Tessaline Therapeutics, Inc.

Series A Financing — Investor Data Room Summary
TSL-201: an oral, selective NLRP3 inflammasome inhibitor for recurrent pericarditis

Prepared for prospective Series A investors · September 2026
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This summary contains forward-looking statements, including projected timelines, costs, market size, and pricing, that reflect management's current expectations and are subject to significant risks and uncertainties.

1. Executive Summary

Tessaline Therapeutics is a clinical-stage biotechnology company based in Cambridge, MA, developing TSL-201, an oral small-molecule inhibitor of the NLRP3 inflammasome. Our lead indication is recurrent pericarditis (RP), a painful, relapsing inflammatory disease of the pericardium in which IL-1β drives recurrence.

Investment highlights

- Phase 1 study completed in June 2026: single- and multiple-ascending-dose cohorts in 72 healthy volunteers, plus an open-label cohort in 10 patients with an active pericarditis recurrence.
- In the open-label patient cohort, 9 of 10 patients achieved a pain response and median C-reactive protein (CRP) normalized in 7 days on 150 mg BID.
- At the planned Phase 2 dose of 150 mg BID, TSL-201 produced 88% mean inhibition of ex vivo LPS/ATP-stimulated IL-1β release at trough (Day 14).
- The only approved targeted therapy for RP is an injectable IL-1 biologic. We believe an oral option can capture a meaningful share of the market.
- Composition-of-matter patent protection is expected to run to 2043, before any patent term extension.
- We are raising a **$42M Series A**, fully committed by a lead and co-lead, which management believes funds the company through Phase 2 topline data.

Key upcoming milestones (management projections)

Milestone	Target timing
End-of-Phase 1 meeting with FDA	Q4 2026
Orphan Drug Designation decision (application submitted July 2026)	Q4 2026
Phase 2 first patient dosed	Q2 2027
Phase 2 enrollment complete	Q3 2028
Phase 2 topline data	Q2 2029

2. Disease Background and Unmet Need

Acute pericarditis accounts for approximately 5% of emergency department visits for non-ischemic chest pain. Between 15% and 30% of patients experience a recurrence after a first episode despite first-line therapy with NSAIDs and colchicine, and a subset of patients experience multiple recurrences over several years.

Management estimates that there are approximately **38,000** patients in the United States with recurrent pericarditis, of whom approximately **14,000** have had two or more recurrences and are candidates for advanced therapy. These estimates are derived from a 2025 claims analysis commissioned by the company and have not been independently validated.

Current treatment paradigm

- First line: NSAIDs plus colchicine.
- Second line: corticosteroids, which are effective but associated with a higher rate of recurrence on taper and with long-term toxicity.
- Advanced therapy: a weekly subcutaneous IL-1 pathway biologic, approved for RP, with a US list price of approximately $250,000 per year. Physician interviews (n=18, conducted by the company) cited injection burden, cost, and payer prior-authorization requirements as the main barriers to use.

Clinical validation of the IL-1 pathway in RP is strong: blocking IL-1 signaling has been shown in a randomized-withdrawal trial to dramatically reduce recurrence. TSL-201 aims to reduce IL-1β production upstream, at the inflammasome, with an oral daily-dosed pill. TSL-201 has been tested in 10 pericarditis patients to date in an open-label, uncontrolled setting (Section 4).

3. Mechanism of Action and Preclinical Data

NLRP3 is an intracellular sensor that, when activated, assembles the inflammasome complex, activates caspase-1, and drives the release of mature IL-1β and IL-18. TSL-201 binds the NACHT domain of NLRP3 and locks it in an inactive conformation.

In vitro potency and selectivity

Assay	TSL-201 result
IL-1β release, human monocyte-derived macrophages (LPS/nigericin)	IC50 = 9 nM
IL-1β release, human whole blood (LPS/ATP)	IC50 = 68 nM
NLRC4 inflammasome (flagellin)	No inhibition up to 10 μM
AIM2 inflammasome (poly dA:dT)	No inhibition up to 10 μM
Kinase panel (97 kinases)	No kinase >50% inhibited at 1 μM

All potency and selectivity assays were performed in the company's own laboratory or by the academic founder's laboratory. No independent replication has been commissioned to date.

In vivo efficacy

In a mouse model of zymosan-induced pericardial inflammation, oral TSL-201 at 30 mg/kg BID reduced pericardial effusion volume by 61% versus vehicle (n=10 per group, $p<0.01$) and reduced pericardial IL-1β by 74%. There is no widely accepted animal model of recurrent pericarditis; the zymosan model reflects acute inflammation only.

GLP toxicology

13-week GLP toxicology studies were completed in rat and dog. In dogs at the highest dose (100 mg/kg/day), reversible hepatocellular hypertrophy with mild ALT elevations (up to 2.4× baseline) was observed. The no-observed-adverse-effect level (NOAEL) in dog provides an estimated 6× exposure margin (AUC) over the planned Phase 2 dose of 150 mg BID.

4. Phase 1 Clinical Results (Study TSL-201-101)

Randomized, double-blind, placebo-controlled SAD/MAD study in healthy adult volunteers conducted at a single site in Australia. SAD: 6 cohorts of 8 (6 active : 2 placebo), 25 mg to 800 mg. MAD: 3 cohorts of 8, 14 days of dosing at 75 mg, 150 mg, and 300 mg BID. Total N=72 (54 TSL-201, 18 placebo). Part C: open-label cohort of 10 patients with recurrent pericarditis presenting with an active recurrence (pain score ≥4/10 and CRP >1.0 mg/dL), treated with 150 mg BID for 28 days in addition to background NSAIDs/colchicine, at 3 Italian sites.

Pharmacokinetics

TSL-201 was rapidly absorbed (Tmax 1.5–2.5 h) with a mean terminal half-life of 11 hours supporting BID dosing. Exposure increased approximately dose-proportionally from 25 mg to 400 mg with less than proportional increase above 400 mg. A food-effect cohort has not yet been run.

Pharmacodynamics

MAD dose (Day 14, trough)	Mean ex vivo IL-1β inhibition
75 mg BID	63%
150 mg BID	88%
300 mg BID	94%

Safety summary

Event	Placebo (n=18)	75 mg BID (n=6)	150 mg BID (n=6)	300 mg BID (n=6)
Any treatment-emergent AE	7 (39%)	2 (33%)	3 (50%)	4 (67%)
Headache	3	1	1	2
ALT >3× ULN	0	0	0	2
Serious AEs	0	0	0	0
Discontinuations due to AE	0	0	0	1

Two subjects in the 300 mg BID cohort had ALT elevations above 3× the upper limit of normal (peak 4.1× and 3.4× ULN) on Days 10 and 13 without bilirubin elevation; both resolved within 21 days of stopping drug. One of the two discontinued. Management attributes these to exposure above the therapeutic range and has selected 150 mg BID for Phase 2. SAD data were unremarkable and are available in the full clinical study report.

Part C: open-label patient cohort (n=10)

Outcome (Day 28)	Result
Pain response (≥50% reduction in pain score)	9 of 10 patients
Median time to CRP normalization	7 days

Recurrence during 28-day treatment	0 of 10
ALT >3× ULN	0 of 10

Part C was uncontrolled and all patients continued background NSAIDs and/or colchicine, which can themselves resolve an acute episode. Recurrence after drug discontinuation was not assessed.

5. Phase 2 Clinical Development Plan (Study TSL-201-201)

Design: Multicenter, randomized-withdrawal study in patients with recurrent pericarditis (≥2 prior recurrences) presenting with an active recurrence. All patients receive open-label TSL-201 150 mg BID during a 12-week run-in; responders are randomized 1:1 to continue TSL-201 or switch to placebo.

Parameter	Plan
Sample size	60 randomized (approx. 80 enrolled in run-in)
Primary endpoint	Time to first pericarditis recurrence in the randomized-withdrawal period
Key secondary endpoints	Time to pain response and CRP normalization in run-in; proportion of recurrence-free patients at Week 24
Sites	~35 sites (US, Italy, Israel)
Enrollment period	~15 months (assumes 0.15 patients/site/month)
Estimated direct cost	$38M including CRO, drug supply, and site costs

The design mirrors the pivotal randomized-withdrawal trial that supported approval of the existing IL-1 biologic in RP. Management believes that a positive Phase 2 could, subject to FDA agreement, be followed by a single confirmatory Phase 3 trial. This has not been discussed with FDA.

Liver monitoring (ALT/AST every 2 weeks for the first 12 weeks) will be included in the protocol. The recruitment rate assumption is based on the enrollment rate reported for the prior pivotal trial in this indication, which enrolled at specialist pericarditis centers; the company has not yet completed a site feasibility survey.

6. Regulatory Strategy

- **IND status:** The US IND was cleared in April 2025 for Phase 1; the Phase 1 study was ultimately conducted in Australia under the CTN scheme for speed and cost.
- **Pre-IND meeting (January 2025):** FDA agreed with the nonclinical package for Phase 1 and requested that the company characterize hepatic safety in Phase 1 and provide a justification for the Phase 2 dose incorporating hepatic safety data.
- **End-of-Phase 1 meeting:** Requested; briefing package in preparation. Management expects to discuss the Phase 2 design and a potential accelerated development path.
- **Orphan Drug Designation:** Application submitted July 2026 for the treatment of recurrent pericarditis; decision pending. Management notes that the existing IL-1 biologic received orphan designation in this indication.
- **Breakthrough Therapy:** Management intends to apply after Phase 2 data if results are supportive.

Because RP is a relapsing disease requiring chronic therapy, management expects FDA to require a long-term safety database (likely several hundred patient-years of exposure) before approval, in addition to efficacy data. A plan for that safety database has not yet been drafted.

7. Intellectual Property

Family	Coverage	Status	Expected expiry
TSL-001	Composition of matter: TSL-201 and a genus of related sulfonamide-pyrazole compounds	PCT filed March 2023 (priority March 2022); US national phase application pending; no claims yet allowed	2043 (before PTE)
TSL-002	Method of use: NLRP3 inhibition in pericardial disease	US provisional filed May 2025	2046 if converted
TSL-003	Crystalline salt form of TSL-201	Planned filing Q1 2027	—

License

Family TSL-001 is exclusively licensed from the University of Northbridge, where the scientific founder is a faculty member. Key terms: worldwide exclusive license in all fields; 3.0% royalty on net sales; 15% of sublicense income; development milestones totaling $4.5M (including $2.5M at initiation of Phase 3); university retains a 4.0% equity stake. The license may be terminated if the company fails to initiate a Phase 2 trial by December 31, 2027.

Freedom to operate

Outside counsel delivered an FTO opinion in 2024 covering two third-party NLRP3 patent families and concluded that TSL-201 does not infringe any valid claim. A third-party US application covering sulfonamide-based NLRP3 inhibitors published in March 2025, after that opinion. Counsel's analysis of that application is underway and is expected in Q4 2026.

8. Market Opportunity and Competition

Management's market model (US only)

Assumption	Value
Addressable patients (≥2 recurrences)	14,000
Peak market share of addressable patients	30%
Net price per patient per year	$180,000
Average duration of therapy	18 months
Implied peak US net sales	~$750M

Management believes an oral therapy priced at a discount to the injectable biologic will be preferred by patients and physicians. Pricing has not been tested with payers. Ex-US sales and additional indications are excluded from the model.

Competitive landscape

- At least five oral NLRP3 inhibitors are in clinical development at other companies across cardiovascular, neurological, and metabolic indications. To management's knowledge, none is currently in development for recurrent pericarditis, though several are well funded and could enter the indication.
- A long-acting (monthly) IL-1 biologic is in Phase 2 for RP at another company.
- Generic colchicine and corticosteroids remain the foundation of care.

Expansion opportunities

The company intends to pursue one or more additional IL-1–mediated indications after Phase 2 data. Specific indications have not been prioritized, and no expansion-indication studies are budgeted in this financing.

9. Team and Governance

Name / role	Background
Chief Executive Officer (co-founder)	15 years in biotech business development; previously led partnering at a mid-size immunology company. First CEO role.
Chief Scientific Officer (scientific founder)	Professor of Immunology, University of Northbridge; 60+ publications on inflammasome biology. Retains a 40% faculty appointment.
Chief Medical Officer	Full-time since May 2026; cardiologist who previously led two Phase 2 programs in inflammatory cardiovascular disease at a large biopharma company.
VP, CMC	Full-time; 20 years small-molecule process chemistry.
Finance	Fractional CFO through an outsourced accounting firm.

Headcount is 11 full-time employees. The company relies on CROs for all clinical operations and on a single contract manufacturer for drug substance.

Board of directors (current)

CEO; scientific founder; one seed investor representative; one independent director with commercial cardiology experience. Upon closing, the Series A lead will receive one board seat.

10. Proposed Series A Terms

Term	Proposal
Amount	$42.0M Series A Preferred
Pre-money valuation	$88.0M (fully diluted, including expanded option pool)
Post-money valuation	$130.0M
Lead investor	$20.0M committed (term sheet signed August 2026)
Co-lead and existing investors	$17.0M committed; $5.0M allocation remaining, offered to the investor receiving this summary
Liquidation preference	1× non-participating
Option pool	Expanded to 12% post-money, included in pre-money
Closing	Single close targeted for November 2026

Pro forma capitalization (post-money, fully diluted)

Holder	Ownership
Founders and employees (common)	30.6%
University of Northbridge	2.8%
Seed preferred and converted SAFEs ($9.0M at a $30M post-money cap)	22.3%
Option pool (granted and unallocated)	12.0%
Series A investors	32.3%
Total	**100.0%**

11. Use of Proceeds, Burn, and Runway

Cash and equivalents at August 31, 2026: **$6.1M**. Current net burn is approximately $1.4M per month.

Planned uses through Phase 2 topline (management estimate)

Use	Amount
Phase 2 study TSL-201-201 (direct costs)	$38.0M
CMC: drug substance scale-up and Phase 2 drug product	$6.0M
Additional nonclinical (6-month rat / 9-month dog chronic tox, food effect)	$4.0M
Personnel and G&A (Q4 2026 – Q2 2029)	$9.0M
Total	**$57.0M**
Less: Australian R&D tax incentive refunds (estimated, Phase 1 and Phase 2 Australian activity)	($3.5M)
Net cash required	**$53.5M**

Monthly net burn is projected to rise to approximately $2.6M per month once Phase 2 enrollment begins in Q2 2027. Cash at closing is expected to be approximately $46.5M after pre-close burn. Management expects to close the remaining ~$7M gap to Phase 2 topline through a Series A extension or venture debt, and has held preliminary conversations with one venture-debt provider.

Key risks identified by management

- Hepatic safety at therapeutic doses in a chronic-dosing population.
- Phase 2 enrollment speed in a rare, specialist-managed population.
- Competitive entry by better-funded NLRP3 programs.
- Outcome of the pending FTO analysis of the March 2025 third-party application.
- Funding gap of ~$7M before Phase 2 topline.