

Citius Pharmaceuticals (NASDAQ/CTXR)

September 29, 2020

BUY: DMC Says, "It's All Good," Enrollment Continues

Citius announced that a Data Monitoring Committee (DMC) meeting was held to review the data being generated and analyzed in the Mino-Lok Phase 3 trial. After reviewing these data, the DMC members stated that they did not find any safety signals; and they also recommended continuing the trial without any modifications. The DMC further requested to have an ad hoc meeting in the near future, which we believe could happen early next year. In fact, we could see top-line data confirming Mino-Lok's efficacy in early 1H21. Stay tuned as Mino-Lok progresses towards the clinical finish line, which we view as critical but lower risk than is typical, with a pivotal trial.

Investment Highlights

Back in October 2019, Citius announced that the first interim analysis point (37 catheter failures, which represents 40% of the anticipated events at ~58 patients) had been reached. The DSMB has reviewed the data and, as we expected, advised that the trial continues, unchanged. We view the DSMB's update as positive. It tells us that the trial has been properly powered. The DSMB could have recommended increasing the trial (add statistical power to see the signal with a p-value). Recall that the trial is designed with 80% power for an assumed 17-day difference between active and standard of care (SOC). We typically expect the SOC arm to fail in 5-14 days.

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 Harmonisation 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.

Trial Background. As a reminder, the current Phase 3 trial being conducted compares Mino-Lok therapy (MLT) to the standard of care, which is antibiotic lock therapy (ALT). This is used to disinfect colonized catheters causing bacteremia and keep the treated catheters functioning and infection-free for eight weeks post-therapy. The current primary endpoint in the study is planned to demonstrate a significant difference in the time to catheter failure when comparing MLT to ALT. This is clinically important because eliminating the source of infection enables antibiotic treatment of the bacteremia to work more effectively and expeditiously. Additionally, if a catheter can be maintained for the time that it is needed, the patient does not need to be subjected to the procedures for removing and replacing the catheter that are associated with some serious adverse events.

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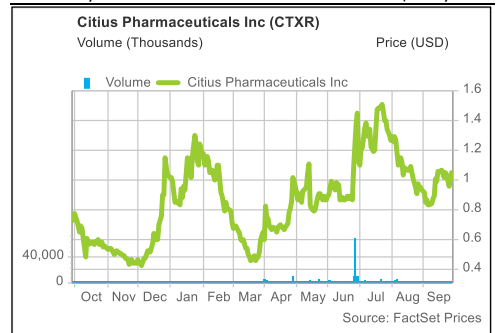
Current Price \$1.01
 Price Target \$ 7.00

| Estimates | F2019A | F2020E | F2021E |
|--------------------------|-----------|-----------|-----------|
| Expenses (\$000s) | \$ 15,596 | \$ 24,334 | \$ 39,190 |
| 1Q December | \$ 3,872 | \$ 4,448 | \$ 9,192 |
| 2Q March | \$ 3,642 | \$ 4,433 | \$ 9,495 |
| 3Q June | \$ 4,427 | \$ 4,689 | \$ 9,797 |
| 4Q September | \$ 3,655 | \$ 10,764 | \$ 10,705 |

| | F2019A | F2020E | F2021E |
|--------------|-----------|-----------|---------|
| EPS | \$ (0.53) | \$ (0.62) | \$ 0.85 |
| 1Q December | \$ (0.21) | \$ (0.15) | \$ 0.20 |
| 2Q March | \$ (0.09) | \$ (0.13) | \$ 0.20 |
| 3Q June | \$ (0.13) | \$ (0.11) | \$ 0.21 |
| 4Q September | \$ (0.10) | \$ (0.23) | \$ 0.24 |

EBITDA/Share
 EV/EBITDA (x)

| Stock Data | | |
|---|-------------|--------|
| 52-Week Range | \$0.40 | \$1.97 |
| Shares Outstanding (mil.) | 55.5 | |
| Market Capitalization (mil.) | \$56 | |
| Enterprise Value (mil.) | \$37 | |
| Debt to Capital | 0% | |
| Book Value/Share | \$2.63 | |
| Price/Book | 0.9 | |
| Average Three Months Trading Volume (K) | 68,256 | |
| Insider Ownership | 25.0% | |
| Institutional Ownership | 1.7% | |
| Short interest (mil.) | 1.3% | |
| Dividend / Yield | \$0.00/0.0% | |



Valuation. Our valuation is based on our therapeutic models and associated assumptions projected to 2028. Our model assumes multiple financial raises, and as such, our share count is based on a fully diluted out year basis. 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 \$7.00 price target.

Exhibit 1. FCFF Model

| | | |
|--------------|----|------|
| | \$ | 7.00 |
| Price Target | \$ | 8.00 |
| Year | | 2020 |

DCF Valuation Using FCF (min):

| units ('000 - Cnd\$) | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E |
|-------------------------------------|----------|----------|--------|---------|---------|---------|---------|---------|---------|---------|
| EBIT (Earnings before income tax) | (15,560) | (22,768) | 42,452 | 107,459 | 145,729 | 185,494 | 226,799 | 269,689 | 314,212 | 360,415 |
| Tax Rate | 0% | 0% | 5% | 10% | 15% | 20% | 25% | 30% | 35% | 38% |
| EBIT(1-t) Earnings after income tax | (15,560) | (22,768) | 40,330 | 96,713 | 123,870 | 148,395 | 170,099 | 188,782 | 204,238 | 223,458 |
| CapEx (equipment) | - | (2) | - | - | - | - | - | - | - | - |
| Depreciation | - | 429 | - | - | - | - | - | - | - | - |
| Change in NWC | - | - | - | - | - | - | - | - | - | - |
| FCF | (15,560) | (22,341) | 40,330 | 96,713 | 123,870 | 148,395 | 170,099 | 188,782 | 204,238 | 223,458 |
| PV of FCF | (20,228) | (22,341) | 31,023 | 57,227 | 56,381 | 51,957 | 45,813 | 39,111 | 32,549 | 27,394 |
| Discount Rate | 30% | | | | | | | | | |
| Long Term Growth Rate | 1% | | | | | | | | | |
| Terminal Cash Flow | 778,249 | | | | | | | | | |
| Terminal Value YE2023 | 95,405 | | | | | | | | | |
| NPV | 394,290 | | | | | | | | | |
| NPV-Debt | - | | | | | | | | | |
| Shares out ('000) | 48,739 | 2028E | | | | | | | | |
| NPV Per Share | \$ | 8.09 | | | | | | | | |

Source: Dawson James estimates

Exhibit 2. Discounted EPS Model

| | |
|-------------------|---------|
| Current Year | 2020 |
| Year of EPS | 2028 |
| Earnings Multiple | 15 |
| Discount Factor | 30% |
| Selected Year EPS | \$ 4.58 |
| NPV | \$ 8.42 |

| Discount Rate and Earnings Multiple Varies, Year is Constant | | | | | | | |
|--|------|----------|---------|---------|---------|---------|----------|
| Earnings Multiple | 8.42 | 2028 EPS | | | | | |
| | | 5% | 10% | 15% | 20% | 25% | 30% |
| 5 | | \$15.50 | \$10.69 | \$7.49 | \$5.33 | \$3.84 | \$ 2.81 |
| 10 | | \$31.01 | \$21.37 | \$14.98 | \$10.65 | \$7.69 | \$ 5.62 |
| 15 | | \$46.51 | \$32.06 | \$22.46 | \$15.98 | \$11.53 | \$ 8.42 |
| 20 | | \$62.02 | \$42.74 | \$29.95 | \$21.31 | \$15.37 | \$ 11.23 |
| 25 | | \$77.52 | \$53.43 | \$37.44 | \$26.64 | \$19.22 | \$ 14.04 |
| 30 | | \$93.02 | \$64.12 | \$44.93 | \$31.96 | \$23.06 | \$ 16.85 |
| 35 | | \$108.53 | \$74.80 | \$52.42 | \$37.29 | \$26.90 | \$ 19.66 |
| 40 | | \$124.03 | \$85.49 | \$59.91 | \$42.62 | \$30.74 | \$ 22.46 |

Source: Dawson James estimates

Exhibit 3. Sum of the Parts Model

| | LT Gr | Discount Rate | Yrs. to Peak | % Success | Peak Sales MMs | Term Val |
|---------------------------|-------|---------------|--------------|-----------|----------------|----------|
| MiniLok LT & ST CVC U.S. | 1% | 30% | 4 | 70% | \$469 | \$1,618 |
| | | | | | | \$5.70 |
| MiniLok LT & ST CVC E.U. | 1% | 30% | 6 | 80% | \$0 | \$0 |
| | | | | | | \$0.00 |
| MiniLok LT & ST CVC China | 1% | 30% | 7 | 80% | \$0 | \$0 |
| | | | | | | \$0.00 |
| Hydro-Lido | 1% | 30% | 5 | 0% | \$0 | \$0 |
| Pre-Clinical Pipeline | | | | | | \$0.00 |
| Net Margin | | | | | | 70% |
| MM Shrs OS | | | | | | 49 |
| Total | | | | | | \$5.70 |

Source: Dawson James estimates

Exhibit 4. Income Statement

| Citius Pharmaceuticals: Income Statement (\$'000) | | | | | | | | | | December | March | June | Sept. YE | | | | | | | |
|--|-----------------|-----------------|-----------------|----------------|----------------|----------------|-----------------|-----------------|---------------|---------------|---------------|---------------|---------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| YE Sept. | 2017A | 2018A | 2019A | 1Q20A | 2Q20A | 3Q20A | 4Q20E | 2020E | 2021E | 2021E | 3Q21E | 4Q21E | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E |
| Mno-Lok, U.S. ST & LT CVC Revenues | | | - | - | - | - | - | - | 18,778 | 19,594 | 20,410 | 22,860 | 81,642 | 166,566 | 212,392 | 259,994 | 309,423 | 360,734 | 413,983 | 469,227 |
| Mno-Lok, E.U. ST & LT CVC Revenues | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Mno-Lok, CHina ST & LT CVC Revenues | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Expenses | | | | | | | | | 18,778 | 19,594 | 20,410 | 22,860 | 81,642 | 166,566 | 212,392 | 259,994 | 309,423 | 360,734 | 413,983 | 469,227 |
| Cost of goods sold | | - | - | - | - | - | - | - | 2,817 | 2,939 | 3,062 | 3,429 | 12,246 | 24,985 | 31,859 | 38,999 | 46,413 | 54,110 | 62,097 | 70,384 |
| COGS % of Revenue | | | | 15% | 15% | 15% | 15% | | 15% | 15% | 15% | 15% | 15% | 15% | 15% | 15% | 15% | 15% | 15% | 15% |
| Research and development | 5,873 | 6,563 | 8,596 | 2,665 | 2,016 | 2,644 | 2,455 | 8,768 | 2,236 | 2,236 | 2,236 | 2,236 | 8,943 | 9,122 | 9,305 | 9,491 | 9,680 | 9,874 | 10,072 | 10,273 |
| R&D % of Revenue | | | | | | | | | | | | | | | | | | | | |
| G&A | 12,126 | 6,447 | 6,285 | 1,563 | 2,258 | 1,870 | 8,309 | 14,000 | 4,140 | 4,320 | 4,500 | 5,040 | 18,000 | 25,000 | 25,500 | 26,010 | 26,530 | 27,061 | 27,602 | 28,154 |
| SG&A % of Revenue | | | | | | | | | | | | | | | | | | | | |
| Stock based comp. G & A | 1,973 | 780 | 715 | 220 | 159 | 175 | | | | | | | | | | | | | | |
| Total expenses | 19,972 | 13,789 | 15,596 | 4,448 | 4,433 | 4,689 | 10,764 | 22,768 | 9,192 | 9,495 | 9,797 | 10,705 | 39,190 | 59,107 | 66,663 | 74,500 | 82,624 | 91,045 | 99,771 | 108,811 |
| Oper. Inc. (Loss) | (19,972) | (13,789) | (15,596) | (4,448) | (4,433) | (4,689) | (10,764) | (22,768) | 9,585 | 10,099 | 10,613 | 12,155 | 42,452 | 107,459 | 145,729 | 185,494 | 226,799 | 269,689 | 314,212 | 360,415 |
| Interest Income | 47 | 818 | 53 | 110 | 12 | 13 | | | | | | | | | | | | | | |
| Gain (loss) on revaluation of derivative warrant liability | | 450 | 19 | | | | | | | | | | | | | | | | | |
| Interest Expense | | (16) | (16) | (4) | (4) | (4) | | | | | | | | | | | | | | |
| Pre-tax income | (20,769) | 1,253 | (15,560) | (4,323) | (4,425) | (4,680) | (10,764) | (22,768) | 9,585 | 10,099 | 10,613 | 12,155 | 42,452 | 107,459 | 145,729 | 185,494 | 226,799 | 269,689 | 314,212 | 360,415 |
| Income Tax Benefit (Provision) | - | - | - | - | - | - | - | - | 479 | 505 | 531 | 608 | 2,123 | 10,746 | 21,859 | 37,099 | 56,700 | 80,907 | 109,974 | 136,958 |
| Tax Rate | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 5% | 5% | 5% | 5% | 5% | 10% | 15% | 20% | 25% | 30% | 35% | 38% |
| GAAP Net Income (loss) | (4,952) | (12,537) | (15,560) | (4,323) | (4,425) | (4,680) | (10,764) | (24,192) | 9,106 | 9,594 | 10,082 | 11,547 | 40,330 | 96,713 | 123,870 | 148,395 | 170,099 | 188,782 | 204,238 | 223,458 |
| GAAP-EPS | (3.55) | (1.22) | (0.53) | (0.15) | (0.13) | (0.11) | (0.23) | (0.62) | 0.20 | 0.20 | 0.21 | 0.24 | 0.85 | 2.03 | 2.59 | 3.09 | 3.53 | 3.90 | 4.20 | 4.58 |
| Non GAAP EPS (dil) | (3.55) | (1.22) | (0.61) | (0.11) | (0.13) | (0.11) | (0.23) | (0.58) | 0.20 | 0.20 | 0.21 | 0.24 | 0.85 | 2.03 | 2.59 | 3.09 | 3.53 | 3.90 | 4.20 | 4.58 |
| Wgtd Avg Shrs (Bas) - '000s | 5,842 | 10,731 | 20,162 | 29,197 | 34,319 | 41,600 | 46,642 | 37,940 | 46,689 | 46,735 | 46,782 | 46,829 | 46,759 | 46,946 | 47,134 | 47,323 | 47,513 | 47,703 | 47,894 | 48,086 |
| Wgtd Avg Shrs (Dil) - '000s | 5,842 | 10,731 | 35,000 | 39,197 | 34,319 | 41,600 | 47,016 | 40,533 | 46,689 | 47,156 | 47,627 | 48,103 | 47,394 | 47,584 | 47,774 | 47,966 | 48,158 | 48,351 | 48,544 | 48,739 |

Source: Dawson James, 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.

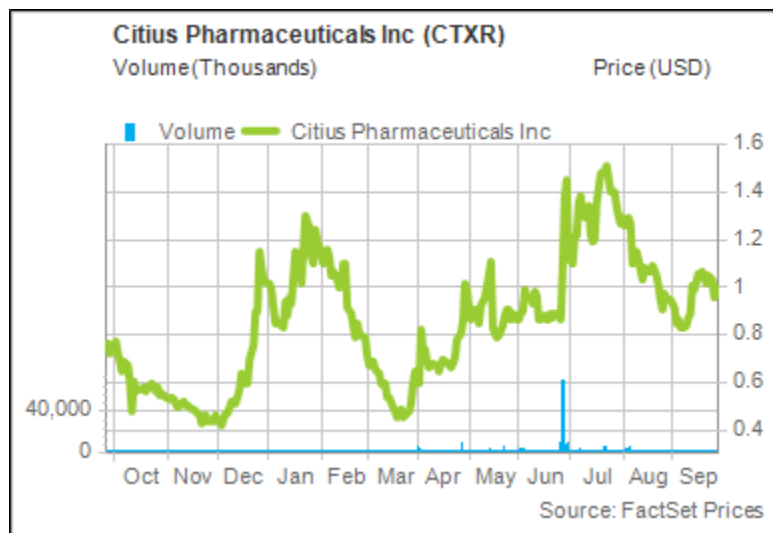
Liquidity Risk. The stock is thinly traded. We note that management owns a significant percentage of the company.

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

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- 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.

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| Ratings Distribution | Company Coverage | | Investment Banking | |
|----------------------------|------------------|-------------|--------------------|-------------|
| | # of Companies | % of Total | # of Companies | % of Totals |
| Market Outperform (Buy) | 23 | 85% | 4 | 17% |
| Market Perform (Neutral) | 4 | 15% | 1 | 25% |
| Market Underperform (Sell) | 0 | 0% | 0 | 0% |
| Total | 27 | 100% | 5 | 19% |

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