

## Intercept Pharmaceuticals (ICPT - \$117.13)

Healthcare / Biotechnology

### OCA for PBC Keeps Trucking Along, NASH Ways Away

ICPT recently reported their 2Q17, beating on top-line as US Ocaliva for Primary Biliary Cholangitis (PBC) builds on its strong start to 2017 with 2Q17 total sales of \$30.9M vs. our estimate of \$25M and consensus of \$27.5M. We have re-adjusted our revenue projections to reflect the strength of the launch and now anticipate \$133M in sales vs. our prior \$111M estimate. Additionally, ICPT announced data readouts from both their Phase 2 CONTROL lipid study (assessing combination of statin therapy in NASH patients) and Phase 2 AESOP in primary sclerosing cholangitis (PSC). In CONTROL, while the lowest available dose of atorvastatin quickly reversed OCA associated LDL changes to below baseline levels in NASH patients, mild-to moderate pruritus was present in 55% of the 25mg OCA patients (2 discontinued treatment). We are also concerned with one patient death due to acute renal and liver failure. Although ICPT isn't ruling out relation to treatment, we are encouraged that the principal investigator and independent data safety monitoring committee believe the mortality is unlikely to be related to OCA. In terms of AESOP, ICPT demonstrated that patients starting on 5mg OCA (option to titrate up to 10mg) showed statistically significant reduction in alkaline phosphatase (ALP) vs. placebo. While pruritus is common in PSC (46% in placebo), severe dose dependent increase in pruritus was noted with OCA and led to 1 (n= 25) in the 1.5-3mg group and 3 (n=26) in the 5-10 mg discontinuations. Although we understand the dearth of options in NASH and PSC, we do believe these AEs could contribute to lowering the barrier to entry in these increasingly crowded fields. We maintain our Hold rating and increase our price target to \$119 based on impressive topline beat.

Ticker: ICPT  
Rating: Hold  
Price Target: ↑ **\$119.00**

#### Trading Data:

|                           |           |
|---------------------------|-----------|
| Last Price (07/31/2017)   | \$117.13  |
| 52-Week High (08/01/2016) | \$177.93  |
| 52-Week Low (11/04/2016)  | \$96.63   |
| Market Cap. (MM)          | \$2,929.0 |
| Shares Out. (MM)          | 25.0      |

- **Topline beats again, opex guidance reiterated.** While the topline beat led by US PBC sales of \$27.9M vs. our estimated \$22.6M, with \$550M of cash and FY17 guidance of adjusted operating expenses of \$380M-\$420M, we think ICPT could come back to the market in 2018.
- **CONTROL and AESOP hit endpoints, AEs could add risk and lower barrier to entry.** Although CONTROL was a relatively small trial (n=84), discontinuations related to high pruritus incidence and 1 death (although probably not OCA related) still add risk to ICPT, in our opinion.
- **Reiterating our Hold rating, \$119 PT.** We value OCA for NASH (US & EU) at \$71/share, Ocaliva at \$33/share, other indications, cash (end '18, net debt) & tech value at \$15/share.

#### Earnings Estimates: (per share)

| (Sep)        | 1Q       | 2Q        | 3Q       | 4Q       | FY        | P/E |
|--------------|----------|-----------|----------|----------|-----------|-----|
| <b>FY18E</b> | (\$2.89) | (\$3.11)  | (\$2.63) | (\$2.93) | (\$11.53) | NA  |
| <b>FY17E</b> | (\$3.01) | (\$2.84)A | (\$3.03) | (\$3.39) | (\$12.28) | NA  |
| <b>FY16</b>  | (\$2.89) | (\$2.93)  | (\$3.06) | (\$4.00) | (\$12.88) | NA  |
| <b>FY15</b>  | (\$1.21) | (\$1.55)  | (\$1.69) | (\$2.95) | (\$8.04)  | NA  |

#### Analyst

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Source: Laidlaw & Company estimates

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Figure 1: Variance Analysis

| Intercept Pharmaceuticals<br>Quarterly variance analysis |                 |                 |                 |                |             |
|--|-----------------|-----------------|-----------------|----------------|-------------|
| (\$000's)  | 2Q16A           | 2Q17A           | 2Q17E           | Variance       | % Y/Y       |
| US PBC sales   |                 | \$27,900        | \$22,629        | \$5,271        | NM          |
| License revenues   | \$5,445         | 446             | 500             | (54)           | -92%        |
| <b>Total Revenue</b>                                     | <b>\$5,520</b>  | <b>\$30,887</b> | <b>\$25,015</b> | <b>\$5,872</b> | <b>460%</b> |
| COGS   | -               | 279             | 2,452           | (2,173)        | NM          |
| <b>Gross Profit</b>                                      | <b>5,520</b>    | <b>30,608</b>   | <b>22,564</b>   | <b>8,044</b>   | <b>454%</b> |
| R&D Expense  | 38,354          | 35,977          | 47,135          | (11,158)       | -6%         |
| SG&A Expense   | 40,149          | 59,782          | 50,985          | 8,797          | 49%         |
| <b>Operating Inc (loss)</b>                              | <b>(72,982)</b> | <b>(65,151)</b> | <b>(75,556)</b> | <b>10,405</b>  | <b>-11%</b> |
| Int & div income   | 796             | 1,224           | 750             | 474            | 54%         |
| <b>Pretax Inc (loss)</b>                                 | <b>(72,186)</b> | <b>(71,206)</b> | <b>(78,556)</b> | <b>7,350</b>   | <b>-1%</b>  |
| <b>NI - ex-1x items</b>                                  | <b>(72,186)</b> | <b>(71,206)</b> | <b>(78,556)</b> | <b>7,350</b>   | <b>-1%</b>  |
| Avg Shares (000)   | 24,612          | 25,029          | 25,431          | (402)          | 2%          |
| <b>EPS ex-1x items</b>                                   | <b>(\$2.93)</b> | <b>(\$2.84)</b> | <b>(\$3.09)</b> | <b>\$0.24</b>  | <b>-3%</b>  |
| <b>EPS as reported</b>                                   | <b>(\$3.14)</b> | <b>(\$3.46)</b> |                 |                |             |

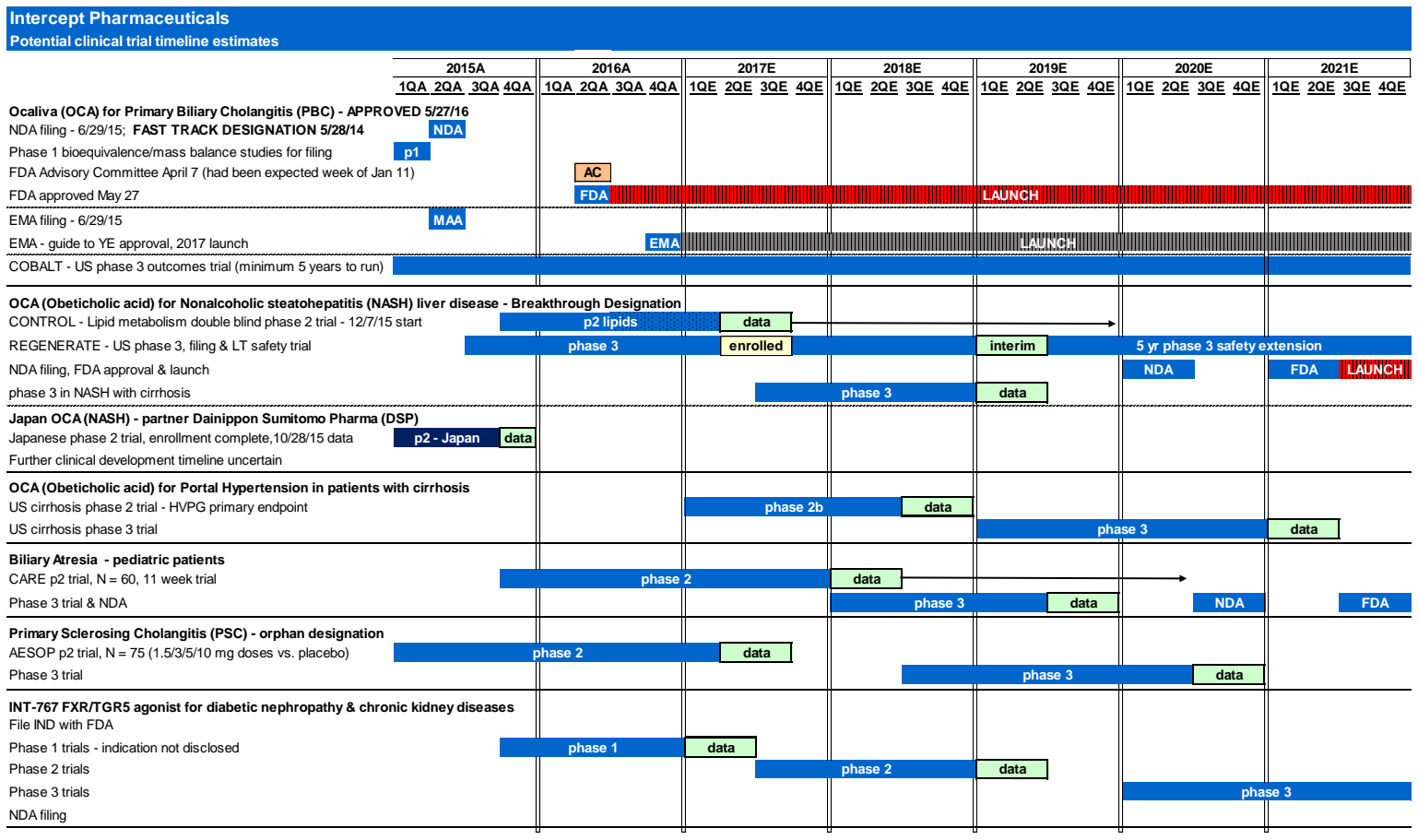
Source: Company reports; Laidlaw &amp; Company estimates

Figure 2: Valuation

| Sum-of-the-parts valuation    |                      |                    |
|-------------------------------|----------------------|--------------------|
| Segment                       | Valuation<br>(000's) | Per share<br>value |
| OCA for NASH in the US        | \$1,963,979          | \$65               |
| Ocaliva for PBC US & EU       | \$990,555            | \$33               |
| OCA for NASH EU royalty       | \$171,013            | \$6                |
| OCA for other indications     | \$188,836            | \$6                |
| Cash (end of '18E) & tech     | \$266,194            | \$9                |
|                               | \$3,580,577          | <b>\$119</b>       |
| 2018 fully diluted shares out |                      | 30,138             |

Source: Company Reports; Laidlaw &amp; Company estimates

Figure 3: Clinical Trial Timeline Estimates



Source: Laidlaw & Company estimates

Figure 4: Quarterly Income Statement

| Intercept Pharmaceuticals<br>Quarterly income statement |                  |                 |                 |                  |                  |                 |                 |                 |                 |                  |
|---|------------------|-----------------|-----------------|------------------|------------------|-----------------|-----------------|-----------------|-----------------|------------------|
| (\$000's except per share)                              | 2016A            |                 |                 |                  | 2016A<br>Year    | 2017E           |                 |                 |                 | 2017E<br>Year    |
|   | 1QA              | 2QA             | 3QA             | 4QA              |                  | 1QA             | 2QA             | 3QE             | 4QE             |                  |
| <b>Revenues</b>   |                  |                 |                 |                  |                  |                 |                 |                 |                 |                  |
| Ocaliva US PBC sales                                    |                  | \$75            | \$4,732         | \$13,364         | \$18,171         | \$19,800        | \$27,900        | \$35,623        | \$35,891        | \$119,214        |
| Ocaliva EU PBC sales                                    |                  |                 |                 |                  |                  | 800             | 2,500           | 3,800           | 4,785           | 11,885           |
| License fees  | \$445            | \$5,445         | 445             | 445              | 6,780            | 445             | 446             | 500             | 500             | 1,891            |
| <b>Total Revenues</b>                                   | <b>\$445</b>     | <b>\$5,520</b>  | <b>\$5,177</b>  | <b>\$13,809</b>  | <b>\$24,951</b>  | <b>\$21,048</b> | <b>\$30,887</b> | <b>\$39,923</b> | <b>\$41,176</b> | <b>\$132,990</b> |
| <b>Expenses</b>   |                  |                 |                 |                  |                  |                 |                 |                 |                 |                  |
| Cost of Goods Sold                                      | 0                | 0               | 0               | 0                | 0                | 97              | 279             | 300             | 4,474           | 5,150            |
| <b>Gross Margin</b>                                     | <b>445</b>       | <b>5,520</b>    | <b>5,177</b>    | <b>13,809</b>    | <b>24,951</b>    | <b>20,951</b>   | <b>30,608</b>   | <b>39,623</b>   | <b>36,702</b>   | <b>127,840</b>   |
| R&D   | 31,607           | 38,354          | 36,923          | 42,595           | 149,479          | 36,000          | 35,977          | 41,485          | 45,935          | 159,397          |
| SG&A  | 40,310           | 40,149          | 38,103          | 64,413           | 182,975          | 54,052          | 59,782          | 67,735          | 69,785          | 251,354          |
| <b>Total Op Expenses</b>                                | <b>71,917</b>    | <b>78,502</b>   | <b>75,026</b>   | <b>107,008</b>   | <b>332,453</b>   | <b>90,051</b>   | <b>95,759</b>   | <b>109,220</b>  | <b>115,720</b>  | <b>410,750</b>   |
| <b>Inc (loss) from Ops</b>                              | <b>(71,472)</b>  | <b>(72,982)</b> | <b>(69,849)</b> | <b>(93,199)</b>  | <b>(307,502)</b> | <b>(69,100)</b> | <b>(65,151)</b> | <b>(69,597)</b> | <b>(79,018)</b> | <b>(282,866)</b> |
| Other income (exp)                                      | 726              | 796             | (7,065)         | 1,096            | 3,904            | 1,240           | 1,224           | 750             | 750             | 3,964            |
| Interest expense  |                  |                 | 1,286           | (7,131)          | (14,196)         | (7,207)         | (7,279)         | (7,500)         | (7,500)         | (29,486)         |
| <b>Pretax Inc (Loss)</b>                                | <b>(70,746)</b>  | <b>(72,186)</b> | <b>(75,628)</b> | <b>(99,234)</b>  | <b>(317,794)</b> | <b>(75,067)</b> | <b>(71,206)</b> | <b>(76,347)</b> | <b>(85,768)</b> | <b>(308,388)</b> |
| Div. pref stock, not declared                           |                  |                 |                 |                  | 0                |                 |                 |                 |                 | 0                |
| <b>Adjusted Net Income/(loss)</b>                       | <b>(70,746)</b>  | <b>(72,186)</b> | <b>(75,628)</b> | <b>(99,234)</b>  | <b>(317,794)</b> | <b>(75,067)</b> | <b>(71,206)</b> | <b>(76,347)</b> | <b>(85,768)</b> | <b>(308,388)</b> |
| Total non-cash expenses                                 | (55,928)         | (5,113)         | (13,187)        | (20,808)         | (95,036)         | (14,863)        | (15,358)        |                 |                 |                  |
| <b>Net income as reported</b>                           | <b>(126,674)</b> | <b>(77,299)</b> | <b>(88,815)</b> | <b>(120,042)</b> | <b>(412,830)</b> | <b>(89,930)</b> | <b>(86,564)</b> |                 |                 |                  |
| <b>Adj-EPS ex-1x</b>                                    | <b>(\$2.89)</b>  | <b>(\$2.93)</b> | <b>(\$3.06)</b> | <b>(\$4.00)</b>  | <b>(\$12.88)</b> | <b>(\$3.01)</b> | <b>(\$2.84)</b> | <b>(\$3.03)</b> | <b>(\$3.39)</b> | <b>(\$12.28)</b> |
| <b>EPS as reported</b>                                  | <b>(\$5.17)</b>  | <b>(\$3.14)</b> | <b>(\$3.59)</b> | <b>(\$4.84)</b>  | <b>(\$16.73)</b> | <b>(\$3.61)</b> | <b>(\$3.46)</b> |                 |                 |                  |
| Shares out (000)  | 24,495           | 24,612          | 24,738          | 24,812           | 24,683           | 24,931          | 25,029          | 25,179          | 25,329          | 25,117           |
| Fully diluted shares (000)                              | 26,510           | 26,635          | 26,720          | 26,608           | 26,618           | 29,688          | 29,786          | 29,936          | 30,086          | 29,874           |

Source: Company Reports: Laidlaw &amp; Company estimates

Figure 5: Annual Income Statement

| Intercept Pharmaceuticals         |                  |                  |                  |                  |                  |                                    |
|-----------------------------------|------------------|------------------|------------------|------------------|------------------|------------------------------------|
| Annual income statement           |                  |                  |                  |                  |                  |                                    |
| (\$000's except per share)        | 2016A            | 2017E            | 2018E            | 2019E            | 2020E            | Comments                           |
| <b>Revenues</b>                   |                  |                  |                  |                  |                  |                                    |
| Ocaliva US PBC sales              | \$18,171         | \$119,214        | \$184,397        | \$239,270        | \$258,856        | US launch 2Q16                     |
| Ocaliva EU PBC sales              |                  | 11,885           | 33,378           | 43,526           | 44,392           | EU launch 2Q17                     |
| License fees                      | 6,780            | 1,891            | 2,000            | 2,000            | 2,000            |                                    |
| <b>Total Revenues</b>             | <b>\$24,951</b>  | <b>\$132,990</b> | <b>\$219,776</b> | <b>\$284,796</b> | <b>\$305,248</b> |                                    |
| <b>Expenses</b>                   |                  |                  |                  |                  |                  |                                    |
| Cost of Goods Sold                | -                | 5,150            | 23,955           | 31,108           | 33,357           |                                    |
| <b>Gross Margin</b>               | <b>24,951</b>    | <b>127,840</b>   | <b>195,820</b>   | <b>253,689</b>   | <b>271,891</b>   |                                    |
| R&D                               | 149,479          | 159,397          | 212,160          | 215,540          | 230,970          |                                    |
| SG&A                              | 182,975          | 251,354          | 293,200          | 319,190          | 321,460          |                                    |
| <b>Total Op Expense</b>           | <b>332,453</b>   | <b>410,750</b>   | <b>505,360</b>   | <b>534,730</b>   | <b>552,430</b>   | 2017 non-GAAP guide: \$380M-\$420M |
| <b>Inc (loss) from Ops</b>        | <b>(307,502)</b> | <b>(282,866)</b> | <b>(309,540)</b> | <b>(281,041)</b> | <b>(280,539)</b> |                                    |
| Interest & dividend inc           | 3,904            | 3,964            | 3,000            | 3,000            | 3,000            |                                    |
| <b>Pretax Inc (Loss)</b>          | <b>(317,794)</b> | <b>(308,388)</b> | <b>(321,540)</b> | <b>(293,041)</b> | <b>(292,539)</b> |                                    |
| Taxes                             | -                | -                | -                | -                | -                | Sig. tax loss carryforwards        |
| <b>Adjusted Net Income/(loss)</b> | <b>(317,794)</b> | <b>(308,388)</b> | <b>(321,540)</b> | <b>(293,041)</b> | <b>(292,539)</b> |                                    |
| Total non-cash expenses           | (95,036)         |                  |                  |                  |                  |                                    |
| <b>Net income as reported</b>     | <b>(412,830)</b> |                  |                  |                  |                  |                                    |
| <b>Adj-EPS ex-1x</b>              | <b>(\$12.88)</b> | <b>(\$12.28)</b> | <b>(\$11.53)</b> | <b>(\$8.77)</b>  | <b>(\$8.09)</b>  |                                    |
| <b>EPS as reported</b>            | <b>(\$16.73)</b> |                  |                  |                  |                  |                                    |
| Shares out (000)                  | 24,683           | 25,117           | 27,888           | 33,410           | 36,172           |                                    |
| Fully diluted shares (000)        | 26,618           | 29,874           | 30,138           | 36,160           | 39,172           |                                    |

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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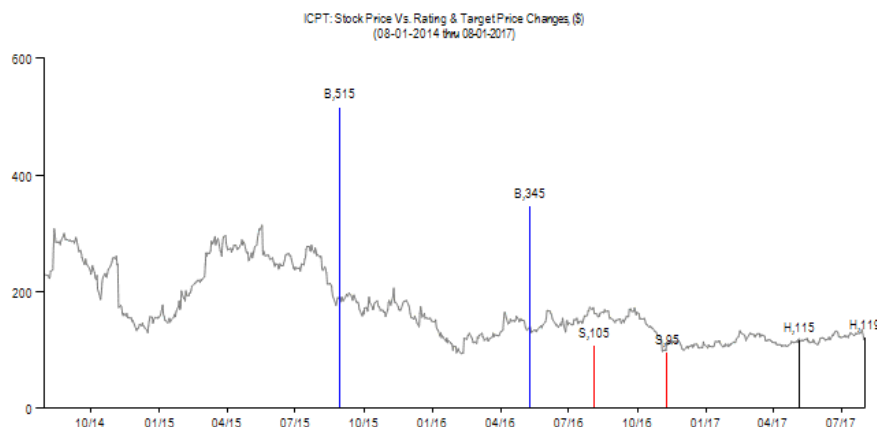
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*Additional information available upon request.*

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#### Rating and Price Target Change History



#### 3 Year Rating Change History

| Date       | Rating    | Closing Price (\$) |
|------------|-----------|--------------------|
| 08/31/2... | Buy (B )  | 189.76             |
| 08/05/2... | Sell (S ) | 162.27             |
| 05/05/2... | Hold (H ) | 118.74             |

#### 3 Year Price Change History

| Date       | Target Price (\$) | Closing Price, (\$) |
|------------|-------------------|---------------------|
| 08/31/2... | 515.00            | 189.76              |
| 05/11/2... | 345.00            | 137.28              |
| 08/05/2... | 105.00            | 162.27              |
| 11/10/2... | 95.00             | 109.00              |
| 05/05/2... | 115.00            | 118.74              |
| 08/01/2... | 119.00            | 117.13*             |

\* Previous Close 7/31/2017

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.                         | 63.04%   | 30.43%  | 2.17%     |
| <b>Hold (H)</b>                  | Expected returns to be in line with the sector average over 12 months.            | 4.35%  | 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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