimates accordingly. Upside beyond our target price may exist from multiple orphan liver disease opportunities with proof-of-concept data over the next 3-12 months, with NASH as a potential transformational opportunity by YE14. While the opportunity for OCA has been dismissed in a broader bile acid diarrhea (BAD) indication, we believe that focus on Crohn's disease with bowel resection could narrow focus on a higher value proposition of short bowel syndrome.

Forecasts

We estimate a loss per share of $2.20 in 2013.

Valuation

Our $107 target is based on 25x our 2018E EPS of $7.75, discounted 20%.

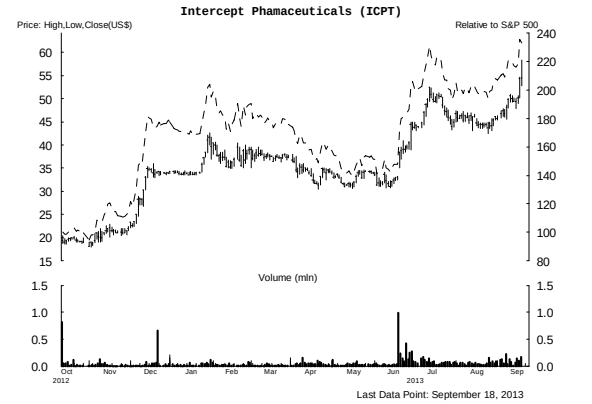
Recommendation

We rate Intercept Pharmaceuticals Outperform.

Securities Info

Price (19-Sep)	**$56.43**	**Target Price**	**$107** ↑
52-Wk High/Low	$58/$18	Dividend	--
Mkt Cap (mm)	$959	Yield	--
Shs O/S (mm, BASIC)	17.0	Float O/S (mm)	6.7
Options O/S (mm)	na	ADVol (30-day, 000s)	76

Price Performance



Valuation/Financial Data

(FY-Dec.)	2011A	2012A	2013E	2014E
EPS GAAP	-$1.17	-$7.36	-$2.20	-$2.51↓
P/E			nm	nm
First Call Cons.			*-$2.30*	*-$2.24*
FCF	na	na	-$1.14	na
P/FCF			nm	na
EBITDA ($mm)	-$14	-$19	-$27	-$41
EV/EBITDA			nm	nm
Rev. ($mm)	$2	$2	$7	$25
EV/Rev			107.8x	31.5x

Quarterly EPS	**1Q**	**2Q**	**3Q**	**4Q**
2012A	-$1.03	-$1.75	-$1.86	-$2.02
2013E	-$0.62A	-$0.79A	-$0.38	-$0.41

Balance Sheet Data (30-Jun)

Net Debt ($mm)	-$162	TotalDebt/EBITDA	nm
Total Debt ($mm)	$0	EBITDA/IntExp	na
Net Debt/Cap.	na	Price/Book	12.3x

Notes: All values in US$.

Source: BMO Capital Markets estimates, Bloomberg, Thomson Reuters, and IHS Global Insight.

Changes	**Annual EPS**	2014E -$2.05 to -$2.51	**Target**	$62.00 to $107.00

Please refer to pages 5 to 8 for Important Disclosures, including the Analyst's Certification.

Overview

The BMO Capital Markets US biotechnology team hosted Intercept Pharmaceuticals management on a non-deal road show (NDRS) in Canada this week. Focus of meetings with CEO Dr. Mark Pruzanski was on progress with lead bile acid analog OCA in the POISE phase 3 study, commercial opportunity and preparedness in primary biliary cirrhosis (PBC) and potential expansion opportunities with OCA in primary sclerosing cholangitis (PSC), portal hypertension, NASH and Crohn's patients with bile acid diarrhea (BAD).

With POISE on track for data in 2Q14, with NASH data expected in 4Q14, and with earlier phase 2 data read-outs expected for portal hypertension and Crohn's disease associated bile acid diarrhea (BAD) by YE13/early 2014, significant investor interest was seen on our NDRS with management. Overall, we believe that commercial opportunity for OCA in PBC has been under-estimated and that several "free call options" exist on additional orphan disease opportunities in PSC, NASH, portal hypertension, and in Crohn's patients with short bowel syndrome (SBS) and bile acid diarrhea. Indeed, the latter opportunity in patients with SBS associated bile acid diarrhea (BAD) has been particularly ignored in the context of GATTEX success in SBS, in our opinion.

POISE Study on Track for Data in 2Q14

- Timelines for POISE phase 3 data remain on track for 2Q14.
- Dropouts due to adverse events (AEs) in POISE remain lower than that seen in phase 2, suggesting that pruritus is being better managed and not a major problem for OCA.
- Recent joint workshop of FDA and AASLD focused on surrogate endpoints in NASH suggest that regulatory focus is shifting in liver disease in general.
- Commercial preparedness is ongoing with the recent hire of Dan Regan from GENZYME and expected salesforce build following POISE data.
- PBC opportunity can be targeted with 25 representatives in the US and EU and with regional collaborations in other territories, such as Asia.
- Unmet need in patients failing to achieve adequate Alkaline phosphatase (ALP) response is recognized by PBC community and increasingly supported by "Super-group" data.
- Additional market research is planned and ongoing in identifying thresholds for concern with ALP levels potentially warranting treatment below the POISE threshold of 1.67x ULN.
- Guidance on pricing has not been provided but a range of $50,000 to $100,000 was not viewed as unreasonable.

End of Phase 2 Meeting Could Clarify Regulatory Path in Portal Hypertension

- Final phase 2 PESTO data for OCA in portal hypertension is expected by YE13/early 2014.
- End of phase 2 meeting will occur following PESTO data release and will clarify regulatory endpoints.
- Reduction of 10% or <12mmHg is viewed as clinically relevant and correlation with reduced variceal bleeding appears clear.

NASH Data in 4Q14 With Recent FDA Workshop Highlighting Regulatory Interest

- Optimism in FLINT study stems from pre-clinical data demonstrating beneficial effect on liver fibrosis and phase 2 data demonstrating benefit in metabolic parameters of fatty liver (insulin sensitivity, weight loss).
- Final data expected from FLINT in 4Q14 following recommendation for study continuation on interim data analysis.
- While NASH represents a broad commercial opportunity, potentially requiring a large partner, smaller niche opportunities may exist for patients with more advanced disease.

Bile Acid Diarrhea (BAD) Could Represent an Orphan Opportunity in Short Bowel Syndrome (SBS)

- Proof-of-concept established for OCA in bile acid diarrhea (BAD) from initial OBADIAH results which demonstrated reduction in stool frequency from 23/week to 14/week.
- Bile acid diarrhea (BAD) accounts for ~one-third of all patients with IBS-D that have FGF-19 production defect.
- Bile acid diarrhea (BAD) in Crohn's disease has 60% rate of non-response in patients with bowel resection and short-bowel syndrome (SBS).
- One area of potential exploration with OCA in patients with SBS and bile acid diarrhea (BAD) is whether nutritional status might improve with lower reliance on TPN.

Adjustment to Financial Model

We are updating our ICPT financial model. We have increased pricing in the US for OCA in primary biliary cirrhosis (PBC) to $50,000 from $20,000.

This change results in sales for the period from 2016-2025 as follows. In OCA in PBC, US sales for 2016-2025 are now projected to be $163.1 million, $224.2 million, $284.7 million, $346.2 million, $408.8 million, $461.3 million, $495.8 million, $530.9 million, $566.6 million, and $602.8 million, respectively. This compares to our former estimates for the period of: $65.2 million, $89.7 million, $113.9 million, $138.5 million, $163.5 million, $184.5 million, $198.3 million, $212.4 million, $226.6 million, and $241.1 million, respectively.

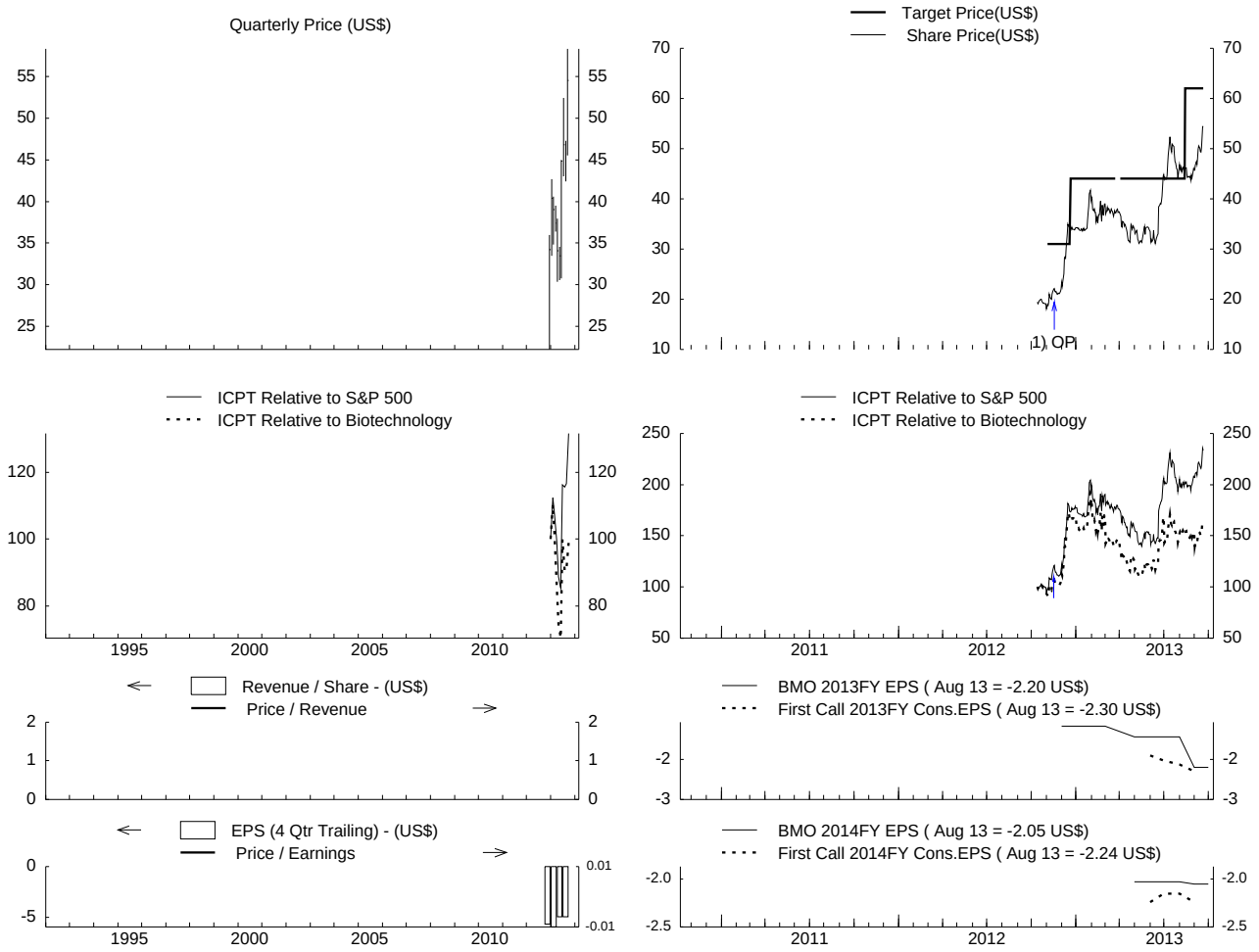
As a result, our EPS forecasts for 2016-2025 are now $3.62, $5.79, $7.75, $10.71, $13.27, $15.54, $16.98, $18.36, $19.74, and $21.16, respectively. This is in comparison to our previous estimates for the period of: $2.23, $3.55, $4.58, $6.30, $7.79, $9.16, $10.02, $10.82, $11.63, and $12.45, respectively.

Exhibit 1: ICPT Income Statement 2012A-2018E

INCOME STATEMENT ($M)	2012A	1Q13A	2Q13A	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E
REVENUES											
Product Revenues	$ -	$ -	$ -	$ -	$ -	$ -	$ 12.1	$ 107.9	$ 226.1	$ 315.3	$ 401.9
Licensing Revenue	2.4	0.4	0.4	3.3	3.3	7.4	13.2	13.2	13.2	13.2	13.2
Grant revenue and other	-	-	-	-	-	-	-	-	-	-	-
TOTAL REVENUES	**$ 2.4**	**$ 0.4**	**$ 0.4**	**$ 3.3**	**$ 3.3**	**$ 7.4**	**$ 25.3**	**$ 121.1**	**$ 239.3**	**$ 328.5**	**$ 415.1**
EXPENSES (GAAP)											
Cost of Goods Sold (COGS)	$ -	$ -	$ -	$ -	$ -	$ -	$ 0.6	$ 5.4	$ 11.3	$ 15.8	$ 20.1
R&D Expense	16.2	4.8	5.1	5.3	5.3	20.6	35.8	45.3	51.1	56.2	61.2
SG&A Expense	5.2	2.4	2.9	4.0	4.5	13.8	35.9	68.2	77.7	83.4	88.4
Other	-	-	-	-	-	-	-	-	-	-	-
TOTAL EXPENSES	21.4	7.2	8.0	9.3	9.8	34.4	66.5	118.9	140.1	155.4	169.6
Operating Income	**(18.9)**	**(6.8)**	**(7.6)**	**(6.0)**	**(6.5)**	**(26.9)**	**(41.2)**	**2.2**	**99.2**	**173.1**	**245.5**
Depreciation and amortization	-	-	-	-	-	-	-	-	-	-	-
EBIT	(18.9)	(6.8)	(7.6)	(6.0)	(6.5)	(26.9)	(41.2)	2.2	99.2	173.1	245.5
Interest and other income	0.1	-	-	0.1	0.1	0.2	0.3	0.2	0.3	0.5	0.8
Interest and other expense	(0.0)	-	(0.3)	-	-	(0.3)	-	-	-	-	-
Other Income (Expense)	(27.4)	(3.4)	(5.6)	(0.6)	(0.6)	(10.2)	(3.2)	(0.3)	5.1	8.7	0.4
Interest and Other Income (Expense)	(27.4)	(3.4)	(5.9)	(0.5)	(0.5)	(10.3)	(2.9)	(0.1)	5.4	9.2	1.2
Pre-Tax Income	(46.3)	(10.2)	(13.5)	(6.5)	(7.0)	(37.2)	(44.1)	2.1	104.6	182.2	246.7
Income Taxes	-	-	-	-	-	-	-	3.8	29.3	51.0	69.1
Net Income (GAAP)	**$ (46.3)**	**$ (10.2)**	**$ (13.5)**	**$ (6.5)**	**$ (7.0)**	**$ (37.2)**	**$ (44.1)**	**$ (1.7)**	**$ 75.3**	**$ 131.2**	**$ 177.6**
EPS (GAAP) (basic)	$ (7.36)	$ (0.62)	$ (0.79)	$ (0.38)	$ (0.41)	$ (2.20)	$ (2.51)	$ (0.11)	$ 3.62	$ 5.79	$ 7.75
EPS (GAAP) (diluted)	**$ (7.36)**	**$ (0.62)**	**$ (0.79)**	**$ (0.38)**	**$ (0.41)**	**$ (2.20)**	**$ (2.51)**	**$ (0.11)**	**$ 3.62**	**$ 5.79**	**$ 7.75**
Total of Reconciliation Items	3.3	1.6	1.9	2.0	2.0	7.5	8.0	8.0	8.0	8.0	8.0
Net Income (Non-GAAP)	$ (42.9)	$ (8.6)	$ (11.6)	$ (4.5)	$ (5.0)	$ (29.7)	$ (36.1)	$ 6.3	$ 83.3	$ 139.2	$ 185.6
Impact of Adjustments to EPS	0.49	0.10	0.11	0.12	0.12	0.44	0.46	0.44	0.39	0.35	0.35
EPS (Non-GAAP) (basic)	$ (6.18)	$ (0.52)	$ (0.68)	$ (0.27)	$ (0.29)	$ (1.76)	$ (2.05)	$ 0.33	$ 4.01	$ 6.15	$ 8.10
EPS (Non-GAAP) (diluted)	$ (6.18)	$ (0.52)	$ (0.68)	$ (0.27)	$ (0.29)	$ (1.76)	$ (2.05)	$ 0.33	$ 4.01	$ 6.15	$ 8.10
Weighted average shares outstanding (basic)	6.3	16.6	17.0	17.0	17.1	16.9	17.6	18.3	20.5	22.6	22.9
Weighted average shares outstanding (diluted)	6.3	16.6	17.0	17.0	17.1	16.9	17.6	18.3	20.5	22.6	22.9

Source: Company reports and BMO Capital Markets.

Intercept Phamaceuticals (ICPT)



FYE (Dec.)	EPS US$	P/E Hi	P/E Lo	DPS US$	Yield% Hi	Yield% Lo	Payout %	BV US$	P/B Hi	P/B Lo	ROE %
2012	-7.36	na	na	0.00	0.0	0.0	0	-0.5	-73.4	-36.7	
Range*:		na	na		0.0	0.0			-73.4	-36.7	
Current*	-4.98	na		0.00	0.0		0	4.6	9.9		na

ICPT - Rating as of 10-Oct-12 = NR

	Date	Rating Change	Share Price
1	15-Nov-12	NR to OP	$22.12

* Current EPS is the 4 Quarter Trailing to Q2/2013.
* Valuation metrics are based on high and low for the fiscal year.
* Range indicates the valuation range for the period presented above.

Last Price (September 18, 2013): $54.53
Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

Important Disclosures

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Methodology and Risks to Our Price Target/Valuation

Methodology: Our $107 price target is based on 25x our 2018E EPS of $7.75 discounted 20%.
Risks: There are a number of risks associated with investment in biotechnology companies. These risks include, but are not limited to, risk of clinical trial delay or failure, adverse regulatory decisions including product non-approval, unanticipated adverse effects of drugs which may result in removal from market, risk of manufacturing difficulties, capital market risk which may impair the ability to fund product discovery, research, regulatory filing, manufacture and/or commercialization, risk in attaining and retaining appropriate development or commercial partners, lower-than-expected product adoption, difficulties in gaining appropriate reimbursement for products from payors, unforeseen generic and branded competition, risk to patents being invalidated, and failure to meet earnings and revenue expectations.

Distribution of Ratings (June 30, 2013)

Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients*****	Starmine Universe
Buy	Outperform	37.9%	17.6%	52.7%	39.6%	51.0%	53.2%
Hold	Market Perform	56.8%	10.2%	45.9%	53.9%	45.5%	41.1%
Sell	Underperform	5.3%	3.2%	1.4%	6.5%	3.5%	5.6%

* Reflects rating distribution of all companies covered by BMO Capital Markets Corp. equity research analysts.
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(S) = Speculative investment;
NR = No rating at this time; and
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http://researchglobal.bmocapitalmarkets.com/documents/2013/prior_rating_system.pdf

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