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Liana Moussatos, Ph.D. (415) 263-6626

Richard Lau (415) 274-6851

Intercept Pharmaceuticals (ICPT - OUTPERFORM): We Believe Recent Publication of Preclinical Data Highlights OCA's Potential Use in NASH; Reiterate OUTPERFORM And \$65 FV

Price: \$44.10 Fair Value Estimate: \$65

- Preclinical results recently published in the Journal of Endocrinology demonstrate the beneficial effect of OCA on liver inflammation and steatosis. The preclinical study looked at OCA treatment in an animal model of metabolic syndrome. One of the key results from the study was that OCA treatment resulted in a normalization of liver steatosis and inflammation. We believe these data bode well for the ongoing Phase 2b FLINT study in NASH. Recall the primary endpoint is improvement in NAFLD Activity Score and the three components of NAFLD are steatosis, lobular inflammation, and hepatocyte ballooning. The title of the article is "The FXR agonist normalizes insulin sensitivity in visceral preadipocytes of a rabbit model of MetS" (Maneschi et al, The Journal of Endocrinology, June 2013) and can be accessed from Intercept's website (http://www.interceptpharma.com/reading-room.php).
- We anticipate topline data from the Phase 2 FLINT study testing OCA in NASH in Q4:14. This Phase 2b study began enrollment in early 2011 and has a 72-week treatment duration (25 mg OCA vs. placebo) with a primary endpoint of biopsydetermined improvement in NAFLD Activity Score. Importantly, the study passed an interim futility analysis in June 2012 conducted after the first 100+ patients reached at least 24 weeks of therapy (with the earliest enrolled patients having reached up to 15 months of therapy).
- We estimate gross peak annual sales of OCA in NASH could reach over \$350 million worldwide. Non-Alcoholic Steatohepatitis (NASH) has become an increasingly prevalent medical problem in recent years as the rates of obesity continue to increase. NASH has an incidence rate of approximately 25% in obese individuals, and is estimated to affect roughly 7.5 million adults in the US (increasing to 25 million by 2025) according to the NIH. If left untreated, patients with NASH can progress to liver cirrhosis, becoming susceptible to a high risk of liver failure and liver cancer. There are currently no approved drug therapies for NASH but there were about \$615 million in off-label sales reported in 2010.
- We see cash runway into 2016 covering transforming milestones. Key milestones include: (1) Q4: full "supergroup" data; (2) YE: full Phase 2a release for OCA treatment of portal hypertension (PESTO); (3) YE: initiation of the confirmatory OCA/PBC Phase 3 trial (indicating FDA acceptance of ALP endpoint); (4) Q2:14: initial results from the pivotal Phase 3 testing OCA treatment of PBC (NCT01473524); (5) Q4:14: initial results from FLINT Phase 2 trial testing OCA treatment of NASH; (6) Q4:14: NDA and MAA filings for OCA/PBC; (7) mid-2015: potential approval and launch of OCA/PBC.
- We are maintaining our OUTPERFORM rating and \$65 fair value. Our fair value is calculated by a summation of applying a 30% annual discount to our net peak WW revenues for each drug/indication and applying a 1-10x multiple depending on stage of development to reflect risk.

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Investment Thesis

Intercept Pharmaceuticals is an emerging biopharmaceutical company developing small molecule drug treatments for significant unmet medical needs in orphan and other chronic liver diseases by leveraging its expertise and intellectual property in bile acid chemistry. We maintain an optimistic outlook for ICPT's attractive risk/reward profile as: 1) clinical success is likely; 2) regulatory risk is reasonable and continues to decline; and 3) commercial risk is below average. Intercept's lead drug, obeticholic acid or OCA, has generated impressive efficacy data in two Phase 2 studies for the treatment of Primary Biliary Cirrhosis (PBC). In short, we believe OCA possesses one of the more clinically-derisked Phase 2 datasets among biotech drugs in development. PBC is a relatively well defined orphan market with a clear unmet medical need. Should OCA be approved, we believe the barriers to commercial adoption will be relatively low as many patients have been identified and are receiving treatment. Moreover, we see upside potential to our estimates of the eligible patient population as well as pricing. We see a high chance of success for Intercept's ongoing Phase 3 POISE study in PBC, with data expected in Q2:2014. Meanwhile, we see significant upside potential beyond PBC from follow-on indications such as portal hypertension, NASH and bile-acid diarrhea.

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Expected Date	Event
H2:2013	Additional data presented on complete 4,000+ patient "supergroup" analysis of PBC biomarkers
H2:2013	Start of Phase 3 OCA confirmatory outcomes study in PBC
FY:2013	Additional data from OCA Phase 2a study in portal hypertension (PESTO)
Q2:2014	Topline data from pivotal Phase 3 POISE study of OCA in PBC
Q4:2014	Topline data from Phase 2 FLINT study of OCA in NASH
Mid:2015	Potential US Approval of OCA for the treatment of PBC

Source: Company data, Wedbush Securities, Inc.

Risks to Attainment of our Fair Value

Risks to the attainment of our fair value include: Intercept's products obtain disappointing clinical trial results and/or fail to gain regulatory approval; Intercept is unable to pursue accelerated approval for OCA in the US or faces lengthy regulatory delays; Intercept or a partner fails to effectively commercialize its drug products due to unenthusiastic physician response or superior clinical results are obtained by a third-party competitor; unexpected safety problems emerge with Intercept's drug products; Intercept is unable to raise additional capital, if necessary, at terms favorable to shareholders.



Analyst Certification

I, Liana Moussatos, Ph.D., Richard Lau, certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

Disclosure information regarding historical ratings and price targets is available at http://www.wedbush.com/ResearchDisclosure/DisclosureQ113.pdf

Investment Rating System:

Outperform: Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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Neutral: 44%	Neutral: 2%
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Wedbush Equity Research Disclosures as of July 1, 2013

Company	Disclosure
Intercept Pharmaceuticals	1,3,4,5,7

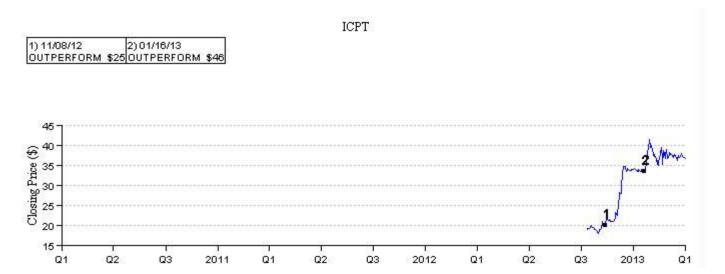
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OTHER DISCLOSURES

RESEARCH DEPT. * (213) 688-4505 * www.wedbush.com

EQUITY TRADING Los Angeles (213) 688-4470 / (800) 421-0178 * EQUITY SALES Los Angeles (800) 444-8076 CORPORATE HEADQUARTERS (213) 688-8000

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EQUITY RESEARCH DEPARTMENT

(213) 688-4529

DIRECTOR OF RESEARCH

Mark D. Benson (213) 688-4435

MANAGER, RESEARCH OPERATIONS

Ellen Kang (213) 688-4529

|--|

Consumer Products

Rommel T. Dionisio (212) 938-9934 Kurt M. Frederick, CFA CPA (415) 274-6822

Footwear, Apparel and Accessories

(212) 668-9876 Corinna Freedman Alicia Reese (212) 938-9927

Healthy Lifestyles

Kurt M. Frederick, CFA CPA (415) 274-6822

Restaurants

Nick Setvan (213) 688-4519 Colin Radke (213) 688-6624

Specialty Retail: Hardlines

Joan L. Storms, CFA (213) 688-4537 John Garrett, CFA (213) 688-4523

Specialty Retail: Softlines

Betty Chen (415) 273-7328 (415) 273-7315 Alex Pham

RETAIL/CONSUMER MARKET RESEARCH

Gabriella Santaniello (213) 688-4557

INDUSTRIAL GROWTH TECHNOLOGY

Clean Technology

(212) 938-9926 Craig Irwin Min Xu (212) 938-9925

Environmental Services / Building Products

(213) 688-4539 Al Kaschalk

Industrial Biotechnology

(415) 263-6626 Liana Moussatos, Ph.D. Christopher N. Marai, Ph.D. (415) 274-6861

Water and Renewable Energy Solutions

(213) 688-4319 David Rose, CFA

TECHNOLOGY, INTERNET, MEDIA & SOCIAL MEDIA

Communications and Application Software

Shyam Patil, CFA (213) 688-8062

Communications Equipment

(212) 668-9871 Saniit Singh (212) 938-9922 Ryan Flanagan (212) 938-9942

Computer Services: Financial Technology

Gil B. Luria (213) 688-4501 Aaron Turner (213) 688-4429

Enterprise Software

Steve Koenig (415) 274-6801

Entertainment: Retail

Michael Pachter (213) 688-4474 Nick McKay (213) 688-4343

Entertainment: Software

Michael Pachter (213) 688-4474 (213) 688-4343 Nick McKay

Internet and E-Commerce

Michael Pachter (213) 688-4474 (213) 688-4343 Nick McKay

Media

James Dix, CFA (213) 688-4315

Movies and Entertainment

Michael Pachter (213) 688-4474 Nick McKay (213) 688-4343

Semiconductors

(415) 274-6869 Betsy Van Hees Ryan Jue, CFA (415) 263-6669

LIFE SCIENCES

Biotechnology/Biopharmaceuticals/BioDefense

Gregory R. Wade, Ph.D. (415) 274-6863 David M. Nierengarten, Ph.D. (415) 274-6862 (415) 274-6861 Christopher N. Marai, Ph.D.

Emerging Pharmaceuticals

Liana Moussatos, Ph.D. (415) 263-6626 (415) 274-6851 Richard Lau Christopher N. Marai, Ph.D. (415) 274-6861

Healthcare Services - Managed Care

Sarah James (213) 688-4503 (212) 938-9937 Daniel Patt

Medical Devices

(212) 938-9948 Tao Levy

Medical Diagnostics and Life Sciences Tools

Zarak Khurshid (415) 274-6823

EQUITY SALES EQUITY TRADING

(213) 688-4470 / (800) 444-8076 (213) 688-4470 / (800) 421-0178 Los Angeles Los Angeles San Francisco (415) 274-6800 San Francisco (415) 274-6811 (212) 938-9931 (212) 344-2382 New York New York Boston (617) 832-3700 **Boston** (617) 832-3700

CORPORATE HEADQUARTERS

1000 Wilshire Blvd., Los Angeles, CA 90017-2465 Tel: (213) 688-8000 www.wedbush.com