Lipella Pharmaceuticals

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

H.C. Wainwright 26th Annual Global Investment Conference

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NASDAQ:LIPO

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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 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 8-19-2024	**$0.41**
52 Week Range	**$0.36 - $2.71**
Average Volume (3 Mo)	**3.4M**
Market Capitalization	**$3.4M**
Cash and Cash Equivalents	**$1.2M**
Debt	**None**
Current Shares Outstanding	**7.6M**
Insider Ownership	**~37.4% as of 8/20/24**

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BUSINESS GROWTH STRATEGY

Focused on rare and orphan drug indications, Lipella is leveraging the 505(b)(2) pathway. This strategy is expected to lower cost and expedite the 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 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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INVESTMENT HIGHLIGHTS

Attractive Market:	Targeting two patient populations with significant unmet needs and no current FDA approved drug treatments.
Compelling Pipeline:	Two IND-approved lead assets in phase 2 clinical trials, both 505(b)(2) drug candidates: • **LP-10**, a bladder intravesical delivery of liposomal formulation of tacrolimus for the treatment of hemorrhagic cystitis (HC). • **LP-310**, a novel liposomal-tacrolimus oral rinse based on the company's lead candidate LP-10, for the treatment of oral lichen planus (OLP).
Near Term Catalysts:	Pivotal clinical milestones over the next 18 months.
Experienced Team:	Executive team, board of directors, and scientific advisory board all deeply entrenched in the biotech space.
Strategic Manufacturing Capabilities:	Manufacturing facility in Pittsburgh, PA, producing clinical supplies and research products, focusing on liposomal formulations; collaboration with Cook Myocyte for commercial-grade manufacturing.

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DE-RISKED LEAD PROGRAMS WITH ROBUST REVENUE OPPORTUNITY

505(b)(2) drug candidates

Positioned For Market Exclusivity

LP-10

- Liposomal tacrolimus for the treatment of Hemorrhagic cystitis. LP-10 has a well-established mechanism of action and has demonstrated safety and efficacy in Phase 2a studies**. LP-10 is the only therapeutic for HC in development.**

- *Hemorrhagic cystitis affects* ***~60,000 annually***
- *Expected annual revenue per patient:* ***$20,000 per drug intravesical instillation***
- *Market penetration of* ***60,000 patients (45%) yields $1.2B annual revenue***

LP-310

- Oral rinse formulation of LP-10 for the treatment for Oral Lichen Planus (OLP). High safety profile with no systemic toxicity observed. **There are no current topical OLP treatments in development.**

- *Target market of* ***6 million Americans***
- *The global OLP market was valued at* ***USD 120 million in 2021*** *and is projected to grow to* ***USD 214.02 million by 2029***

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DIFFERENTIATED TECHNOLOGY PLATFORM:

Liposomal Formulation of Tacrolimus

Maximizing Therapeutic Responses with Directed Localized Administration

Optimized Efficacy	By encapsulating tacrolimus in liposomes, our technology ensures a more stable and controlled release, maximizing therapeutic benefits while minimizing systemic exposure.
Reduced Adverse Effects	The liposomal delivery method offers localized treatment, reducing the risk of severe side effects typically associated with systemic administration.
Potential for Broader Applications	Liposomal encapsulation of tacrolimus enables targeted treatment for a broad range of mucosal tissue diseases, including the bladder, urethra, oral cavity, esophagus, and colon.
In House CMC Advantage	Ensures consistent quality from clinical studies to the marketed drug, maintaining high standards throughout development and commercialization

Strong potential for our technology in partnerships and commercial licensing agreements

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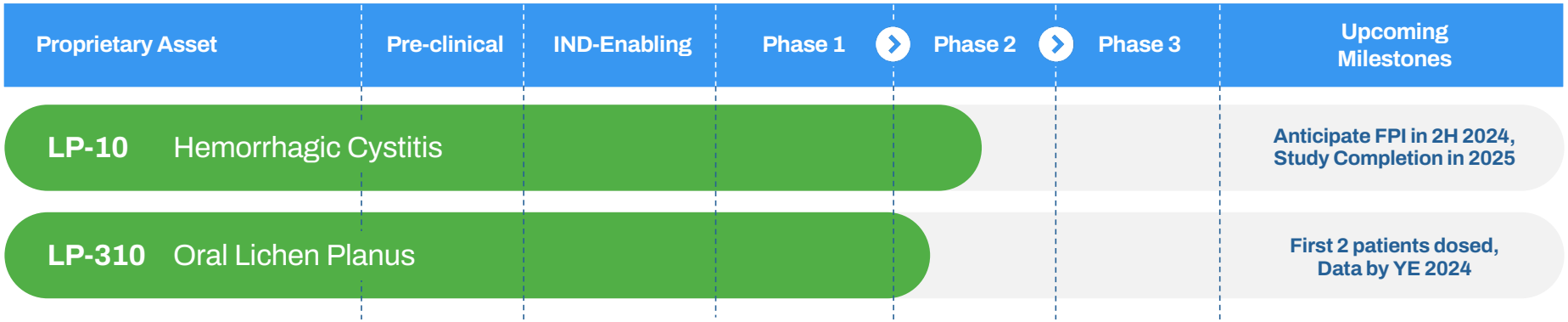
NEAR TERM CATALYSTS



H2 2024

- Patients dosed in Phase 2a trial in LP-310 for OLP
- Initiated Phase 2b trial in LP-10 for HC

H1 2025

- Topline data from Phase 2a trial in LP-310 for OLP
- Recruitment for Phase 2b trial in LP-10 for HC

H2 2025

- **Projected completion of Phase 2a trial in LP-310 for OLP**
- **Clinical progress for Phase 2b study in LP-10 for HC**

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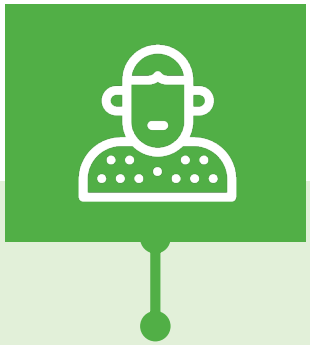
HEMORRHAGIC CYSTITIS, UNCONTROLLED URINARY BLOOD LOSS

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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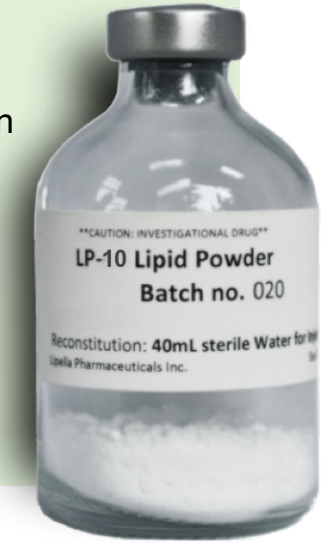
LP-10 FOR HEMORRHAGIC CYSTITIS (HC)

Liposomal tacrolimus treatment for hemorrhagic cystitis

Urgent Need For Effective HC Treatment Options

- HC is challenging to treat due to poor blood flow in affected tissue
- Existing therapies, including steroids and vitamin E, are largely ineffective.
- Adjusting radiation fields and limiting bladder dose offers limited success.
- Current approach can compromise radiation treatment effectiveness.

Patent protection secured for LP-10 through 2034



- **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**

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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

- Initiate Phase 2b trial in LP-10 in 1H 2025

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ORAL LICHEN PLANUS (OLP)

OLP is a chronic inflammatory, T-cell-mediated autoimmune oral mucosal disease

- **Complications:** Pain, weight loss, stress, depression, scarring from erosive lesions, secondary oral yeast or fungal infections
- **Malignant Potential:** Malignant transformation (squamous cell carcinoma) between 0.4-5% (annual rate between 0.2-0.5%)

There is no current pharmacotherapy for oral lichen planus

Current OLP Treatments: Palliative with Significant Side Effects

- **Topical Steroids:** Require precise application and adherence to protocols, such as avoiding food and drink after use. Can cause oropharyngeal candidiasis, necessitating antifungal treatment.
- **Systemic Corticosteroids:** Carry serious risks, including bone marrow issues, retinal damage, and increased cancer risk.
- **Alternative Treatments:** Second-line options, like calcineurin inhibitors and retinoids, have adverse effects such as burning sensations and carry significant FDA warnings, limiting their use.

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LP-310

(liposomal-tacrolimus) for Oral Lichen Planus

- Similar formulation of LP-10 for oral rinse
- Increased local concentration in oral cavity while minimalizing systemic toxicity
- High safety profile with no systemic toxicity observed
- Low COGS and fast development plan
- LP-310 provides the first drug treatment of oral lichen planus in adult men and women
- First two patients dosed
- Top Line Data Expected Year-End 2024

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LP-310 CLINICAL SNAPSHOT

Design : Randomized, prospective multicenter dose escalation study with 24 patients.

Efficacy : Anticipate a statistically significant decrease in oral lichen planus lesion score within 1 week of administration, maintained for at least 4 weeks.

Quality of Life : Expect a clinically relevant improvement in quality-of-life measures.

Safety : No systemic or renal function toxicity projected.

Dosage and Administration

- **Regimen**: Twice daily oral rinse of 10 ml of LP-310 (27 mg sphingomyelin and 0.25 mg, 0.5 mg and 1 mg tacrolimus, respectively) for 3 minutes for four weeks.
- **Monitoring**: Whole blood tacrolimus levels checked after one week.

Mechanism of Action

- **Active Ingredient**: Tacrolimus, a calcineurin inhibitor.
- **Function**: Serves as a potent immunosuppressant that improves barrier function of the skin and mucosa.
- **Impact**: Disrupts inflammatory signaling events mediated by calcineurin and suppresses inflammation associated with oral lichen planus.

Safety Profile

- **Anticipated Adverse Events**:
  - Oral cavity infection (~2%)
  - Mouth burning (~5%)
- **Toxicity**: No systemic or renal function toxicity associated with LP-310.

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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						Anticipate phase 2b trial to start in 1H 2025
LP-310 oral lichen planus						First 2 patients dosed, Topline data by YE 2024
LP-410 oral graft –versus-host disease						Anticipate moving into Patients 2H 2025
LP-50 bladder cancer						Pre-clinical on-going

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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

Oral Graft-Versus-Host Disease Mouth Rinse

LP-410

- Alternative oral rinse formulation of LP-10 for the indication of oral 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, expects to initiate human clinical trials in 2H 2025.

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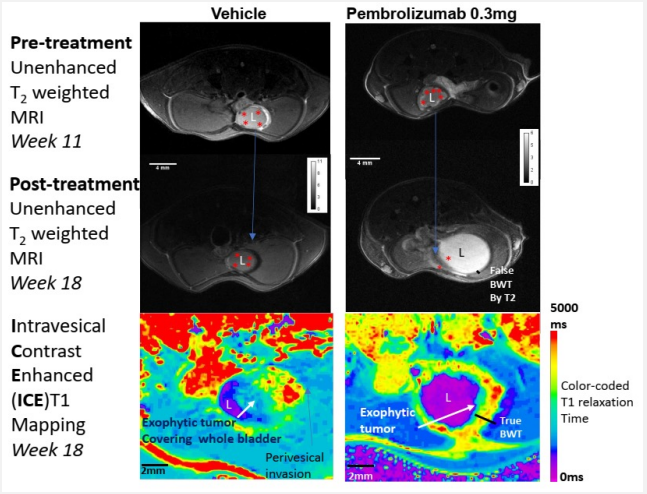
LP-50 FOR BLADDER CANCER

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

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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 MyoSite (a subsidiary of Cook Medical) regarding commercial grade manufacturing.

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EXPERIENCED MANAGEMENT TEAM

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

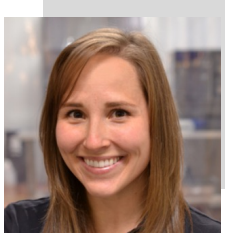
Chief Medical Officer

- 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.

Doug Johnston, CPA

Chief Financial Officer

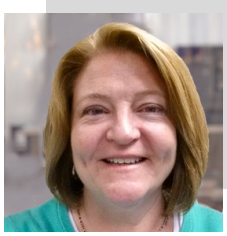
- 15+ Years Experience
- Jointed Lipella in 2021
- Experience in global and early-stage pharma finance operations
- Certified public accountant in Pennsylvania



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

Lipella is led by a seasoned team with complementary expertise and a proven track record of successful collaboration.

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KEY TAKEAWAYS

- Broad portfolio of three promising IND-approved assets.
- LP-10 and LP-410 granted FDA Orphan Drug Designation; positioned for multiple accelerated pathways.
- Successfully completed Phase 2a trial for LP-10; Phase 2b trial to initiate 2H 2024.
- IND approvals for LP-310 and LP-410, LP-310 Phase 2a study is ongoing with topline results expected in 4Q 2024.
- Targeting multiple patient populations including:
  - ~60,000 new diagnoses of hemorrhagic cystitis each year.
  - 6 million patients living with OLP.
  - 2,500 new diagnoses of oral GvHD annually.
- Patent protection secured for LP-10 through 2034.
- In-house facility manufacturing capabilities.

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