Lipella Pharmaceuticals

A Clinical Stage Biotechnology Company Addressing Serious Diseases with Significant Unmet Need

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lipellapharmaceuticals.com

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Mission

Lipella is dedicated to improving the quality of life for patients living with serious diseases where no approved drug therapy exists.

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Business Growth Strategy

Focused on rare and orphan drug indications and leveraging the 505(b)(2) pathway. Lipella anticipates this strategy will lower cost and allow for a faster approval process

Why rare and orphan drugs?

- Lipella can be first to market by pursuing conditions for which there are no current FDA approved treatments.
- Requires smaller and less costly drug trials with greater flexibility from the FDA.
- Orphan drug market exclusivity limits additional market entrants.
  - 7 years in the US, 10 years in the EU and Japan.

Why leverage the 505(b)(2) pathway?

- Bypasses Phase 1 trials by utilizing drugs and mechanisms of action where safety and efficacy have already been established.
- Can immediately initiate Phase 2 clinical trials.
- Potentially mitigates risk from a CMC, safety and clinical development standpoint.
- Greater flexibility from the FDA.

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About

Lipella Pharmaceuticals is a clinical-stage biotechnology company developing and commercializing treatments for serious diseases.

Our proprietary drug delivery technology has potential applications in addressing diseases of the mucosal tissue including the bladder, urethra, oral cavity, esophagus and colon.

We see strong potential for our technology in partnerships and commercial licensing agreements.

Market Data

SYMBOL	NASDAQ: LIPO
Price as of 4-24-2024	$0.72
52 Week Range	$0.67 - $2.44
Average Volume 52 Week	1.4M
Market Capitalization	$5.0M
Current Shares Outstanding	7.0M
Insider Ownership	38%

Near Term Catalysts

H1 2024

- FDA Type C meeting to discuss proposed Phase-2b clinical trial design for the evaluation of LP-10
- Preclinical results from LP-50 studies

H2 2024

- Recruitment of patients for Phase 2a clinical trial in oral lichen planus
- Initiating Phase 2b trial in LP-10
- Initiating Phase 2a studies in LP-310

H1 2025

- Initiating Phase 2a clinical trial in GvHD pending interim safety results in LP-310 trial

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De-Risked Assets

Lipella has a broad portfolio of de-risked candidates that offer increased probability of success:

LP-10	Liposomal tacrolimus has a well-known mechanism of action and has demonstrated safety and efficacy in Phase 2a studies.
LP-310	Oral rinse formulation of liposomal tacrolimus that minimizes systemic toxicity. Large market size opportunity (6 million US).
LP-410	Alternative oral rinse formulation of LP-10 that has been granted Orphan Disease Designation by the FDA.
LP-50	An intravesical liposomal formulation of checkpoint inhibitor that has demonstrated efficacy in preclinical studies of bladder cancer.

Revenue Opportunity

Hemorrhagic cystitis: ~60,000 annually

Hemorrhagic cystitis is a potentially fatal disease with great unmet need and no currently approved drug treatment. It causes chronic, painful urinary inflammation and blood loss.

Oral Graft-versus-Host disease: ~2,500 annually
Oral GvHD is a rare complication of Graft-versus-Host disease, which affects 30,000 Americans each year. Oral GvHD results in significant oral pain and discomfort, making it difficult for patients to eat, drink and speak.

Oral lichen planus: 6 million
Oral lichen planus affects more than six million Americans and is characterized by pain, bleeding and inflammation that causes difficulty with speaking, chewing and swallowing and an increased risk of developing oral Cancer.

Bladder cancer: ~63,000 annually
Non-muscle invasive bladder cancer (NMIBC) accounts for 75-85% of all newly diagnosed bladder cancers. There are approximately 63,000 new cases of NMIBC diagnosed in the United States each year.

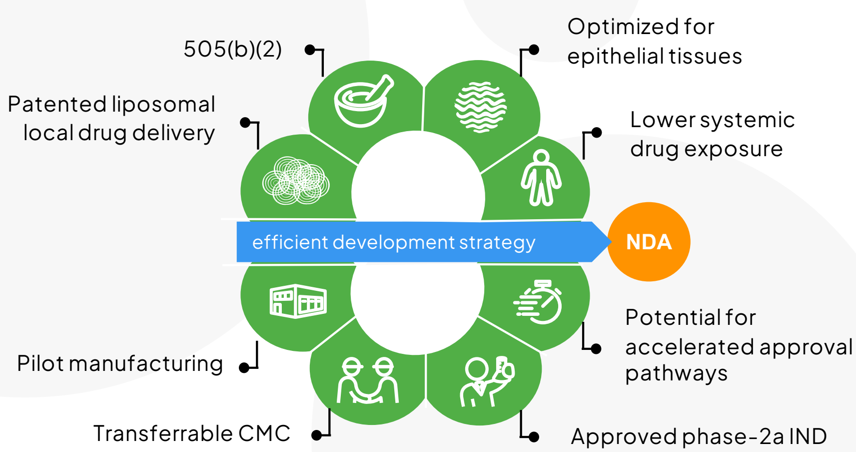
Expected annual revenue per patient **$20,000 per drug intravesical installation**

Market penetration of 60,000 patients (50%) yields **$1.2 billion** annual revenue in US

Executive Summary

Emerging, clinical-stage, proprietary 505(b)(2) opportunity

Drug-Delivery Focused Biotech



Impressive Revenue Potential

$20,000 annual revenue per patient[7] → **$1.2 billion annual revenue potential[8]**

Prostate and other pelvic malignancies → **Pelvic radiation theraphy** → **Radiation-hemorrhagic cystitis**

- **Over 3,000,000 survivors in US[4]**
- **Over 900,000 survivors in US[5]**
- **Over 60,000 patients per year[6]**

(4) American Cancer Society Cancer Treatment and Survivorship Fact and Figures 2019-2021, (5) based on the Company's 30% estimate (6) 8% estimate, (7) based on the Company's estimate, (8) $20,000 average revenue per each of an estimated 60,000 patients treated per year.

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Asset Pipeline

A growing pipeline with strong patent protection

Proprietary Asset	Pre-clinical	IND-Enabling	Phase 1	Phase 2	Phase 3	Upcoming Milestones
LP-10 hemorrhagic cystitis						FDA Type C meeting 2Q2024
LP-310 oral lichen planus						Patient recruitment 3Q2024
LP-410 oral graft –versus-host disease						Patient recruitment 1Q2025
LP-50 bladder cancer						Pre-clinical results 2Q2024

- **LP-10:** Intravesical liposomal formulation being evaluated as a treatment for hemorrhagic cystitis.
- **LP-310:** Oral rinse liposomal formulation of LP-10 as a potential treatment for oral lichen planus.
- **LP-410:** Oral rinse liposomal formulation of LP-10 as a potential treatment for oral graft vs. host disease.
- **LP-50:** Intravesical liposomal formulation of checkpoint inhibitors evaluated as a treatment for non muscle invasive bladder cancer.

Hemorrhagic Cystitis, Uncontrolled Urinary Blood Loss

Hemorrhagic cystitis is a serious, life-threatening bladder damage from pelvic radiation therapy and/or bladder-toxic chemotherapy.

Millions of patients are diagnosed each year with pelvic malignancies including prostate cancer, and cancers of the uterine corpus, requiring treatment.

20% of these patients receive pelvic radiation therapy during the treatment of their cancer, in addition to surgery and chemotherapy.

An increasing US population is surviving cancer therapies, including pelvic radiation, and chemotherapies that damage DNA.

Years after receiving treatment, many patients acquire hemorrhagic cystitis, uncontrolled bladder blood loss.

Hemorrhagic cystitis is a potentially chronic, highly morbid condition with no approved drug therapy, and a four percent mortality rate.

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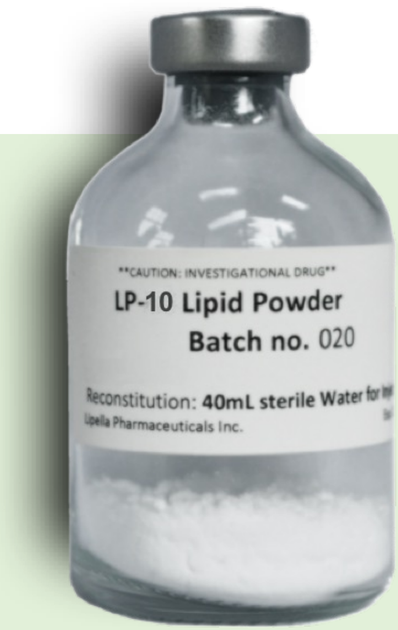
LP-10 for Hemorrhagic Cystitis

Liposomal tacrolimus treatment for hemorrhagic cystitis

Potent vasoconstrictor; reduces capillary blood flow to the bladder lumen

Potent anti-inflammatory; inhibits cytokine cascade and reduces injury to the bladder tissue

Well known pharmacologic mechanisms increase the probability of efficacy



- Sterile powder
- Easy to deliver
- Low COGS
- In-house CMC

LP-10: Phase 2a Trial

A Phase 2a clinical trial (NCT01393223):

- Multi-center, dose-escalation study
- 13 subjects with moderate to severe refractory hemorrhagic cystitis
- Subjects treated with up to two courses of LP-10 intravesical bladder instillations.

Top line results

- All subjects tolerated LP-10 instillations with no serious adverse events (SAE) reported
- LP-10 demonstrated short duration of systemic uptake
- Decreased cystoscopic bleeding hematuria and improved urinary incontinence
- 58% of patients achieved complete or near complete resolution of bleeding per cystoscopy

Next Steps

- LP-10: FDA Type-C mtg Scheduled May 21, 2024
- LP-310: First Patient Expected 2H 2024
- LP-410: Study Initiation Expected 1Q 2025
- LP-50: CMC development Ongoing.

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LP-10 Phase 2b Trial Design

Key criteria:

- Randomized, double-blind, placebo controlled , multi-center clinical trial of 36 Male and Female hemorrhagic cystitis patients, randomized 1:1:1
- Subjects will be randomized into one of three groups: 2mg LP-10 , 4 mg LP-10 or Placebo

Primary Efficacy Endpoint:

- Change in number of hematuria episodes from baseline to Week 4 on a 7-day voiding diary.

Secondary Efficacy Endpoints:

- Change in number of urinary incontinence episodes from baseline to Week 4 on a 7-day voiding diary.
- Cystoscopic number of bleeding sites
- Urine analysis with microscopy including RBC/hpf at baseline and Week 4

LP-310 for Oral Lichen Planus

Oral Lichen Planus (OLP) is a chronic inflammatory, T-cell-mediated autoimmune oral mucosal disease

- Painful and comes with the risk of complications including infections, scarring, stress and depression.
- Has malignant potential.
- Most currently available therapies are palliative rather than curative.

LP-310

- Oral rinse formulation of LP-10
- Increased local concentration in oral cavity while minimalizing systemic toxicity
- 505(b)(2) pathway, platform technology expansion
- Low COGS and fast development plan
- Large market size opportunity (6 million US) with no current approved therapy
- Phase 2a IND approval received Q4, 2023
- First patient treatment expected summer 2024.

LP-310

Oral Lichen Planus Mouth Rinse

LP-410 for Oral Graft-Versus-Host Disease

Oral Graft-Versus-Host Disease (GVHD) is a clinical syndrome where donor-derived immunocompetent T cells react against patient tissues directly or through exaggerated inflammatory responses following HCT.

- GVHD is a major cause of morbidity and mortality with chronic GVHD being the leading cause of nonmalignant fatality post Hematopoietic Cell transplantation (HCT).
- Oral GVHD is one of the most debilitation manifestation of GVHD and has a prevalence of approximately 30,000 in the US.
- Malignant transformation may occur with oral chronic GVHD.

LP-410

- Alternative oral rinse formulation of LP-10 for the indication of oral GVHD
- LP-10 fills an unmet medical need, as there are currently no FDA-approved therapies for oral chronic GVHD.
- 505(b)(2) pathway, platform technology expansion
- Lipella received FDA Orphan Disease Designation on LP-410 for the treatment of GVHD.
- Received IND approval in Q1, 2024 for Phase 2a clinical trial.

LP-410

Oral Graft-Versus-Host Disease Mouth Rinse

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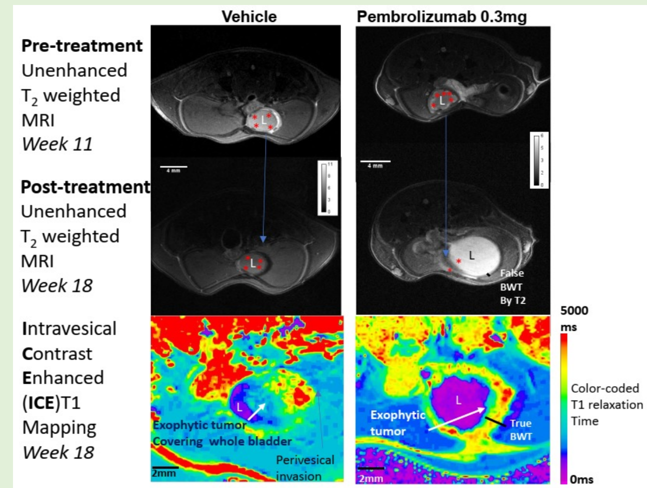
LP-50 for Bladder Cancer

Novel liposomal formulation of checkpoint inhibitors

- Intravesical formulation for local, intravesical PD-1 (i.e. checkpoint) inhibition, intended for the treatment of non-muscle invasive bladder cancer (NMIBC).
- Intravesical immunotherapy presents a promising avenue for bladder cancer treatment, offering the potential for increasing efficacy while minimizing systemic toxicity.

LP-50

- LP-50 is an intravesical liposomal formulation of checkpoint Inhibitor for the treatment of bladder cancer.
- Preclinical study has been accepted for abstract publication at ASCO
- Preclinical work continuing with journal article publication and advisory board.



LP-50

Intravesical Liposomal Delivery of Checkpoint Inhibitor

Manufacturing Capabilities

- Lipella maintains a sterile manufacturing facility in Pittsburgh, PA for the production of clinical supplies and research products.
- LP-10 has been produced at high quantities in this facility for Lipella's clinical trials.
- The facility is also used for development of liposomal formulations intended for intravesical delivery.
- Lipella is currently collaborating with Cook Myocyte (a subsidiary of Cook Medical) regarding commercial grade manufacturing.

Experienced Management Team

Lipella is led by an experienced team with complementary skillset and years of experience working together.

Jonathan Kaufman, PhD
Chief Executive Officer

- 23+ Years Experience
- Co-founded Lipella in 2005
- Co-founder of Knopp Biosciences. CFO of Semprus Biosciences. CSO LaunchCyte LLC.
- PhD Penn. MBA Wharton.

Michael Chancellor, MD
Chief Medical Officer

- 30+ Years Experience
- Lipella co-founder. Joined Lipella in 2008
- Co-founder of Cook-Myosite; Professor of Urology, William Beaumont Medical Center.
- MD University of Michigan.

Michele Gruber
Director of Operations

- 12+ Years Experience
- Joined Lipella in 2009
- CMC development, facilities, R&D management.
- BS Carnegie Mellon

Janet Okonski
Director Clinical Operations

- 20+ Years Experience
- Joined Lipella in 2021
- Clinical trial management, safety monitoring
- BS Indiana University of Pennsylvania

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Key Takeaways

Drug Development

- Broad portfolio of three promising IND-approved assets: **LP-10**, a 505(b)(2) drug candidate for hemorrhagic cystitis, **LP-310** in oral lichen planus (OLP) and **LP-410** in oral graft-versus-host disease (GvHD).
- LP-10 and LP-410 granted FDA Orphan Drug Designation; potential candidates for multiple accelerated pathways.
- Successfully completed Phase 2a clinical trial in LP-10; Phase 2b trial planned for 2024.
- IND applications approved for LP-310 and LP-410, LP-310 Phase 2a studies to commence in 2H 2024.
- Targeting multiple patient populations including:
  - ~60,000 new diagnoses of hemorrhagic cystitis each year,
  - >2,500 new diagnoses of oral GvHD annually, and
  - 6 million patients living with OLP.
- Patent protection secured for LP-10 through 2034.
- Manufacturing capabilities at in-house facility.

Drug Delivery

- Proprietary drug delivery technology with potential applications in bladder, urethra, oral cavity, esophageal and colonic.
- Designed for use with other lipophilic drugs; potential for technology partnerships, commercial licensing agreements.

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