Citius Pharmaceuticals, Inc.

Corporate Presentation

Spring 2019

NASDAQ: CTXR

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Investment Opportunity

Olympic Motto: "**Citius, Altius, Fortius**" *(Faster, Higher, Stronger)*

- Low Risk/ High Reward Strategy
  - Low development risk … focused on 505(b)2 regulatory pathway products,
    - avoids unnecessary duplication of studies already performed on previously approved drugs
    - results in a much less expensive and much faster route to approval, compared with a traditional development path [such as 505(b)(1)], while creating new, differentiated products with high commercial value expected.
  - Unique indications…little or no competition
  - Anticipated quick market acceptance (effective, safe and cost-saving/effective solutions)
- Successful management team with extensive experience
  - Approximately $23 million invested privately by founders and $14 million by the public
- Multiple near-term milestones and catalysts

Unique Pipeline in Progressive Stages

- **Phase 3: Mino-Lok®**
  - Lead product (Mino-Lok) is a unique antibiotic lock therapy that salvages central lines in bacteremic patients. This is a very serious problem with a clear unmet medical need. We estimate the market to be >$1 billion worldwide.
- **Phase 2: CITI-002 (Halo-Lido)**
  - Hydrocortisone/lidocaine completed Phase 2a. New formulation (with halobetasol) requires animal tox study prior to phase 2b trial. Would be the only FDA approved Rx therapy for hemorrhoids. We estimate the market to be >$1 billion in US.
- **Pre-Clinical: CITI-101 (Mino-Wrap)**
  - Unique product that prevents infections associated with breast implants. Preclinical data suggest prolonged protection against colonization by key organisms during time when most susceptible. We estimate the market to be ~$200 million worldwide.
- **Targeted Acquisitions**
  - Business development activity focused on 505(b)2 products with unique indications.

Mino-Lok®

Citius Lead Product
Minocycline/EDTA/Ethanol
Antibiotic Lock Therapy for Salvaging Catheters That Cause Bloodstream Infections

The Problem: Removing and Replacing an Infected Catheter in CRBSI is Risky and Costly
The Solution: Mino-Lok® to Sterilize and Salvage the Catheter

- Central venous catheters (CVCs) are life-saving vascular access ports for patients requiring long term intravenous therapy.
- Of the 7,000,000 CVCs used annually in US, up to 472,000 become infected leading to serious, life threatening infections called CRBSI/CLABSI.
- These infections are associated with 12-25% mortality and morbidity, prolonging hospital stay and increasing the cost of care significantly.
- Current SOC is to remove and replace the CVC while treating the patient for their blood stream infection with systemic antibiotic(s).
- The removal and replacement of the CVC is a risky and costly procedure.
- Mino-Lok is the first therapy under investigation that can be used to sterilize and salvage the infected CVC avoiding the complications, discomfort and costs of removal and replacement.
- There are no lock solutions under development for treating and salvaging infected CVCs.

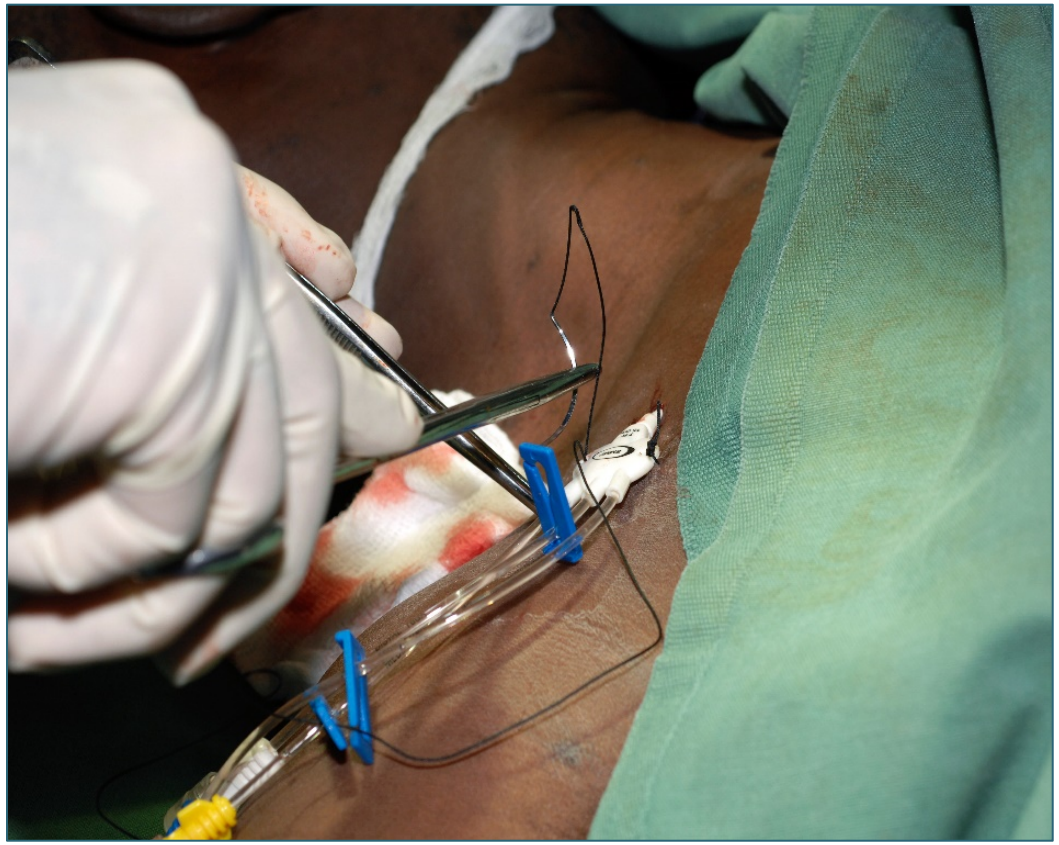
CVC Insertion Complications

Complications include infection, thrombosis, occlusion, and mechanical complications.

- ✓ Infectious complications are reported to occur in 5% to 26% of patients;
- ✓ Mechanical complications in 5% to 19%; and,
- ✓ Thrombotic complications in 2% to 26% (1,2).

Mechanical complications associated with the insertion of CVCs include arterial puncture, hematoma, hemothorax, pneumothorax, arterial-venous fistula, venous air embolism, nerve injury, thoracic duct injury (left side only), intraluminal dissection, and puncture of the aorta (3).

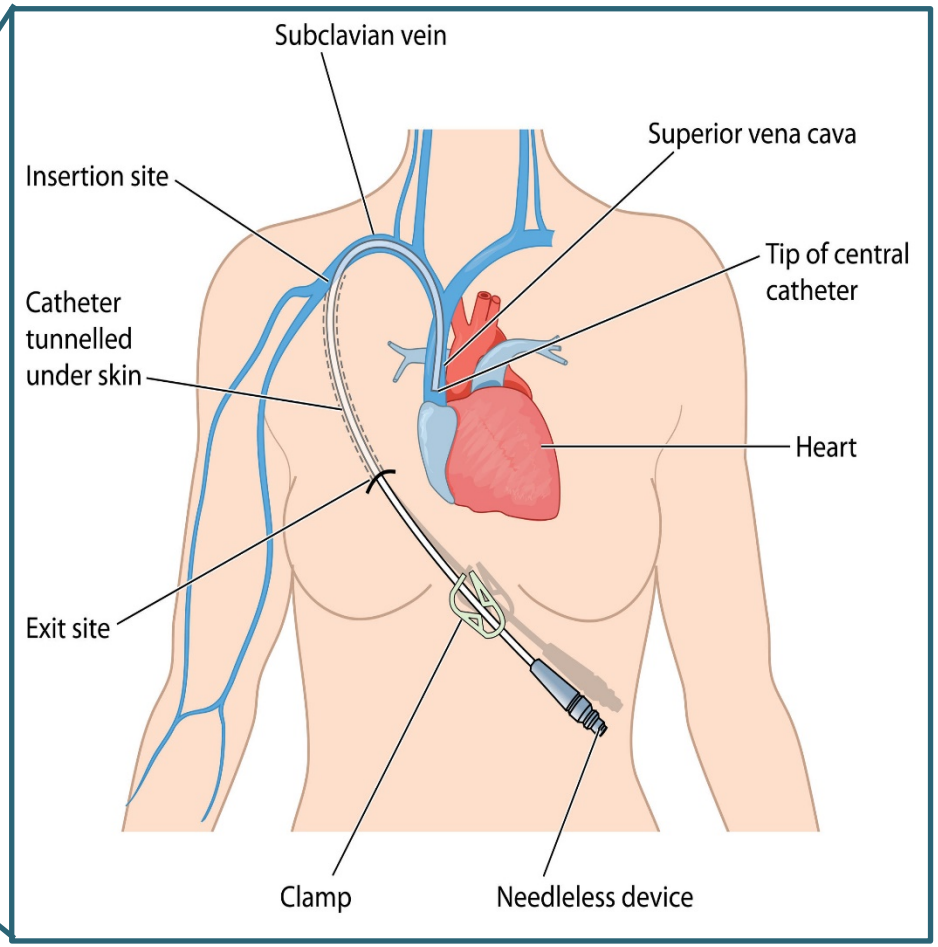
Catheter removal and reinsertion causes physical and psychological symptoms in 57% to 67% of patients, respectively (4).



Sources (NCBI: Annals of Translational Medicine):

1. McGee DC, Gould MK.. Preventing complications of central venous catheterization. N Engl J Med 2003;348:1123-33.
2. Merrer J, De Jonghe B, Golliot F, et al. Complications of femoral and subclavian venous catheterization in critically ill patients: a randomized controlled trial. JAMA 2001;286:700-7.
3. Polderman KH, Girbes AJ.. Central venous catheter use. Part 1: mechanical complications. Intensive Care Med 2002;28:1-17.
4. Chaftari, AM et al,. Unnecessary Removal of CVCs in Cancer Patients with CRBSI: Impact on Symptom Burden. Poster presentation at ID Week 2017, Infectious Diseases Society of America (IDSA)Oct 04 - 08, 2017

Locking a Central Venous Line with Mino-Lok®



**Mino-Lok™ is not flushed into the venous system.*

Locking a Catheter is a Standard Operating Procedure

1. Using Mino-Lok does not require any novel methodologies.
2. Any RN or LPN or Technician can perform the procedure.
3. There is no change in normal workflow and does not require exceptional training.
4. The patient does not experience any sensations similar to the threading of a central line through a vein or artery.
5. The procedure does not require any change to the tunneling or change in placement of the central line.
6. No anesthesia (general or local) is needed.
7. Standard sterile techniques still apply.

Phase 2b Trial Results

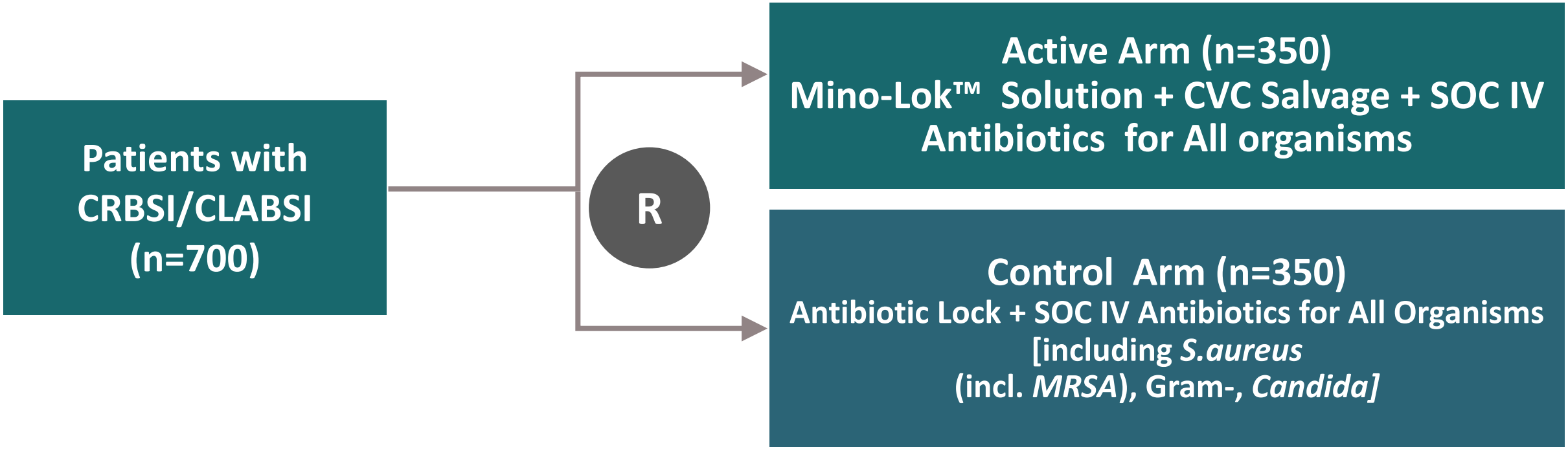
Parameter	Mino-Lok Arm N	(%)	Control Arm N	(%)
Patients	30	(100%)	60	(100%)
Cancer Type				
- Hematologic	20	(67)	48	(80)
- Solid tumor	10	(33)	12	(20)
ICU Admission	4	(13)	4	(7)
Mech. Ventilator	3	(10)	0	(0)
Bacteremia				
- Gram+	17	(57)*	32	(53)
- Gram -	14	(47)*	28	(47)
Neutropenia (<500)	19	(63)	36	(60)
Microbiologic Eradication	30	(100)	60	(100)
- Relapse	0	(0)	3	(5)
Complications	0	(0)	8	(13)
SAEs related to R&R	0	(0)	6	(10)
Overall Complication Rate	**0**	**(0%)**	**11****	**(18%)**

*1 polymicrobial patient had a Gram+ and a Gram – organism cultured

** 6 patients had >1 complication

Mino-Lok® Phase 3 Study Design

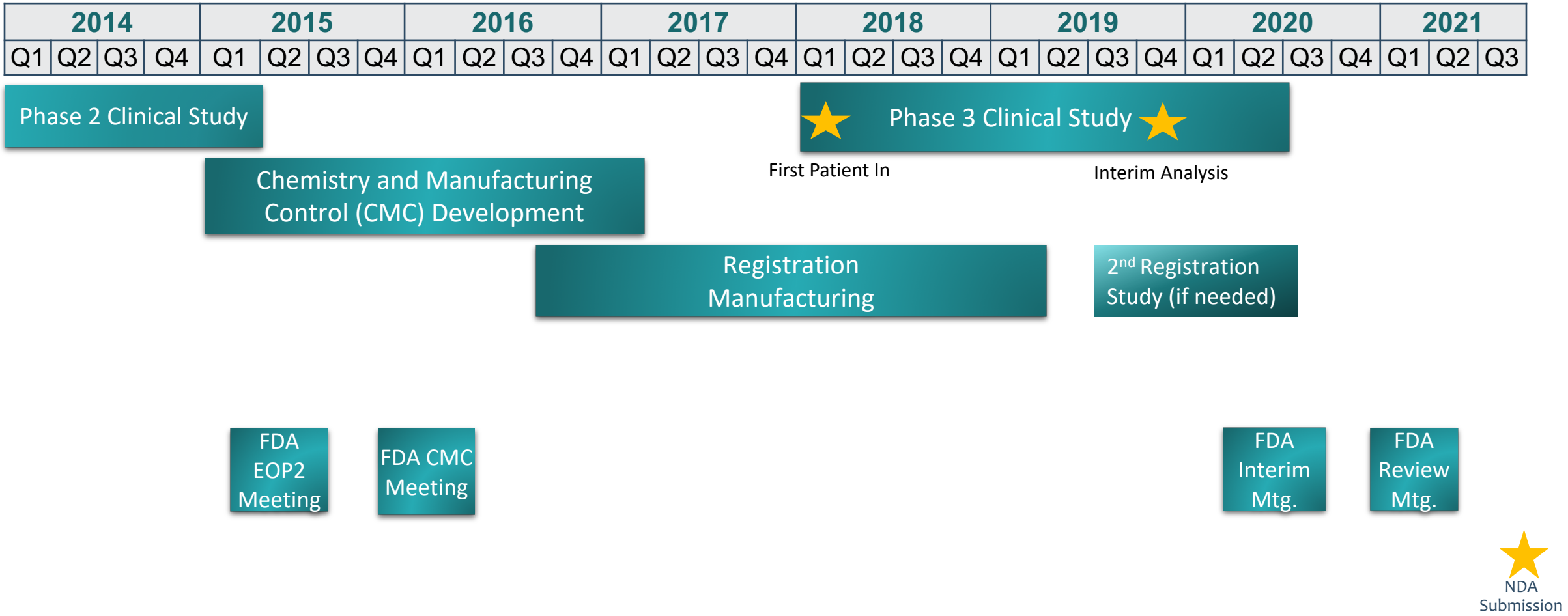
Multi-center, randomized, open label, blinded assessor, active control superiority study



Primary End Point: Proportion of ITT Patients who have Overall Success at TOC week (8)

Interim Analysis to be Performed at 50% and 75% Completion.

Mino-Lok® Development Plan (as of 02/2019)



Intellectual Property

Mino-Lok™ is supported by a robust intellectual property portfolio Composition of Matter patent that provides protection until June 7, 2024. Formulation Patent has been issued and will add protection through 2036.

Creators	Description of Patent	All U.S. and Foreign Patent Applications / Patent Numbers
Issam Raad, M.D. et al	Antimicrobials in Combination with Chelators and Ethanol for the Rapid Eradication of Micro-organisms Embedded in Biofilm (Composition of Matter)	• U.S. Patent No.: 7,601,731; • EP Ser. No.: 04754538.9; • CA Ser. No.: 2,528,522;
Issam Raad, M.D. Joel Rosenblatt, Ph.D. et al	Antimicrobial Catheter Lock / Flush Solutions with Enhanced Stability (Formulation)	• Pub.No.: US 2017/051373 A1 • Global IP: UTFC.P1283WO

U.S. Patent No. 7,601,731 (Composition of Matter) was filed on June 7, 2004 priority date of Provisional Application No. 60/476,555 of June 6, 2003 and issued on October 13, 2009. The expiration date is **June 7, 2024**.
U.S. Patent No. 10,086,114 (Formulation/Enhanced Stability) was filed on November 4, 2016 and issued on Oct. 2, 2018. The expiration date is **November 4, 2036.**
Patent applications for Global IP filed on June 12, 2018 incl. Canada, China, Japan, Korea, European Patent Office.

Regulatory Protection

Qualified Infectious Disease Product (QIDP)

- Eligibility for Fast Track Status, enables frequent communication and collaboration with FDA;
- Priority Review, reduces the NDA review time from 12 to 6 months; and,
- Market Exclusivity, grants an additional 5 years of market exclusivity at NDA, combined with Hatch-Waxman.

Fast Track Granted (October 2017)

- Fast Track expedites review of drugs which treat a serious or life-threatening condition and fills an unmet medical need.
  - More frequent meetings with FDA to discuss the development plan and ensure collection of appropriate data needed to support approval;
  - More frequent correspondence with FDA about the design of the clinical trials;
  - Priority review to shorten the review process from 10-12 months to 6 months; and,
  - Rolling review which allows for completed sections of the New Drug Application (NDA) to be submitted and reviewed by FDA rather than waiting until the entire application is compiled and submitted for review.

Mino-Lok® (minocycline/disodium EDTA/ethyl alcohol)

- **Treats** catheter-related blood stream infections (CRBSIs).
- **Penetrates** biofilm, eradicates bacteria and salvages infected, indwelling vascular catheters while providing anti-clotting properties.
- **Preserves** central venous access in patients highly dependent on central lines and avoids the serious and expensive complications and morbidities associated with catheter removal and reinsertion.
- **Expected to be indicated** as adjunctive therapy for the treatment of Catheter-Related Blood Stream Infections (CRBSI) in combination with appropriate systemic antibiotic(s).
- **Will have worldwide rights** with appx. **16 years of exclusivity** at time of launch.

A major step forward in addressing a serious unmet medical need.

CITIUS PHARMA

Mino-Wrap

CITI-101

Minocycline/Rifampin (M/R) Gelatin Film
Bioabsorbable Extended Release Antimicrobial Wrap for the
Prevention of Breast Tissue Expander Infections

Mino-Wrap: Thesis

- To decrease the high rate of TE infections, Mino-Wrap is a malleable, bioabsorbable, antimicrobial wrap that is placed in the surgical pocket as a solid film. It slowly liquefies *in situ* for a specified period of time providing extended protection against infection from the most likely pathogens.

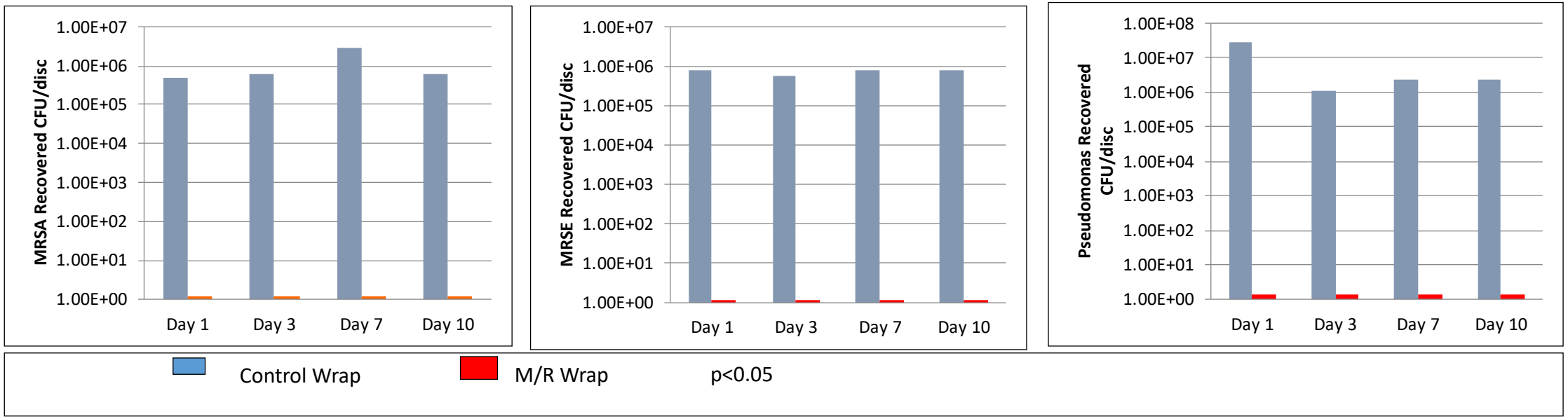
- Mino-Wrap is designed to allow the temporary tissue expander to be inflated without any restrictions, protect tissue from inflammatory responses, and also prevent infection and biofilm formation on the implant over longer durations than current practice – which are primarily irrigation with an antimicrobial solution.

- Mino-Wrap would also be used with breast implants during reconstruction post-TE removal.

Mino-Wrap Pre-Clinical Development Summary

Four Aspects Have Been Evaluated Preclinically

1. Physical changes over time and durability
   - Assessed if wrap could retain physical presence in a simulated TE pocket environment
     - evaluated in patient drain fluid samples following mastectomy and observed over a 1 week duration
   - Expected bio-absorption time is 2-4 weeks
2. Antimicrobial efficacy
   - MRSA, MRSE, and Pseudomonas aeruginosa clinical isolates were used



Conclusion

The *in vitro* preclinical experiments reveal that Mino-Wrap delivers minocycline and rifampin to the silicone surface in an active form

- Remains intact at least for 1 week after being submerged in a collagenase-saline solution at 37°C,
- Is safe and not cytotoxic towards human fibroblasts,
- Remains active after gamma radiation sterilization,
- Is active against the most common bacterial clinical isolates responsible for TE infections, for at least 10 days.

- Mino-Wrap appears to have the characteristics necessary for an advance in the protection of human implants from subsequent infection.

Next Steps: Determine Regulatory and Development Pathway

Intellectual Property


US009849217B2

(12) **United States Patent**
Rosenblatt et al.

(10) **Patent No.: US 9,849,217 B2**
(45) **Date of Patent: Dec. 26, 2017**

(54) **ANTIMICROBIAL WRAPS FOR MEDICAL IMPLANTS**

(71) Applicant: **Board of Regents, The University of Texas System**, Austin, TX (US)

(72) Inventors: **Joel Rosenblatt**, Pottstown, PA (US); **Issam Raad**, Missouri City, TX (US); **Andrew P. Dennis**, Seabrook, TX (US)

(73) Assignee: **Board of Regents, The University of Texas System**, Austin, TX (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/784,697**

(22) PCT Filed: **Apr. 17, 2014**

(86) PCT No.: **PCT/US2014/034556**

(52) **U.S. Cl.**
CPC ***A61L 27/54*** (2013.01); ***A61F 2/12*** (2013.01); ***A61L 27/222*** (2013.01); ***A61L 27/502*** (2013.01); ***A61L 27/52*** (2013.01); *A61F 2250/006* (2013.01); *A61F 2250/0018* (2013.01); *A61F 2250/0057* (2013.01); *A61F 2250/0067* (2013.01); *A61L 2300/404* (2013.01); *A61L 2430/04* (2013.01); *A61M 27/00* (2013.01)

(58) **Field of Classification Search**
CPC A61F 2/12; A61L 27/54
USPC 623/7–8
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,042,524 A 7/1962 Albus et al.
4,936,858 A 6/1990 O'Keeffe
(Continued)

- US Patent filed April 17, 2014
- US Patent Issued Dec. 26, 2017
- If CDER, then apply for Orphan Drug Designation (+7 years) , QIDP (+5 years) Priority Review and Fast Track

CITIUS PHARMA

Halo-Lido

CITI-002

Halobetasol/Lidocaine
Prescription Strength Topical for Symptomatic Hemorrhoid Treatment

CITI-002 (halobetasol + lidocaine)

Citius' product candidate is expected to be the first FDA-approved prescription product to treat hemorrhoids in the US

OTC Products are the Mainstay for Treatment of Grade I and II

- Up to 5% of the U.S. population suffers from hemorrhoids, but there are no FDA-approved prescription products on the market
- Over 10 million patients admit to symptoms of hemorrhoidal disease and one-third of them seek physician treatment
- OTC hemorrhoid product sales are approximately 20 million units annually

Existing Rx Treatments: "Grandfathered Products"

- Several DESI topical cream formulations containing hydrocortisone and lidocaine are commonly prescribed to treat grade I and II hemorrhoids, but none are FDA-approved
- In 2011, more than 4 million prescriptions were written in the U.S. for hemorrhoidal medications
- Other topical DESI products for hemorrhoids contain hydrocortisone and pramoxine and have annual sales in excess of $80 million

Commonly Used OTC Treatments

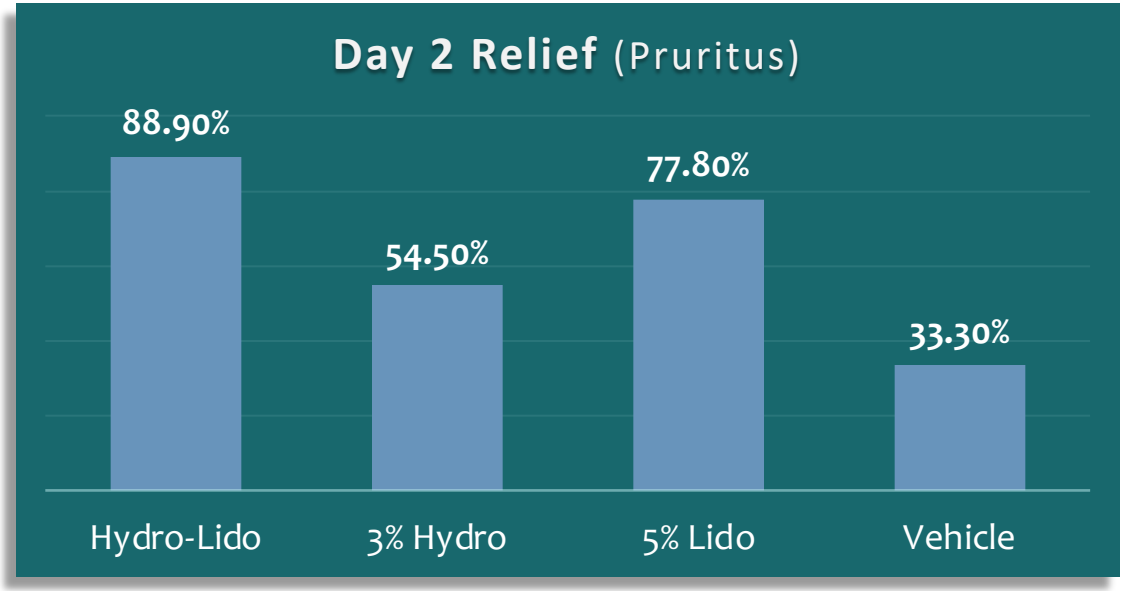
Prescription, Non-approved Treatments

Phase 2a Trial Results - *Positive Directional Improvement*

Faster Relief at Day 2*

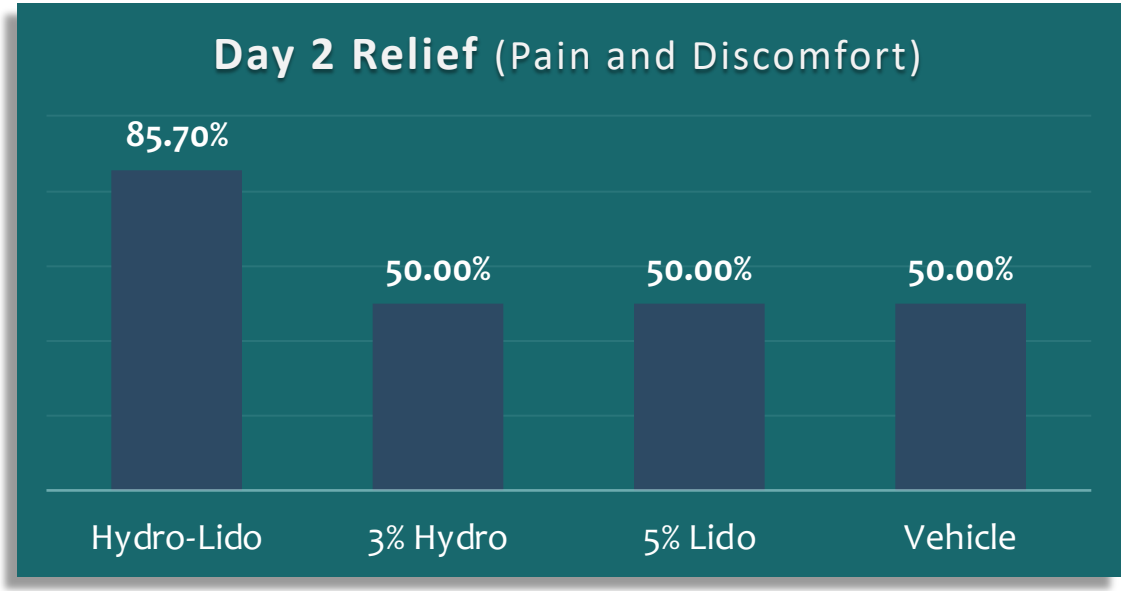
Pruritus

Hydro-Lido achieved 88.9% relief at Day 2 compared to any of its components



Pain and Discomfort

Hydro-Lido achieved 85.7% relief of pain and discomfort at Day 2 compared to any of its components



* Study was not powered to show statistical significance; its purpose was to inform future study design.

Summary

- Addressing attractive diversified multi-billion dollar opportunities – Adjunctive Cancer Care/Infectious Disease, Gastrointestinal Disease
- Portfolio addressing recognized unmet medical needs with cost-saving or cost-effective solutions with low risk development pathways
- Multiple staged near-term milestones
- Highly experienced and successful Management Team, Board of Directors, and Scientific Advisory Board

Financial Summary

Current Cap Table	Shares	% of Fully Diluted
Basic Shares Outstanding	18,520,360	56.0%
Warrants	12,871,623	38.9%
Options	1,601,034	4.8%
Unit Purchase Options	100,667	0.3%
Fully Diluted Shares Outstanding	**33,093,684**	**100%**

Principal Insider and Former Insider Shareholders (1) (101 Holders of Record)	
Leonard Mazur	(48.7%)
Myron Holubiak	(11.0%)
Reinier Beeuwkes, PhD	(2.9%)
Geoffrey Clark	(2.9%)

Stock Price	
Current Price (2/18/19)	$1.17
52 Week High	$3.39
52 Week Low	$0.95

(1) Beneficial stock ownership as calculated under rules of the Securities Exchange Commission.

CITIUS PHARMA

Management Team

Executives, Directors, & Board Members

Citius Management Team (Leadership)

Leonard Mazur, Director and Chairman of the Board

Mr. Mazur is a highly accomplished entrepreneur and pharmaceutical industry executive with notable accomplishments in founding, building and creating value and returns for the investors. He has been instrumental in launching many brands which have been at the forefront in their respective categories. Mr. Mazur is a founder/co-founder of the following companies: Genesis, Triax, Akrimax, and Rouses Point Pharmaceuticals. He has previously served in Executive Management positions at Medicis Pharmaceuticals, ICN Pharmaceuticals, Knoll Pharma (divison of BASF) and Cooper Laboratories. Mr. Mazur is a member of the Board of Trustees of Manor College and is a recipient of the Ellis Island Medal of Honor. Mr. Mazur received both his BA and MBA from Temple University and has served in the U.S. Marine Corps Reserves.

Myron Holubiak, President & CEO and Director

Mr. Holubiak has extensive experience in managing and leading both large and emerging pharmaceutical and life sciences companies. He is Co-founder, Director and CEO of Leonard Meron Biosciences, Inc., and served as CEO until the merger with Citius Pharmaceuticals, Inc. in March 2016, and then assuming the CEO role for the merged entity, Citius Pharmaceuticals, Inc.. He is the former President of Roche Laboratories, Inc., a major research based pharmaceutical company. During his tenure as President of Roche, Holubiak transformed Roche Labs into a leading antibiotic and biotechnology company. He was also founder of Emron, Inc., a pioneering health economics and managed care consulting company, and helped to create the Academy of Managed Care Pharmacy (AMCP). He is a former director and past Chairman of Bioscrip, Inc., a national home infusion services provider. He is currently a director of bioAffinity, Inc., and Assembly Biosciences, Inc. He received a BS in the double majors of Molecular Biology and Biophysics with post-graduate work in Biophysics from the U of Pittsburgh; he received advanced business training from the Harvard Business School, the Amos Tuck School at Dartmouth, and the University of London; and, advanced training in health economics from the University of York's Centre for Health Economics.

Citius Management Team

Jaime Bartushak, CFO

Mr. Bartushak is an experienced finance professional for early stage pharmaceutical companies, and has over 20 years of corporate finance, business development, restructuring, and strategic planning experience. Most recently in 2014, Mr. Bartushak helped lead the sale of PreCision Dermatology to Valeant Pharmaceuticals. Mr. Bartushak is also one of the founders of Leonard-Meron Biosciences and was instrumental in their startup as well as obtaining initial investment capital.

Gary F. Talarico, EVP, Operations

Mr. Talarico is highly experienced in leading commercial activities for a number of start up companies and corporate expansions. He has directed all of the commercial disciplines including marketing, sales, operations, training, trade and managed markets, and KOL development. Most recently he was partner and Executive Vice President of Leonard Meron Biosciences, and was instrumental in acquiring its lead product. Previously, Mr. Talarico served as Senior Vice President of Triax Pharmaceuticals from its founding to the sale of its assets. Mr. Talarico was also a founder and Executive Vice President of Sales and Marketing for Reliant Pharmaceuticals. Before Reliant, he was Executive Vice President of Business Development for Ventiv Health. Mr. Talarico is a graduate of Lewis University.

Citius Management Team

Alan Lader, Ph.D., VP, Clinical Operations

Dr. Lader has over 25 years of experience in medical research. Prior to joining Citius, Dr. Lader was the Director of Clinical Operations for Ischemix, Inc. Dr. Lader was an Instructor in Medicine at Harvard Medical School and Brigham and Women's Hospital where he taught Integrated Human Physiology, and was Principal Investigator for NIH funded studies in mechanisms of lung cancer metastasis. Dr. Lader has authored over 20 publications in peer reviewed journals and has presented more than 20 abstracts in scientific meetings. He received his Ph.D. from University of South Carolina School of Medicine. He received an MS degree from Rensselaer Polytechnic Institute in Biomedical Engineering and a BS degree in Bioengineering from Syracuse University.

Andrew Scott, VP, Corporate Development

Mr. Scott has 25 years of transactional experience in strategic planning, product identification, asset acquisition and capital markets services. Mr. Scott was an investment banker at Bear Stearns and focused on the life sciences sector before transitioning to the specialty pharma world. Mr. Scott has licensed over 12 technologies, provided capital raising services, restructurings and advised on M&A transactions. He is actively identifying and speaking with key opinion leaders in various therapeutic areas.

Corporate Profile

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