

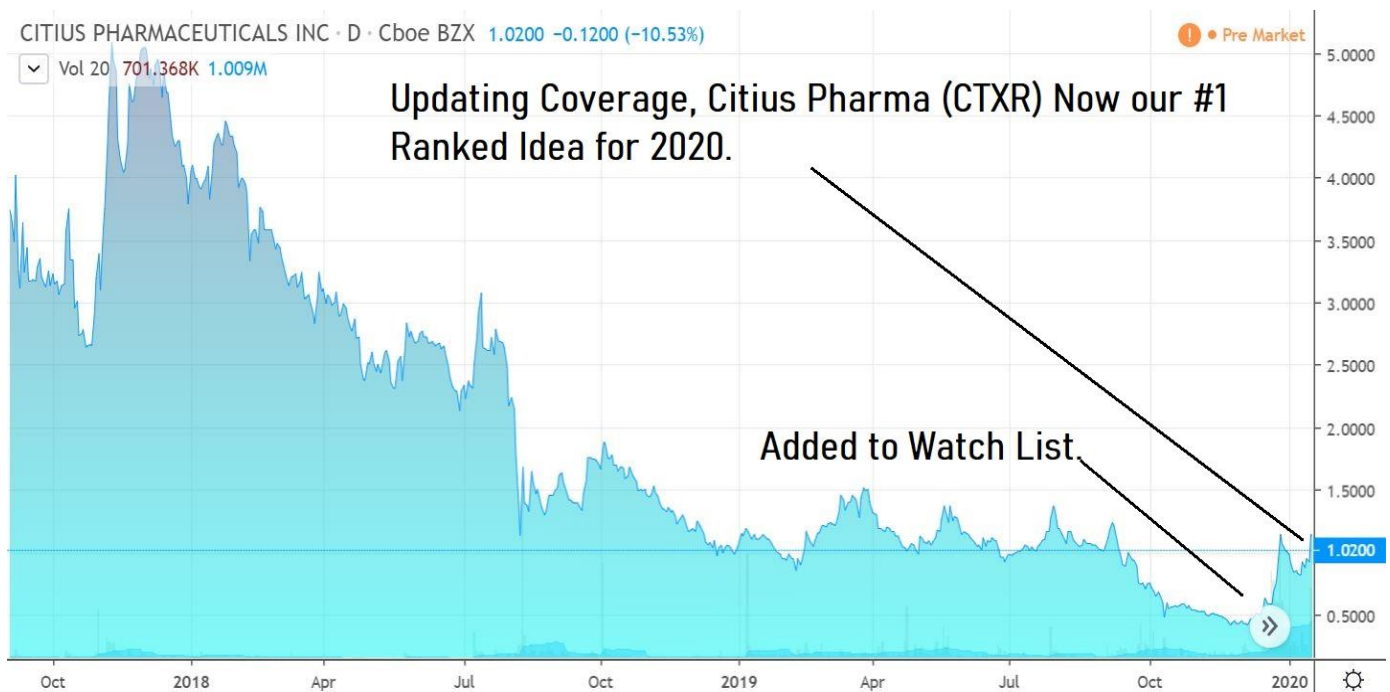
BiotechStockReview

LOS ANGELES - CHICAGO – NEW YORK – DELRAY BEACH

Biotech – Health Technology - Medical Devices – Medical Networks – Pharma - Stem Cells

Citius Pharma (NASDAQ: CTXR) \$1.02

Saving Lives of Hospital Patients with Catheters Infected by Deadly Bacteria



Lancet Medical Journal Reports 11 Million Deaths Globally, from 49 Million Cases of Sepsis in 2017.

What is Sepsis? Sepsis is often confused with being a bacteria or an antibiotic resistant bacteria like *Candida Auris*. Sepsis is not a bacterium, but rather it can occur when a person's immune system **overreacts** to an infection, which can be caused by bacteria potentially causing organ failure and death.

As anyone can get an infection – anyone – you or a loved one, can also get Sepsis. However, some of those most at risk to Sepsis are individuals with weakened immune systems and/or individuals who are hospitalized. Those hospitalized for cancer and/or undergoing dialysis face yet an even higher risk, because they are often on catheters and the **catheter itself can become infected**. A serious situation indeed.

This is where the Citius novel treatment '**Mino-Lok**' comes into the picture. Created to kill infected catheters, Mino-Lok was developed by clinicians and technologists at the **M.D. Anderson Cancer Center**.

CITIUS, A MASSIVE YET EASY TO UNDERSTAND OPPORTUNITY

Citius Pharmaceuticals (CTXR) is hands down one of the most exciting long-term opportunities we have come across since we first launched the Biotech Stock Review in 2002.

The Mini-Lok technology while complex is easy for investors to understand. Their market is huge, estimated at \$500 million to \$1 billion annually, and fairly-easy for investors to identify. The need for Mino-Lok is rather obvious as we will later explain. Also, studies to date have proven it to be much safer, more effective and less expensive than the alternatives and once again, easy for investors to grasp.

Finally, the time (they're in Phase III), path and cost to approval are modest in comparison to Biotech companies creating drugs from scratch. A 'five-fecta' so to speak.

In sum, Citius has pretty much everything we look for in a Biotech idea including (if not most importantly) a tiny market valuation with only 31 million shares outstanding, plus top-rated management with decades of proven success. Enough success to enable them to invest more than \$27 million of their own money into Citius. Make that a 'seven-fecta.' This is an opportunity not to be ignored.

While long-term subscribers are quite aware, we are not a 'trading' firm trying to ferret out short term gains in the ideas we present – we'd liked to emphasize the opportunity here is extraordinarily large. So large that we would urge shorter term investors who might find themselves with gains exceeding 100% currently or soon, to be cautious and patient about selling too early.

Principal Insider and Former Insider Shareholders ⁽¹⁾ (98 Holders of Record)	
Leonard Mazur	(47.4%)
Myron Holubiak	(11.3%)
Reinier Beeuwkes, PhD	(2.1%)
Geoffrey Clark	(2.1%)

In companies this small, with such a large insider ownership stake (60%), significant news in 2020 or 2021 could spur the shares far beyond what current fundamentals might normally warrant.

The Citius story is such an **easy to understand** story for investors, there could be a massive rush to buy shares upon news of an FDA approval (of course unassured) leaving many early investors wondering "why did they ever sell" after any near-term news related price spikes.

See our report ["Biotech 5 Pack. 5 Biotech's We Expect to Double in 2020"](#) to understand the issue of selling too early.

In the coming year or years, we will closely report on the progress that Citius is having in advancing the science and dealing with the capital markets to fund that progress. We anticipate reporting through both thick and thin, as they journey through the FDA approval process.

This is a **short report** to be followed by a more detailed report. Officially we added Citius to the Watch List in November at \$0.55 a share after hearing management present at an Investor Conference in South Florida hosted by Dawson James. They explained the opportunity so well, we signed them as a client. We would not be surprised to see gains that could exceed ten-fold, after approval of commercialization.

MINO-LOK

- WHAT IS MINO-LOK?
- HOW DOES MINO-LOK WORK?
- HOW LARGE IS MINO-LOK'S ADRESSABLE MARKET?
- WHERE IS MINO-LOK IN THE PROCESS OF FDA APPROVAL?
- SUMMARY

WHAT IS MINO-LOK?

Part of the Citius business strategy is to build a successful company by developing and commercializing *cost-effective* products that address unmet medical needs. It seeks to leverage the [FDA's 505\(b\)\(2\)](#) pathway for new drug approvals and bring products to market *faster and with lower cost* than other FDA new drug approval pathways (meaning creating drugs from scratch).

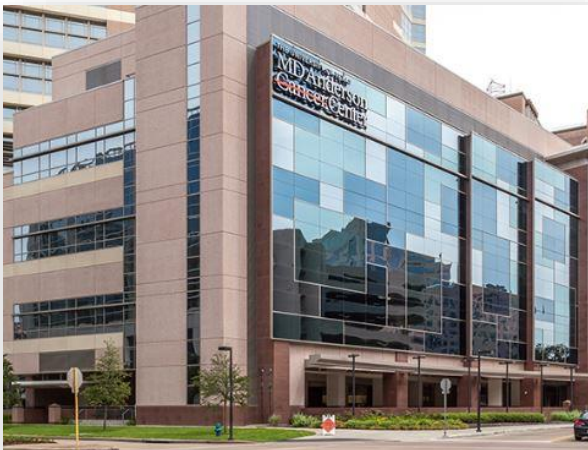
The folks running Citius are genius at finding these types of drugs – as they've been there, done that.

The Mino-Lok solution was created to kill bacteria **that cannot be eradicated** using current methods, resulting in the catheter needing to be removed and replaced. A dangerous and complicated procedure, Mino-Lok is the first – and only – therapy under investigation that can be used to sterilize and save the infected catheter.

Mino-Lok is a patented solution that **combines [Minocycline](#)**, an antibiotic from the Tetracycline family with two other well-known ingredients. Minocycline was patented around the time we were born, as in 60 years ago – and prescribed 2 million times last year. It's now a generic costing about \$12 a dose. The list of use includes things like Anthrax and even the Bubonic Plague. So were guessing the FDA will recognize both its usefulness *and* safety profile.

It also includes Disodium Ethylenediaminetetraacetic Acid, also called [Edetate](#) or EDTA. That's been around since 1935. The uses are so broad we'll simply refer to the link for more information and note that the safety profile is such that it can be used in soft drinks and cosmetics, as the FDA will no doubt also later note. Dentists can use it to **loosen calcifications** in root canals (there's a new use discovery hint) and it has been used as a slime dispersant effective in **reducing bacterial growth** during implantation of intraocular lenses (more hints).

Finally, there is [Ethyl Alcohol](#) also known as ethanol. That's been around since before they built the Great Wall of China and probably even cheaper to procure than Minocycline and EDTA.



In the end, some very bright minds at [MD Anderson Cancer Center](#) experimented with synergistically combining these ingredients to come up with Mino-Lok. Pure genius, if approved!

MD Anderson Cancer Center was the number-one ranked cancer hospital in America in last year's annual ratings from US News & World Report. The Houston specialty hospital has been ranked first in 15 of the 18 years that the cancer-specific ratings have been conducted.

The stated mission of The MD Anderson Cancer Center is to eliminate cancer in Texas, the nation, and the world. They are saving lives every day and with their help, the Citius goal is to help save even more lives. Issam Raad, M.D., Chairman of MD Anderson's Dept of Infectious Diseases proudly sits on the Citius Scientific Advisory Board.

Which leads us to the next obvious question, how does the solution work?

HOW DOES MINO-LOK WORK?

There is a huge problem out there that can cause sleepless nights for all individuals on catheters. They can get infected.

The catheters we are talking about are called **Central Venous** (as in vein) **Catheters** (CVC's).

Often when a patient needs medicine, they're of course prescribed pill form medication. But at other times the Doctor may need to give drugs or fluids that go right into one of the veins.

If it's only needed it for a few days, like when healing from surgery, a patient will likely get a regular intravenous tube (IV). It's thin and about an inch long and goes into the arm or hand. But if care is needed for longer than that, a CVC may be recommended.

A CVC is also a thin tube, but it's much longer than a regular IV. It typically goes into a large vein in the arm or chest. The key with CVCs is that they can stay in for weeks or even years, depending on the type. This can make long-term treatment a lot easier. Getting needles or a regular IV over and over can damage veins. Plus, constantly getting stuck with needles can take a toll on the patient. A CVC helps avoid those problems.

But one problem solved can mean the arrival of a new set of problems. Having a catheter for years ups the chances of it getting infected. CVC's are often needed for patients needing lots of blood tests, getting chemotherapy, kidney dialysis or long-term antibiotics for an infection. Most long-term CVC users have compromised immune systems and the last thing they need is to be fighting some bacterial infection, that can take down the healthiest.

Technically catheter infections that can happen at home or at the hospital or anywhere, are called **CRBSI's** or catheter-related **bloodstream** infections. And it's just as scary as it sounds.

While we earlier stated Mino-Lok was created to kill infected catheters, in reality, it was created to kill the bacteria in the catheter.



Today, two things can happen when a catheter gets infected, in addition to red lights flashing in the ICU and all hands-on deck. One is to kill the bacteria in the catheter with cleaning and antibiotics. The second is to take out the catheter and replace it - if the bacteria can't be killed.

Note it takes surgery to remove a catheter and surgery to reinsert it. We don't have to get into the gory details, other than to say is the last thing a patient with a compromised immune system wants to undergo is having their catheter replaced. As the picture to the left depicts - uncomplicated, is not the definition of placement or removal.

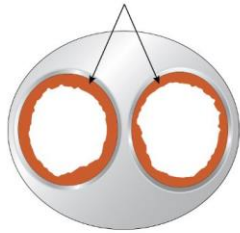
And it's particularly difficult for children and the elderly.

MINI-LOK SOLUTION: The reason why some bacteria can't be killed isn't necessarily that it is an antibiotic resistant bacteria, but rather that once in a catheter, some bacteria actually **form a hard biofilm** on the surface of the catheter, that is resistant to most antimicrobial solutions.

This is where Mino-Lok can prove to be a live saving solution for hundreds of thousands.



Before
Biofilm accumulation
[Bacterial growth environment]



After use of Mino-Lok



Mino-Lok **breaks down biofilm barriers** formed by bacterial colonies, eradicates the bacteria, and provides anti-clotting properties. It works by filling the catheter with the Mino-Lok solution for two hours while the catheter is not in use. That's two hours a day, typically for five days. After the catheter is treated, the Mino-Lok solution is aspirated and flushed with normal saline each time.

Clinical studies to date have shown little or no Minocycline or EDAT leaked into the patient's blood. The studies also showed that microbiological eradication was achieved **in all cases**. As in 100%. None of the patients experienced any serious adverse events (SAE) related to the Mino-Lok therapy compared to 18% of patients having the catheter replaced reporting SAE's.

Problems occurring from the replacement of a catheter can include arterial puncture, hematoma, hemothorax, pneumothorax, arterial-venous fistula, venous air embolism, nerve injury, thoracic duct injury, intraluminal dissection, and puncture of the aorta.

Add to that, the actual surgery which can cost \$10,000 - with complications bumping the number to \$45,000 to \$65,000 as well as increasing the potential for lawsuits. If Mino-Lok is available as a standard of care, a patient attorney would clearly be motivated to ask if Mini-Lok could have been used. As well as ask if it could have prevented any of their clients from suffering catheter replacement and any related SAE's or death from complications.

The need for Mino-Lok which we mentioned earlier, which prevents the need to replacing the catheter is quite clear.

HOW LARGE IS MINO-LOK'S ADRESSABLE MARKET?

If a few hundred, a few thousand or even 10,000 catheters were infected each year– we wouldn't be writing this report. But the reality is the *annual* numbers are nothing short of staggering.

And it's not that the catheter getting infected can be blamed on poor hospital or hospital staff technique or hygiene. Bacteria a living organism that is just simply getting nastier and cleverer every year. Candida Auris, for example, is spreading in hospitals worldwide and causing something of a panic in New York hospitals and nursing homes where 801 patients were recently infected.

The CDC recently called Candida Auris a serious global health threat and that it is often multidrug-resistant, meaning that it is resistant to multiple antifungal drugs commonly used to treat Candida infections. Some strains are resistant to all three available classes of antifungals. While no Citius trial patients have encountered C. Auris to date, [Citius reported](#) last summer that complete eradication C. Auris occurred within an hour of exposure to the Mino-Lok solution *in vitro*.

So, here are the numbers:

Of the 7,000,000 CVCs used annually in the US, up to **472,000 become infected** leading to serious, life threatening infections. These infections are associated with 12-25% mortality and morbidity. Management believes a similar if not larger numbers of infections occur worldwide.

This led to one Wall Street analyst estimating the market for Mino-Lok, if it became the standard of care, of between \$500 million (250,000 CRBSI's) and \$1 billion (500,000 CRBSI's). This suggests per treatment revenues in the hundreds of dollars per day or \$2,000 for 7 days, 5 days in-patient and 2 days out-patient. Quite reasonable when compared to the risk of catheter replacement.

Management has publicly stated the market potential for an effective antibiotic lock therapy is estimated at \$750 million per year in the U.S. and approximately \$1.5 billion per year worldwide.

Versus a \$30 million market valuation – which explains our enthusiasm for Citius’s potential.

WHERE IS MINO-LOK IN THE PROCESS OF FDA APPROVAL?

On September 4th Citius released extremely positive FDA related news. The company released news that the FDA agreed to changes in its Phase III trial that would result in fewer than 150 total subjects. These changes would enable Citius to realize clinical trial cost savings approaching \$10 million.

On December 19th Citius announced a positive outcome of the pre-specified interim analysis for the Phase III clinical trial of Mino-Lok. The Company stated it reached and completed the prespecified 40% enrollment required for the interim analysis in late September and, based on the analysis of the data and recommendations of an independent panel of experts charged with periodically monitoring the safety and efficacy, will proceed with the current trial as planned.

Citius additionally stated Topline data from the superior efficacy interim analysis, the next major milestone in the Mino-Lok trial, is expected in the **first half of 2020**. Myron Holubiak, the Chief Executive Officer of Citius stated, "We would also like to thank all of the patients, study investigators, and support personnel at the 32 clinical sites that are participating in our trial. Lastly, we also want to acknowledge the research and guidance of Dr. Issam Raad and his team at MD Anderson Cancer Center in advancing this novel therapy.

Program	Market (Worldwide)	Preclinical	Phase I	Phase II	Phase III
Mino-Lok® Treat CVC Infections	> \$1.5B	Next milestone: 75% superiority interim analysis (Mar 2020)			
CITI-002 (Halo-Lido) Rx Therapy for Hemorrhoids	> \$2B	Next milestone: Phase 2B Initiated (Q3 2020)			
CITI-101 (Mino-Wrap) Prevent Infections Associated with Breast Implants	~ \$400M	Pre-IND c FDA			

SUMMARY

By all counts, this looks like a lift-off year for Citius Pharma (CTXR).

Biotech companies can make significant price moves 2-3 years prior to Phase III trials. When we are fortunate enough to find one in Phase III, with a market valuation under \$100 million, along with an

addressable market in excess of \$500 million - we have to get involved if for no other reason than we would be dissatisfied if it took off without us, after our knowing it possessed those three features.

What makes our conviction and confidence level so high, is the fact management has invested \$27 million and owns 60% of the shares leaving few shares available for purchase once and if significant news is released by the Company. This, we have learned from experience, creates a powder keg of share price appreciation potential. The kind of potential that could create a ten-bagger in short order leaving investors watching from the sidelines unable to react quickly enough to acquire a meaningful position.

Sentiment appears to be edging higher in the last three months with risk-based investors taking positions, many who have bought and sold hoping for a pull-back which in many micro-cap often never comes once news related sentiment brings in longer term investors.

We are additionally not alone in our assessment, as a [Florida based broker](#) recently stated they "assume a 70% probability of success in our models" and updated coverage with a \$7.00 price target. Adding, "Topline data from the superior efficacy interim analysis should represent the next major milestone in the Mino-Lok trial. It is expected, based on the current events rate and enrollment, to occur in the first half of 2020."

Less venturesome investors can, of course, wait for this topline data.

Lancet's Global Accounting of Sepsis

*Past performance is no indication or even inkling into future performance and investors shouldn't assume we or any of our subscribers rode these previous Watch List stocks from low to subsequent high. The Biotech Stock Review rarely issues buy or sell targets. So, the shares of a Company we are following could conceivably trade from \$1.00 to \$10 and back to \$1.00 – without us ever saying "sell, take your gain." It's just not something we can be expected to do. Readers are on their own and should react to share price movements as their risk parameters dictate.

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dates. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price.

Factors that could cause actual results to differ materially from those currently anticipated are: risks associated with conducting our Phase 3 trial for Mino-Lok, including completing patient enrollment; our need for substantial additional funds; the estimated markets for our product candidates and the acceptance thereof by any market; risks relating to the results of research and development activities; risks associated with developing Mino-Wrap, including that preclinical results may not be predictive of clinical results and our ability to file an IND; uncertainties relating to preclinical and clinical testing; the early stage of products under development; risks related to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; our ability to identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; our ability to attract, integrate, and retain key personnel; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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