

## Intercept Pharmaceuticals (ICPT - \$141.08)

### REGENERATE trial enrollment likely completed 1H17

ICPT recently reported 1Q16 roughly in-line with our expectations on an adjusted basis excluding the one-time \$45M lawsuit settlement. More importantly, in our opinion, ICPT guided to a 1H17 enrollment completion for their groundbreaking REGENERATE Phase 3 trial for treating NASH. This pushes back our estimate of the trial completion to 2H18 (given the 72 week duration of the trial) and launch to late 2020; which naturally impacts our estimate of the value of the compound. We are lowering our price target to \$345 from \$515 previously, primarily driven by changes in our OCA for NASH estimates. The next key catalyst for ICPT remains the upcoming March 29<sup>th</sup> PDUFA date for OCA for treating PBC, which we continue to believe will be approved and launched this year. This is based on our review of the public data, and the 17-0 vote in favor of approval at the April 7<sup>th</sup> Advisory Committee. While we are lowering our price target we continue to believe there is significant upside from current levels and we are reiterating our Buy rating, with a \$345 price target.

- **NASH timeline clarified.** Management guided to a 1H17 enrollment completion for REGENERATE trial, with the interim look likely in 2H18 given the 72 week duration of the trial. We continue to believe that the interim look for OCA for NASH will support an NDA filing and approval in 2020.
- **Sales estimates & pricing post approval.** We currently project 2016E-2019E PBC sales of \$15.9M, \$147.9M, \$276.6M, and \$202.8M respectively. We model in a \$50K annual cost of therapy for PBC in the US, with sales dropping off in 2019 as we anticipate OCA for NASH approval & launch and a subsequent reduction in annual cost of therapy to the ~\$15K range.
- **2016 guidance for spending reiterated.** Management reiterated 2016 operating expense guidance of \$360M-\$400M, which likely means another funding event is likely in late-2016 given ICPT's cash balance of \$557M.
- **Reiterate Buy rating and lowering price target to \$345.** Our price target is based on a sum-of-the-parts analysis, with NASH at \$266/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 |
|--------------|-----------|----------|----------|----------|-----------|-----|
| <b>FY17E</b> | NA        | NA       | NA       | NA       | (\$7.80)  | NA  |
| <b>FY16E</b> | (\$2.89)A | (\$3.56) | (\$3.75) | (\$4.20) | (\$14.46) | NA  |
| <b>FY15</b>  | (\$1.21)  | (\$1.54) | (\$1.69) | (\$2.95) | (\$8.04)  | NA  |
| <b>FY14</b>  | (\$0.58)  | (\$0.84) | (\$1.44) | (\$1.46) | (\$4.36)  | NA  |

Source: Laidlaw & Company estimates

Healthcare / Biotechnology

|               |                   |
|---------------|-------------------|
| Ticker:       | ICPT              |
| Rating:       | <b>Buy</b>        |
| Price Target: | ↓ <b>\$345.00</b> |

### Trading Data:

|                           |          |
|---------------------------|----------|
| Last Price (05/10/2016)   | \$141.08 |
| 52-Week High (05/18/2015) | \$314.88 |
| 52-Week Low (02/11/2016)  | \$89.76  |
| Market Cap. (MM)          | \$3,470  |
| Shares Out. (MM)          | 24.60    |

### Analyst

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Figure 1: Variance analysis

| <b>Intercept Pharmaceuticals</b>   |                 |                 |                 |               |             |
|------------------------------------|-----------------|-----------------|-----------------|---------------|-------------|
| <b>Quarterly variance analysis</b> |                 |                 |                 |               |             |
| (\$000's)                          | 1Q15A           | 1Q16A           | 1Q16E           | Variance      | % Y/Y       |
| License revenues                   | \$1,445         | \$445           | \$500           | (\$55)        | -69%        |
| <b>Total Revenue</b>               | <b>\$1,445</b>  | <b>\$445</b>    | <b>\$500</b>    | <b>(\$55)</b> | <b>-69%</b> |
| COGS                               | -               | -               | -               | 0             | NM          |
| <b>Gross Profit</b>                | <b>1,445</b>    | <b>445</b>      | <b>500</b>      | <b>(55)</b>   | <b>-69%</b> |
| R&D Expense                        | 21,916          | 31,607          | 40,000          | (8,393)       | 44%         |
| SG&A Expense                       | 8,288           | 40,310          | 38,250          | 2,060         | 386%        |
| <b>Operating Inc (loss)</b>        | <b>(28,758)</b> | <b>(71,472)</b> | <b>(77,750)</b> | <b>6,278</b>  | <b>149%</b> |
| Int & div income                   | 272             | 726             | 500             | 226           | 167%        |
| <b>Pretax Inc (loss)</b>           | <b>(28,486)</b> | <b>(70,746)</b> | <b>(77,250)</b> | <b>6,504</b>  | <b>148%</b> |
| Income Taxes                       | 0               | 0               | 0               | 0             | NM          |
| Div pref. stock                    | 0               | 0               | 0               | 0             | NM          |
| <b>NI - ex-1x items</b>            | <b>(28,486)</b> | <b>(70,746)</b> | <b>(77,250)</b> | <b>6,504</b>  | <b>148%</b> |
| Avg Shares (000)                   | 22,172          | 24,495          | 24,851          | (356)         | 10%         |
| <b>EPS ex-1x items</b>             | <b>(\$1.21)</b> | <b>(\$2.89)</b> | <b>(\$3.11)</b> | <b>\$0.22</b> | <b>139%</b> |
| <b>EPS as reported</b>             | <b>(\$1.78)</b> | <b>(\$5.17)</b> |                 |               |             |

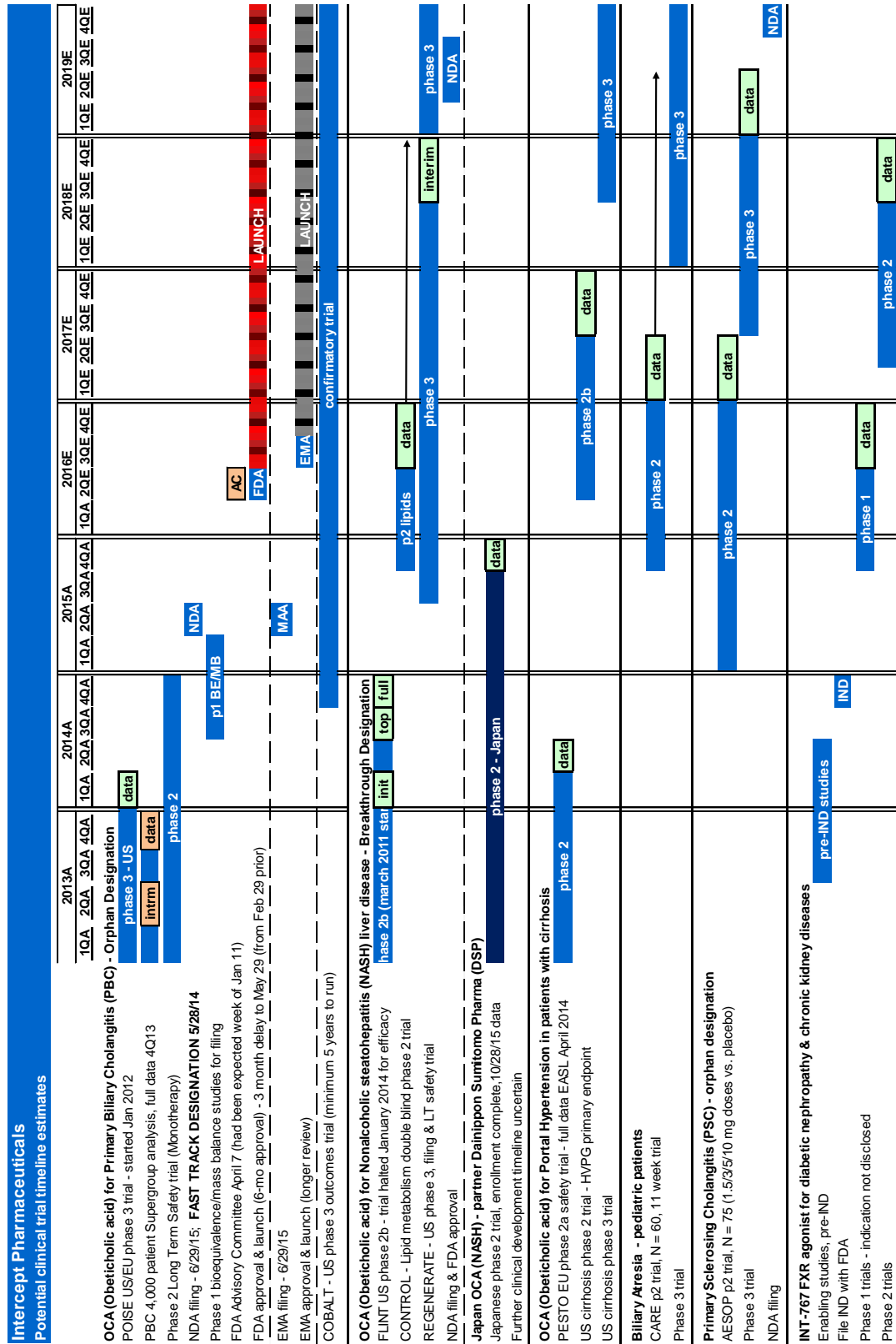
Source: Company Reports: Laidlaw &amp; Company estimates

Figure 2: Valuation

| <b>Sum-of-the-parts valuation: ICPT</b> |                      |                    |
|---|----------------------|--------------------|
| Segment                                 | Valuation<br>(000's) | Per share<br>value |
| OCA for NASH in the US                  | \$5,595,815          | \$206              |
| OCA for NASH EU royalty                 | \$1,599,170          | \$60               |
| OCA for PBC US & EU                     | \$1,007,594          | \$36               |
| OCA for other indications               | \$475,825            | \$17               |
| Cash (end of '16E) & tech               | \$688,772            | \$26               |
|   | \$9,367,176          | <b>\$345</b>       |
| 2016 fully diluted shares out           |                      | 27,120             |

Source: Company Reports: Laidlaw &amp; Company estimates

Figure 3: Clinical trial timeline estimates



Source: Company Reports; Laidlaw & Company estimates

Figure 4: Quarterly Income Statement

| <b>Intercept Pharmaceuticals</b>  |                 |                 |                 |                 |                  |                  |                 |                 |                  |                  |
|-----------------------------------|-----------------|-----------------|-----------------|-----------------|------------------|------------------|-----------------|-----------------|------------------|------------------|
| <b>Quarterly income statement</b> |                 |                 |                 |                 |                  |                  |                 |                 |                  |                  |
| (\$000's except per share)        | 2015A           |                 |                 |                 | 2015A<br>Year    | 2016E            |                 |                 |                  | 2016E<br>Year    |
|                                   | 1QA             | 2QA             | 3QA             | 4QA             |                  | 1QA              | 2QE             | 3QE             | 4QE              |                  |
| <b>Revenues</b>                   |                 |                 |                 |                 |                  |                  |                 |                 |                  |                  |
| License fees                      | \$1,445         | \$445           | \$445           | \$447           | \$2,782          | \$445            | \$445           | 445             | 445              | 1,780            |
| <b>Total Revenues</b>             | <b>\$1,445</b>  | <b>\$445</b>    | <b>\$445</b>    | <b>\$447</b>    | <b>\$2,782</b>   | <b>\$445</b>     | <b>\$445</b>    | <b>\$5,713</b>  | <b>\$11,061</b>  | <b>\$17,664</b>  |
| <b>Expenses</b>                   |                 |                 |                 |                 |                  |                  |                 |                 |                  |                  |
| Cost of Goods Sold                | 0               | 0               | 0               | 0               | 0                | 0                | 0               | 1,054           | 1,592            | 2,646            |
| <b>Gross Margin</b>               | <b>1,445</b>    | <b>445</b>      | <b>445</b>      | <b>447</b>      | <b>2,782</b>     | <b>445</b>       | <b>445</b>      | <b>4,660</b>    | <b>9,469</b>     | <b>15,018</b>    |
| R&D                               | 21,916          | 22,895          | 22,337          | 37,747          | 104,894          | 31,607           | 45,000          | 50,000          | 60,000           | 186,607          |
| SG&A                              | 8,288           | 17,674          | 21,892          | 38,816          | 91,163           | 40,310           | 45,750          | 52,750          | 62,250           | 201,060          |
| <b>Total Op Expenses</b>          | <b>30,203</b>   | <b>40,569</b>   | <b>44,229</b>   | <b>76,562</b>   | <b>196,057</b>   | <b>71,917</b>    | <b>90,750</b>   | <b>102,750</b>  | <b>122,250</b>   | <b>387,667</b>   |
| <b>Inc (loss) from Ops</b>        | <b>(28,758)</b> | <b>(40,124)</b> | <b>(43,784)</b> | <b>(76,115)</b> | <b>(193,275)</b> | <b>(71,472)</b>  | <b>(90,305)</b> | <b>(98,090)</b> | <b>(112,781)</b> | <b>(372,649)</b> |
| Other income (exp)                | 272             | 929             | 889             | 637             | 2,727            | 726              | 500             | 500             | 500              | 2,226            |
| Int exp                           |                 |                 |                 |                 | 0                |                  |                 |                 |                  |                  |
| <b>Pretax Inc (Loss)</b>          | <b>(28,486)</b> | <b>(39,195)</b> | <b>(42,895)</b> | <b>(75,478)</b> | <b>(190,548)</b> | <b>(70,746)</b>  | <b>(89,805)</b> | <b>(97,590)</b> | <b>(112,281)</b> | <b>(370,423)</b> |
| Div. pref stock, not declared     |                 |                 |                 |                 | 0                |                  |                 |                 |                  | 0                |
| <b>Adjusted Net Income/(loss)</b> | <b>(28,486)</b> | <b>(39,195)</b> | <b>(42,895)</b> | <b>(75,478)</b> | <b>(190,548)</b> | <b>(70,746)</b>  | <b>(89,805)</b> | <b>(97,590)</b> | <b>(112,281)</b> | <b>(370,423)</b> |
| Total non-cash expenses           | (10,900)        | (8,700)         | (8,000)         | (12,774)        | (35,881)         | (55,928)         |                 |                 |                  | (55,928)         |
| <b>Net income as reported</b>     | <b>(39,386)</b> | <b>(47,895)</b> | <b>(50,895)</b> | <b>(88,252)</b> | <b>(226,429)</b> | <b>(126,674)</b> |                 |                 |                  | <b>(426,351)</b> |
| <b>Adj-EPS ex-1x</b>              | <b>(\$1.21)</b> | <b>(\$1.54)</b> | <b>(\$1.69)</b> | <b>(\$2.95)</b> | <b>(\$8.04)</b>  | <b>(\$2.89)</b>  | <b>(\$3.56)</b> | <b>(\$3.75)</b> | <b>(\$4.20)</b>  | <b>(\$14.46)</b> |
| <b>EPS as reported</b>            | <b>(\$1.78)</b> | <b>(\$1.99)</b> | <b>(\$2.10)</b> | <b>(\$3.62)</b> | <b>(\$9.56)</b>  | <b>(\$5.17)</b>  |                 |                 |                  | <b>(\$16.64)</b> |
| Shares out (000)                  | 22,172          | 24,014          | 24,215          | 24,351          | 23,694           | 24,495           | 25,245          | 25,995          | 26,745           | 25,620           |
| Fully diluted shares (000)        | 23,581          | 25,514          | 25,443          | 25,601          | 25,035           | 25,995           | 26,745          | 27,495          | 28,245           | 27,120           |

Source: Company Reports: Laidlaw &amp; Company estimates

Figure 5: Annual Income Statement

| <b>Intercept Pharmaceuticals</b>  |                  |                  |                  |                  |                  |                                       |
|-----------------------------------|------------------|------------------|------------------|------------------|------------------|---------------------------------------|
| <b>Annual income statement</b>    |                  |                  |                  |                  |                  |                                       |
| (\$000's except per share)        | <b>2015A</b>     | <b>2016E</b>     | <b>2017E</b>     | <b>2018E</b>     | <b>2019E</b>     | <b>Comments</b>                       |
| <b>Revenues</b>                   |                  |                  |                  |                  |                  |                                       |
| US PBC sales for OCA              |                  | \$15,884         | \$147,985        | \$276,642        | \$167,972        | <b>US launch 2H16</b>                 |
| EU PBC sales for OCA              |                  |                  | 53,355           | 137,177          | 138,948          | <b>EU launch 1H17</b>                 |
| US NASH royalties for OCA         |                  |                  |                  | 0                | 0                | <b>Launch 2020</b>                    |
| License fees                      | \$2,782          | 1,780            | 2,000            | 2,000            | 2,000            |                                       |
| <b>Total Revenues</b>             | <b>\$2,782</b>   | <b>\$17,664</b>  | <b>\$149,985</b> | <b>\$278,642</b> | <b>\$169,972</b> |                                       |
| <b>Expenses</b>                   |                  |                  |                  |                  |                  |                                       |
| Cost of Goods Sold                | -                | 2,646            | 22,198           | 33,197           | 20,157           |                                       |
| <b>Gross Margin</b>               | <b>2,782</b>     | <b>15,018</b>    | <b>127,787</b>   | <b>245,445</b>   | <b>149,815</b>   |                                       |
| R&D                               | 104,894          | 186,607          | 195,000          | 200,000          | 200,000          |                                       |
| SG&A                              | 91,163           | 201,060          | 148,000          | 126,000          | 123,000          |                                       |
| <b>Total Op Expense</b>           | <b>196,057</b>   | <b>387,667</b>   | <b>343,000</b>   | <b>326,000</b>   | <b>323,000</b>   | <b>2016 OpEx guide: \$360M-\$400M</b> |
| <b>Inc (loss) from Ops</b>        | <b>(193,275)</b> | <b>(372,649)</b> | <b>(215,213)</b> | <b>(80,555)</b>  | <b>(173,185)</b> |                                       |
| Interest & dividend inc           | 2,727            | 2,226            | 2,000            | 2,000            | 2,000            |                                       |
| <b>Pretax Inc (Loss)</b>          | <b>(190,548)</b> | <b>(370,423)</b> | <b>(213,213)</b> | <b>(78,555)</b>  | <b>(171,185)</b> |                                       |
| Taxes                             | -                | -                | -                | -                | -                |                                       |
| Div. pref stock                   | -                | -                | -                | -                | -                |                                       |
| <b>Adjusted Net Income/(loss)</b> | <b>(190,548)</b> | <b>(370,423)</b> | <b>(213,213)</b> | <b>(78,555)</b>  | <b>(171,185)</b> |                                       |
| Total non-cash expenses           |                  |                  |                  |                  |                  |                                       |
| <b>Net income as reported</b>     | <b>(226,429)</b> |                  |                  |                  |                  |                                       |
| <b>Adj-EPS ex-1x</b>              | <b>(\$8.04)</b>  | <b>(\$14.46)</b> | <b>(\$7.80)</b>  | <b>(\$2.75)</b>  | <b>(\$5.75)</b>  |                                       |
| <b>EPS as reported</b>            |                  |                  |                  |                  |                  |                                       |
| Shares out (000)                  | 23,694           | 25,620           | 27,320           | 28,570           | 29,770           |                                       |
| Fully diluted shares (000)        | 25,035           | 27,120           | 28,770           | 30,570           | 31,770           |                                       |

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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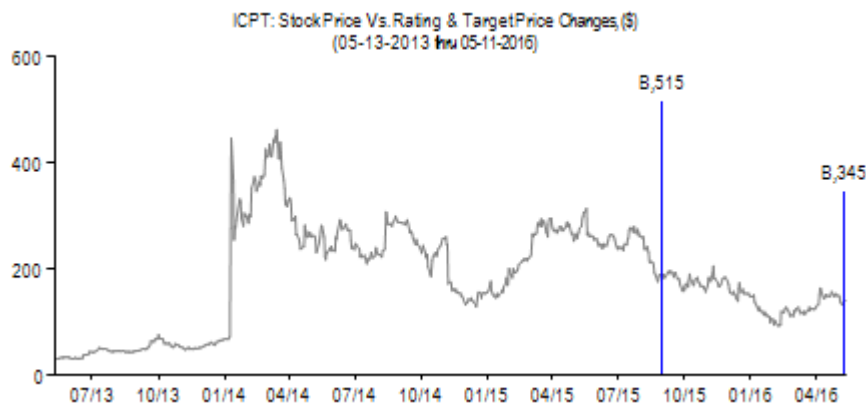
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*Additional information available upon request.*

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**Rating and Price Target Change History**



| Date       | Rating  | Closing Price (\$) |
|------------|---------|--------------------|
| 08/31/2015 | Buy (B) | 189.76             |

| Date       | Target Price (\$) | Closing Price, (\$) |
|------------|-------------------|---------------------|
| 08/31/2015 | 515.00            | 189.76              |
| 05/11/2016 | 345.00            | 141.08*             |

\* Previous Close 5/10/2016

Source: Laidlaw & Company

Created by: Blue-Compass.net

| 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 |
| <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.                         | 66.67%   | 27.78%  | 2.78%     |
| <b>Hold (H)</b>                  | Expected returns to be in line with the sector average over 12 months.            | 0.00%  | 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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