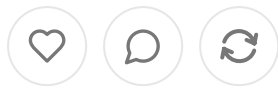


Gene Editing Has the Science Figured Out and Now Needs an Entire Stack of New Business Models, Reimbursement Mechanics, and Healthcare Operating Infrastructure Before Any of This Scales to Patients

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🎧 Gene Editing Has the Science Figured Out and Now Needs an Entire Stack of New Business Models, Reimbursement Mechanics, and Healthcare Operating Infrastructure Before Any of This Scales to Patients

CASGEVY is approved, priced at \$2.2M, and has 500+ patient initiations globally. Vertex reported \$43M in Q1 revenue. That sounds like progress. It is also a signal that gene editing has a much bigger problem than the science...

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Table of Contents

Abstract

The CASGEVY tell

Why a one-time cure breaks the operating system

The diagnosis problem nobody wants to fund

Outcomes-based contracting and the Medicaid math

Treatment centers as managed service lines

Off-target analytics becomes a regulated lab category

CMC comparability is now a strategy job

Editor foundries and the semiconductor analogy

Registries that payers, regulators, and reinsurers actually trust

Reinsurance and stop-loss for curative therapies

Trial operations for genetically segmented populations

The punchline

- Q1 2026 CASGEVY revenue was about \$43M (Vertex), with 500+ patient initiations globally since launch. CMS lists CASGEVY at \$2.2M. Pediatric expansion (ages 5 to under 12) submission is filed in the U.S., and a Germany pricing agreement is in place.

- Beam reported \$1.2B cash, runway into mid-2029, BEAM-302 dose selected mg, pivotal cohort planned in H2 2026, risto-cel BLA possibly by year-end 2 BEACON Phase 1/2 data published in NEJM.
- Intellia announced positive Phase 3 HAELO data for lonvo-z in HAE on Apr 2026, with rolling BLA underway and possible launch H1 2027 if approved.
- Prime Medicine plans IND/CTA for PM577 (Wilson disease) in H1 2026 and PM647 (AATD) around mid-2026, initial clinical data 2027.
- FDA issued April 2026 draft guidance on safety assessment of genome editing using NGS, applicable to ex vivo and in vivo products. ASGCT Q1 2026 landscape report counted only two new approvals globally in the quarter, both non-genetically modified cell therapies.
- Thesis: the bottleneck is no longer scientific. It is operational, financial, and regulatory. The next cycle of returns belongs to infrastructure companies (activation, contracting, orchestration, registry, reinsurance, foundry, regulated NGS lab) at least as much as to editor platforms.

The CASGEVY tell

Pretty much everything anyone needs to know about where gene editing is right now lives inside two facts from Vertex's Q1 2026 release. CASGEVY did about \$43 m of revenue. More than 500 patients have started the treatment journey since launch. Both numbers can be read two completely different ways depending on what story is being told that day. If the story is "CRISPR works as a commercial product," the \$43 million in a quarter is meaningful for a one-time, ultra-rare, infused cell therapy whose treatment journey is measured in months. If the story is "approved gene editing scales easily through normal pharma channels," then \$43 million on a \$2.2 million price is, charitably, a reminder that the slope of adoption is going to look nothing like a small molecule launch and probably not even like a typical biologic.

The reason the slope is weird is the part that almost nobody outside the actual transplant centers fully understands. CASGEVY is not really a drug. It is a multi-month coordinated services bundle that happens to include a drug substance

somewhere in the middle. A patient gets identified, gets screened against clinical psychosocial eligibility, gets offered fertility preservation, has cells mobilized and apheresed, ships those cells to a manufacturing site, waits for editing and release testing, gets conditioned with busulfan, gets infused, sits inpatient for engraftment then enters years of follow-up. Most of that is not a Vertex problem. Most of that is a hospital problem, a Medicaid problem, a fertility clinic problem, a benefit design problem, and a workforce problem. Anyone trying to underwrite the future of gene editing without understanding that breakdown is basically valuing the engine without checking if the rest of the car exists.

CRISPR Therapeutics' own Q1 release captured the same dynamic from the patient side. Roughly 60,000 eligible patients across approved geographies, the same 500 clinical initiations, an active push into pediatric expansion, the Germany pricing deal, and continued profit-share with Vertex on the launch. That is encouraging activity for the quarter, and it is also a flashing yellow light on the gap between approved and true Demand exists. Capacity is the bottleneck. And capacity is not something that gets fixed with another R&D dollar.

Why a one-time cure breaks the operating system



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