

## Citius Pharmaceuticals (NASDAQ/CTXR)

July 1, 2021

### BUY: DSMB Gives the Thumbs Up – Data in Early 2022

*Citius announced that the DMC interim safety and efficacy review of the Mino-Lok Phase 3 Trial concluded with favorable recommendation to continue the trial as planned, with the protocol-defined sample size and power to achieve the primary endpoint.*

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### Investment Highlights

**What's the Timeline?** Enrollment continues post COVID. Based on our analysis, we believe the trial is likely to complete in early 2022. Good data sets the stage for management to file an NDA in 2022. Fast Track designation is possible, which would mean an expedited review.

**Background:** Recall that the trial has enrolled approximately n=144 patients diagnosed with CRBSI/CLABSI who meet all necessary criteria for the study. Patients are randomized in a 1:1 ratio to receive either Mino-Lok therapy or standard of care antibiotic lock therapy. To date, the company has achieved more than 80% of the expected enrollment. Subjects in the Mino-Lok arm receive one MLT dose daily with a dwell time of two to four hours for a total of seven doses. For subjects in the Control arm, the investigator determines the antibiotic used in the lock, dose, dwell time, and number of days of administration based on institutional standards or Infectious Diseases Society of America (IDSA) guidelines.

**What is Mino-Lok?** Three active drug substances (minocycline, ethanol, and EDTA), which are combined into two vials, MLT01 (minocycline) and MLT02 (ethanol and EDTA). Citius has manufactured three registration lots of Mino-Lok using the commercial manufacturing process, part of the planned New Drug Application (NDA). Citius has placed all registration lots on stability at the appropriate ICH (The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) conditions to support the NDA filing. Citius has also developed a new exclusive synthesis process for disodium edetate, a chelating agent that supplants heparin as the anti-clotting agent in Mino-Lok.

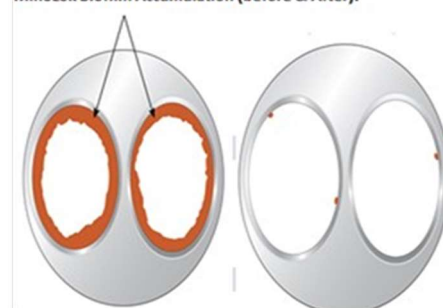
**Fiscal 2Q Results:** Citius closed the period with \$103.7M in cash. Management expects these funds to support operations through Mino-Lok's projected approval and launch, in 2023.

**Valuation.** Our valuation is based on our therapeutic models and associated assumptions projected to 2028. The lead product, Mini-Lok, is now in a Phase 3 trial. We conservatively assume just 50% probability of success in our models. On top of this, we also use a 30% risk rate in our free cash flow to the firm (FCFF), our discounted EPS (dEPS) and sum-of-the-parts (SOP) models. We equal weight and average these metrics and then round to the nearest whole number to derive our \$8.00 price target.

**Risk Factors:** These include Clinical Risk, Partnership Risk, Financial Risk, Regulatory Risk, and Legal and Commercial Risks.

 Current Price \$2.98  
 Price Target \$ 8.00

MinoLok Biofilm Accumulation (before &amp; After):



Source: Citius

| Stock Data                              |             |   |        |
|---|-------------|---|--------|
| 52-Week Range                           | \$0.78      | - | \$4.56 |
| Shares Outstanding (mil.)               | 135.5       |   |        |
| Market Capitalization (mil.)            | \$403       |   |        |
| Enterprise Value (mil.)                 | \$384       |   |        |
| Debt to Capital                         | 0%          |   |        |
| Book Value/Share                        | \$2.63      |   |        |
| Price/Book                              | 1.7         |   |        |
| Average Three Months Trading Volume (K) | 3,695       |   |        |
| Insider Ownership                       | 9.1%        |   |        |
| Institutional Ownership                 | 8.1%        |   |        |
| Short Interest (mil.)                   | 11.3%       |   |        |
| Dividend / Yield                        | \$0.00/0.0% |   |        |



**Exhibit 1. Income Statement**

| Citius Pharmaceuticals: Income Statement (\$000)           |                 |                 |                 |                 | December       | March          | June           | Sept. YE       |                 |               |               |               |               |               |                |                |                |                |                |                |
|--|-----------------|-----------------|-----------------|-----------------|----------------|----------------|----------------|----------------|-----------------|---------------|---------------|---------------|---------------|---------------|----------------|----------------|----------------|----------------|----------------|----------------|
| YE Sept.   | 2017A           | 2018A           | 2019A           | 2020A           | 1Q21A          | 2Q21E          | 3Q21E          | 4Q21E          | 2021E           | 1Q22E         | 2Q22E         | 3Q22E         | 4Q22E         | 2022E         | 2023E          | 2024E          | 2025E          | 2026E          | 2027E          | 2028E          |
| Mno-Lok, U.S. ST & LT CVC Revenues                         |                 |                 | -               | -               |                |                |                |                |                 | 19,155        | 19,988        | 20,821        | 23,319        | 83,283        | 169,914        | 216,661        | 265,220        | 315,642        | 367,985        | 469,227        |
| Mno-Lok, E.U. ST & LT CVC Revenues                         |                 |                 | -               | -               | -              | -              | -              | -              | -               | -             | -             | -             | -             | -             | -              |                |                |                |                |                |
| Mno-Lok, CHina ST & LT CVC Revenues                        |                 |                 |                 |                 |                |                |                |                |                 |               |               |               |               |               |                |                |                |                |                |                |
|  |                 |                 | -               | -               | -              | -              | -              | -              | -               | 19,155        | 19,988        | 20,821        | 23,319        | 83,283        | 169,914        | 216,661        | 265,220        | 315,642        | 367,985        | 469,227        |
| <b>Expenses</b>  |                 |                 |                 |                 |                |                |                |                |                 |               |               |               |               |               |                |                |                |                |                |                |
| Cost of goods sold   |                 | -               | -               | -               | -              | -              | -              | -              | -               | 2,873         | 2,998         | 3,123         | 3,498         | 12,492        | 25,487         | 32,499         | 39,783         | 47,346         | 55,198         | 70,384         |
| COGS % of Revenue  |                 |                 |                 |                 | 15%            | 15%            | 15%            | 15%            |                 | 15%           | 15%           | 15%           | 15%           | 15%           | 15%            | 15%            | 15%            | 15%            | 15%            | 15%            |
| Research and development                                   | 5,873           | 6,563           | 8,596           | 8,813           | 6,191          | 6,191          | 6,191          | 6,191          | 8,989           | 2,292         | 2,292         | 2,292         | 2,292         | 9,169         | 9,352          | 9,539          | 9,730          | 9,925          | 10,123         | 10,326         |
| R&D % of Revenue   |                 |                 |                 |                 |                |                |                |                |                 |               |               |               |               |               |                |                |                |                |                |                |
| G&A  | 12,126          | 6,447           | 6,285           | 8,095           | 1,689          | 2,400          | 2,500          | 3,411          | 10,000          | 3,750         | 3,750         | 3,750         | 3,750         | 15,000        | 15,300         | 15,606         | 15,918         | 16,236         | 16,561         | 16,892         |
| SG&A % of Revenue  |                 |                 |                 |                 |                |                |                |                |                 |               |               |               |               |               |                |                |                |                |                |                |
| Stock based comp. G & A                                    | 1,973           | 780             | 715             | 803             | 277            |                |                |                |                 |               |               |               |               |               |                |                |                |                |                |                |
| <b>Total expenses</b>                                      | <b>19,972</b>   | <b>13,789</b>   | <b>15,596</b>   | <b>17,462</b>   | <b>8,156</b>   | <b>8,591</b>   | <b>8,691</b>   | <b>9,603</b>   | <b>35,041</b>   | <b>8,915</b>  | <b>9,040</b>  | <b>9,165</b>  | <b>9,540</b>  | <b>36,661</b> | <b>50,139</b>  | <b>57,644</b>  | <b>65,431</b>  | <b>73,507</b>  | <b>81,882</b>  | <b>97,602</b>  |
| Oper. Inc. (Loss)  | (19,972)        | (13,789)        | (15,596)        | (17,462)        | (8,156)        | (8,591)        | (8,691)        | (9,603)        | (35,041)        | 10,240        | 10,948        | 11,655        | 13,779        | 46,622        | 119,775        | 159,017        | 199,788        | 242,135        | 286,103        | 371,624        |
| Interest Income  | 47              | 818             | 53              | 68              | 13             |                |                |                |                 |               |               |               |               |               |                |                |                |                |                |                |
| Gain (loss) on revaluation of derivative warrant liability |                 | 450             |                 | 110             | (4)            |                |                |                |                 |               |               |               |               |               |                |                |                |                |                |                |
| Interest Expense   |                 | (16)            | (16)            | (16)            |                |                |                |                |                 |               |               |               |               |               |                |                |                |                |                |                |
| <b>Pre-tax income</b>                                      | <b>(20,769)</b> | <b>1,253</b>    | <b>(15,560)</b> | <b>(17,299)</b> | <b>(8,147)</b> | <b>(8,591)</b> | <b>(8,691)</b> | <b>(9,603)</b> | <b>(35,041)</b> | <b>10,240</b> | <b>10,948</b> | <b>11,655</b> | <b>13,779</b> | <b>46,622</b> | <b>119,775</b> | <b>159,017</b> | <b>199,788</b> | <b>242,135</b> | <b>286,103</b> | <b>371,624</b> |
| Income Tax Benefit (Provision)                             | -               | -               | -               | -               | -              | (430)          | (435)          | (480)          | (1,344)         | 1,024         | 1,095         | 1,166         | 1,378         | 4,662         | 17,966         | 31,803         | 49,947         | 72,640         | 100,136        | 141,217        |
| <b>Tax Rate</b>  | <b>0%</b>       | <b>0%</b>       | <b>0%</b>       | <b>0%</b>       | <b>5%</b>      | <b>5%</b>      | <b>5%</b>      | <b>5%</b>      | <b>5%</b>       | <b>10%</b>    | <b>10%</b>    | <b>10%</b>    | <b>10%</b>    | <b>10%</b>    | <b>15%</b>     | <b>20%</b>     | <b>25%</b>     | <b>30%</b>     | <b>35%</b>     | <b>38%</b>     |
| <b>GAAP Net Income (loss)</b>                              | <b>(4,952)</b>  | <b>(12,537)</b> | <b>(15,560)</b> | <b>(17,299)</b> | <b>(8,147)</b> | <b>(8,162)</b> | <b>(8,257)</b> | <b>(9,122)</b> | <b>(33,688)</b> | <b>9,216</b>  | <b>9,853</b>  | <b>10,490</b> | <b>12,401</b> | <b>41,959</b> | <b>101,808</b> | <b>127,214</b> | <b>149,841</b> | <b>169,494</b> | <b>185,967</b> | <b>230,407</b> |
| <b>GAAP-EPS</b>  | <b>(3.55)</b>   | <b>(1.22)</b>   | <b>(0.53)</b>   | <b>(0.46)</b>   | <b>(0.15)</b>  | <b>(0.06)</b>  | <b>(0.06)</b>  | <b>(0.07)</b>  | <b>(0.34)</b>   | <b>0.07</b>   | <b>0.07</b>   | <b>0.08</b>   | <b>0.09</b>   | <b>0.31</b>   | <b>0.72</b>    | <b>0.87</b>    | <b>1.00</b>    | <b>1.10</b>    | <b>1.17</b>    | <b>1.40</b>    |
| Non GAAP EPS (dil)   | (3.55)          | (1.22)          | (0.61)          | (0.46)          | (0.15)         | (0.06)         | (0.06)         | (0.07)         | (0.34)          | 0.07          | 0.07          | 0.08          | 0.09          | 0.31          | 0.72           | 0.87           | 1.00           | 1.10           | 1.17           | 1.40           |
| Wgtd Avg Shrs (Bas) - '000s                                | 5,842           | 10,731          | 20,162          | 39,165          | 55,577         | 106,463        | 106,570        | 106,676        | 93,821          | 106,783       | 106,890       | 106,997       | 107,104       | 106,943       | 107,372        | 107,802        | 108,234        | 108,667        | 109,102        | 109,539        |
| Wgtd Avg Shrs (Dil) - '000s                                | 5,842           | 10,731          | 35,000          | 39,165          | 55,577         | 132,379        | 133,702        | 135,039        | 114,174         | 135,039       | 136,390       | 137,754       | 139,131       | 137,079       | 141,232        | 145,512        | 149,921        | 154,464        | 159,144        | 163,966        |

Source: Dawson James estimates, company reports

## **Risk Analysis**

In addition to the typical risks associated with development stage specialty pharmaceutical companies, potential risks specific to Citius Pharmaceuticals, Inc. are as follows:

**Partnership risk.** Citius Pharmaceuticals, Inc. is in discussions with possible partners today, but there can be no assurances that the company will be able to secure a favorable partnership.

**Commercial risk.** There are no assurances that the company will be able to achieve significant market share and become profitable.

**Clinical and regulatory risk.** Lead products have to complete clinical trials. Trials may not produce results sufficient for regulatory approval.

**Financial risk.** The company may need to raise capital in the marketplace, and there can be no assurances that the company will be able to successfully raise capital and or do so at favorable terms.

**Liquidity Risk.** The stock is thinly traded. We note that management owns a significant percentage of the company.

**Legal and intellectual property risk.** The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and or that the company may infringe on third parties' patents.

Companies mentioned in this report

**Important Disclosures:**

**Price Chart:**



**Price target and rating changes over the past three years:**

Initiation – Buy – 12/15/2017 – Price Target \$10.00  
 Update – Buy – 7/6/2018 – Price Target \$10.00  
 Transfer – Buy – 9/6/2019 – Price Target \$7.00  
 Update – Buy – 10/7/2019 – Price Target \$7.00  
 Update – Buy – 12/19/2019 – Price Target \$7.00  
 Update – Buy – 2/4/2020 – Price Target \$7.00  
 Update – Buy – 2/25/2020 – Price Target \$7.00  
 Update – Buy – 5/26/2020 – Price Target \$7.00  
 Update – Buy – 9/28/2020 – Price Target \$7.00  
 Update – Buy – 9/29/2020 – Price Target \$7.00  
 Update – Buy – 11/30/2020 – Price Target \$7.00  
 Update – Buy – 1/26/2021 – Price Target \$6.00  
 Price Target Change – Buy – 2/18/2021 – Price Target \$8.00  
 Update – Buy – 3/10/2021 – Price Target \$8.00  
 Update – Buy – 5/21/2021 – Price Target \$8.00  
 Update – Buy – 6/9/2021 – Price Target \$8.00  
 Update – Buy – 7/1/2021 – Price Target \$8.00

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- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
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As of: 28-Jun-21

|                             | <b>Company Coverage</b> |                   | <b>Investment Banking</b> |                    |
|-----------------------------|-------------------------|-------------------|---------------------------|--------------------|
| <b>Ratings Distribution</b> | <b># of Companies</b>   | <b>% of Total</b> | <b># of Companies</b>     | <b>% of Totals</b> |
| Market Outperform (Buy)     | 24                      | 71%               | 4                         | 17%                |
| Market Perform (Neutral)    | 10                      | 29%               | 0                         | 0%                 |
| Market Underperform (Sell)  | 0                       | 0%                | 0                         | 0%                 |
| <b>Total</b>                | <b>34</b>               | <b>100%</b>       | <b>4</b>                  | <b>12%</b>         |

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