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Citius Pharmaceuticals (NASDAQ/CTXR)

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BUY: Receives FDA Guidance - Resubmission of LYMPHIR

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Citius announced the company has received additional guidance from the FDA regarding the planned resubmission of the company's Biologics License Application (BLA) for LYMPHIR (denileukin diftitox), an engineered IL-2-diphtheria toxin fusion protein for the treatment of patients with relapsed or refractory cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy. The guidance from the FDA provides Citius with a path for completing to support the resubmission of the company's Biologics License Application (BLA) for denileukin diftitox. No additional clinical efficacy or safety trials have been requested by the FDA for the resubmission.

Investment Highlights

What's the Issue with LYMPHIR? The FDA has requested some additional product testing and CMC product controls. The issues do not require re-tooling and as such likely represent a type I (2-month delay). As stated in the company's press release – "there were no concerns relating to the safety and efficacy clinical data package submitted with the BLA, or the proposed prescribing information".

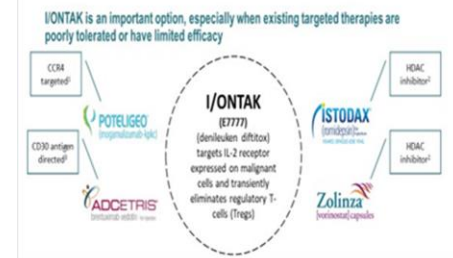
What is it? LYMPHIR is an engineered IL-2-diphtheria toxin fusion protein (denileukin diftitox – E7777) for the treatment of rare forms of cancer. Citius has a purified reformulation of denileukin diftitox, (which is a previously FDA-approved cancer immunotherapy for the treatment of persistent or recurrent cutaneous T-cell lymphoma CTCL), a rare form of non-Hodgkin lymphoma. Improvements to the original formulation resulted in a therapy that maintains the same amino acid sequence but features greater purity and bioactivity.

Background: In 2011 and 2013, the FDA granted orphan drug designation to LYMPHIR for the treatment of PTCL and CTCL, respectively. In 2021, denileukin diftitox received regulatory approval in Japan for the treatment of CTCL and peripheral T-cell lymphoma (PTCL). Subsequently in 2021, Citius acquired an exclusive license with rights to develop and commercialize LYMPHIR in all markets except for Japan and certain parts of Asia.

Valuation. We 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 on top of a 15% risk rate in our therapeutic models for both products. 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 \$0.89
Price Target \$8.00



LIMITATIONS OF EXISTING TARGETED THERAPIES

| | | |
|--|--|----------------|
| Often discontinued due to toxicity / AEs | Limited duration of response / Development of resistance | "non-curative" |
|--|--|----------------|

Source: Citius

| Stock Data | | | |
|---|-------------|---|--------|
| 52-Week Range | \$0.77 | - | \$1.71 |
| Shares Outstanding (mil.) | 158.9 | | |
| Market Capitalization (mil.) | \$141 | | |
| Enterprise Value (mil.) | \$121 | | |
| Debt to Capital | 0% | | |
| Book Value/Share | \$2.63 | | |
| Price/Book | 1.7 | | |
| Average Three Months Trading Volume (K) | 1,195 | | |
| Insider Ownership | 7.7% | | |
| Institutional Ownership | 15.9% | | |
| Short Interest (mil.) | 12.5% | | |
| Dividend / Yield | \$0.00/0.0% | | |



Exhibit 1. Income Statement

| Citius Pharmaceuticals: Income Statement ('000) | | December | | March | | June | | Sept. YE | | | | | | | | | | | |
|--|-----------------|-----------------|-----------------|-----------------|----------------|-----------------|----------------|----------------|-----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| YE Sept. | 2019A | 2020A | 2021A | 2022A | 1Q23A | 2Q23A | 3Q23A | 4Q23E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E | 2029E | 2030E | 2031E | 2032E | 2033E |
| Mino-Lok, U.S. ST & LT CVC Revenues | - | - | - | - | - | - | - | - | - | 105,236 | 214,702 | 328,526 | 446,839 | 569,775 | 581,228 | 592,910 | 604,828 | 616,985 | 629,386 |
| CTCL Revenues | - | - | - | - | - | - | - | - | - | 79,937 | 114,162 | 133,093 | 135,768 | 138,497 | 141,281 | 144,121 | 147,018 | 149,973 | 152,987 |
| | - | - | - | - | - | - | - | - | - | 185,173 | 328,863 | 461,619 | 582,607 | 708,272 | 722,509 | 737,031 | 751,845 | 766,957 | 782,373 |
| Expenses | | | | | | | | | | | | | | | | | | | |
| Cost of goods sold | - | - | - | - | - | - | - | - | - | 27,776 | 49,330 | 69,243 | 87,391 | 106,241 | 108,376 | 110,555 | 112,777 | 115,044 | 117,356 |
| COGS % of Revenue | | | | | 15% | 15% | 15% | 15% | | 15% | 15% | 15% | 15% | 15% | 15% | 15% | 15% | 15% | 15% |
| Research and development | 8,596 | 8,813 | 12,241 | 17,655 | 3,446 | 4,727 | 3,765 | 2,063 | 14,000 | 14,280 | 14,566 | 14,857 | 15,154 | 15,457 | 15,766 | 16,082 | 16,403 | 16,731 | 17,066 |
| R&D % of Revenue | | | | | | | | | | | | | | | | | | | |
| G&A | 6,285 | 8,095 | 9,836 | 11,755 | 2,603 | 4,793 | 3,733 | 860 | 11,990 | 18,000 | 18,000 | 18,000 | 18,000 | 18,000 | 18,000 | 18,000 | 18,000 | 18,000 | 18,000 |
| SG&A % of Revenue | | | | | | | | | | | | | | | | | | | |
| Stock based comp. G & A | 715 | 803 | 1,455 | 3,906 | 1,201 | 1,166 | 1,174 | 1,174 | 1,174 | 1,174 | 1,174 | 1,174 | 1,174 | 1,174 | 1,174 | 1,174 | 1,174 | 1,174 | 1,174 |
| Total expenses | 27,540 | 17,711 | 23,532 | 33,317 | 7,250 | 10,685 | 8,672 | 4,097 | 27,164 | 61,230 | 83,069 | 103,274 | 121,719 | 140,872 | 143,317 | 145,810 | 148,354 | 150,949 | 153,596 |
| Oper. Inc. (Loss) | (27,540) | (17,711) | (23,532) | (33,317) | (7,250) | (10,685) | (8,672) | (4,097) | (27,164) | 123,943 | 245,794 | 358,345 | 460,888 | 567,400 | 579,192 | 591,221 | 603,491 | 616,008 | 628,777 |
| Interest Income | 53 | 68 | 262 | 251 | 215 | 303 | 337 | 337 | 337 | 337 | 337 | 337 | 337 | 337 | 337 | 337 | 337 | 337 | 337 |
| Gain (loss) on revaluation of derivative warrant liability | | 110 | 216 | | 3,586 | | | | | | | | | | | | | | |
| Interest Expense | (16) | (16) | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Pre-tax income | (27,503) | (17,548) | (23,055) | (33,641) | (3,450) | (10,382) | (8,335) | (3,761) | (26,827) | 124,280 | 246,131 | 358,682 | 461,225 | 567,737 | 579,529 | 591,557 | 603,828 | 616,345 | 629,114 |
| Pretax Margin | | | | | | | | | | | | | | | | | | | |
| Income Tax Benefit (Provision- Warrant) | - | - | 1,451 | - | 144 | 144 | 144 | - | - | 12,177 | 36,543 | 71,234 | 114,678 | 169,568 | 173,105 | 176,714 | 180,395 | 184,150 | 187,981 |
| Income Tax Expense | | | | | | | | | | | | | | | | | | | |
| Tax Rate | 0% | 0% | 5% | | 0% | 0% | 0% | 0% | 0% | 10% | 15% | 20% | 25% | 30% | 30% | 30% | 30% | 30% | 30% |
| GAAP Net Income (loss) | (27,474) | (30,976) | (42,834) | (33,641) | (3,594) | (10,526) | (8,479) | (3,761) | (26,827) | 112,103 | 209,588 | 287,448 | 346,546 | 398,170 | 406,424 | 414,844 | 423,433 | 432,195 | 441,133 |
| GAAP-EPS | (1.39) | (0.84) | (0.46) | (0.23) | (0.02) | (0.07) | (0.05) | (0.02) | (0.16) | 0.73 | 1.11 | 1.39 | 1.57 | 1.72 | 1.70 | 1.68 | 1.66 | 1.64 | 1.62 |
| Non GAAP EPS (dil) | (1.39) | (0.84) | (0.23) | (0.23) | (0.02) | (0.06) | (0.05) | (0.02) | (0.16) | 0.73 | 1.11 | 1.39 | 1.57 | 1.72 | 1.70 | 1.68 | 1.66 | 1.64 | 1.62 |
| Wgtd Avg Shrs (Bas) - '000s | 20,162 | 36,071 | 108,599 | 146,066 | 146,211 | 146,252 | 153,775 | 153,929 | 150,042 | 154,314 | 154,933 | 155,553 | 156,176 | 156,802 | 157,430 | 158,061 | 158,694 | 159,330 | 159,968 |
| Wgtd Avg Shrs (Dil) - '000s | | | | 146,067 | 146,211 | 172,673 | 174,400 | 176,144 | 167,357 | 178,804 | 184,222 | 189,804 | 195,555 | 201,481 | 207,586 | 213,876 | 220,356 | 227,033 | 233,913 |

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.

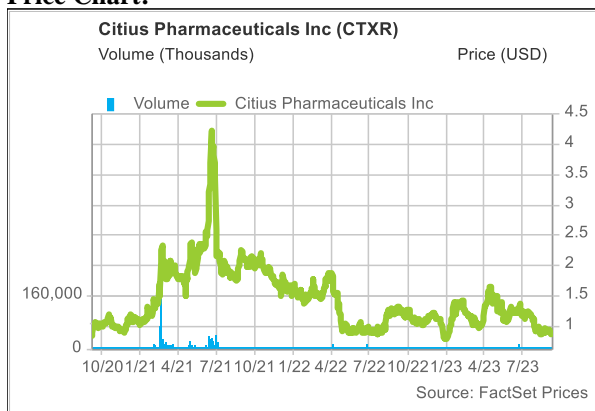
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the Company.

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:

- 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
- Price Target Change – Buy – 9/9/2021 – Price Target \$10.00
- Update – Buy – 12/6/2021 – Price Target \$10.00
- Update – Buy – 2/11/2022 – Price Target \$10.00

Update – Buy – 2/15/2022 – Price Target \$10.00
Update – Buy – 4/6/2022 – Price Target \$10.00
Update – Buy – 4/18/2022 – Price Target \$10.00
Update – Buy – 4/26/2022 – Price Target \$10.00
Update – Buy – 5/5/2022 – Price Target \$10.00
Update – Buy – 5/13/2022 – Price Target \$10.00
Update – Buy – 5/25/2022 – Price Target \$10.00
Update – Buy – 7/12/2022 – Price Target \$10.00
Update – Buy – 8/15/2022 – Price Target \$10.00
Update – Buy – 9/28/2022 – Price Target \$10.00
Update – Buy – 12/6/2022 – Price Target \$10.00
Update – Buy – 12/23/2022 – Price Target \$10.00
Update – Buy – 2/14/2023 – Price Target \$10.00
Update – Buy – 3/31/2023 – Price Target \$10.00
Update – Buy – 4/25/2023 – Price Target \$10.00
Update – Buy – 5/4/2023 – Price Target Change \$10.00 to \$8.00
Update – Buy – 5/18/2023 – Price Target \$8.00
Update – Buy – 6/21/2023 – Price Target \$8.00
Update – Buy – 7/31/2023 – Price Target \$8.00
Update – Buy – 8/15/2023 – Price Target \$8.00
Update – Buy – 9/11/2023 – Price Target \$8.00

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- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18

- months;
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Current as of 22-Aug-23

| | Company Coverage | | Investment Banking | |
|----------------------------|------------------|------------|--------------------|-------------|
| Ratings Distribution | # of Companies | % of Total | # of Companies | % of Totals |
| Market Outperform (Buy) | 23 | 65.70% | 3 | 8.60% |
| Market Perform (Neutral) | 12 | 34.30% | 3 | 8.60% |
| Market Underperform (Sell) | 0 | 0% | 0 | 0.00% |
| Total | 35 | 100% | 6 | 17.20% |

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