

Diligence Report: SURGE Therapeutics

Series C Investment Diligence | Elliot Silk | June 2026

Bottom Line: Recommended to invest. This is primarily a bet on the lead asset SRG-514, with the urology franchise as embedded optionality. A clinically de-risked payload, a genuinely novel and defensible delivery context, a capital-efficient model, a strong team, and a fast 505(b)(2) regulatory path together justify participation, subject to the diligence milestones set out below.

Company Overview

SURGE Therapeutics is a clinical-stage oncology company commercializing intraoperative immunotherapy through its SURGERx platform, an injectable, biodegradable hydrogel placed directly into the tumor resection cavity at the time of surgery. The thesis rests on a well-established, paradoxical clinical problem: surgery triggers local inflammation and immune suppression, residual disease exploits that window, and standard adjuvant therapy does not begin until weeks later. SURGE delivers a concentrated, single, localized dose during the procedure to reprogram that window.

Founder and CEO Michael Goldberg brings deep experience in chemical biology, having worked with leaders in the cancer field, which culminated in an assistant professorship at the Dana-Farber Cancer Institute. Having lost friends to post-surgical cancer recurrence, Goldberg pursued SURGE full-time to address this gap in care. Management brings relevant operational depth, including CMO Chuck Carignan, with extensive medical-device and clinical-leadership experience, and head of formulations Paul Konowicz, formerly of Genzyme and Anokion and a co-inventor of an approved injectable hydrogel device. The scientific advisory board is strong, including Bob Langer and translational immuno-oncology leaders. SURGE has raised approximately \$64M to date^[8] from a credible syndicate and operates at roughly \$1.2M per month across three clinical programs, which is capital-efficient for a three-asset clinical pipeline.

All three programs are built on the same hydrogel delivery platform, giving the company a pipeline-in-a-product structure in which one delivery technology underwrites multiple shots on goal.

Market Opportunity

The global macro-opportunity is significant: roughly 9 million cancer patients undergo solid-tumor surgical resections annually, with a stark percentage suffering local or distant recurrence. SURGE's internal materials rely on high-level consultant assessments, projecting a Serviceable Obtainable Market (SOM) of ~\$470M in TNBC (with an additional \$1.5B across broader breast-cancer subtypes), ~\$1.0B in high-risk non-muscle-invasive bladder cancer (NMIBC), and ~\$1.2B in high-risk prostate cancer.

To pressure-test these assumptions, a bottom-up epidemiological analysis was built for the lead indication (early-stage, non-metastatic TNBC) using US ACS and SEER data:

- **Total incidence.** Annual US invasive female breast-cancer incidence stands at 316,950 cases.^[1]
- **Subtype and operability.** Applying a 12% phenotypic allocation for the triple-negative subtype and a 95% operable clinical fraction isolates ~36,000 non-metastatic, surgical TNBC cases annually in the US.
- **Surgical segmentation.** While SURGE's deck claims 70% to 75% of these patients receive breast-conserving surgery, population-level SEER data demonstrate a true lumpectomy rate of 50% to 55%,^[2] with the remainder undergoing mastectomy. Assuming conservatively that the hydrogel cannot be cleanly retained within a wide, flat mastectomy cavity, the true US addressable pool constricts to 18,000 to 20,000 patients per year.
- **Peak valuation.** Modeling a conservative 40% to 50% peak penetration and a premium net price of \$20,000 to \$30,000 per treatment course yields a realistic bottom-up US peak annual revenue range of \$160M to \$300M.

While lower than the company's unadjusted deck figures, a ~\$300M single-market peak for a first-in-category product is an attractive standalone return profile for a Series C entry. The larger bladder (~85,000 annual cases) and prostate (~314,000 annual cases)^[1] indications serve as unvalued call options. The platform's structural moat is its positioning within the surgical moment, a point in the care pathway entirely unoccupied by traditional pre-surgical or post-surgical developers.

Product and Technology

SRG-514 (lead asset, TNBC) is a thermosensitive hydrogel formulation of ketorolac, an NSAID approved since 1989 for perioperative pain. Its anti-cancer rationale is inhibition of COX-2 and the resulting reduction in PGE2-driven local immunosuppression, shifting the post-surgical microenvironment toward T-cell-dependent tumor control.

The Human Translation Gap

Human clinical evidence supporting perioperative NSAID use in oncology has historically been retrospective and observational.^[4] Crucially, the only prospective, randomized, double-blind, placebo-controlled trial evaluating perioperative ketorolac in high-risk breast cancer failed to demonstrate a statistically significant improvement in 2-year disease-free or overall survival; the authors note it was severely underpowered due to lower-than-anticipated baseline recurrence rates.^[3] Furthermore, the KBC trial used a single systemic intravenous dose (30mg) that cleared the body within hours. SURGE's entire scientific bet rests on the premise that transient systemic exposure is insufficient, and that its hydrogel solves this via continuous, multi-week local concentration. This remains an unproven clinical gamble that the pivotal trial must validate.

Wound-Healing Risk

A second-order point on the payload: ketorolac is a non-selective COX inhibitor that is comparatively COX-1 selective, which is why systemic ketorolac carries the strongest GI, renal, and antiplatelet liabilities among NSAIDs. COX-1 mediates synthesis of thromboxane A2, which drives platelet aggregation, and standard surgical protocols frequently pause NSAIDs perioperatively due to bleeding and hematoma risk. Saturating a fresh resection cavity with a ketorolac-loaded hydrogel therefore risks localized microvascular bleeding that could disrupt the surgical closure or cause site complications, and is a specific safety question for the data room.

STM-416 and STM-416p (Resiquimod)

STM-416 (bladder) and STM-416p (prostate) are hydrogel formulations of resiquimod, a TLR7/8 agonist roughly 50 to 100 times more potent than the approved topical imiquimod. The localized-delivery rationale is compelling: systemic resiquimod has repeatedly failed in the clinic because intravenous dosing produces severe grade 3 and 4 immune-related toxicity from high circulating cytokines, and no systemic formulation is approved anywhere.^[5] A localized depot that activates innate immunity at the resection site while limiting systemic spillover is the right strategy to rescue a molecule the field already believes in.

Two caveats belong in the record. First, the preclinical efficacy data use mouse models, and resiquimod activates both TLR7 and TLR8 in humans but only TLR7 in mice, so the mouse package does not capture the TLR8-driven myeloid biology prominent in humans. Second, the entire safety advantage depends on the gel retaining the drug locally; systemic leakage would reintroduce the cytokine toxicity that killed systemic development.

Formulation, Dose Control, and Hydrogel Safety

Formulation and dose control are less of an open risk than the deck alone suggests, because the founding Science Translational Medicine paper provides real data.^[5] Confocal microscopy showed that hydrophilic small molecules and biologics distribute uniformly across the hydrogel, and in vivo imaging of a resiquimod surrogate showed sustained rather than burst release, with the ~60% signal loss seen within two hours from a solution taking 24 hours from the gel. Loaded biologics were recovered intact and fully functional, confirming the PEGDA crosslinking chemistry does not inactivate the payload. The two payloads still differ in principle, since water-soluble ketorolac tends to release faster than poorly soluble resiquimod, and the published homogeneity

imaging used a physicochemical surrogate rather than resiquimod itself. The remaining questions are therefore second-order CMC items rather than fundamental ones: GMP-grade content uniformity, release reproducibility for both clinical payloads, and human dose reproducibility.

Hyaluronic-acid-based hydrogels are broadly biocompatible and biodegradable, with extensive precedent in dermal fillers and viscosupplements. The toxicity risk is concentrated not in the base polymer but in the crosslinker chemistry and degradation products, and in the foreign-body inflammatory response to the gel itself, which is a particular concern when the product is simultaneously trying to provoke a specific, controlled immune response. The crosslinker chemistry is undisclosed and is a diligence item.

Competitive Landscape and Business Model

At the level of direct competition, SURGE's first-in-category claim is largely fair: there is no commercial competitor doing intraoperative resection-cavity localized immunotherapy, and the only approved analog, the Gliadel carmustine wafer, is a differentiated chemotherapeutic delivery^[9] that would not take share. However, the claim is weaker than presented in two respects. The academic literature on postsurgical in-situ hydrogels is crowded, which constrains long-run defensibility, and the real competition is at the indication level, where it is heaviest precisely where the deck claims it is lightest.

TNBC. The deck's no-targeted-therapies framing is outdated for the early-stage setting. The KEYNOTE-522 regimen, neoadjuvant pembrolizumab plus chemotherapy followed by adjuvant pembrolizumab, is the standard of care for high-risk early TNBC, with a confirmed overall-survival benefit and pathologic complete response rates near 65%.^[6] The setting has also gained targeted options absent a decade ago, including the Trop-2 antibody-drug conjugates sacituzumab govitecan and datopotamab deruxtecan and, for HER2-low disease, trastuzumab deruxtecan,^[10] though these are metastatic-setting agents acting as downstream standard of care rather than head-to-head competitors. SRG-514's differentiation is therefore not that it fills a targeted-therapy void but that it occupies the intraoperative window none of these agents address, with a plausible tolerability edge versus the heavy immune-related toxicity of the pembrolizumab regimen and a focus on the residual-disease population.

Bladder. STM-416 enters the most competitive localized-delivery market in oncology. High-risk NMIBC has seen recent approvals of nadofaragene firadenovec and nogapendekin alfa, plus pembrolizumab, on top of four decades of BCG, and there is a direct sustained-local-delivery competitor in J&J's TAR-200, an intravesical gemcitabine-releasing system placed after resection that is under FDA priority review,^[7] alongside cretostimogene and others. This is where the deck's low-competition claim is least credible.

Prostate. The localized-delivery field is comparatively open, but the program is the earliest and least validated.

The business model is attractive where it works: single-dose administration during a standard-of-care procedure implies low COGS, simple administration, and no adherence problem, underpinning the capital-efficiency story and a high commercial gross margin. The natural exit is acquisition by an oncology or surgical-oncology strategic following positive registrational data.

Financial Model and Projections

Balance Sheet and Forward Runway

Following its \$32M Series B in July 2023 (led by Bioluminescence Ventures),^[8] SURGE combined the new capital with residual Series A cash to reach an estimated starting balance of roughly \$36M to \$38M. At a steady ~\$1.2M monthly burn across three programs, that balance would have been largely depleted by early 2026, which explains the timing of the current \$60M Series C, of which approximately 70% (\$42M) is already committed. On a reconciled basis, unencumbered cash today is on the order of \$36M to \$38M, securing a forward runway of roughly 30 months, into early-to-mid 2029. Critically, this round funds Phase 3 initiation, full enrollment, and the exploratory ctDNA readout expected by year-end 2028, but it does not by itself reach the mature recurrence-free survival readout that constitutes the lead program's primary value inflection; a follow-on raise is therefore likely before that pivotal endpoint, as reflected in the financing risk below.

Revenue Architecture and Post-Launch Projections

To evaluate the long-term return profile of this Series C entry, a bottom-up commercial model was constructed for the lead drug (SRG-514):

- **Target addressable volume (US lumpectomy TNBC).** Fixed at ~19,000 stable annual patients, adjusted downward from management's deck using strict SEER registry metrics.
- **Pricing architecture.** Gross price of \$30,000 per single intraoperative dose; applying a conservative 20% gross-to-net deduction for formulary rebates and oncology discounts models a net price of \$24,000 per patient.
- **Cost of goods sold.** Modeled at 8% of net revenue given the off-patent ketorolac payload and basic crosslinked hyaluronic-acid polymer, yielding an elite 92% commercial gross margin.
- **Adoption S-curve.** Year 1 penetration is conservatively pinned at 2.5% (475 patients), reflecting the 6-to-9-month hospital P&T formulary bottleneck, the lag in securing a permanent CMS J-code, and the surgical onboarding required to train oncologists on cavity-injection workflows.

Financial Metric	Year 1 (Launch)	Year 2	Year 3	Year 4	Year 5 (Peak)
Market Penetration	2.5%	7.5%	15.0%	30.0%	45.0%
Treated US Patients	475	1,425	2,850	5,700	8,550
Gross Revenue (\$M)	14.3	42.8	85.5	171.0	256.5
Net Revenue (\$M)	11.4	34.2	68.4	136.8	205.2
Gross Profit @92% (\$M)	10.5	31.5	62.9	125.9	188.8

Because the Series C capitalizes the company through its primary registrational value-inflection activities, this round represents an asymmetric entry point. The underlying asset possesses three characteristics attractive to acquirers: ~92% commercial gross margins, an absence of patient non-adherence risk given the single, surgeon-administered workflow, and a completely differentiated perioperative delivery.

Consequently, upon validation of Phase 3 efficacy data, SURGE becomes a premier bolt-on acquisition target for major pharmaceutical or surgical-oncology strategics (e.g., J&J, Merck, Roche) seeking to defend multi-billion-dollar adjuvant franchises. Modeling an industry-standard 5x to 7x multiple on Year 5 net TNBC revenue implies an enterprise value scaling toward \$1.0B to \$1.4B, a clean power-law return on the Series C valuation.

Key Risks and Open Questions

1. **Efficacy extrapolation.** The lead advances to a pivotal trial on retrospective ketorolac data, with the one prospective randomized trial negative. The bet is that sustained local delivery changes the outcome.
2. **Formulation and CMC (substantially mitigated).** Preclinical data show uniform distribution of hydrophilic and biologic payloads and sustained, non-burst release; the open items are GMP-grade content uniformity and human dose reproducibility, not whether the platform works.
3. **Local payload toxicity.** A COX-1 inhibitor concentrated in a fresh resection bed raises a bleeding and wound-healing question; a TLR7/8 agonist that leaks systemically reintroduces cytokine toxicity.
4. **Translational gap.** Mouse resiquimod data capture only the TLR7 arm of a TLR7/8 mechanism.
5. **Competition.** Bladder is crowded with approved products and a J&J depot; TNBC sits on top of an OS-proven immunotherapy standard of care.
6. **Financing and timing.** The \$60M funds trial starts and the urology Phase 2a programs, but the value-inflecting efficacy readout likely arrives after this runway, probably requiring a follow-on raise.
7. **IP and license.** The foundational estate is owned by Dana-Farber and in-licensed, so license terms qualify the wholly-owned framing. The claims map cleanly onto the resiquimod programs but less

obviously onto the lead, since ketorolac is a COX inhibitor rather than an immune agonist, so confirm what specifically protects SRG-514. Freedom to operate is not pristine given third-party resection-cavity hydrogel patents.

Open Diligence Questions

1. What methods ensure homogeneous distribution of ketorolac and resiquimod across the hydrogel for reliable dosing, and how are the payloads manufactured or sourced under GMP?
2. What are the terms of the Dana-Farber license (exclusivity, field, territory, royalty stack, and diligence obligations)?

Final Recommendation and De-Risking Milestones

The final recommendation is to invest. This position recognizes that the thesis is primarily a bet on SRG-514, with the urology franchise as optionality. The combination of a de-risked payload, a novel delivery context, a capital-efficient model, a strong team, and a fast regulatory path justifies participation, sized and priced to the base-case sensitivity. Milestones to underwrite against:

- Phase 1 proof-of-principle data showing a biomarker or ctDNA signal, not safety alone, before the Phase 3 starts.
- A CMC data package demonstrating content uniformity and reproducible release for both clinical payloads.
- Confirmed Phase 3 design with FDA, including endpoint and the accelerated-approval mechanism, plus evidence the round and follow-on fund the program to a value-inflecting readout.
- Clean Dana-Farber license terms and confirmed composition- or method-of-use protection specific to SRG-514.
- Local-safety data on hemostasis and wound healing for the ketorolac gel, and on systemic cytokine exposure for the resiquimod programs.

References

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