Geron Corporation (GERN) - 2026 Outlook and Competitive Positioning

Executive summary

Geron Corporation is in the middle of a structural transition: from a long-time development-stage biotech focused on telomerase biology to a fully commercial hematology company with a first-in-class product on the market and a credible path to operational profitability.

The company's lead asset, the telomerase inhibitor imetelstat, is now marketed under the brand name RYTELO in the United States and in the European Union for lower-risk myelodysplastic syndromes (LR-MDS) with transfusion-dependent anemia after failure or ineligibility for erythropoiesis-stimulating agents (ESAs). In parallel, imetelstat is being advanced in late-stage development for relapsed / refractory myelofibrosis (MF) after JAK-inhibitors, with a phase 3 trial powered for overall survival and an interim analysis expected in the second half of 2026.

For 2026, Geron has communicated net product revenue guidance for RYTELO in the range of 220-240 million USD and total operating expenses between 230-240 million USD. Combined with a sizeable cash position and access to additional non-dilutive funding, this implies a realistic path toward operating break-even by the end of 2026, if the commercial ramp executes as planned.

On the strategic side, the company is concentrating its resources around three pillars: (1) maximising the commercial opportunity of RYTELO in the US; (2) executing a disciplined, stepwise launch in selected European countries as reimbursement decisions are secured; and (3) delivering on the imetelstat pipeline, with myelofibrosis as the next major value-creating catalyst.

Overall, the risk profile is not trivial - this is still a single-asset story in practical terms - but the combination of an already approved product, growing revenue, disciplined cost control, and a highly differentiated mechanism of action supports a moderately constructive stance on Geron's medium-term outlook.

1. 2026 financial guidance and operating sustainability

1.1 Revenue and cost guidance

For full-year 2026 Geron has guided to:

- Net product revenue from RYTELO in the United States in the range of 220-240 million USD. - Total operating expenses in the range of 230-240 million USD.

This guidance is important because it explicitly frames 2026 as a transition year in which revenue is expected to essentially cover the operating cost base. If Geron executes toward the upper end of the revenue range and manages expenses near the lower end of the guidance, management believes it can reach operating profitability by the end of 2026 or shortly thereafter.

The cost side already reflects the effect of a strategic restructuring plan executed in 2025. As part of that plan, Geron implemented a significant reduction in its workforce - on the order of roughly one third of total headcount - and streamlined non-critical spending in order to re-allocate capital to commercial support for RYTELO and to the highest-priority clinical programs. The company disclosed one-time restructuring charges of roughly 18 million USD, mainly related to severance and associated costs, with the expectation of durable structural savings in subsequent years.

The resulting 2026 operating-expense guidance of 230-240 million USD is noticeably lower than previous run-rate levels and embeds both continued commercial investment and ongoing R&D; spend for the myelofibrosis program. In other words, the company is not "starving" future growth in order to show near-term profitability; rather, it is trying to reach sustainable scale while continuing to fund late-stage development.

1.2 Balance sheet, debt structure and funding flexibility

From a balance-sheet perspective, Geron entered 2026 with several supportive elements:

- A solid cash and marketable securities position built through multiple equity raises during the registrational phase of imetelstat and the early commercial rollout. - A structured, predominantly non-dilutive financing package put in place with Royalty Pharma and Pharmakon Advisors.

Under this package, Royalty Pharma paid an upfront amount in exchange for a tiered synthetic royalty on US net sales of RYTELO, capped at a pre-agreed multiple of the initial investment and subject to a time limit. In parallel, Pharmakon provided a multi-tranche senior secured loan facility with an initial draw used partly to refinance prior debt and partly to support the launch. The remaining tranches - up to a total of 125 million USD of additional capital - can be drawn at Geron's discretion based on pre-defined revenue milestones.

Crucially, in early 2026 Geron and Pharmakon agreed to extend the deadline for drawing the remaining tranches to 30 July 2026. This extension signals confidence from the lender in the commercial trajectory of RYTELO and provides extra liquidity optionality if the company sees attractive opportunities to accelerate growth (for example, a faster-than-planned European rollout or additional investments around the myelofibrosis program).

The loan structure has no financial maintenance covenants and provides for a bullet repayment at maturity, which reduces near-term cash drain. Together with the royalty structure, this gives Geron meaningful flexibility: if the RYTELO ramp is on or ahead of plan, the company can choose not to draw the additional debt; if the ramp is slower or if extra capital is needed for strategic initiatives, the facility acts as a buffer without forcing equity dilution in an unfavourable market.

Overall, the combination of cash on hand, expected RYTELO revenue, and access to further non-dilutive capital supports the view that Geron is funded to execute its current strategy through the key myelofibrosis read-out and the initial years of the European launch.

2. Commercial roll-out of RYTELO in the United States

2.1 Indication and clinical value proposition

RYTELO (imetelstat) is approved in the United States for adult patients with lower-risk myelodysplastic syndromes who have transfusion-dependent anemia and do not have deletion 5q, after failure or ineligibility for ESA therapy. These are patients who typically require frequent red blood cell transfusions and have limited disease-modifying options.

The pivotal phase 3 IMerge study showed that imetelstat can induce clinically meaningful and durable transfusion independence in a significant proportion of these patients. The primary endpoint was the proportion of patients achieving at least 8 consecutive weeks without transfusions. Imetelstat roughly doubled this rate versus placebo and, importantly, many responders maintained transfusion independence for extended periods - in some cases close to or beyond one year.

Follow-up analyses have suggested that patients who achieve durable transfusion independence or a substantial rise in haemoglobin may also show a trend towards improved long-term outcomes, including progression and overall survival, compared with non-responders. While IMerge was not formally powered for survival, these signals contribute to the perception of imetelstat as more than a purely symptomatic therapy: it is increasingly viewed as a potential disease-modifying agent acting at the level of the malignant stem and progenitor cells.

The main safety concern with imetelstat is early-onset cytopenias (neutropenia and thrombocytopenia), typically occurring in the first cycles. At the 2025 ASH meeting, detailed analyses showed that these cytopenias are generally transient, reversible with dose holds or reductions, and - importantly - appear to correlate with better clinical response. This "on-target cytopenia" pattern is similar to what haematologists are used to seeing with other disease-modifying agents such as lenalidomide in del(5q) MDS. As a result, prescribers are increasingly comfortable managing this aspect of therapy.

2.2 Early commercial performance in the US

Since its US launch in the second half of 2024, RYTELO has shown a constructive, if still early, commercial trajectory. By mid-2025, the product had accumulated tens of millions of dollars in net sales and had been ordered by more than one thousand treatment centres across the United States. The account base expanded quarter after quarter, indicating that awareness among community haematologists and academic centres is steadily rising.

There have been some fluctuations in quarter-to-quarter sales and volume growth, which is not unusual for a new oncology drug being adopted into real-world practice. Geron's new CEO and commercial leadership have responded by reinforcing the field organisation - expanding the US sales force and doubling the medical science liaison team - and by sharpening the focus on education around patient

selection and management of early cytopenias.

A dedicated patient-support programme (REACH4RYTELO) helps patients and providers navigate reimbursement, prior authorisations and co-pay assistance. On the payer side, RYTELO now has broad coverage in both Medicare and commercial plans, supported by a permanent J-code for billing. The drug has also been incorporated into leading guidelines, which lowers barriers for clinicians who want to adopt it as a standard option after ESA failure.

Looking forward, the company expects US RYTELO sales to accelerate into 2026 as:

- More physicians gain hands-on experience with imetelstat. - Early cohorts of responding patients remain transfusion-independent and share their experiences. - The clinical community digests longer-term data on durability and possible survival trends.

From a modelling perspective, the US opportunity is significant: Geron estimates that the eligible LR-MDS population runs into the low tens of thousands of patients, and penetration is still in the early single-digit percentages. There is thus substantial room to grow US revenue over the next several years even before considering any label expansion into myelofibrosis.

3. European launch and international expansion

3.1 European approval and orphan-drug status

In March 2025, the European Commission granted a centralised marketing authorisation for imetelstat as monotherapy for adult patients with transfusion-dependent anemia due to very-low, low or intermediate-risk MDS, without del(5q), after failure or ineligibility to ESA. This authorisation covers all 27 EU member states as well as Iceland, Norway and Liechtenstein.

Imetelstat is the first and only telomerase inhibitor approved in Europe, and it retains orphan-drug status in the region for the MDS indication. Orphan designation supports reduced regulatory fees and, crucially, ten years of market exclusivity from the date of approval, subject to the usual conditions. In parallel, Geron has applied for supplementary protection certificates and other patent-term extensions in key jurisdictions, which together with existing patents are expected to keep effective market exclusivity well into the 2030s.

3.2 Reimbursement and launch strategy in Europe

Approval by the EMA and Commission is only the first step in Europe; actual patient access depends on national health technology assessment (HTA) and pricing & reimbursement (P&R;) processes. Geron is pursuing a phased launch strategy, initially concentrating on a handful of "wave 1" countries where access pathways are relatively efficient and where the MDS burden and specialist infrastructure are substantial - typically markets such as Germany, France, Italy, Spain and the UK (via separate UK regulatory routes).

In Germany, for example, newly approved oncology drugs can be made available relatively quickly with temporary reimbursement while the AMNOG benefit-assessment process is ongoing. Imatelstat's clinical profile - sizeable and durable transfusion independence, meaningful reduction in transfusion burden, and strong unmet need in non-SF3B1 / ring-sideroblast populations - provides a compelling value proposition for these assessments. In other markets, such as France and Italy, health-technology bodies will evaluate imetelstat's added therapeutic value compared with existing options (notably luspatercept in SF3B1-positive patients and essentially no disease-modifying option in SF3B1-negative disease).

Parallel to formal P&R; processes, Geron is working with national authorities and key centres to set up expanded-access and named-patient programmes where appropriate. These mechanisms allow certain eligible patients to receive RYTELO ahead of formal reimbursement, especially in indications with high unmet need. Beyond the EU, additional opportunities exist in countries such as the UK, Canada and Australia, where imetelstat could be introduced either directly or via local partners.

The company does not intend to overextend its footprint; rather, it is building a focused European commercial and medical organisation tailored to the haemato-oncology setting. Over time, as reimbursement decisions are obtained across the major markets, Europe should evolve from a cost centre into an important second pillar of revenue alongside the United States.

4. Clinical pipeline: beyond LR-MDS

4.1 IMpactMF: phase 3 in relapsed / refractory myelofibrosis

The most important development programme for imetelstat beyond LR-MDS is the phase 3 IMpactMF trial in patients with intermediate-2 or high-risk myelofibrosis who are relapsed, refractory or otherwise intolerant to JAK-inhibitor therapy. This is a severely ill population with a poor prognosis and no established standard of care after JAK failure.

IMpactMF enrols approximately 320 patients randomised 2:1 to imetelstat versus best available therapy (BAT) at the investigator's choice. The design is notable in that the **primary endpoint is overall survival**, making it the first phase 3 study in this setting powered to show a survival benefit. Secondary endpoints include symptom improvement, spleen-volume reduction, quality of life and safety.

Patient enrolment has been completed, and the trial includes two planned time-points for efficacy evaluation:

- An **interim analysis** of overall survival in the second half of 2026, at around 35% of total expected death events. - A **final analysis** anticipated in the second half of 2028, around 50% of total events.

Earlier phase 2 work with imetelstat in MF suggested a potentially meaningful survival advantage compared with historical controls, alongside improvements in spleen size, symptoms and fibrosis grade in a subset of patients. These data, together with biomarker evidence of reductions in driver mutation allele burden and inflammatory cytokines, underpin the hypothesis that imetelstat may modify disease

biology rather than just palliate symptoms.

If IMpactMF confirms a statistically and clinically significant survival benefit, imetelstat could become the **first therapy with proven overall-survival impact after JAK-inhibitor failure**, opening a second major commercial indication and profoundly reshaping the treatment algorithm in MF. Even a strong trend at interim, if supported by secondary endpoints, could trigger a constructive dialogue with regulators about potential avenues for earlier approval.

4.2 Combination approaches in first-line myelofibrosis

Geron is also exploring imetelstat in combination with ruxolitinib in earlier-line MF through a phase 1b study. The concept is straightforward: combine a JAK-inhibitor that rapidly improves symptoms and spleen with a telomerase inhibitor that targets the malignant stem-cell compartment, with the aim of deepening and prolonging responses.

Early data from dose-escalation cohorts have shown that the combination is feasible from a safety standpoint, without unexpected toxicity beyond manageable cytopenias. There are preliminary signals of improved spleen-volume reduction and encouraging changes in molecular markers (such as decreases in driver mutation allele frequencies).

These findings are still very early, and any expansion into pivotal development in front-line MF would require more mature data. Nevertheless, they support the broader narrative that imetelstat could eventually play a role across the MF continuum, not only in the ruxolitinib-failure setting targeted by IMpactMF.

4.3 High-risk MDS and AML: early-stage exploration

An academic, investigator-sponsored trial is evaluating imetelstat in patients with high-risk MDS or acute myeloid leukaemia who have failed prior hypomethylating agents. This is an extremely challenging population with limited options. In this context, imetelstat monotherapy has so far shown limited activity, which is not surprising given the aggressive biology of these diseases at that stage.

The main value of this programme lies in demonstrating that imetelstat can be administered safely in heavily pre-treated patients and in generating hypotheses for future **combination strategies**. For example, one could imagine combining telomerase inhibition with targeted agents, BCL-2 inhibitors or post-remission maintenance approaches. For now, however, these ideas remain exploratory and are not central to the near-term investment thesis.

4.4 Long-term follow-up in LR-MDS

Finally, extended follow-up from IMerge and its extension cohorts continues to support the view that imetelstat's benefits in LR-MDS may translate into better long-term outcomes. Analyses at approximately 45 months of median follow-up suggest favourable trends in overall survival and progression endpoints for patients who achieved transfusion independence or meaningful haemoglobin improvements compared with non-responders.

Although these analyses are exploratory and not the basis of the current label, they are important in shaping clinical perception: many haematologists increasingly view RYTELO not only as a way to "cut the transfusion cord" temporarily but as a treatment that may slow disease trajectory in at least a subset of patients.

5. Regulatory and market-access landscape

5.1 United States (FDA and payers)

Regulatorily, the situation in the US is straightforward. Imetelstat is fully approved by the FDA for its LR-MDS indication, supported by standard post-marketing commitments focused on long-term safety and effectiveness in real-world practice. The drug has orphan-drug exclusivity for MDS, which provides seven years of market exclusivity from approval.

On the payer side, the key enablers - permanent J-code, Medicare Part B coverage, and broad commercial coverage - are in place. Geron's responsibility is now mainly to continue educating payers and providers on appropriate use and on the clinical and economic value of reducing transfusion burden and hospital resource utilisation.

If IMpactMF is positive, Geron will likely pursue a supplemental new drug application (sNDA) with the FDA for the MF indication. Given the orphan setting and the prior Fast Track status of imetelstat in MF, this could allow relatively efficient regulatory review. Whether any form of accelerated pathway is feasible will depend on the strength and consistency of the data at interim and final analyses.

5.2 Europe (EMA, HTA and national reimbursement)

In Europe, the EMA approval and orphan status provide a solid regulatory foundation. The real work now is at the HTA and P&R; level, where Geron must convince national decision-makers that imetelstat delivers meaningful added value versus existing options and warrants premium pricing in a rare-disease setting.

The clinical case is strong, especially in patient segments where no effective alternatives exist (for example, non-SF3B1 / non-ring-sideroblast LR-MDS). In SF3B1-positive patients, imetelstat competes with or complements luspatercept; here, the duration of transfusion independence and the emerging evidence of deeper disease impact will be central to the value narrative.

Different countries will move at different speeds. Germany is likely to be among the first markets with broad funded access; countries with more complex budget-impact hurdles may take longer. Geron's stepwise launch strategy, combined with early access programmes where feasible, should help maintain clinical momentum while formal pricing rounds are in progress.

6. Competitive landscape: MDS and MF

6.1 Lower-risk MDS

In LR-MDS, the main branded competitor is luspatercept (Reblozyl, Bristol Myers Squibb). Luspatercept is approved for anemia in SF3B1-mutated or ring-sideroblast-positive LR-MDS after ESA, and it has become a standard of care in that molecularly defined subgroup.

However, luspatercept does not address the much larger population of non-SF3B1 / non-ring-sideroblast patients. Moreover, while it improves haemoglobin and reduces transfusion burden in responders, its median duration of effect is shorter than what has been observed with imetelstat in IMerge.

RYTELO's positioning is therefore quite attractive:

- It covers **both** SF3B1-positive and SF3B1-negative patients after ESA failure. - It has demonstrated **deep and durable** transfusion independence, with a meaningful proportion of patients remaining off transfusions for a year or longer. - It increasingly appears to have signs of **disease modification**, which luspatercept has not demonstrated to the same extent.

In practice, many clinicians are likely to use both agents over the course of a patient's disease - for example, starting with luspatercept in certain SF3B1-positive cases and then transitioning to imetelstat upon non-response or loss of response. In non-SF3B1 disease, imetelstat is essentially the only targeted option, which gives Geron a quasi-monopolistic position in that segment.

6.2 Myelofibrosis

The myelofibrosis landscape is more crowded and dynamic, with multiple players:

- Incyte's **ruxolitinib** remains the backbone of front-line therapy. - GSK's **momelotinib** offers an attractive option for MF patients with significant anemia, particularly because it can improve haemoglobin while controlling symptoms. - BMS's **fedratinib** and Sobi's **pacritinib** address specific niches (such as patients with severe thrombocytopenia). - Combination strategies (e.g. ruxolitinib plus BCL-2 / BCL-XL inhibitors or BET inhibitors) are being explored to deepen first-line responses.

However, none of these agents has convincingly shown a robust overall-survival benefit in the post-JAK failure setting. They are primarily symptomatic and cytoreductive in nature, whereas imetelstat is designed to attack the underlying malignant clone via telomerase inhibition.

If IMpactMF delivers on its primary endpoint, imetelstat would sit in a unique position as **the only therapy with proven survival benefit after JAK failure**. It could then become the default option in that line, with other drugs used around it for symptom optimisation. Moreover, the mechanistic complementarity between JAK-inhibitors and telomerase inhibition creates natural opportunities for rational combinations in earlier lines, as already hinted by the phase 1b work.

In short, while competition is real, Geron's asset is differentiated both in mechanism and in the clinical endpoints it is targeting. That differentiation is the core of the company's competitive moat.

7. Community and market sentiment

7.1 Clinical community

Among haematologists and MDS specialists, sentiment around RYTELO is steadily improving. With more than a year of real-world use behind them, clinicians are gaining confidence in selecting patients, managing cytopenias and interpreting responses. Testimonials from both physicians and patients highlight the impact that long periods of transfusion independence can have on quality of life, reducing hospital visits, transfusion-related complications and caregiver burden.

At major congresses, imetelstat has moved from being a "controversial" experimental drug to a central part of educational sessions on LR-MDS and an emerging topic in MF discussions. Key opinion leaders increasingly describe imetelstat as a **disease-modifying therapy** with the potential to change clinical practice, particularly if the myelofibrosis survival data confirm earlier signals.

7.2 Investor sentiment

On the capital-markets side, Geron has long had a large and vocal retail shareholder base, complemented more recently by a growing presence of specialised biotech and healthcare funds. The approval and launch of RYTELO have de-risked the story meaningfully compared with the past, shifting the narrative from "if" to "how big and how fast".

Analyst coverage generally frames Geron as a high-beta but fundamentally improving story: a company transitioning into a commercial stage with a differentiated asset, clear revenue growth and a major late-stage catalyst (IMpactMF) on the horizon. Consensus expectations for the stock over the next 12-24 months are tied to two questions:

1. Can Geron deliver on its **2026 revenue and cost guidance**, demonstrating operating discipline and visibility around break-even? 2. Will the **interim survival analysis in IMpactMF** provide a strong enough signal to support regulatory discussions and investor confidence in the MF expansion?

Risks remain - including the possibility of a slower-than-expected ramp, unforeseen safety issues, or underwhelming MF data - and a minority of sceptical voices still view the stock as vulnerable if any of these materialise. Nevertheless, the balance of sentiment has shifted from the deep scepticism of earlier years to a more balanced, but overall positive, outlook.

8. Outlook 2026-2028

Looking ahead, several key milestones will shape Geron's trajectory:

- **2026** - Execution of the US RYTELO commercial plan and demonstration of high-teens to low-twenties percent growth in product revenue. - Initial **European launches** in selected countries

following national reimbursement decisions. - **Interim overall-survival analysis** from IMpactMF in relapsed / refractory myelofibrosis in the second half of the year. - Progress updates from combination studies in front-line MF.

- **2027** - Potential submission of supplemental regulatory applications for the MF indication, depending on the strength of interim data and ongoing follow-up. - Expansion of European and possibly other international markets with increasing contribution to total revenue. - Continued generation of real-world evidence in LR-MDS.

- **2028 and beyond** - Final overall-survival read-out from IMpactMF. - Full assessment of imetelstat's role in MF, including potential front-line strategies. - Strategic decisions on life-cycle management, partnerships and potential new indications.

From a strategic perspective, Geron is now more than a binary event around a single trial. The LR-MDS franchise provides a growing revenue base and validates telomerase as a drug target in human disease. The MF programme, if successful, would roughly double the commercial opportunity and reinforce the perception of imetelstat as a platform-level therapy in myeloid malignancies.

In parallel, the company has put in place a funding structure that reduces immediate financing risk and allows management to focus on execution rather than capital raising. The main execution risks are commercial - ensuring that RYTELO reaches the many patients who could benefit - and clinical - delivering robust, reproducible data in MF.

9. Concluding view

Taken together, the current picture for Geron in early 2026 is that of a company at an inflection point. It has:

- A first-in-class drug approved in a meaningful niche of LR-MDS, with clear signs of clinical value and growing adoption. - A credible path to operating break-even based on 2026 guidance, supported by disciplined cost control and thoughtful use of non-dilutive capital. - A high-impact late-stage trial in myelofibrosis that, if positive, could transform both patient care and the company's financial profile. - A differentiated scientific story around telomerase inhibition that sets it apart from more crowded mechanism classes.

This is not a risk-free situation; setbacks in MF, commercial underperformance or unforeseen safety signals could materially change the outlook. But under reasonable assumptions, Geron appears well positioned to create significant long-term value by consolidating its emerging role as a focused, innovation-driven hematology company.