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# Intercept Pharmaceuticals (ICPT)

Raising FV to \$46 on Increased Optimism and Clinical Proof-Of-Concept for an Additional OCA Indication

- ICPT is commanding a premium as investor enthusiasm for OCA indications outside of PBC continues to grow. Our recent conversations with biotech investors suggest that enthusiasm for OCA is high and extends beyond Primary Biliary Cirrhosis (PBC). Specifically, we note a growing appreciation of the drug's potential applicability for treating portal hypertension following the release of new Phase 2a data at AALSD. Portal hypertension represents a significant unmetmedical need with no currently approved therapies. After reviewing the market opportunity for portal hypertension and the available data on OCA, we are now including the indication in our fair value alongside PBC and NASH.
- Initial Phase 2a data demonstrates the therapeutic potential of OCA in portal hypertension. Portal hypertension leads to a number of life-threatening complications in cirrhotic patients (e.g., varices, sepsis and renal failure) and is a significant cause of mortality. Initial results of the Phase 2a PESTO study of OCA in portal hypertension demonstrated a reduction in hepatic venous pressure gradient (HVPG) in 6/8 patients, with 5 patients meeting the primary efficacy endpoint of ≥15% reduction in HVPG to below 12 mm Hg. We expect data from additional cohorts to be reported later this year, but view the initial proof-of-concept results as highly encouraging.
- We see additional potential upside to ICPT from continued clinical progress with OCA. Intercept emerged as the top-performing biotech IPO in 2012. We believe the stock can continue to outperform in 2013 as the company appears to have become a halo-investment in the small-cap biotech space. Potential catalysts during the next 12 months include OCA-related progress in a number of therapeutic areas including PBC, NASH, portal hypertension and bile-acid diarrhea.
- Reiterate OUPTERFORM rating and raising fair value to \$46 from \$25. Our fair value is calculated by applying a 30% annual discount to our peak worldwide sales estimates for ICPT's drug candidates, incorporating a 1-10x multiple based on stage of clinical development. Our sum-of-parts valuation has increased after including portal hypertension as a potential indication to OCA, along with PBC and NASH. Given the growing appreciation of this additional indication, as well as the availability of additional data since our initiation report, we believe its inclusion in our fair value is justified at this time.

| FYE Dec   | 2011A   |  | 2012E |          |   | 2013E |              |
|---|---|--|-------|----------|---|-------|--------------|
| REV (M)   | ACTUAL  | CURR.  | PREV. | CONS.    | CURR.   | PREV. | CONS.        |
| Q1 Mar  | \$0.0A  | \$0.8A   |       |          | \$0.4E  |       |              |
| Q2 Jun  | 0.0A  | 0.8A   |       |          | 0.4E  |       |              |
| Q3 Sep  | 0.0A  | 0.5A   |       |          | 0.4E  |       |              |
| Q4 Dec  | 0.0A  | 0.4E   |       |          | 0.4E  |       |              |
| Year*   | \$1.8A  | \$2.4E   |       | \$4.0E   | \$1.6E  |       | \$4.8E       |
| Change  | n/a   | n/a  |       |          | n/a   |       |              |
|   | 2011A   |  | 2012E |          |   | 2013E |              |
|   |   |  |       |          |   |       |              |
| EPS   | ACTUAL  | CURR.  | PREV. | CONS.    | CURR.   | PREV. | CONS.        |
| EPS<br>Q1 Mar   | ACTUAL<br>\$0.00A                               | CURR.<br>(\$1.03)A   | PREV. | CONS.    | CURR.<br>(\$0.40)E  | PREV. | CONS.        |
|   |   |  | PREV. |          |   | PREV. |              |
| Q1 Mar  | \$0.00A   | (\$1.03)A  | PREV. |          | (\$0.40)E   | PREV. |              |
| Q1 Mar<br>Q2 Jun                                      | \$0.00A<br>0.00A                                | (\$1.03)A<br>(1.75)A   | PREV. |          | (\$0.40)E<br>(0.39)E  | PREV. |              |
| Q1 Mar<br>Q2 Jun<br>Q3 Sep                            | \$0.00A<br>0.00A<br>0.00A                       | (\$1.03)A<br>(1.75)A<br>(1.86)A                                | PREV. | <br><br> | (\$0.40)E<br>(0.39)E<br>(0.39)E                                 | PREV. |              |
| Q1 Mar<br>Q2 Jun<br>Q3 Sep<br>Q4 Dec                  | \$0.00A<br>0.00A<br>0.00A<br>0.00A              | (\$1.03)A<br>(1.75)A<br>(1.86)A<br>(0.33)E                     | PREV. | <br><br> | (\$0.40)E<br>(0.39)E<br>(0.39)E<br>(0.39)E                      | PREV. | <br><br><br> |
| Q1 Mar<br>Q2 Jun<br>Q3 Sep<br>Q4 Dec<br><b>Year</b> * | \$0.00A<br>0.00A<br>0.00A<br>0.00A<br>(\$4.73)A | (\$1.03)A<br>(1.75)A<br>(1.86)A<br>(0.33)E<br><b>(\$3.15)E</b> | PREV. | <br><br> | (\$0.40)E<br>(0.39)E<br>(0.39)E<br>(0.39)E<br>( <b>\$1.57)E</b> | PREV. | <br><br><br> |

Consensus estimates are from Thomson First Call.

January 16, 2013

Price **\$34.18** 

# Rating OUTPERFORM

Fair Value Estimate \$46 (from \$25)

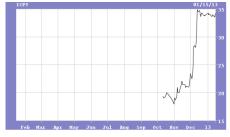
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| <b>Company Information</b> |                   |
|----------------------------|-------------------|
| Shares Outst (M)           | 18.2              |
| Market Cap (M)             | \$622.0           |
| 52-Wk Range                | \$17.96 - \$35.99 |
| Book Value/sh              | \$4.97            |
| Cash/sh                    | \$6.05            |
| Enterprise Value (M)       | \$511.9           |
| LT Debt/Cap %              | 0.0%              |

### **Company Description**

Intercept Pharmaceuticals is an emerging biopharmaceutical company specializing in the development of bile acid therapies. The company's lead drug, Obeticholic Acid (OCA), is currently in Phase III development for the treatment of Primary Biliary Cirrhosis (PBC).



Source: Thomson Reuters

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<sup>\*</sup> Numbers may not add up due to rounding.



#### **Near-term Milestones**

We estimate the following near and longer-term milestones for Intercept:

| Expected Date | Event  |
|---------------|--|
| Q2:2013       | Presentation of PBC biomarker supergroup analysis (potentially at EASL in April) |
| Mid:2013      | Top-line results from Phase 2a OCA trial in bile acid diarrhea (OBADIAH)         |
| H2:2013       | Potential positive clarity from FDA on regulatory pathway for OCA in PBC         |
| 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       | Top-line data from pivotal Phase 3 POISE study of OCA in PBC                     |
| Q4:2014       | Top-line data from Phase 2 FLINT study of OCA in NASH                            |
| Mid:2015      | Potential US Approval of OCA for the treatment of PBC                            |
|               |  |

#### Valuation and Risks

Our new fair value of \$46 is calculated using a sum-of-parts analysis, applying a 30% annual discount to our peak worldwide sales estimates for ICPT's drug candidates, incorporating a 1-10x multiple based on stage of clinical development. Our sum-of-parts valuation includes the contribution of OCA for the treatment of PBC, portal hypertension and NASH. Our fair value has increased from \$25 a share after including OCA for portal hypertension following positive proof-of-concept data, as well as an increased contribution from PBC due to the Phase 3 POISE study completing enrollment ahead of schedule (leading to an earlier launch date) as well a modest over-enrollment which we believe bodes favorably for the drug's commercial prospects.

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.

|   |               | or clinical and reç<br>of development. | gulatory risk                                |   |                            |  |  | Today:                | 1/16/13                 | Stock                      | MktCap (\$000)                          | Upside                         |
|---|---------------|--|--|---|----------------------------|--|--|-----------------------|-------------------------|----------------------------|---|--------------------------------|
|   | NOVEL I       | DRUGS .                                |  |   |                            |  | Wedbusl                                    | n Fair Value          | for ICPT                | \$45.70                    | \$831,690                               | 34%                            |
| In preclinical testing     Passed preclinical |               | 6: In Pivotal Trial<br>7: Pivotal data |  |   |                            |  |  | Full Pipel            | ine Value:<br>Net Cash: | \$30.50<br>\$6.05          | \$555,031<br>\$110,044                  |                                |
| 3: IND filed 4: Phase I data                  |               | 8: Regulatory review 9: Approved       |  |   |                            |  |  | ICPT To<br>Current IC | tal Value:<br>PT Stock: | \$36.55<br>\$34.18         | \$665,074<br>\$621,984                  |                                |
| 5: Phase II data                              |               | 10: Launched                           |  |   |                            | IC                                       | PT Diluted Sha                             | res Outstandi         | ng (000s):              | 18,197                     |   |                                |
|   |               |  |  | Intercep  | t Pipeli                   | ne Valu                                  | ation                                      |                       |                         |                            |   |                                |
| Pro   | duct          | Indication                             | Eligible #<br>Annual WW<br>Treatments<br>Est | Pricing \$<br>per Patient<br>per Year<br>Est/Actual | Peak<br>Penetration<br>Est | Gross WW<br>Peak<br>Sales Est<br>(\$000) | ICPT Net<br>Peak Revs<br>Est WW<br>(\$000) | Estimated<br>Launch   | Multiple                | Annual<br>Discount<br>Rate | Wedbush<br>MktCap Fair<br>Value (\$000) | Wedbush<br>Stock Fair<br>Value |
| FXR Agonist                                   | OCA (INT-747) | PBC                                    | 58,200                                       | \$18,844  | 32%                        | \$391,323                                | \$391,323                                  | 4/1/2015              | 6                       | 30%                        | \$460,907                               | \$25.33                        |
| FXR Agonist                                   | OCA (INT-747) | Portal<br>Hypertension                 | 800,000                                      | \$4,625   | 19%                        | \$689,000                                | \$689,000                                  | 7/1/2017              | 5                       | 30%                        | \$288,115                               | \$15.83                        |
| FXR Agonist                                   | OCA (INT-747) | NASH                                   | 7,225,000                                    | \$2,340   | 2%                         | \$321,250                                | \$321,250                                  | 7/1/2018              | 4                       | 30%                        | \$82,668                                | \$4.54                         |
| FXR/TGR5<br>Agonist                           | INT-767       | Fibrosis                               | 2,750,000                                    | \$2,500   | 5%                         | \$343,750                                | \$343,750                                  | 1/1/2021              | 1                       | 30%                        | \$11,456                                | \$0.63                         |

Source: Company reports, Wedbush Securities research.



## Intercept Pharmaceuticals (NASDAQ: ICPT)

Wedbush PacGrow LifeSciences

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Historical and Projected Income Statement (In thousands except per share data) (Fiscal Year Ends on December 31)

|                                      | 2011A       |            |            | 2012       |            |             | 2013E       | 2014E       | 2015E       |
|--------------------------------------|-------------|------------|------------|------------|------------|-------------|-------------|-------------|-------------|
|                                      | FY:11A      | Q1A        | Q2A        | Q3A        | Q4         | FY:12E      | FY:13E      | FY:14E      | FY:15E      |
| Revenues:                            |             |            |            |            |            |             |             |             |             |
| Revenues/Royalties on Product Sales  | \$ -        | \$ -       | \$ -       | \$ -       | \$ -       | \$ -        | \$ -        | \$ -        | \$ 26,775   |
| OCA for Primary Biliary Cirrhosis    | -           | -          | -          | -          | -          | -           | -           | -           | 26,775      |
| OCA for NASH                         | -           | -          | -          | -          | -          | -           | -           | -           | -           |
| Collaboration Revenue                |             |            |            |            |            | \$ 2,441    | \$ 1,600    | \$ 1,600    | \$ 1,600    |
| Licensing revenue and Milestones     | 1,805       | 759        | 759        | 523        | 400        | 2,441       | 1,600       | 1,600       | 1,600       |
| Total Revenues                       | \$ 1,805    | \$ 759     | \$ 759     | \$ 523     | \$ 400     | \$ 2,441    | \$ 1,600    | \$ 1,600    | \$ 28,375   |
| Operating Expenses                   |             |            |            |            |            |             |             |             |             |
| Research and Development             | 11,426      | 3,060      | 5,018      | 3,318      | 4,200      | 15,596      | 20,800      | 26,000      | 20,000      |
| Sales, General and Administrative    | 4,209       | 1,059      | 944        | 991        | 1,600      | 4,594       | 7,200       | 14,000      | 24,000      |
| Other                                | -           | -          | -          | -          | -          | -           | -           | -           | -           |
| Total Operating Expenses             | 15,636      | 4,119      | 5,962      | 4,309      | 5,800      | 20,190      | 28,000      | 40,000      | 45,787      |
| Operating Income (Loss)              | (13,830)    | (3,360)    | (5,203)    | (3,786)    | (5,400)    | (17,749)    | (26,400)    | (38,400)    | (17,411)    |
| Interest and dividend income         | 61          | 10         | 7          | 13         | 6          | 37          | 93          | 71          | 24          |
| Interest (expense)                   | (13)        | (7)        | (0)        | 3          | 3          | (1)         | 14          | 10          | -           |
| Revaluation of warrants              | 1,045       | 678        | 302        | (1,418)    | -          | (438)       | -           | -           | -           |
| Other income (expense)               | -           | -          | (192)      | -          | -          | (192)       | -           | -           | -           |
| Income Before Income Taxes           | (12,738)    | (2,680)    | (5,086)    | (5,187)    | (5,391)    | (18,343)    | (26,294)    | (38,319)    | (17,387)    |
| Other comprehensive income (loss)    | (3,000)     | (750)      | (750)      | (1,000)    | -          | (2,500)     | -           | -           | -           |
| Provision for Income Taxes (benefit) | -           | -          | -          | -          | -          | -           | -           | -           | 484         |
| Net Income (Loss)                    | \$ (15,738) | \$ (3,430) | \$ (5,836) | \$ (6,187) | \$ (5,391) | \$ (20,843) | \$ (26,294) | \$ (38,319) | \$ (17,871) |
| EPS ( Basic & Diluted; Pro forma)    | (4.73)      | (1.03)     | (1.75)     | (1.86)     | (0.33)     | (3.15)      | (1.57)      | (2.24)      | (1.00)      |
| Shares Outstanding (Basic)           | 3,330       | . ,        |            |            |            | 6,618       | 16,733      |             | 17,908      |
| Fully Diluted Shares Outstanding     | 3,330       | 3,330      | 3,330      | 3,330      | 18,197     | 0,010       | 18,447      |             | 19,247      |
| Net Cash                             | \$17,908    |            | \$10,026   | \$36,049   |            | \$110,121   |             |             |             |
| Change in Cash (Burn)                | \$2,412     |            | \$10,020   | Ψ30,047    | Ψ110,121   | \$92,213    |             |             | (\$22,658)  |

Source: Company reports, Wedbush Securities research.



#### Analyst Biography

Mr. Felt is a Research Analyst covering Biopharmaceutical and Medical Technology companies. He previously served as a senior associate on the healthcare team at Wedbush PacGrow Lifesciences from 2009-2012. Prior to joining Wedbush, Mr. Felt worked for two years as an associate analyst covering the biotechnology sector and one year in industry as a clinical research assistant.

Mr. Felt holds a B.S. in Biomedical Engineering from Washington University and a Master's degree in Biotechnology from Columbia University.

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I, Akiva Felt, Liana Moussatos, Ph.D., 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.

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| Rating Distribution (as of December 31, 2012) | Investment Banking Relationships (as of December 31, 2012) |
|---|--|
| Outperform:53%                                | Outperform:14%   |
| Neutral: 42%                                  | Neutral: 2%  |
| Underperform: 5%                              | Underperform: 0%   |

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#### Wedbush Equity Research Disclosures as of January 16, 2013

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

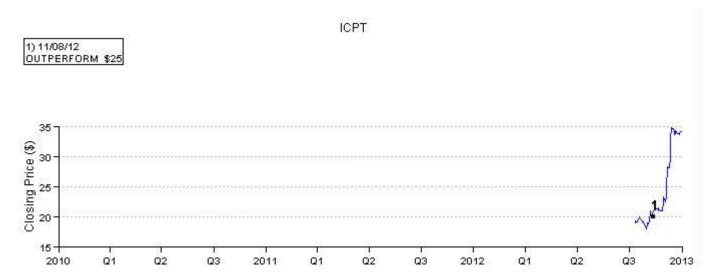
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