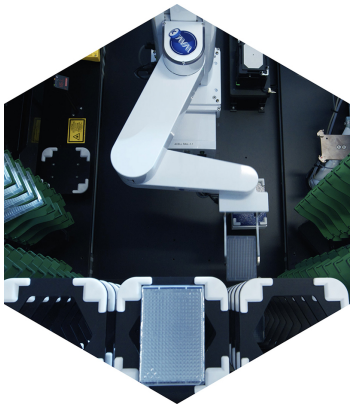
A Letter from Our CEO

Dear Shareholders,

2025 marked an important inflection point for Recursion — the year our AI-native foundation began translating from theoretical advantage into clinical reality. We moved from vision and promise to demonstrating tangible clinical evidence powered by our end-to-end AI-native operating system for creating medicines, and we did so with growing confidence, discipline, and momentum. As I reflect on the year behind us and look ahead to 2026 and beyond, I believe Recursion is entering one of its most consequential chapters yet.

The foundational question is no longer whether AI can play a role in drug discovery and development. We have demonstrated that it can — and we believe the next decade will be defined by how deeply AI is embedded into the fabric of new medicines itself. The more important question now is: what value does it create, and how does that value show up in the lives of patients? Quality medicines are the standard by which AI in medicine will ultimately be judged. That value will not come from AI layered onto the margins of R&D, but from seamlessly integrating AI into the drug discovery and development process itself — improving probability of success, compressing timelines, and deploying capital more efficiently. We are positioning Recursion not only to meet that standard, but to define it.

My conviction in our path forward is rooted in the foundation we have built and the proof points we are beginning to generate through our full stack AI platform. Our strategy is organized around three core pillars, underpinned by exceptional people and a culture grounded in rigor and curiosity.



"THE FOUNDATIONAL QUESTION IS NO LONGER WHETHER AI CAN PLAY A ROLE IN DRUG DISCOVERY AND DEVELOPMENT. WE HAVE DEMONSTRATED THAT IT CAN — AND WE BELIEVE THE NEXT DECADE WILL BE DEFINED BY HOW DEEPLY AI IS EMBEDDED INTO THE FABRIC OF NEW MEDICINES ITSELF. THE MORE IMPORTANT QUESTION NOW IS: WHAT VALUE DOES IT CREATE, AND HOW DOES THAT VALUE SHOW UP IN THE LIVES OF PATIENTS?"

First: Translating Insights into Proof Points — and Ultimately into Medicines.

In 2025, we achieved our first AI-enabled clinical proof of concept. In familial adenomatous polyposis (FAP), REC-4881 demonstrated that a novel, platform-derived biological insight — identifying MEK1/2 inhibition as a therapeutic entry point — can translate into meaningful clinical outcomes. For patients living with a progressive, lifelong disease with no approved pharmacotherapies, this represents tangible progress.

This milestone is more than a single data readout. It is early validation of a core premise: that systematically decoding biology at scale can yield differentiated medicines — and that the more we learn, the stronger the system becomes.

We enter 2026 with five clinical programs advancing with defined differentiation and clear go/no-go criteria, alongside a growing discovery pipeline informed by platform-generated insights. We are also delivering for our partners, having achieved over $500 million in upfront and progress-based milestone payments to date. With Roche and Genentech, we have delivered whole-genome CRISPR phenomaps in human neuronal and microglial cells, generating $213 million in cash inflows. With Sanofi, we are advancing AI-driven small-molecule programs in oncology and immunology, contributing $134 million in cash inflows to date.

These are not isolated successes; they are signals that our platform is beginning to compound — generating insights, molecules, and proof from a shared technological core.

Second: Surgically Doubling Down on our Full Stack AI Platform Innovation, Grounded in Impact.

AI must improve outcomes across the full R&D value chain — not just isolated steps. Our focus is therefore on building and operating an integrated, end-to-end platform spanning biology, chemistry, and clinical development — designed to continuously learn across programs and improve with scale.

"MAKING MEDICINES HAS ALWAYS BEEN PERSONAL FOR ME. RECURSION WAS FOUNDED ON A BELIEF I DEEPLY SHARE: THAT BIOLOGY IS COMPLEX, BUT NOT UNKNOWABLE — AND THAT ADVANCES IN AI AND AUTOMATION CAN FUNDAMENTALLY RESHAPE HOW MEDICINES ARE DISCOVERED."

Drug discovery has historically been fragmented, with biological hypotheses, molecular design, and clinical execution optimized independently. We have built Recursion to close that gap — not through incremental tools, but through a deeply integrated architecture that connects experimental data, machine learning, and execution in a unified feedback loop.

In biology, phenomics combined with multi-omic and patient-derived data is strengthening translational insight. In chemistry, precision generative design — strengthened by the integration of Exscientia — accelerates convergence on high-quality candidates, including against historically difficult targets. In clinical development, our newly created AI-enabled ClinTech system applies patient-level inference to improve trial design, patient selection, and execution, increasing signal quality and operational efficiency.

When AI functions as a continuous system rather than a collection of tools, its impact compounds— and that compounding effect is the foundation of our long-term strategic advantage. That is the platform we are building.

Third: Pairing Bold Ambition with Discipline.

Ambition must be matched with focus to create durable value. In 2025, we sharpened our portfolio, streamlined operations, and applied more rigorous capital allocation. We materially reduced projected cash burn while preserving investment in our highest-impact programs and platform capabilities.

This discipline extends beyond financial stewardship. It shapes how we set milestones, evaluate data, and make transparent go/no-go decisions. As we move into 2026, you should expect continued execution rigor and a relentless orientation toward value creation.

The foundation of this progress is our people — teams fluent in both science and AI, who approach biology with humility and technology with rigor. They are connecting data, models, and clinical insight into a unified system designed to deliver differentiated therapies.

Making medicines has always been personal for me. Recursion was founded on a belief I deeply share: that biology is complex, but not unknowable — and that advances in AI and automation can fundamentally reshape how medicines are discovered.

The next phase is about scaling that belief into durable impact — across programs, partnerships, and ultimately across diseases.

We will continue advancing the Recursion Operating System as a source of long-term differentiation while prioritizing programs and partnerships where we have the strongest conviction and greatest opportunity to deliver for patients. Ambition and discipline are not opposing forces — they are mutually reinforcing.

Approximately 80% of diseases still lack disease-modifying therapies. The opportunity before us is vast. The credibility of AI in medicine will not be earned through better models alone, but through translation — from data to decisions, from platforms to pipelines, and from science to patients. We intend to be the company that defines that standard.

Our objective is clear: apply AI and science with rigor, focus, and humanity to deliver meaningful medicines. Thank you for your continued partnership as we build a company defined not only by impact and discipline, but by the ambition to drive durable value creation to reshape how medicines are discovered and delivered for generations to come.

Sincerely,

Najat Khan, Ph.D.

Chief Executive Officer, President, and Board Member Recursion

Item 1. Business.

Business Overview

Recursion is a clinical-stage TechBio company with a mission to decode biology to radically improve lives. We have advanced a portfolio of differentiated internal programs and strategic partnerships powered by our integrated drug discovery and development platform, the Recursion Operating System (OS). This platform provides end-to-end, AI-native capabilities that span from novel biological ideas through the clinic, integrating multimodal biological data generation, AI-powered small molecule synthesis, and AI-enabled clinical development. All of our technologies are designed to translate complex science into medicines that matter — faster, better, and at scale — for patients who are waiting.

Historically, it has taken over ten years and an average capitalized R&D cost of approximately $2-3.5 billion to move a drug discovery project from early discovery to an approved therapeutic, with less than 4% of drug discovery programs initiated resulting in an approved medicine.[1,2,3,4,5,6] Today, we are working to transform the traditional high-attrition, “V-shaped” discovery funnel by pivoting to a ‘T-shaped’ model. By leveraging advanced computational tools across biology, chemistry and clinical development, we aim to rapidly narrow a broad set of potential medicines to the candidates with the highest probabilities of success, with the goal to move programs through development more efficiently and with less attrition.

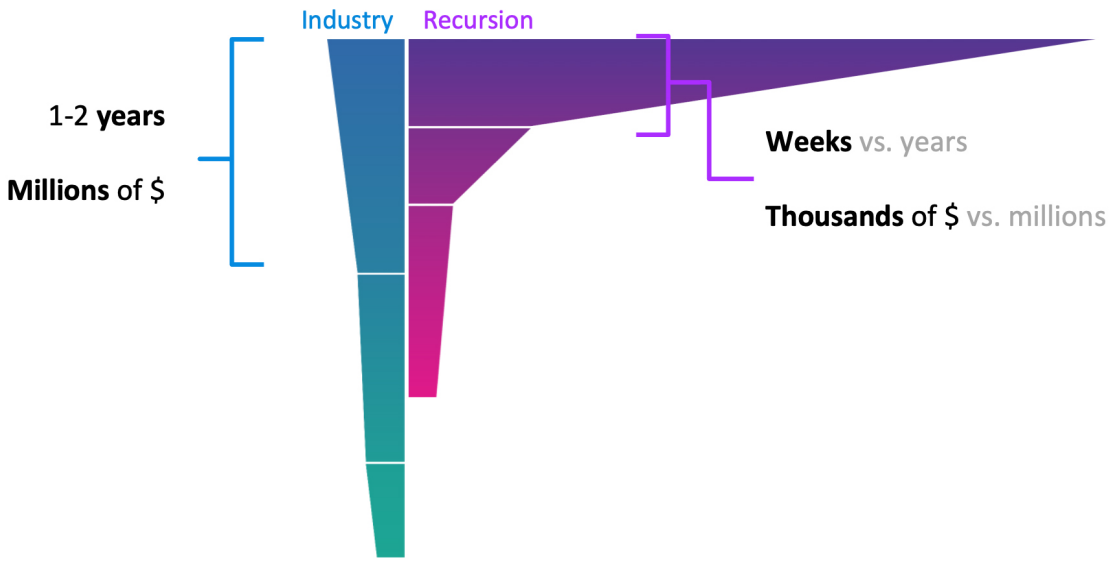


Figure 1. Illustrative. Reshaping the drug discovery funnel. Recursion’s goal is to leverage technology to reshape the typical drug discovery funnel towards its ideal state by moving failure as early as possible to rapidly narrowing the funnel into programs with the highest probability of success.

In recent years, advances in artificial intelligence and machine learning (“AI/ML”) have increasingly influenced both the technology and biopharmaceutical industries. Industry reports estimate that a majority of large biopharmaceutical companies now employ AI/ML in some aspect of drug discovery or development, and global investment in AI-enabled drug discovery has grown to several billions of dollars annually. Regulators and policymakers have also engaged more actively in this area, with AI/ML-enabled approaches being applied across multiple stages of drug discovery and development, including target identification, molecular design, chemical synthesis, clinical development, and manufacturing. We believe the increasing adoption of these technologies reflects a growing industry consensus that AI/ML has the potential to improve efficiency, decision-making, and productivity in drug discovery and development — the extent and timing of these benefits remain subject to ongoing validation and focus on proof-of-concept by leading players, including Recursion.

[1] *Zhou, S. and Johnson, R. (2018). Pharmaceutical Probability of Success. Alacrita Consulting, 1-42.*
[2] *Steedman, M, and Taylor, K. (2024). Measuring the return from pharmaceutical innovation. Deloitte. 1-28.*
[3] *DiMasi et al. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics. 47, 20-33.*
[4] *Paul, et al. (2010). How to improve R&D productivity: the pharmaceutical industry’s grand challenge. Nature Reviews Drug Discovery. 9,203-214.*
[5] *Martin et al. (2017). Clinical trial cycle times continue to increase despite industry efforts. Nature Reviews Drug Discovery. 16, 157.*
[6] *European Federation of Pharmaceutical Industries and Associations (EFPIA). (2024). The pharmaceutical industry in figures: Key data 2024.*

Our Strategic Focus Across Three Pillars

The Recursion OS provides a common foundation for mapping biology, navigating disease space, designing molecules, and optimizing clinical trials across therapeutic areas and modalities. We deploy these capabilities to meet the specific differentiation and risk-reward needs of each program, tailoring our approach based on medical, market, regulatory, and capital considerations through a combination of internal pipeline development and strategic partnerships.

This approach allows us to balance near-term learning and proof generation with longer-term platform innovation, while allocating capital where Recursion has the highest confidence and greatest potential for differentiation. The three strategic pillars described below reflect how we operationalize this model to drive disciplined value creation and impact.

Figure 2. Recursion's strategy is organized around three core pillars, described below.

Pillar 1 – Translate insights to proof points – on the path to new medicines

A core pillar of our strategy is demonstrating that our AI platform can consistently translate scientific insights into medicines that deliver meaningful patient impact. In 2025, we made tangible progress against this objective, including a positive clinical readout from our familial adenomatous polyposis (FAP) program, where our novel platform-derived insight, identifying the potential therapeutic benefit of MEK1/2 inhibition in FAP, translated into clinically meaningful reductions in polyp burden in a disease with no approved therapies. We have several clinical-stage and multiple preclinical programs that are differentiated by novel biology, chemistry, and/or patient understanding from our platform. We have achieved key progress-based milestones across multiple strategic partnerships that further validate the applicability of our platform across diverse aspects of discovery and therapeutic areas. To date, we have received over $500 million in partner payments for novel data generation (e.g. maps optioned by Roche and Genentech) and advancing AI-designed small molecule programs with Sanofi and others. We expect to receive additional milestone payments as programs continue to progress. Together, these advancements across our internal and partnered pipeline provide growing evidence that our approach can convert insights into early proof points.

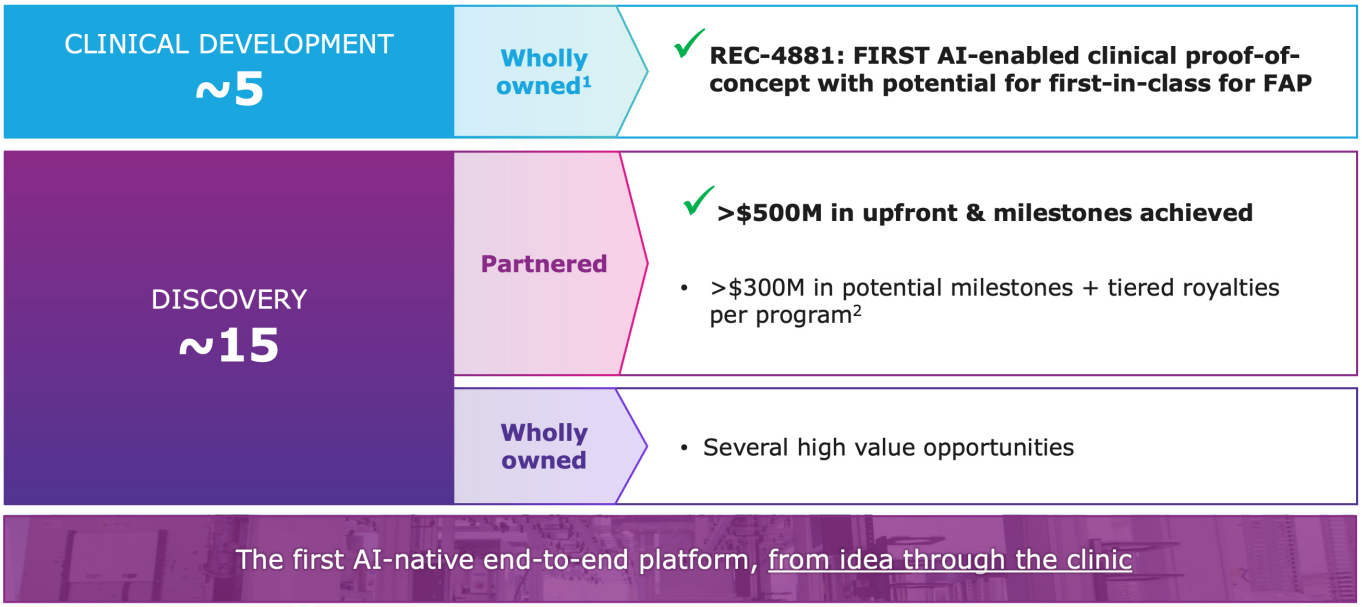


Figure 3. Recursion: Progress, by the numbers. 1. Includes preclinical programs that are expected to enter the clinic within the next 18 months. 2: Milestones: Potential Roche and Genentech and Sanofi milestones per small molecule program. Royalties: Recursion is eligible for tiered royalties up to high single digits (Roche and Genentech) and up to double digits (Sanofi).

Pillar 2 – Focused innovation, grounded in clear impact

We have built an end-to-end, AI-native platform that spans biological discovery, small molecule design, and clinical development, and our strategy is to continue investing selectively in capabilities that improve the probability of success, speed, and confidence of scientific and clinical decision-making. For example, a key area of focus in 2025 was the build out of our ClinTech capabilities, where we are applying data, automation, and AI to enable more efficient trial design, patient stratification, and evidence generation. Leveraging our Recursion OS platform, we have also been able to advance small molecule drug candidates that potentially solve complex design problems, while synthesizing approximately 90% fewer compounds than the industry average. Looking ahead, we will continue to direct resources toward platform capabilities that address critical bottlenecks in research and development and that we believe can drive durable differentiation and long-term value creation.

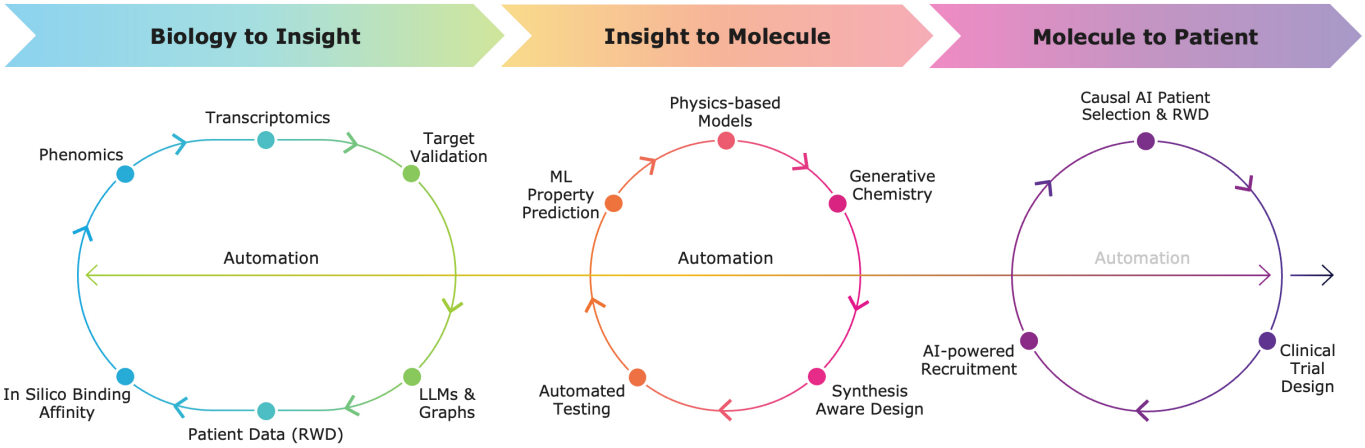


Figure 4. The Recursion OS. The Recursion OS is designed to use AI to advance and accelerate decision-making and insight across the entire R&D value chain with the end goal to make novel medicines that matter. The Recursion OS generates value by advancing a pipeline of differentiated investigational medicines, in addition to building pipelines for our partners.

Pillar 3 – Pair bold ambition with disciplined execution

Our strategy emphasizes pairing long-term ambition with disciplined execution, clear prioritization, and prudent capital allocation. We apply rigorous go/no-go decision-making across our portfolio and focus resources on programs and initiatives where we believe we have a true strategic advantage. Actions taken in 2025, including prioritizing our clinical portfolio and streamlining operations, reflect this disciplined approach and are intended to support sustainable execution over the long term. Going forward, we will continue to balance investment in innovation with operational and financial discipline, aligning resources with our highest-impact opportunities while maintaining flexibility as we advance our mission.

Foundation – Empowering exceptional, bilingual teams to deliver impact with humanity

As Recursion works to transform how better medicines are brought to patients, we believe a new, integrated culture is essential to success. A core foundation of our strategy is our people, which we view as a critical operating advantage in translating platform capability into real-world impact. Recursion has intentionally built integrated, bilingual teams that operate fluently across science, computation, and engineering, enabling tight collaboration between wet-lab experimentation, model development, and clinical strategy. We continue to invest in our people and teams to reduce friction across workflows, accelerate iteration, and ensure that experimental design, AI models, and development decisions are informed by a common context. Paired with a culture that emphasizes rigor, accountability, and disciplined execution, this talent model is expected to enable us to pursue bold scientific ambition while consistently delivering progress toward medicines that matter — with speed, confidence, and humanity.

Building a Pipeline – Wholly Owned and Partnered Discovery

Our combined wholly-owned and partnered pipeline represents the primary vehicle for translating novel insights and capabilities from the Recursion OS into tangible medicines. We utilize a wide range of AI and automation to achieve differentiation in biology, chemical design, and clinical development, targeting areas of high unmet need with a speed and precision unique to our AI-native approach. The progression of the portfolio through clinical development represents a critical step in validating our OS-driven methodology. Our goal remains for these proprietary insights to be translated into successful clinical outcomes across our internal focus areas of oncology and rare disease, as well as for our partners across oncology, neuroscience, immunology, and other therapeutic areas with high unmet need. All of our programs target differentiated medicines in select patient populations.

Advancing our Wholly Owned Pipeline

We are accelerating critical clinical milestones while delivering measurable progress against diseases with high unmet medical needs. To focus resources on programs with the strongest scientific rationale and the highest potential for near- and long-term impact, such as REC-4881 in FAP and REC-617 in advanced solid tumors, we streamlined our portfolio in May 2025. As part of this prioritization, the clinical programs REC-2282 for NF2, REC-994 for CCM, and REC-3964 for *C. difficile* were discontinued and/or partnering opportunities are being pursued.

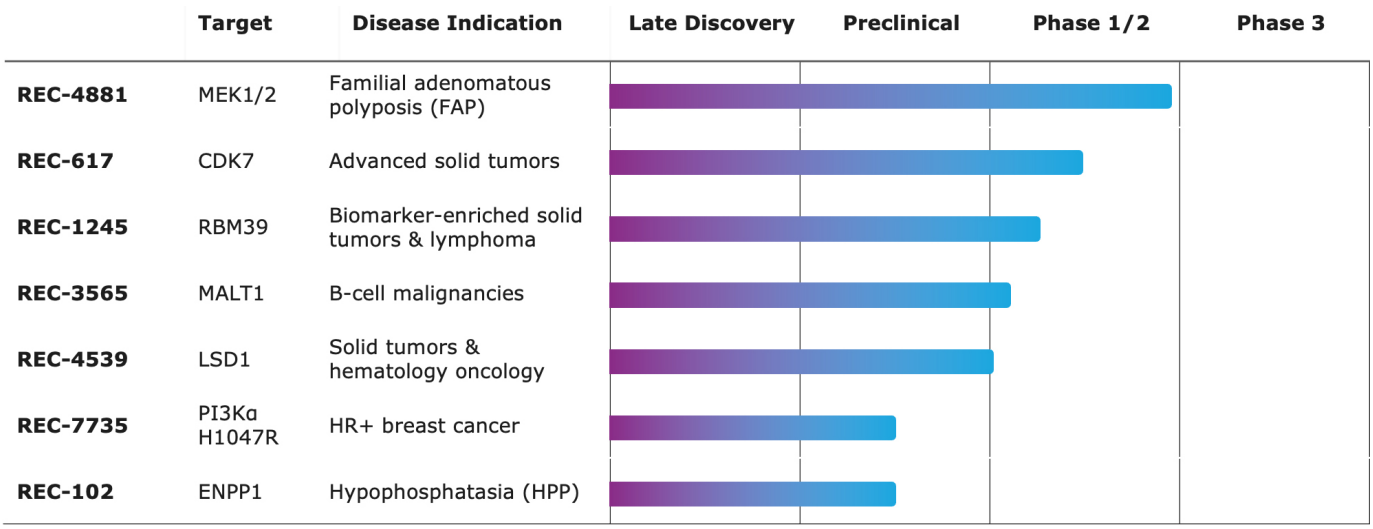


Figure 5. Recursion's wholly-owned clinical pipeline includes differentiated medicines across oncology and rare disease. The current pipeline consists of 5 clinical programs and 2 preclinical programs with the potential to enter Phase 1 pending go/no go decision.

Pipeline Highlights from 2025

In 2025, we reported the first clinical validation of the Recursion OS, with positive Phase 1b/2 results from our REC-4881 MEK1/2 inhibitor program in FAP. The rapid and durable reduction in polyp burden observed in the Phase 2 portion of the TUPELO study shows how unbiased phenotypic and mechanistic insights from the Recursion OS, such as MEK1/2 rescue of APC loss-of-function, can translate to novel, differentiated therapeutics for diseases like FAP. We expect to engage with the FDA to define a potential registration path for REC-4881 while further optimizing dosing schedule in the ongoing TUPELO trial, to continue to progress in this disease with no approved pharmacotherapies.

In parallel, Recursion has three other clinical studies ongoing: ELUCIDATE (Phase 1/2, REC-617, CDK7i), DAHLIA (Phase 1/2, REC-1245, RBM39 degrader) and EXCELERIZE (Phase 1, REC-3565, MALT1i). A fourth study, ENLYGHT (REC-4539, LSD1i) is expected to enter Phase 1 for solid tumors in 2026. IND-enabling studies are ongoing for REC-7735 (PI3Kα H1047Ri) and REC-102 (ENPP1i), with the potential to enter Phase 1 studies pending go/no go decision.

Anticipated Near-term Catalysts

Recursion is poised for a catalyst-rich period, with multiple programs reaching meaningful milestones over the next 24 months. In the first half of 2026, we will engage with the FDA to define a registration path for REC-4881, and we will report early monotherapy safety and PK data for REC-1245 (RBM39 degrader) during the same period. Go/no-go decisions on the initiation of Phase 1 studies for REC-7735 (PI3Kα H1047Ri) and REC-102 (ENPP1i) are expected in the second half of 2026. Additional clinical data for REC-4881 (MEK1/2i), early combination safety and PK data for REC-617 (CDK7i), and early monotherapy safety and PK data for REC-3565 (MALT1i) will be reported in the first half of 2027, with early monotherapy safety and PK data for REC-4539 (LSD1i) reported in the second half of that year.

Impact Through Partnered Pipeline

Through our partnerships with leading pharmaceutical companies including Roche and Genentech, Sanofi, Bayer, and Merck KGaA (Darmstadt, Germany), we have secured more than $500 million in upfront and progress-based milestone payments to date, with the potential for over $20 billion in additional milestones before royalties. These global collaborations not only provide near-term cash flows but also combine our scaled biology, precision chemistry, and automated synthesis capabilities to pave the way for transformative therapies in oncology, neuroscience, immunology, and other therapeutic areas with high unmet need. By partnering with some of the best biopharmaceutical companies in their respective areas, our platform and team have an opportunity to learn from some of the most experienced in the industry. By uniting our AI-driven platforms, vast proprietary data, and deep scientific expertise, we continue to unlock powerful innovations and expand patient impact. Below are some of the latest developments illustrating this momentum:

Sanofi: *Designing molecules against difficult and diverse protein targets in challenging data-poor and data-rich environments*

- **Small Molecule Joint Portfolio:** Recursion is using its platform to discover and advance a joint portfolio of 5+ AI-driven and differentiated novel small molecule programs in immunology and oncology therapeutic areas. The joint collaboration has the potential for up to 15 AI-driven small molecule programs.
- **Milestones and Collaboration:** In February 2026, we achieved our fifth milestone across the collaboration, generating a $4 million payment from Sanofi. In total, we have achieved $134 million in upfront and progress-based milestones to date. There is potential for additional near-term milestones as the first programs advance towards development candidate milestones and earlier-stage programs progress.

Roche and Genentech: *Turning novel insights from proprietary digital maps of complex biology into potential novel therapeutics*

- **Neuron Map:** In partnership with Roche and Genentech, Recursion built the first whole-genome CRISPR knockout map generated from a subset of 1 trillion internally manufactured iPSC-derived neuronal cells ($30 million milestone payment, accepted in 2024). This proprietary dataset is being used in partnership with Roche and Genentech to identify potential new targets in neuroscience, a field which has historically suffered from limited new discoveries.
- **Microglia Map:** Recursion built and Roche and Genentech accepted a second neuroscience Phenomap, a first-of-its-kind whole-genome CRISPR knockout map generated from over 100 billion internally manufactured iPSC-derived microglial cells ($30 million milestone payment, accepted in 2025). With approximately 46 million images, the scale and quality of this proprietary map enables us, in partnership with Roche and Genentech, to leverage the power of AI to explore novel targets and pathways.
- **Gastrointestinal-Oncology Advancements:** We have built four proprietary Phenomaps which are being leveraged under the collaboration to identify novel insights that can be used to initiate programs for a gastrointestinal-oncology indication including continuing to advance one program optioned by Roche and Genentech.
- **Milestones and Collaboration:** In total, Recursion has received $213 million in upfront and milestone payments from the collaboration. Roche and Genentech have accepted six Phenomaps and initiated one small molecule program based on Phenomap insights to date. The companies have also identified a number of biological insights from Phenomaps that are now being validated or advanced as potential novel targets.

Bayer: *Developing programs in challenging oncology indications with high unmet need*

- **Oncology:** With our partners at Bayer, we are advancing multiple programs towards lead series milestones in precision oncology.

Merck KGaA (Darmstadt, Germany): *Leveraging Recursion's discovery engine to identify differentiated targets across oncology and immunology*

- **Oncology and immunology:** With our partners at Merck KGaA, we are focused on identifying differentiated targets across oncology and immunology and assessing target tractability using our precision design chemistry platform.

The Recursion OS – A Platform that Powers a Portfolio

The Recursion OS is a unified, AI-native operating system for drug discovery and development that integrates biology, chemistry, and clinical execution end-to-end. Built on proprietary, multimodal data generated at unprecedented scale through automated wet and dry labs and partnerships, the OS combines large-scale phenomics, emerging omics layers, AI-driven chemistry design, and clinical development intelligence into a single, closed-loop system. Powered by purpose-built models, scalable compute, and bilingual teams fluent in both science and AI, the Recursion OS enables faster translation of insights into proof points, reduces R&D bottlenecks, and supports the delivery of better medicines at scale for patients who are waiting.

Figure 6. Recursion combines proprietary multimodal data, purpose-built models and compute, and our bilingual teams and culture to create the first AI-native, end-to-end platform spanning idea through the clinic.

Rather than optimizing isolated steps, the Recursion OS improves decision-making across the entire R&D value chain—from decoding unknown biology and generating first-in-class targets, to designing synthetically feasible molecules, to selecting the right patients and executing trials more efficiently. By systematically generating, integrating, and analyzing high-dimensional experimental and real-world data, we train purpose-built machine learning and foundation models that translate complex biology into actionable insights across discovery and development. Throughout these processes, we are deploying AI agents and automated systems to help orchestrate our wet-lab experimentation and dry-lab modeling, standardizing workflows, coordinating data generation and analysis, and enabling faster, more consistent, and higher-confidence decisions at scale.

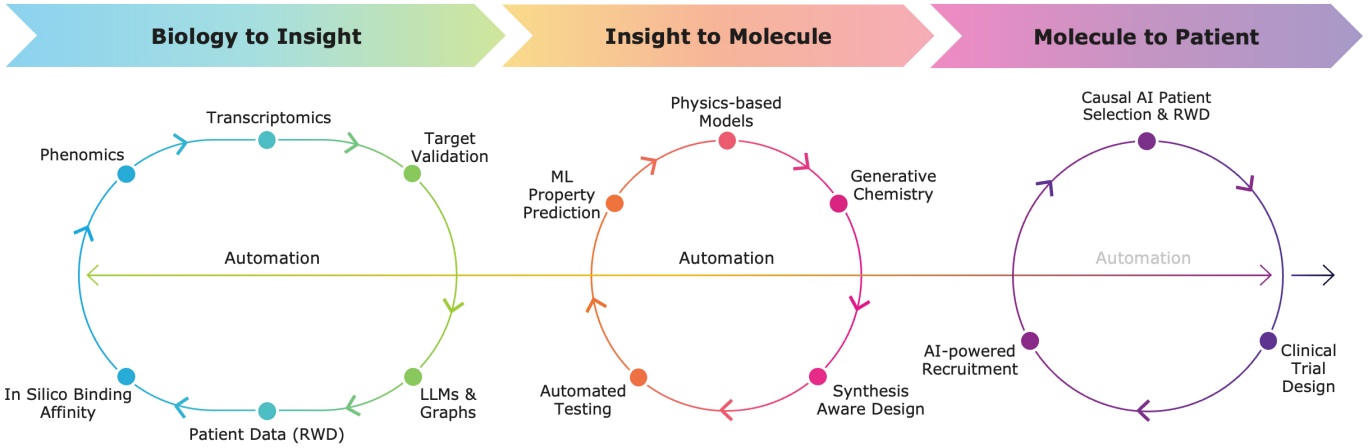


Figure 7. The Recursion OS. The Recursion OS is designed to use AI to advance and accelerate decision-making and insight across the entire R&D value chain with the end goal to make novel medicines that matter. The Recursion OS generates value by advancing a pipeline of differentiated investigational medicines, in addition to building pipelines for our partners.

As models are increasingly integrated across biology, chemistry, and clinical data, Recursion is building a systems-level representation of how biology and chemistry function. This enables high-confidence predictions about previously untested hypotheses and shifts the role of the wet lab from primarily generating data to scaled validation of model-derived insights. In practice, the platform is used to simulate and prioritize targets, mechanisms, and chemistries with the highest probability of clinical success and a well-defined target product profile, followed by rapid experimental validation.

Bilingual Teams and Culture – Fluent in Tech and Science

Our mission at Recursion, ***Decoding Biology to Radically Improve Lives***, flows naturally from our vision. We interpret our mission expansively and believe it to be a durable direction and source of inspiration for our team. We seek not only to radically improve the lives of patients who could benefit from the medicines we help to deliver, but the lives of those who care for those patients, the lives of our employees and their families, as well as the communities in which we operate our company.

We've intentionally designed our culture to fuel the pursuit of our mission. Our Guiding Principles are guideposts for scientific and technical decisions, and our Values underpin how our employees engage day-to-day with colleagues inside and outside the company. The Recursion Mindset, a deep commitment to achieving impact at unprecedented scale through new industrialized approaches, is an essential component of building our TechBio ecosystem. Our employees bring all these to life, contributing their unique expertise and experiences from their incredible breadth of fields and industries.

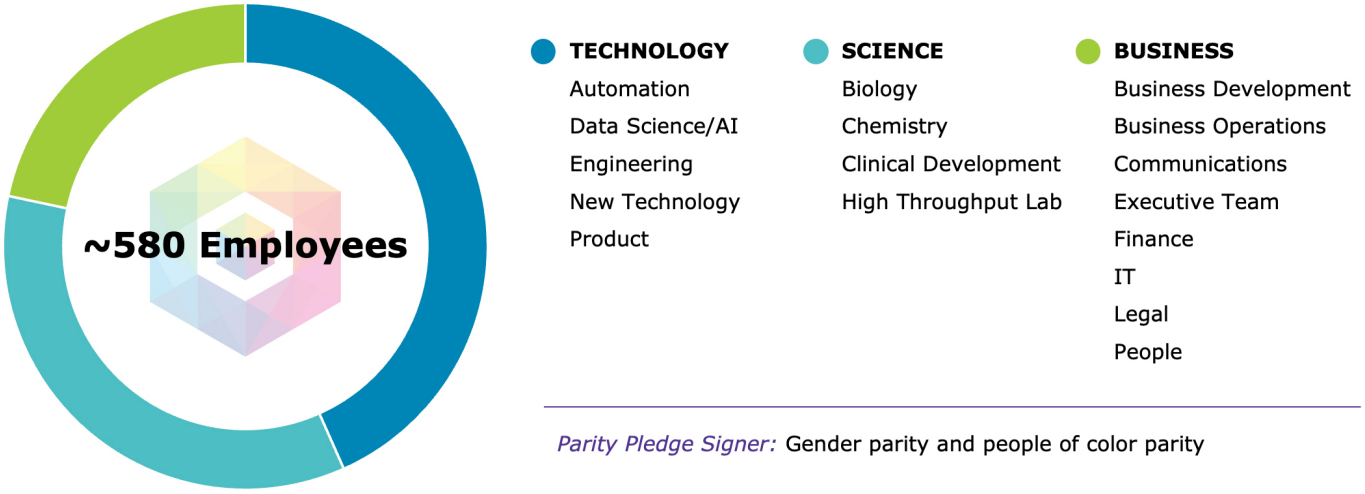


Figure 8. Recursion's teams operate at the interface of many diverse fields. We have bilingual teams and cultures, scientists that understand AI, and AI researchers that understand science.

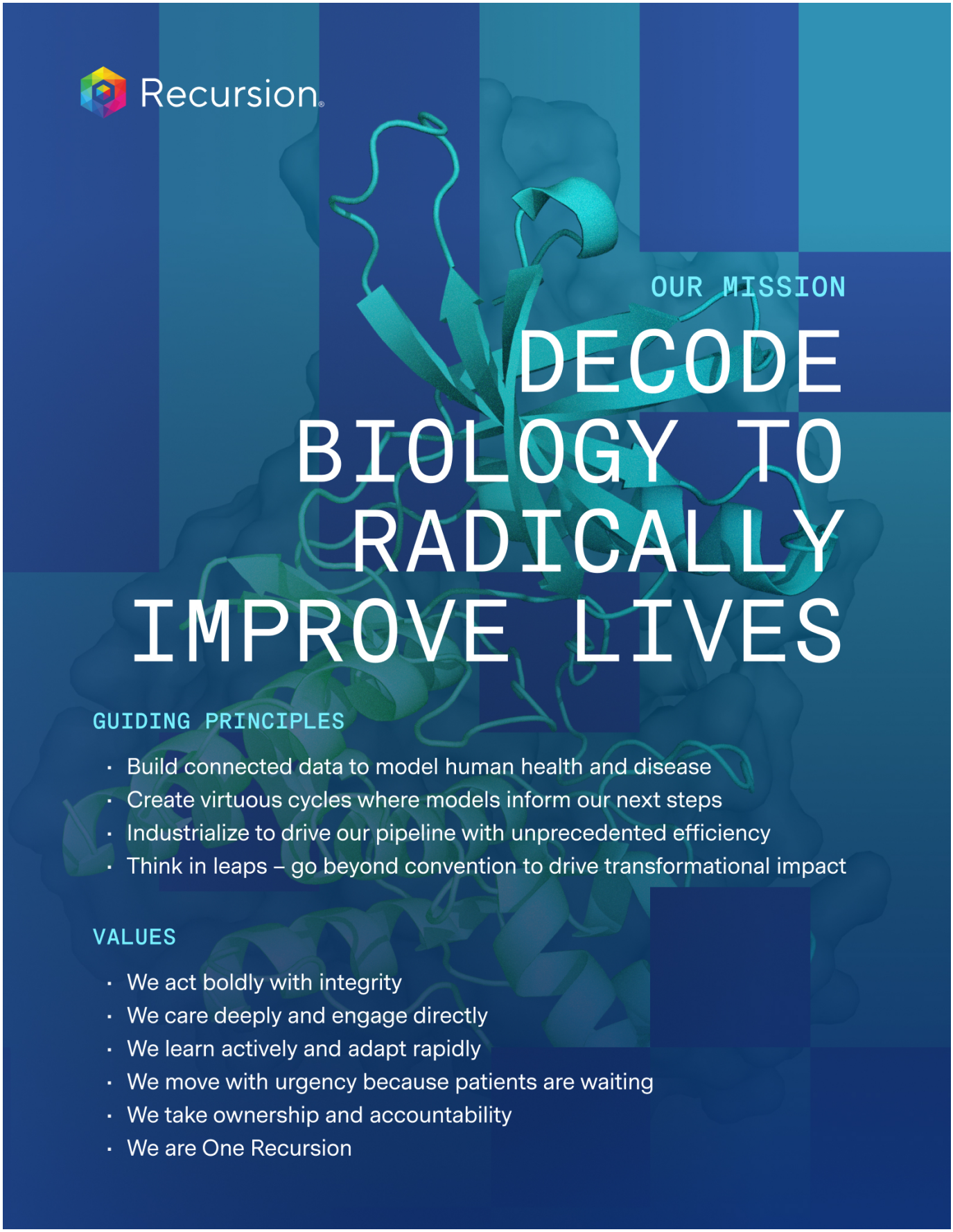


Figure 9. Recursion's Guiding Principles and Values support our ambitious mission. Together, these elements shape Recursion's culture by guiding our people to high-impact decision-making and behaviors.

Recursion In-Depth

AI-native end-to-end platform from idea to clinic: making novel medicines that matter

We have built an integrated, AI-native platform to decode complex biology and chemistry from multi-modal data into potentially transformative medicines. The strength of our platform is not defined by a single asset or model, but by the scale and quality of our core capabilities and underlying infrastructure, including:

- **Proprietary Data:** We have generated one of the largest relatable data sets in biopharma using our automated high throughput labs, which can run over 2 million experiments per week. Our data includes cellular phenomics, captured using brightfield microscopy, as well as chemical synthesis, transcriptomics, proteomics, ADMET, genomics, and patient data.
- **Models & Compute:** We use our proprietary data to train purpose-built AI models that accelerate learning and address specific bottlenecks across the R&D value chain. We largely train models using our own supercomputer, BioHive-2, one of the largest supercomputers in biopharma, built in collaboration with NVIDIA.
- **People & Culture:** A core differentiator is our people and culture—a unique, "bilingual" team of experts fluent in both life sciences (biology/chemistry) and technology (data science/engineering).

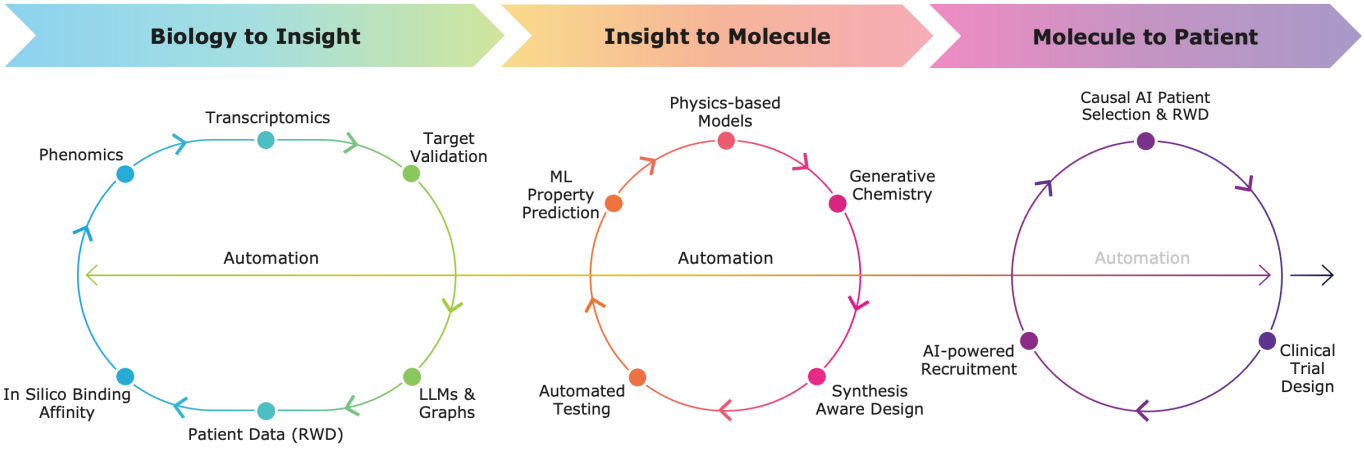


Figure 10. The Recursion OS. The Recursion OS is designed to use AI to advance and accelerate decision-making and insight across the entire R&D value chain with the end goal to make novel medicines that matter. The Recursion OS generates value by advancing a pipeline of differentiated investigational medicines, in addition to building pipelines for our partners.

Our Portfolio

Our portfolio reflects the industrial scale of our discovery engine, comprising a robust pipeline of wholly owned programs alongside strategic partnerships with leading pharmaceutical companies. This pipeline currently includes approximately five wholly owned programs in clinical development and roughly 15 discovery-stage programs spanning our internal and partnered efforts. Each milestone across this diverse portfolio serves as a critical proof point for our ability to translate AI-native insights into meaningful clinical candidates, with the breadth of the pipeline providing multiple, concurrent opportunities to validate the Recursion OS as a transformative engine for drug discovery.

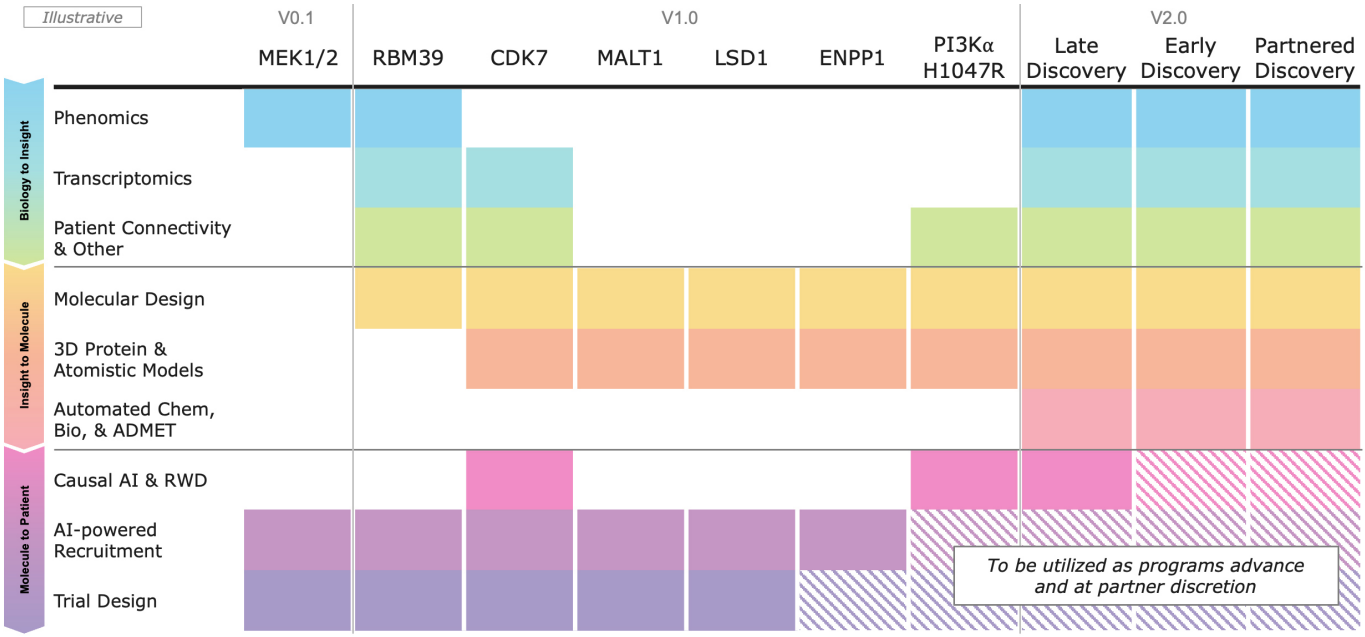


Figure 11. All pipeline programs leverage our platform, which has evolved, across biology to insight, insight to molecule, and molecule to patient. We leverage and track how we use our platform across every single program. For example. some programs are focused on novel biological insight, design, or both.

Our Internal Pipeline: Clinical Programs Overview in Oncology and Rare Disease

REC-4881 – *Familial Adenomatous Polyposis*

We are developing REC-4881, a highly potent and selective, potential best-in-class MEK1/2 inhibitor, for familial adenomatous polyposis (FAP). FAP is a genetic condition characterized by the development of adenomas throughout the GI tract. It is an orphan disease caused by inactivating mutations in APC, with most patients undergoing prophylactic colectomy due to nearly 100% likelihood of CRC by age 40.

During a collaboration with Takeda, we leveraged machine learning and automated analysis to quantify hundreds of cellular parameters linked to APC siRNA knockdown. We screened numerous compounds in this genetic background within 24 hours and identified REC-4881 as a potent molecule that rescued the phenotype in a concentration dependent manner. In preclinical studies, REC-4881 demonstrated over 1,000-fold selectivity in APC-mutant tumor cell lines and effectively inhibited spheroid growth and organization. In the APC^{min} mouse model of FAP, REC-4881 showed up to a 70% reduction in total polyps, surpassing celecoxib's 30% reduction, highlighting its potential as a highly selective and efficacious therapy for FAP.

The IND was reactivated by Recursion and the Phase 1b/2 trial (TUPELO) of REC-4881 was initiated. As of December 31, 2025, Part 1 of the study is complete and Part 2 remains ongoing. In Part 1, which assessed safety, tolerability, and PK in FAP patients, REC-4881 was observed to have a safety profile consistent with other MEK inhibitors. A 4 mg dose of REC-4881 was shown to be pharmacologically active in FAP and progressed to Part 2. In May 2025, preliminary Phase 1b/2 data was shared at Digestive Disease Week 2025 for 6 patients following 13 weeks of treatment with REC-4881, demonstrating reduced polyp burden and an early safety profile generally consistent with that of prior MEK1/2 inhibitors. Expanded data was shared in December 2025 for a larger cohort of FAP patients treated for 12 weeks with REC-4881, followed by a 12 week off-treatment phase. Rapid reductions in polyp burden were demonstrated by week 13 (median polyp burden reduction of 43%), with a durability of effect and reductions maintained through the off-treatment phase at week 25 (median polyp burden reduction of 53%). The safety profile of REC-4881 was consistent with MEK1/2 inhibition, with adverse events predominantly low grade and N=4 discontinuations. This data provided the first clinical validation of the Recursion OS, from an unbiased phenotypic signal identifying MEK1/2 inhibition as a rescue mechanism for APC loss-of-function, through mechanistic confirmation and clinical translation, to positive clinical data. In the first half of 2026, we expect to engage with the FDA to define a registration path while further optimizing dosing schedule in the ongoing TUPELO trial. We expect to provide additional clinical data in the first half of 2027.

REC-617 – *Advanced Solid Tumors*

REC-617 is a potential best-in-class, potent and selective oral small molecule inhibitor of CDK7 with demonstrated activity in preclinical studies. CDK7 controls cell cycle progression and gene transcription, often overexpressed in advanced stage cancers reliant on transcriptional pathways. This program utilized our generative AI and active learning platform to optimize molecule design, including non-covalent binding and improved ADME/PK for rapid absorption. This rapid design cycle enabled us to synthesize 136 novel compounds and select REC-617 as our lead candidate in under 11 months.

A multicenter, open-label, Phase 1/2 dose escalation and dose expansion study (ELUCIDATE) is currently ongoing in advanced solid tumors. Initial results from 19 patients were presented at the 2024 AACR Special Conference in Cancer Research, with data from a larger cohort of 29 heavily pretreated patients reported in November 2025. From this monotherapy dose escalation (QD and BID) portion of the study, REC-617 demonstrated signs of preliminary efficacy. One heavily pre-treated ovarian cancer patient achieved a confirmed durable partial response (PR), which correlated with significant reductions in clinical tumor markers (CA125 and TK1). Five additional patients achieved durable stable disease (SD) as their best response. REC-617 was generally well-tolerated, with adverse events predominantly low grade and the most common DLTs being nausea and thrombocytopenia. 7% (N=2) discontinued due to a treatment-related adverse event. The MTD was established at 10 mg once daily.

Monotherapy dose escalation remains ongoing to assess alternative dosing schedules, and in 2025 the ELUCIDATE study was expanded into platinum-resistant ovarian cancer (PROC), with a Phase 2 dose expansion monotherapy cohort ongoing and a Phase 1 dose escalation combination arm also initiated. Initial combination regimens include bevacizumab plus paclitaxel or pegylated liposomal doxorubicin (PLD). We expect to provide early safety and PK combination data in 2027.

REC-1245 – *Biomarker-enriched Solid Tumors and Lymphoma*

REC-1245 is a potential first-in-class, novel, potent, and selective molecular glue degrader of RBM39, a critical RNA-binding protein involved in alternative splicing and DNA damage repair (DDR) pathways. Leveraging the Recursion OS, we discovered that genetic knockout of RBM39 can phenotypically mimic CDK12 loss – a validated DDR target – without impacting CDK13 which, to our knowledge, is the first report of this novel biological insight. Utilizing our phenomics based platform for SAR, we synthesized 204 candidates and advanced this program from target ID to IND-enabling studies in 18 months (vs. industry average of 42 months).

Preclinical data confirmed strong anti-tumor activity, including tumor regressions in a BRCA-proficient ovarian cancer model, minimal off-target effects, and no CDK12 kinase inhibition. With over 100,000 addressable patients in the US and EU5 each year, REC-1245 has the potential to be a novel therapy in a biomarker-enriched advanced solid tumor and lymphoma patient population – either as a monotherapy and/or in combination regimens.

Following IND clearance, we initiated a Phase 1/2 study (DAHLIA) to evaluate the safety, tolerability, PK/PD, and preliminary efficacy of REC-1245 in unresectable, locally advanced, or metastatic cancers. This includes a biomarker-enriched population that may benefit most from targeted RBM39 degradation. In the third quarter of 2025, we reported updated information on the population being enrolled into the DAHLIA study, to include cancers with high genomic instability (for example endometrial cancer) and to confirm specific biomarker-enriched populations (for example 2L+ MSI-H/dMMR) based on early preclinical data that showed that REC-1245 reduces viability in tumors characterized by replication stress and DNA repair vulnerabilities (DDR defects) across multiple solid tumor types. The trial is currently enrolling at sites in the US and Canada, and we expect to share early safety and PK data from the Phase 1 monotherapy dose-escalation portion of the study in the first half of 2026.

REC-3565 – *Relapsed / Refractory B-cell Malignancies*

We are advancing REC-3565, our reversible allosteric potential best-in-class MALT1 inhibitor, for the treatment of patients with relapsed or refractory B-cell malignancies. A variety of mutations seen in lymphomas induce constitutive MALT1 protease activation, leading to aberrant NF-κB signaling that drives survival and proliferation of B-cell tumors. Key preclinical data demonstrates sustained anti-tumor activity as a single-agent or in combination with BTK inhibitors.

We leveraged physics-based predictive modelling using our molecular dynamics toolkit and AI-powered hotspot analysis to deliver a candidate with lower predicted safety risk in the clinic. We synthesized 344 novel compounds and advanced this program from hit ID to lead candidate in 15 months.

The molecule's unique profile minimizes UGT1A1 inhibition risk, demonstrating superior target selectivity compared to oral competitors, both of which reported treatment-related hyperbilirubinemia in early Phase 1/2 studies. As a result, REC-3565's enhanced selectivity supports the potential for a more favorable therapeutic index not only as a monotherapy, but also in combinations with BTK and BCL2 inhibitors. A multicenter, open-label, dose escalation Phase 1 study (EXCELERIZE) is ongoing, with the first patient dosed in April 2025. We expect to share early safety and PK monotherapy data in the first half of 2027.

REC-4539 – *Solid Tumors and Hematology Oncology*

REC-4539 is a reversible, CNS penetrant, orally bioavailable, and potential best-in-class inhibitor of LSD1. LSD1 is an epigenetic enzyme that removes methyl groups from histones to control gene expression. LSD1 is abnormally overexpressed in a broad spectrum of solid tumors including lung, breast, prostate, esophageal, and bladder cancers, as well as acute myeloid leukemia, with evidence suggesting that LSD1 is a promising therapeutic target. This is exemplified within lung cancer by small cell lung cancer (SCLC). SCLC is particularly dependent on LSD1 to maintain a neuroendocrine phenotype that drives tumor cell survival in this aggressive lung cancer subtype. In AML, LSD1 has been shown to disrupt normal hematopoiesis by modulating key oncogenic pathways and transcriptional regulators like GFI1 and SNAI1. Preclinical studies demonstrate that REC-4539 shows anti-tumor activity in SCLC and AML human xenografts with limited impact on platelets.

Our program used multi-parameter optimization to design a unique candidate combining reversibility with CNS penetrance. We synthesized 414 novel candidates to arrive at our lead candidate in 22 months. Following IND clearance in January 2025, the program was placed on strategic pause in May 2025. While the broader field has faced safety challenges, REC-4539 remains highly differentiated by its optimized profile, with a potential improved therapeutic index through better management of on-target toxicities e.g. reduced impact on platelets. We now expect to initiate the Phase 1 trial (ENLYGHT) in the first half of 2026, with early monotherapy safety and PK data expected in the second half of 2027.

Deep Dive into Clinical Programs

REC-4881 for Familial Adenomatous Polyposis (FAP) - Phase 1b/2

REC-4881 is an orally bioavailable, non-ATP-competitive, allosteric small molecule inhibitor of MEK1 and MEK2 currently under development for familial adenomatous polyposis (FAP). REC-4881 demonstrated dose-dependent increases in exposure and pharmacological activity, with a safety profile consistent with other MEK inhibitors. We are currently enrolling patients in TUPELO, a Phase 1b/2, open-label, multicenter study to evaluate the effect of REC-4881 on polyp burden reduction. Orphan Drug Designation in the US and EU as well as Fast Track Designation in the US were granted to REC-4881 for FAP. Following positive clinical data from TUPELO shared in 2025, in the first half of 2026 we expect to engage with the FDA to define a registration path while further optimizing dosing schedule within the trial. We expect to provide additional clinical data from TUPELO in the first half of 2027.

Disease Overview

FAP is a rare, inherited tumor predisposition syndrome affecting more than 50,000 patients in the US and EU5, resulting from autosomal dominant mutations in the APC gene, a key negative regulator of the Wnt signaling pathway. FAP is a lifelong continuum of disease progression and intervention driven by chronic polyposis, with an almost 100% lifetime risk of colorectal cancer by the age of approximately 40 if untreated.

In adolescence and early adulthood, patients typically develop hundreds to thousands of precancerous adenomas in their colon and rectum. As disease burden increases, most patients will require a colectomy to remove the colon and manage disease progression and cancer risk. While this surgery addresses immediate cancer risk in the colon, it does not stop the development of further adenomas in the remaining rectum, pouch, or duodenum. Post-colectomy, patients with FAP still require decades of repeat endoscopies and excisional procedures. Approximately 50% of these patients will eventually require removal of the remaining rectum pouch in order to manage uncontrolled polyposis, a life-altering surgery that impacts quality of life. Disease progression continues in the upper GI tract, where approximately 90% of FAP patients will develop duodenal adenomas, which can often be difficult to manage endoscopically. Around 6% of these patients will undergo duodenectomy or Whipple surgeries, which are some of the most significant life-altering surgeries associated with high morbidity and mortality. Despite this substantial disease burden, no approved therapies currently exist for FAP.

Insights from Recursion OS

REC-4881 was identified as a potential first-in-disease therapy for FAP using a high-content phenotypic screening approach targeting APC-deficient human cells. In this screen, REC-4881 emerged as a potent allosteric MEK1/2 inhibitor that rescued an APC siRNA genetic knockdown-associated morphological phenotype. Compared to other MEK inhibitors, REC-4881 demonstrated a highly selective and concentration-dependent response, suggesting best-in-class potential. As a result, REC-4881 was in-licensed from Takeda and subsequently advanced into preclinical studies.

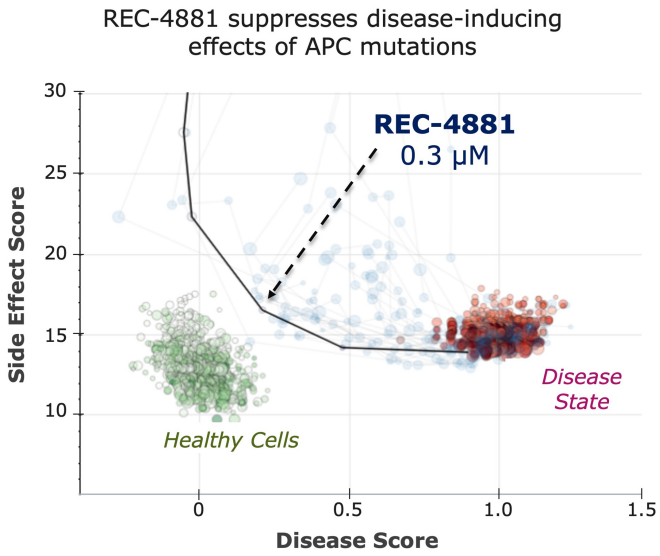


Figure 12. Discovery of REC-4881 in Recursion OS. Compared to thousands of other molecules tested, REC-4881 rescued phenotypic defects associated with APC siRNA genetic knockdown.

REC-4881 is an orally bioavailable, non-ATP-competitive allosteric inhibitor of MEK1 (IC_{50}: 2-3 nM) and MEK2 (IC_{50}: 3-5 nM) being developed as a potential first-in-disease therapy for FAP. Loss of APC disrupts β-catenin regulation, leading to uncontrolled Wnt signaling, RAS stabilization, and ERK pathway activation, which drives MYC-dependent proliferation. REC-4881 inhibits MEK1/2, and blocks ERK phosphorylation downstream. This reduces MYC expression levels in the cell and potentially restores Wnt pathway control. Given ERK signaling activity in both adenoma epithelium and tumor stroma, as well as frequent MAPK-activating mutations in FAP, MEK inhibition offers a targeted strategy to suppress disease progression.

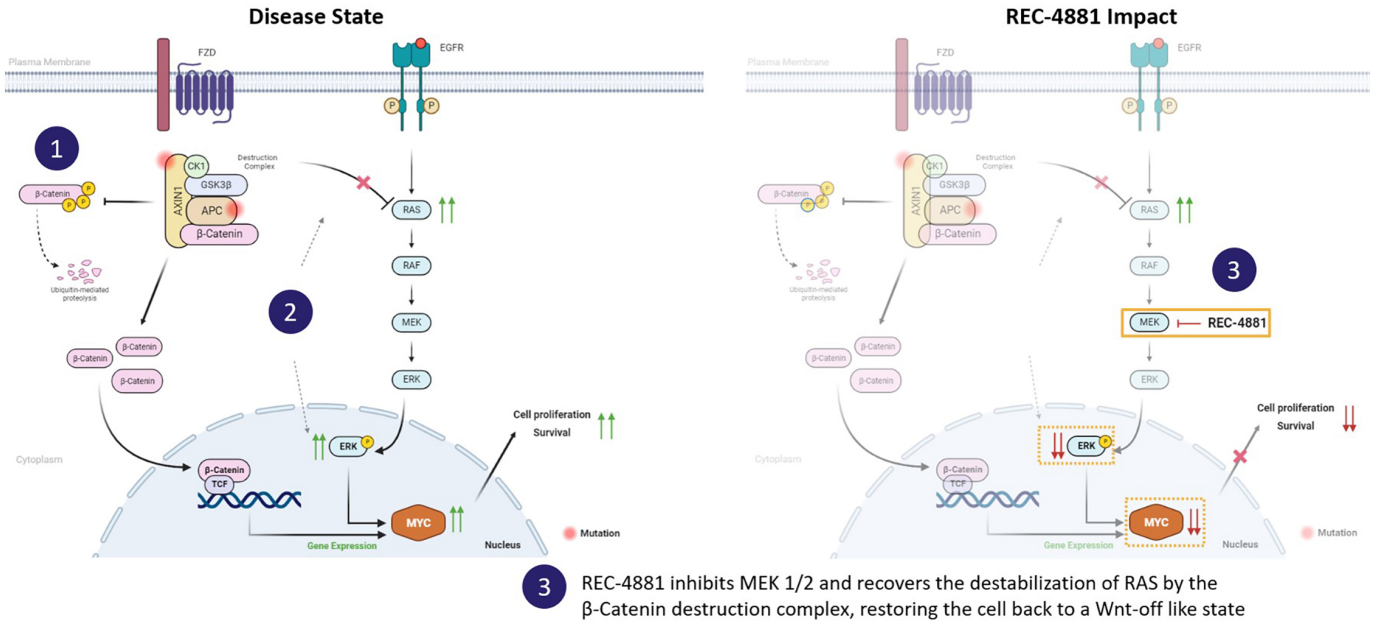


Figure 13. REC-4881 inhibits APC-mutation induced MAPK signaling to block cell proliferation in the context of FAP. A potential mechanism of action of REC-4881 in cells with loss of function mutations in APC.[7]

[7] *Jeon, WJ, et al. (2018). Interaction between Wnt/β-catenin and RAS-ERK pathways and an anti-cancer strategy via degradations of β-catenin and RAS by targeting the Wnt/β-catenin pathway. NPJ Precision Oncology, 2(5).*

Preclinical

REC-4881's activity was validated in tumor cell lines and spheroid models derived from APC-mutant human epithelial tumor cells. In these systems, REC-4881 inhibited spheroid growth and disrupted cellular organization, demonstrating over 1,000-fold selectivity in APC-mutant cells. In a disease-relevant FAP model, $Apc^{Min/+}$ mice were treated with multiple oral doses of REC-4881 or celecoxib over eight weeks. While celecoxib reduced polyp formation by approximately 30% compared to vehicle, REC-4881 treatment led to a reduction of 50% (1-3 mg/kg), and 70% (10 mg/kg). Mice that were treated with 10 mg/kg REC-4881, the highest dose tested, exhibited an approximately 70% reduction in total polyps. Histological analysis of gastrointestinal tissues further revealed that, unlike celecoxib, which primarily affected benign polyps, REC-4881 significantly reduced both benign polyps and high-grade adenomas. These findings suggest that REC-4881 not only limits early polyp formation but may also inhibit progression to advanced adenomas, highlighting its potential to address both pre- and post-colectomy FAP populations.

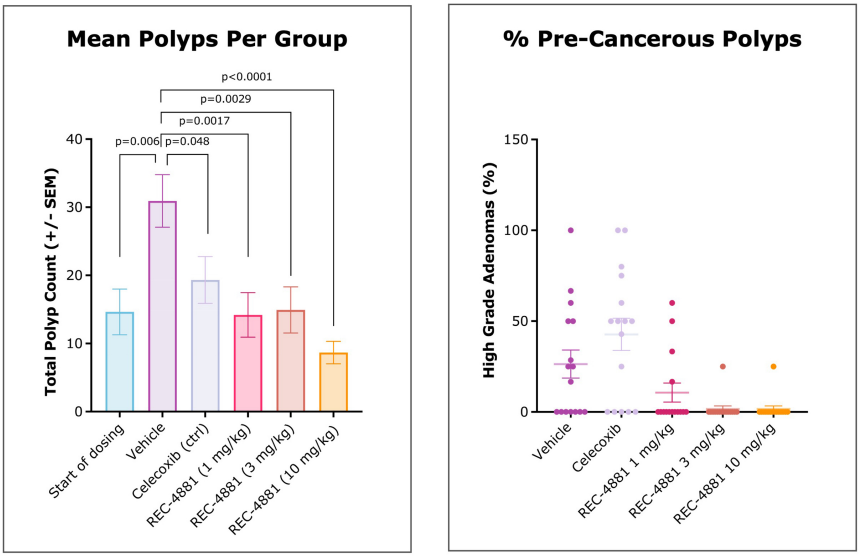


Figure 14. REC-4881 reduces GI polyp count and pre-cancerous, high-grade adenomas in the $APC^{Min/+}$ mouse model of FAP. GI polyp count (left) and the percentage of high-grade adenomas (right) after oral administration of indicated dose of REC-4881, celecoxib, or vehicle control for 8 weeks. Polyp count at the start of dosing reflects animals sacrificed at the start of study (15 weeks of age). $P < 0.001$ for all REC-4881 treatment groups vs. vehicle control. Quantification of high-grade adenomas versus total polyps was based on blinded histological review by a pathologist. While celecoxib reduces benign polyps, most remaining lesions are high-grade adenomas. By contrast, REC-4881 reduces both polyps and high-grade adenomas.[8]

Clinical

REC-4881 has been evaluated in multiple clinical studies, demonstrating a well-tolerated safety profile and pharmacological activity.

Phase 1 Oncology Studies

In a prior dose-escalation study (C20001) conducted by Millennium Pharmaceuticals in 51 participants with advanced solid tumors, REC-4881 (formerly TAK-733) was administered at doses ranging from 0.2 mg to 22 mg once daily on days 1–21 of 28-day treatment cycles. The maximum tolerated dose (MTD) was determined to be 16 mg. The most common adverse events (AEs) were rash (67%; 57% Gr1-2, 10% Gr3), diarrhea (29%, All Gr1-2), and increased blood CPK (20%, 10% Gr1-2, 10% Gr3). Treatment-related serious adverse events (SAEs) were infrequent. No unexpected safety concerns emerged, and pharmacokinetic analyses showed a less-than-dose proportional increase in exposure.

REC-4881-101 (Healthy Volunteers)

We conducted a Phase 1 study to evaluate the safety and pharmacokinetics of REC-4881 in 25 healthy participants receiving single doses of 4 mg, 8 mg, and 12 mg. REC-4881 was well tolerated, with no SAEs or dose-related safety concerns. The most common treatment-emergent adverse events (TEAEs) were mild and self-limiting, including transient blurred vision and vitreous floaters. No QTcF abnormalities were observed.

[8] *Data on file.*

Phase 1b/2 in FAP (TUPELO)

We are currently enrolling patients in a Phase 1b/2 open-label, multicenter study (TUPELO) evaluating the efficacy, safety, pharmacokinetics, and pharmacodynamics of REC-4881 in FAP. Part 1 assessed safety, tolerability, and pharmacokinetics in FAP patients receiving 4 mg once daily for 14 days. REC-4881 was generally well-tolerated, with a safety profile consistent with other MEK inhibitors. Pharmacodynamic data showed that the 4 mg dose was pharmacologically active in FAP, and this dose progressed to Part 2 of the study. Part 2 is evaluating efficacy, safety, and pharmacokinetics in post-colectomy FAP patients with confirmed germline APC mutations. Participants will receive once-daily REC-4881 for three months (the on-treatment phase, with readout at week 13), followed by a 3 month off-treatment phase (with a readout at week 25).

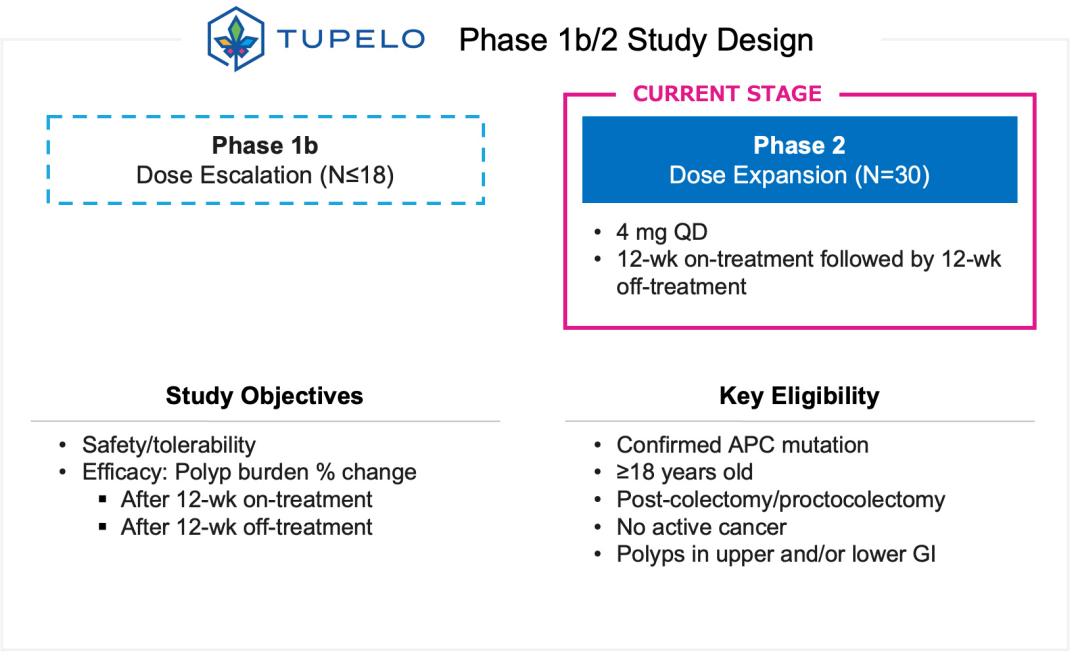


Figure 15. TUPELO study design. Phase 1b/2 clinical study to assess the efficacy, safety, and pharmacokinetics of REC-4881 in patients with classical familial adenomatous polyposis (FAP)

As of December 2025, treatment with REC-4881 (4 mg QD) demonstrated meaningful and durable reductions in polyp burden in patients with FAP within the Phase 2 portion of TUPELO. A rapid reduction in polyp burden was reported at week 13. The majority of evaluable patients responded, with 75% showing reductions in polyp burden, and a median 43% reduction in total polyp burden observed among 12 efficacy-evaluable patients. 40% of patients also achieved a ≥1-point improvement in Spigelman stage from baseline, which is a clinically meaningful measure of upper GI disease severity to assess surveillance and clinical management. Durability of effect was maintained at week 25, following the 12 week off-therapy phase. 82% (N=9) of 11 evaluable patients responded to treatment with REC-4881, with a 53% median reduction in total polyp burden observed from baseline, which is shown in the figure below. 40% of patients also maintained a ≥1-point improvement in Spigelman stage from baseline.

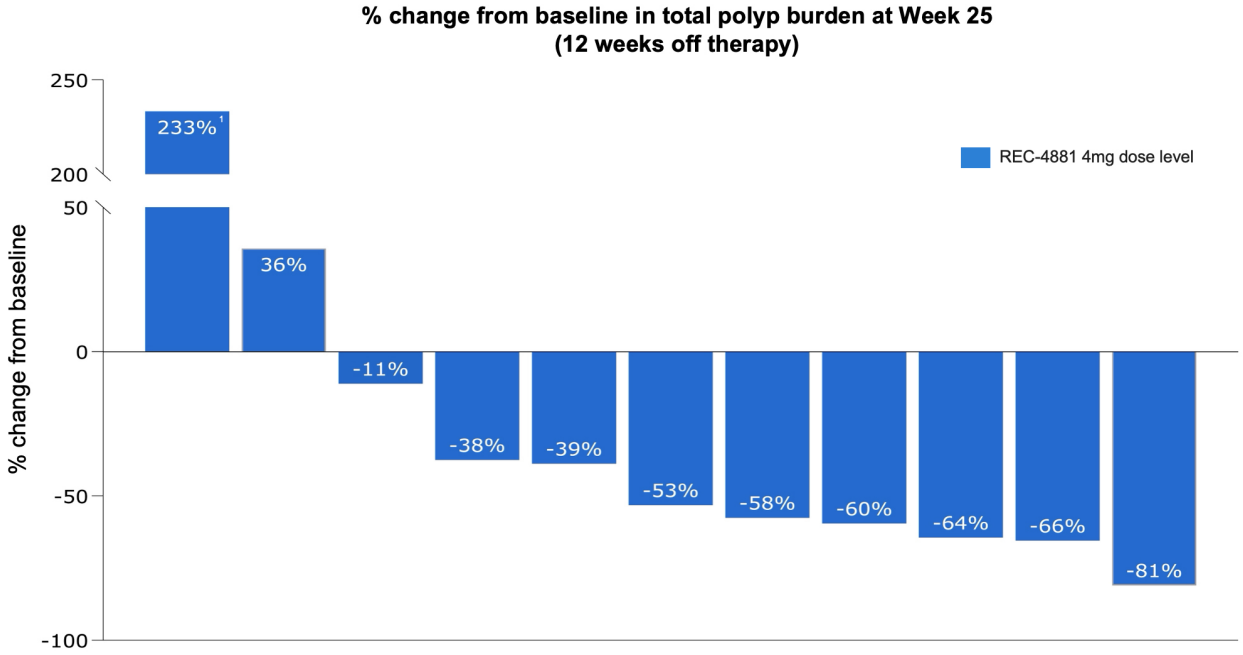


Figure 16. Durable reductions in polyp burden at week 25 of the TUPELO study. Percent change in baseline in total polyp burden at week 25 (12 weeks on therapy / 12 weeks off therapy) for patients with FAP treated with 4mg REC-4881. Percent (%) change from baseline calculates the change between post-resection value from screening visit to the pre-resection value at Week 25/EOT visit. Note: Polyp burden defined as the sum of all diameters of polyps in the GI. [1]Non-responder with 233% increase – polyp burden increased from 3mm to 10mm due to one polyp growth at Week 25. Efficacy Evaluable Population: Defined as all participants who have measurable disease (non-zero polyp burden) at end of baseline endoscopy, received at least 75% of study drug, and have at least one post-baseline on study endoscopic assessment. One patient who had a week 13 endoscopy did not have a Week 25 endoscopy.[9]

The safety profile of REC-4881 4 mg QD across the combined Phase 1b/2 cohort (19 safety evaluable patients) was consistent with prior MEK1/2 inhibitors. Treatment-related adverse events were predominantly low grade and N=4 discontinuations occurred due to TRAEs. The most frequent TRAEs (at greater than or equal to 10%) included dermatitis acneiform (57.9%; 52.6% Grade 1/2, 5.3% Grade 3) / rash (31.6%; all Grade 1/2) and blood CPK increase (36.8%; 26.3% Grade 1/2, 10.5% Grade 3).

Natural History Analysis

In December 2025, we reported on a natural history analysis in collaboration with Amsterdam University Medical Centre to contextualize the single-arm efficacy TUPELO trial of REC-4881, and to better understand the natural history of FAP. The study analyzed a subset of 55 patients from a FAP registry which met key inclusion criteria of TUPELO. Results suggested that the natural history of FAP is to progress: 87% of untreated patients in the registry experienced annualized increase in polyp burden, with 10% being stable and 3% experiencing a modest decrease in polyp burden, shown in the figure below. A mean increase of 60% and median increase of 28% in annualized polyp burden was observed.

[9] *Data on file.*

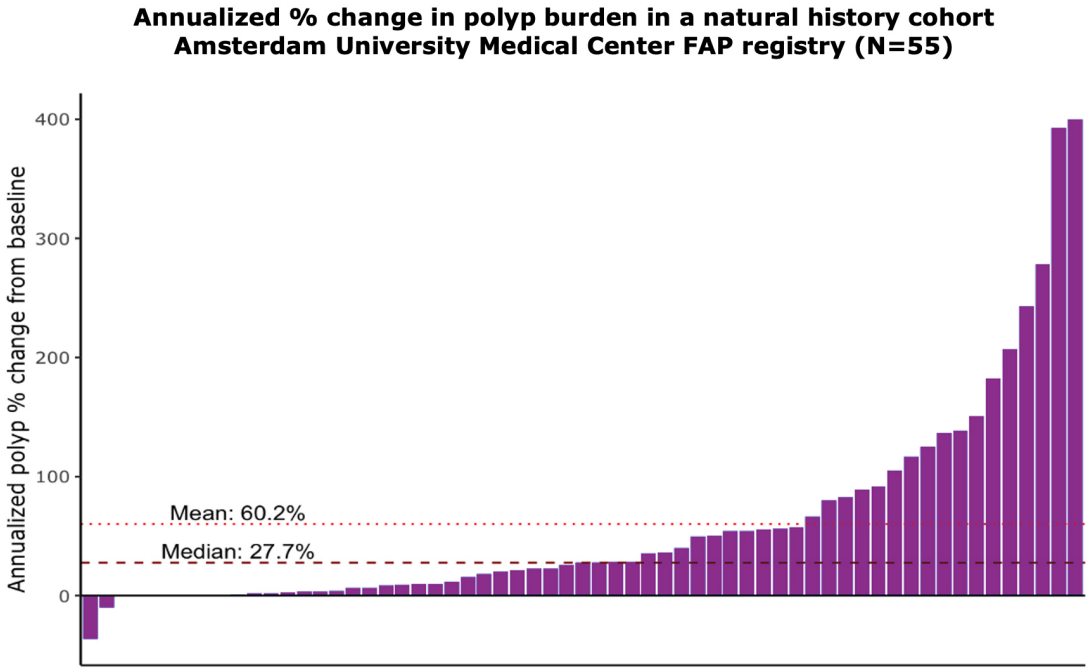


Figure 17. Annualized percent change in polyp burden in a natural history cohort. Each bar represents one patient. 6 patients had separate endoscopic evaluations for upper and lower GI involvement and have repeated bars. Data includes 55 patients aged ≥55 with a history of colectomy and measurable polyp burden at baseline endoscopy. In routine care, endoscopies for lower and upper GI are performed annually with variability. Therefore, polyp burden percent change was annualized. 52 (97%) of the 55 patients had an increase or stable polyp burden.[10]

Competitors

No drugs have been approved for FAP patients, though some generic drugs are used in selected patients to reduce polyp burden. The following programs represent the most clinically advanced efforts specifically evaluated in FAP populations:

- **Flynpovi (Panbela Therapeutics)** — A fixed-dose combination of sulindac and eflornithine. The combination of the individual drugs was previously evaluated vs. the individual drugs alone in a randomized Phase 3 trial in FAP. Post hoc analyses suggested a potential effect on delaying lower gastrointestinal surgery; Panbela had indicated plans for a new Phase 3 study in FAP patients, including those with an intact colon, although the company has provided no updates on development plans since 2023.
- **eRapa (Biodexa Pharmaceuticals)** — A formulation of rapamycin currently being evaluated in a Phase 3 study in FAP patients both prior to and following colectomy, with primary completion in 2030.
    - Phase 2 data among adult patients with and without intact colon in cohort 2 (Phase 3 dose) showed a 29% median reduction in total polyp burden at 12 months.
- **Eicosapentaenoic Acid (SLA Pharma)** — A derivative of an omega-3 fatty acid which was under evaluation in a Phase 3 study for polyp suppression in FAP, completed over 6 years in 2024 and is pending data updates. It has previously shared data from a Phase 2/3 study:
    - A 17% reduction in polyp size (diameters) vs baseline at 6 months, which translates to 29.8% mean reduction vs. placebo.
    - A decrease 34% from baseline in global rectal polyp burden was reported vs. a 9% increase with placebo.

  Depending on jurisdiction, this product may be regulated differently from traditional prescription pharmaceuticals.

The following programs are in early clinical development or include FAP as a subset of a broader development strategy:

- **FOG-001 (zolucatetide, Parabilis Medicines)** — A peptide-based investigational therapy with early clinical evidence reported in FAP. Additional clinical data are expected in 2026.
- **TPST-1495 (Tempest Therapeutics)** — A dual EP2/EP4 antagonist with a Phase 2 study in FAP(NCI run study) anticipated to initiate in 2026.
- **ZKN-013 (Eloxx Pharmaceuticals / Almirall)** — A small-molecule read through agent currently in a Phase 1 clinical trial that includes a cohort of patients with FAP.

[10] *Data on file.*

REC-617 for Advanced Solid Tumors – Phase 1/2

REC-617 is an orally bioavailable, cyclin-dependent kinase 7 (CDK7) inhibitor currently under development for the treatment of advanced solid tumors. Inhibiting CDK7 targets both cell cycle dysregulation and transcriptional "addiction", which are hallmarks of multiple aggressive cancers including, but not limited to, CDK4/6 resistant breast cancer, ovarian cancer, and other solid tumors. There are currently no CDK7 inhibitors approved by the FDA. ELUCIDATE, a Phase 1/2 open-label, multicenter, safety, PK, PD and preliminary efficacy study is currently underway. Interim monotherapy Phase 1 safety, PK, PD, and efficacy data were shared in the fourth quarter of 2024, with expanded data from a larger cohort of patients shared in the fourth quarter of 2025. Phase 1 monotherapy dose escalation is ongoing in 2026, to evaluate alternative dosing schedules. Phase 1 dose escalation combination cohorts were initiated in 2L+ PROC in 2025, with initial combination regimens including bevacizumab plus paclitaxel or pegylated liposomal doxorubicin (PLD). A Phase 2 dose expansion monotherapy cohort in PROC was also initiated in 2025. We expect to provide early safety and PK combination data in 2027.

Disease Overview

The importance of cell cycle inhibitors in oncology has been established with CDK4/6 inhibitors, which generated approximately $10.5 billion in sales in 2023. Aberrant CDK7 overexpression is common in many cancer indications and associated with poor prognosis. CDK7 presents an opportunity to improve treatment outcomes over CDK4/6 inhibitors due to CDK7's dual role in cell cycle progression and transcription. Potential specific indications include ovarian cancer, HR+ breast cancer, triple negative breast cancer, pancreatic cancer, ovarian cancer, head and neck cancer, and NSCLC for which we estimate an addressable population of approximately 150,000 drug-treatable patients per year in the US and EU5.

Insight from Recursion OS

CDK7 inhibitor development has faced significant challenges, primarily due to off-target effects and suboptimal pharmacokinetics. Previous attempts often employed covalent binding mechanisms or exhibited poor oral bioavailability, leading to undesirable side effects in the clinic. Current candidates in development for CDK7 feature covalent binding or extended half-lives potentially resulting in substantial on-target toxicity. In addition, the reversible inhibitors under investigation are transporter substrates, likely compromising their absorption and exacerbating gastrointestinal adverse events. These limitations underscore the critical need for novel CDK7 inhibitor designs that optimize both safety and efficacy profiles.

Leveraging our AI-driven multi-parameter optimization approach, we identified critical design limitations in existing CDK7 inhibitors. This insight led to an improved target product profile and a novel molecule design. REC-617 is an orally bioavailable, potent and selective CDK7 inhibitor with enhanced oral bioavailability. It has a non-covalent, reversible mechanism of action, and a predicted shorter human half-life compared to other drugs in development. These characteristics potentially offer an improved therapeutic index, less off-target effects, and more consistent absorption.

Preclinical

REC-617 has demonstrated strong anti-tumor activities in preclinical studies, and in vivo experiments showed potent tumor regression across multiple solid tumor types. Notably, in the OVCAR3 ovarian cancer xenograft model as shown below, complete tumor regression was observed in all 8 mice treated with 10 mg/kg by Day 27. Importantly, no significant body weight loss was observed across treatment arms. Mouse PK studies revealed that maintaining 8-10 hours of CDK7 IC_{80} coverage resulted in potent tumor regression with minimal side effects, while coverage beyond 10 hours led to significant body weight loss. This defined an optimal therapeutic window that guided target efficacious exposures in the clinic.

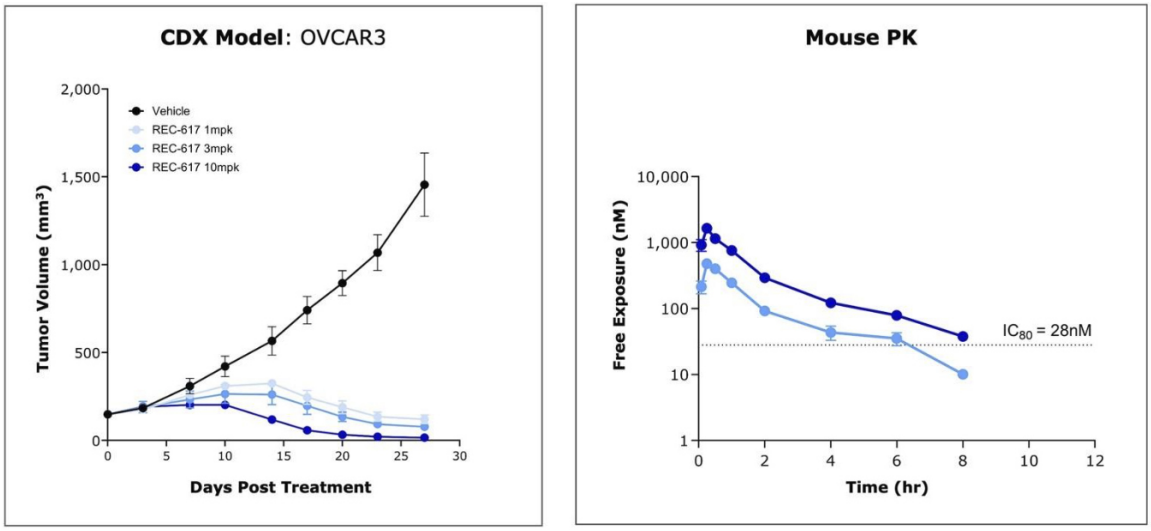


Figure 18. REC-1245 anti-tumor activity and PK in preclinical tumor models. (Left) REC-617 induces tumor regression in the OVCAR3 cell line derived xenograft mouse model. N=8, 28 days of treatment, REC-617 administered QD PO. (Right) REC-617 administration results in 8-10 hours of therapeutic coverage at IC_{80}. PK studies conducted in CD1 mice, single-dose administration PO.[11,12]

Clinical

In the third quarter of 2023, we initiated a Phase 1/2 open-label, multicenter study (ELUCIDATE) in patients with advanced solid tumors, with the design shown in the figure below.

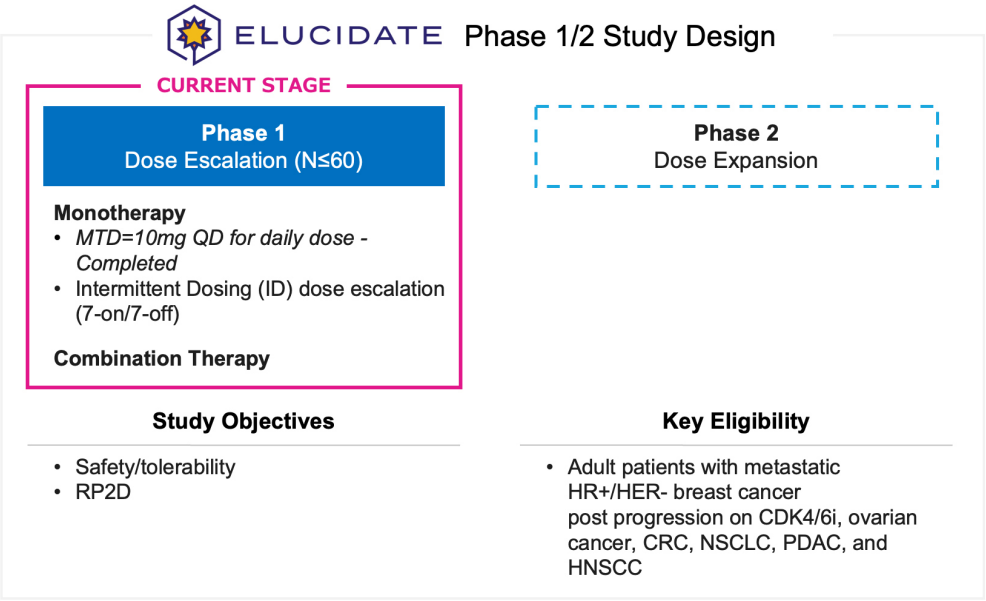


Figure 19. ELUCIDATE study design. Phase 1/2 trial design to assess the safety, PK, exploratory PD, and efficacy of REC-617 in patients with advanced solid tumors.

[11] Besnard, et al. (2022). AI-driven discovery and profiling of GTAEXS-617, a selective and highly potent inhibitor of CDK7 [abstract]. AACR; Cancer Res 2022;82(12_Supplement): 3930.
[12] Hallett, et al. (2024). Overcoming traditional design limitations with AI-based discovery. AACR Special Conference in Cancer Research: Optimizing Therapeutic Efficacy and Tolerability through Cancer Chemistry; Plenary Session 1

In December 2024, we presented results from the initial 18 response evaluable patients from Phase 1 monotherapy dose escalation at an AACR Special Conference in Cancer Research. In November 2025, updated results from a monotherapy cohort of 29 heavily pre-treated patients who received 6 dose levels of REC-617 (QD and BID) were reported. REC-617 was well-tolerated with predominantly Grade 1-2 adverse events, and fewer GI side-effects than reported for other CDK7 inhibitors. The most common DLTs were nausea and thrombocytopenia, and 6.9% (N=2) of patients discontinued due to a TRAE. The MTD was established at 10 mg once daily. PK data support dose-proportional exposure (see figure below), rapid absorption, and a short half-life (~5h).

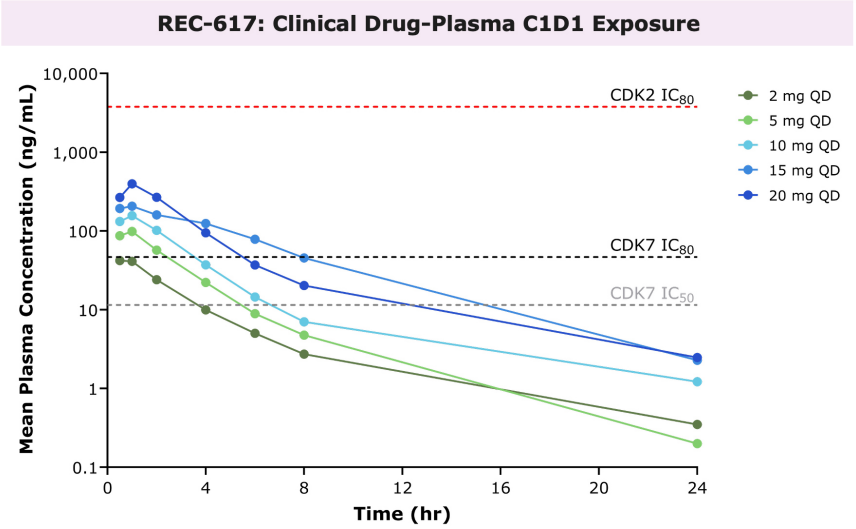


Figure 20. REC-617 clinical plasma pharmacokinetics. REC-617 demonstrates dose-proportional exposures exceeding CDK7 IC50. Exposures remain below CDK2 IC80, supporting selective target inhibition.[13]

Encouraging antitumor activity included a confirmed partial response (PR), in a heavily pre-treated metastatic ovarian cancer patient. The patient had a maintained durable response and was treated with REC-617 for approximately 7 months. Patient LDH levels were also normalized, and reductions were observed in CA125 (-44%) and TK1 (-68%). Five additional patients achieved the best response of stable disease (SD) lasting up to six months.

Competitors

Several investigational CDK7 inhibitor programs have entered clinical development; however, the competitive landscape remains relatively limited, with only a small number of programs currently advancing in active clinical development. These programs vary by mechanism, combination strategy, geographic focus, and development priority.

Programs with active clinical development and strategic focus

- **Samuraciclib (Carrick Therapeutics)** — An oral CDK7 inhibitor currently in Phase 2 clinical development, primarily in combination with selective estrogen receptor degraders (SERDs) for patients with HR-positive, HER2-negative breast cancer following progression on CDK4/6 inhibitors.
    - **Recent data update from Ph2 randomized study evaluating samuraciclib + fulvestrant vs. fulvestrant alone in, fulvestrant naive, post CDK4/6+AI patient population was directionally positive but with limited quantitative power**
        - Positive direction holds true across ORR, CBR, PFS and in sub-cohorts (TP53wt)
            - ORR: 28% with combo (n=32) vs. 14% (n=14) with fulvestrant alone
            - mPFS: 7.8mo to 8.5mo (n=39) vs. 5.6mo (n=20)
            - In TP53mut not detected: mPFS of 9.6-14.5mo (n=30) vs 6.8mo (n=11)
        - The drug continues to show GI toxicities in >80% patients at RP2D (360mg)
- **Q-901 (Qurient)** — An intravenous CDK7 inhibitor in Phase 1/2 clinical development as monotherapy and in combination with PD-1 inhibitors across solid tumors. No efficacy data has been shared so far. Qurient is also developing a HER2-targeted antibody–drug conjugate (QP-101) that incorporates a CDK7 inhibitor payload in combination with a topoisomerase I inhibitor, currently in preclinical development.

[13] *Data on file.*

Other notable programs with limited or geographically-constrained clinical presence

- **TY-2699a (TYK Medicines)** — A CDK7 inhibitor currently in Phase 1 clinical development in China.
- **EOC-237 (EOC Pharma)** — A CDK7 inhibitor currently in Phase 1 clinical development in China.

REC-1245 for Solid Tumors and Lymphoma – Phase 1/2

REC-1245 is a novel, potent and selective molecular glue degrader of RNA-binding motif protein 39 (RBM39) currently under development for the treatment of biomarker-enriched solid tumors and lymphoma. There are currently no RBM39 degraders approved by the FDA. We initiated a Phase 1/2 open-label, multicenter study (DAHLIA) to evaluate the safety, tolerability, PK, PD, RP2D, and preliminary efficacy of REC-1245. In the third quarter of 2025, we reported updated information on the population being enrolled into the DAHLIA study, to include cancers with high genomic instability (for example endometrial cancer) and to confirm specific biomarker-enriched populations (for example 2L+ MSI-H/dMMR). We expect to share early safety and PK data from the Phase 1 monotherapy dose-escalation portion of the study in the first half of 2026.

Disease Overview

Alternative splicing and RNA-binding proteins (RBPs) have emerged as attractive therapeutic targets for cancer due to their critical roles in the regulation of post-transcriptional modifications, impacts on DNA damage repair pathways, and modulation of cell cycle functions. Of these, RNA-binding motif protein 39 (RBM39) is a critical splicing factor that many high-risk cancers rely on to maintain transcriptional integrity and drive tumor progression. As a target, RBM39 is vulnerable to a 'molecular glue' approach, where its selective degradation triggers a cascade of lethal splicing errors across key oncogenic pathways, including those involving DNA damage repair. With over 100,000 addressable patients, with biomarker-enriched solid tumors and other select histologies where RBM39 could be targeted in the US and EU5 each year, REC-1245 has the potential to be used as a single agent or in combination with chemotherapy and/or immunotherapy.

Insight from Recursion OS

Reports suggest that genetic or pharmacologic depletion of CDK12 can reduce the expression of several genes involved in the homologous recombination repair pathway such as BRCA1 and BRCA2, inducing a BRCA-like phenotype and DDR response. Therefore, CDK12 has received considerable interest as a therapeutic target and tumor biomarker for HR-proficient cancers; however, success has been limited by toxicity associated with CDK12 inhibitors also inhibiting the structurally related CDK13. Despite reports of functional redundancy, we observed that the genetic knockout of CDK12 could be clearly distinguished phenotypically from that of CDK13. Using map-based inference to characterize and relate cellular phenotypes, we identified RBM39 as an alternative target that selectively mimics CDK12 loss, but not CDK13, providing a novel approach for targeting CDK12 biology while circumventing any toxicities that may arise due to CDK13. We subsequently discovered REC-1245 as an RBM39 molecular glue degrader that closely mimics the phenotypic loss of CDK12 and RBM39, but not CDK13. Functionally, REC-1245 treatment globally impacts the expression of many DDR genes but does so in a CDK12 independent manner.

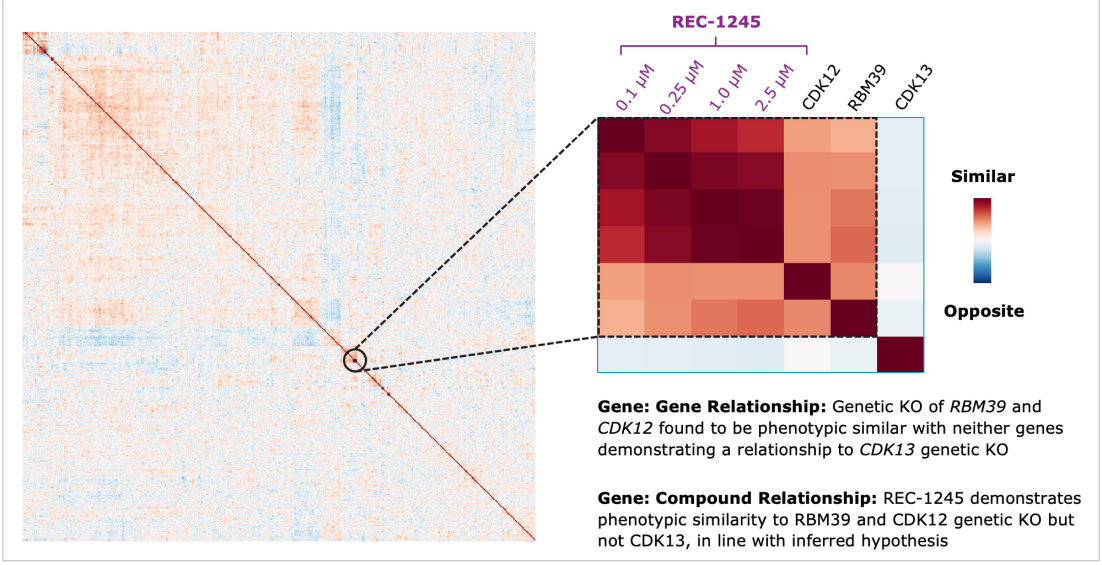


Figure 21. Inferred map relationships between CDK12, CDK13, RBM39, and REC-1245. Map representation demonstrates a high degree of phenotypic similarity between CDK12, RBM39, and multiple concentrations of REC-1245. CDK13 shows little or no functional similarity to CDK12, RBM39, or any concentration of REC-1245.

Preclinical

REC-1245 is a potent, potential first-in-class RBM39 molecular glue degrader with compelling preclinical activity. It showed no significant in vitro safety concerns (CEREP, hERG), no CDK12 kinase activity, and minimal ITGA2 liability – an off-target effect seen with prior RBM39 degraders. As shown in the figures below, REC-1245 demonstrated strong antitumor activities as a single-agent, including tumor regression in an ovarian cancer BRCA-proficient, p53 mutant, OVK18 in vivo cell line derived xenograft (CDX) model. In addition, dose-dependent anti-tumor activity correlated with increases in RBM39 degradation confirming target engagement and an exposure-response-efficacy relationship.

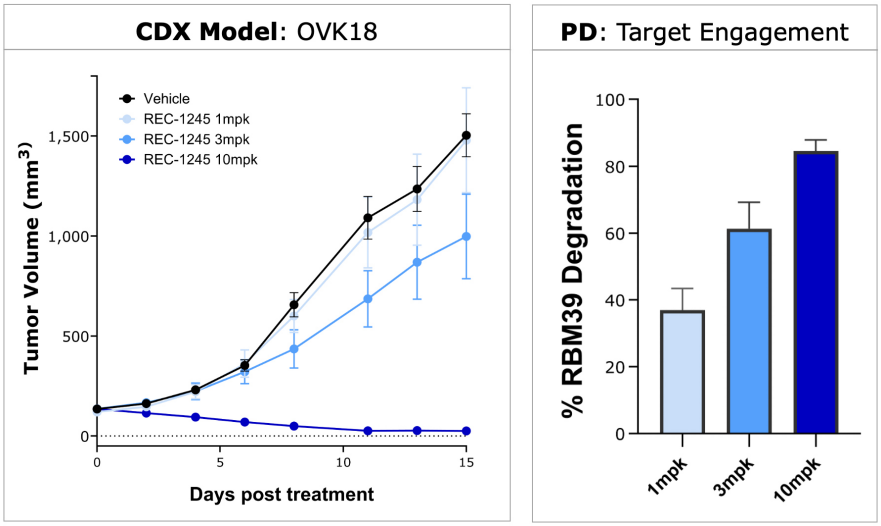


Figure 22. REC-1245 single-agent activity and target engagement. (Left) REC-1245 administered BID PO at doses noted for 15 days. N=8 mice per group. (Right) Percent RBM39 degradation (PD) evaluated at REC-1245 doses noted after 5 days BID oral administration of REC-1245. N=3 mice per group.[14]

Emerging preclinical data has shown that REC-1245 reduces viability in tumors characterized by replication stress and DNA repair vulnerabilities (DDR defects) across multiple solid tumor types, including MSI-H/dMMR, HRR altered cancers, and other tumors, as shown below, which could provide a potential signature for REC-1245 sensitivity. The data also suggests greater sensitivity to REC-1245 for tumors with high replicative stress signatures and DNA repair vulnerabilities, as shown below.

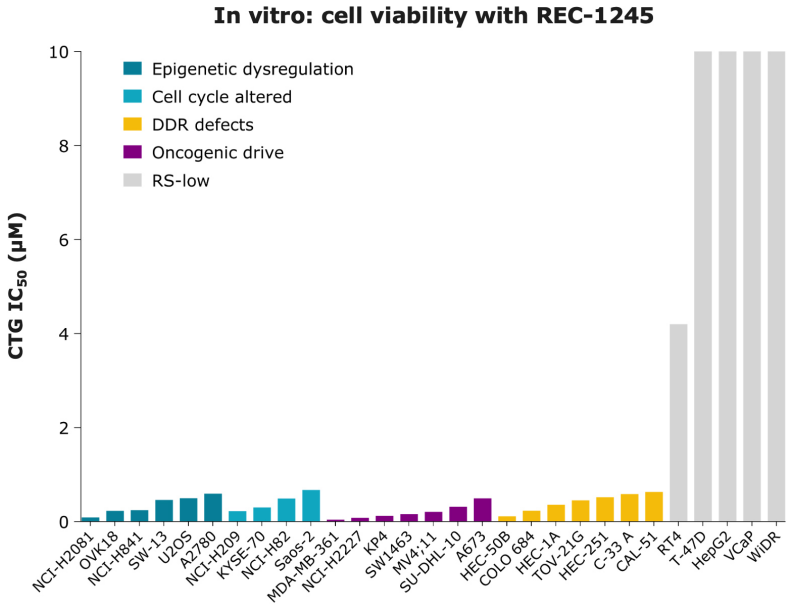


Figure 23. In vitro cell viability following REC-1245 treatment. Cell lines were assigned to broad pathway dysregulation contexts based on 1 or more documented alteration from CCLE/GSDC databases.[15]

[14] *Data on file.*
[15] *Data on file.*

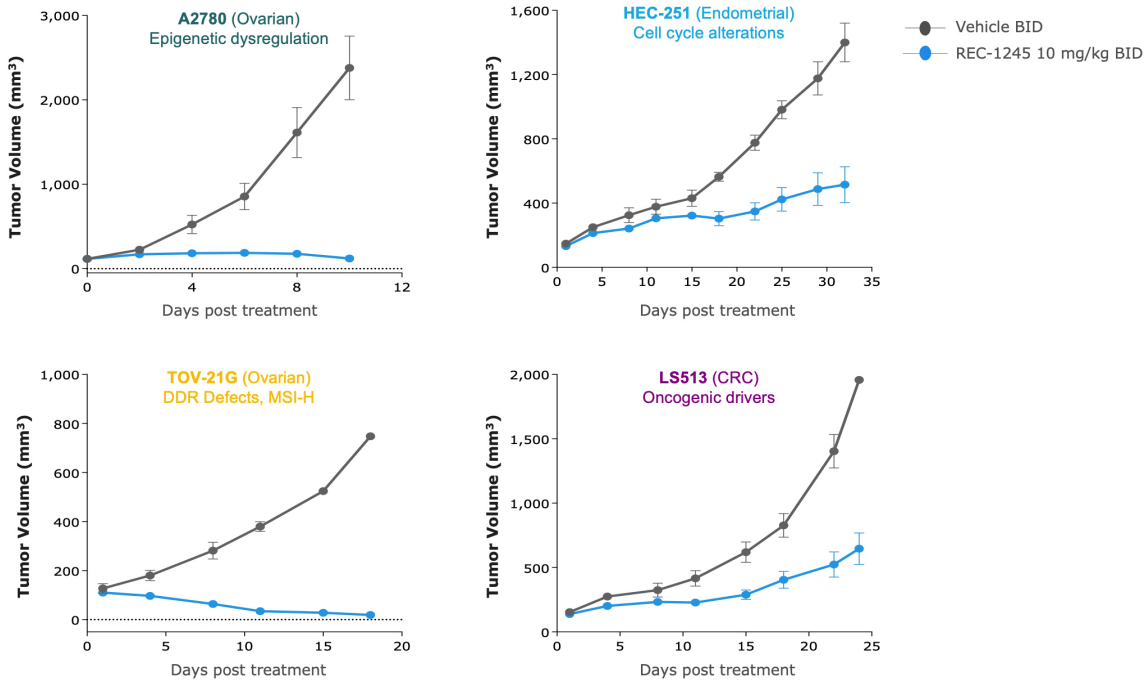


Figure 24. Reduction in tumor volume across different tumors with high replication stress and DNA repair vulnerabilities. N=4 mice per group.[16]

Clinical

In December 2024, we initiated a Phase 1/2 open-label, multicenter study to characterize the safety, tolerability, PK, PD, and preliminary anti-tumor activity of REC-1245 in participants with unresectable locally advanced or metastatic cancer. As of December 31, 2025, the trial is currently active and enrolling at sites in the US and Canada. We expect to share early safety and PK data from the Phase 1 monotherapy dose-escalation portion of the study in the first half of 2026.

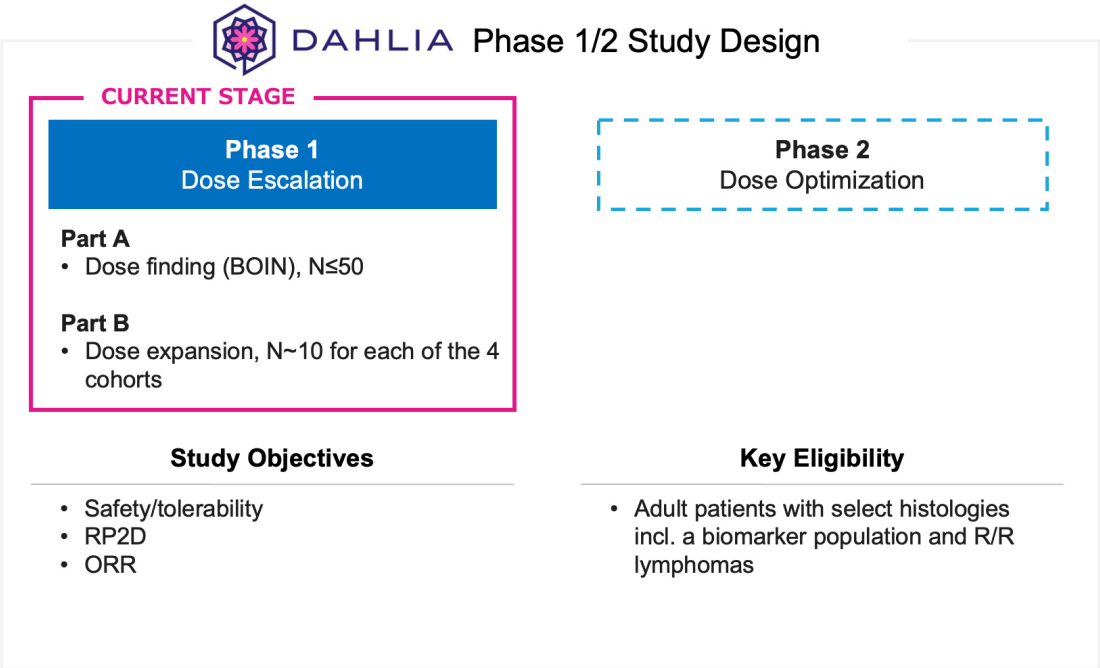


Figure 25. DAHLIA study design. Phase 1/2 trial design to assess the safety, tolerability, PK, PD, and preliminary anti-tumor activity of REC-1245 in participants with unresectable locally advanced or metastatic cancer, and who are refractory to, had a relapse on, or intolerant of, established standard of care treatment.

[16] *Data on file.*

The clinical development landscape for RBM39 degraders remains limited. While the mechanism of RBM39 degradation has been explored historically through legacy aryl-sulfonamide compounds, only a small number of programs are currently believed to be under active clinical development as purpose-built RBM39 degraders.

Active RBM39-focused development programs

- **ST-01156 (SEED Therapeutics)** — An investigational RBM39 degrader that initiated a Phase 1a open-label clinical trial in patients with advanced solid tumors, with first patient dosed in January 2026.
- **E7820 (Eisai)** — A legacy aryl-sulfonamide compound now understood to induce RBM39 degradation via DCAF15. Eisai is collaborating with the National Cancer Center (NCC) Japan, which is conducting a Phase 1 investigator-initiated trial (CIRCUS) evaluating E7820 in Japanese patients with unresectable tumors. Advancement to Phase 2 is expected to be considered following determination of tolerability and a recommended Phase 2 dose.

REC-3565 for B-Cell Malignancies – Phase 1

REC-3565 is an orally bioavailable, highly potent and selective, potential best-in-class MALT1 inhibitor currently under development for the treatment of B-cell malignancies, including chronic lymphocytic leukemia (CLL). MALT1 is a protease crucial for activation of the NF-κB pathway, which drives the proliferation of malignant B-cells in hematological cancers. There are currently no MALT1 inhibitors approved by the FDA. Following clearance of a CTA by the MHRA in December 2024, we initiated EXCELERIZE, a Phase 1 open-label, multicenter, dose escalation study to evaluate the safety, tolerability, PK, PD, and preliminary anti-tumor activity of REC-3565 in 2025. The first patient was dosed in April 2025, and we expect to share early safety and PK monotherapy data in the first half of 2027.

Disease Overview

B-cell malignancies encompass a range of hematological cancers, including lymphomas such as diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL), mantle cell lymphoma (MCL), and leukemias such as CLL and small lymphocytic lymphoma (SLL). These diseases are characterized by the dysregulated growth or function of B-cells and are often driven by chronic B-cell receptor (BCR) signaling, which leads to unchecked NF-κB activation. MALT1 functions downstream of the BCR and the widely targeted Bruton's tyrosine kinase (BTK), mediating pro-tumorigenic signals in malignant B-cells. Current therapies (e.g. BTK inhibitors) have transformed the treatment landscape, yet resistance remains a significant challenge. By inhibiting MALT1, REC-3565 may help overcome resistance and improve therapeutic outcomes, either as a monotherapy or in combination with BTK and/or BCL2 inhibitors. Notably, the total addressable population for MALT1 inhibitors spans multiple hematologic indications, with approximately 41,000 relapsed and/or refractory (R/R) patients with CLL and B-cell lymphomas in the US and EU5 annually.

Insight from Recursion OS

BTK inhibitors and other therapies for B-cell malignancies can cause drug-induced liver injury (DILI), limiting combination treatment options. Current MALT1 inhibitor scaffolds significantly inhibit UGT1A1, leading to dose-limiting toxicities, potentially restricting their utility in combination. Leveraging our AI-driven, multi-parameter optimization approach, we focused on an allosteric mechanism to enhance potency, selectivity, and safety for REC-3565. Hotspot analyses and physics-based molecular dynamics guided our design strategy, helping us address the hydrophobic and highly mobile nature of the allosteric binding site. As a result, REC-3565 does not significantly inhibit UGT1A1, potentially mitigating liver toxicity risks and facilitating higher target engagement. This profile also supports combination strategies with agents known to affect liver function like BTK and BCL2 inhibitors, offering a path to potentially deeper and more durable responses.

Preclinical

REC-3565 demonstrated significant antitumor activity across multiple B-cell lymphoma models. As a monotherapy, it drove tumor regressions in ABC-DLBCL xenografts, and in combination with zanubrutinib – a next-generation BTK inhibitor – it produced durable responses, with 70% of mice displaying no palpable tumors 10 days after the last dose. Additional in vitro analyses revealed minimal UGT1A1 inhibitory effects relative to other MALT1 inhibitor scaffolds in clinical development, suggesting an improved safety and combination therapy profile.

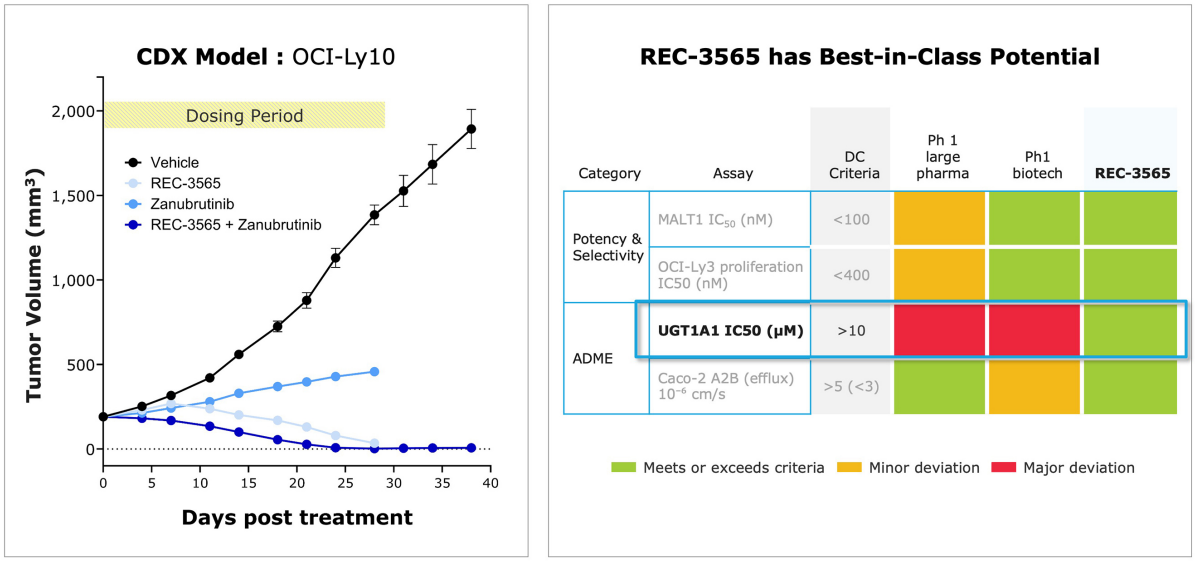


Figure 26. Preclinical data highlighting REC-3565 as a potential best-in-class MALT1 inhibitor. (Left) REC-3565 showed tumor growth regression as a single agent and when combined with zanubrutinib. N=10 per group mice per group, REC-3565 and zanubrutinib dosed BID. PD evaluated after 5 days BID oral administration of REC-1245 at doses noted. N=3 mice per group in PD portion. N=8 mice per group REC-3565 administered BID PO at doses noted. (Right) REC-3565 has best-in-class potential, especially given REC-3565 has >10 uM vs. <1 uM for other MALT1 inhibitors in clinical development. Development candidate criteria: MALT1 IC50 nM: green <100 nM; yellow >100-<300 nM; red>300 nM; OCI-Ly3 IC50 nM: green <400 nM; yellow >400-<1000 nM; red>1000 nM; UGT1A1 IC50 uM: green >10 uM; yellow <10->1 uM; red<1 uM; Caco-2 A2B (efflux): green >5(<3); yellow >1-<5(>3-<10); red <1(>10).[17,18]

Clinical

EXCELERIZE is a Phase 1 open-label, multicenter, dose escalation study designed to evaluate the safety, tolerability, PK, PD and preliminary anti-tumor activity of REC-3565 in patients with R/R B-cell malignancies. Part A will assess monotherapy dosing to identify a recommended dose for combination in Part B, which will evaluate combination regimens to inform future studies in B-cell cancers. The first patient was dosed in the second quarter of 2025, and we expect to share early safety and PK monotherapy data in the first half of 2027.

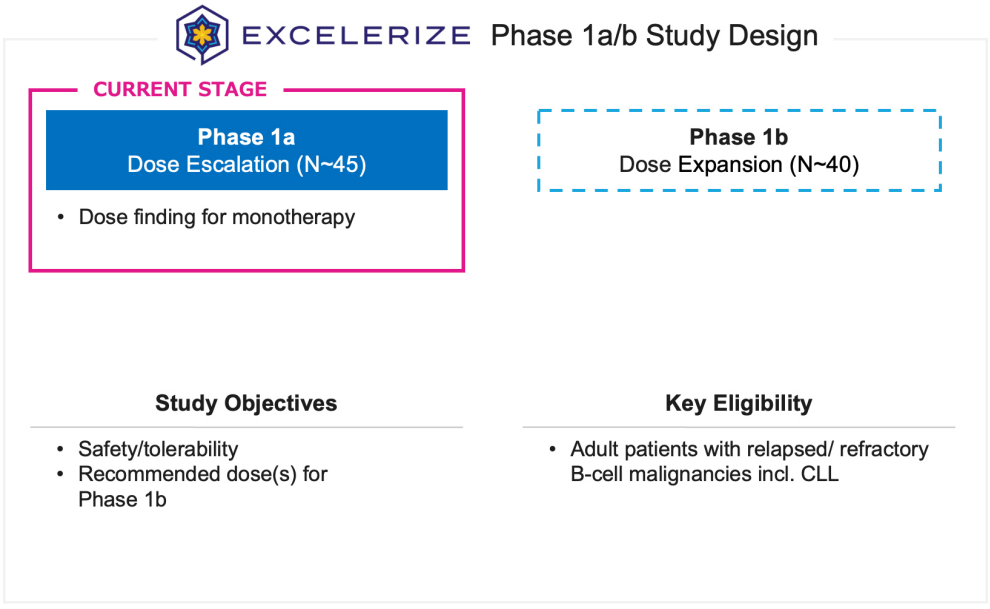


Figure 27. EXCELERIZE study design. Phase 1 trial to evaluate safety, tolerability, PK, PD and preliminary anti-tumor activity of REC-3565 in patients with R/R B-cell malignancies.

[17] Payne, et al. (2024). Combining next-generation BTK and MALT1 inhibitors to enhance efficacy and therapeutic utility in B-cell malignancies [poster]. EORTC-NCI-AACR (ENA) Symposium: PB206.
[18] Data on file.

Competitors

Early MALT1 inhibitors have shown UGT1A1 liability that has led to instances of hyperbilirubinemia in the clinic and limited combinability, while also potentially leaving efficacy on the table. The following competitors have or are currently generating data in the clinic with a strategic focus on B-cell lymphomas:

- **JNJ-6786633 (Johnson & Johnson) -** An oral MALT1 inhibitor, that showed significant hyperbilirubinemia in the clinic. Ph2 trials in combination with BTK inhibitors have since started and been marked complete, though no further data has been disclosed.
- **SGR-1505 (Schrödinger) -** An oral MALT1 inhibitor with Phase 1 monotherapy results reported for the ongoing trial in R/R B-cell lymphomas. Received US orphan drug designation for Waldenström's macroglobulinemia (WM) and mantle cell lymphomas (MCL), along with a fast track designation for treatment of WM patients in post BTK 3L+ setting.
- **ABBV-525 (AbbVie/Lupin) -** An oral MALT1 inhibitor with a Phase 1/2a trial ongoing in R/R B-cell malignancies. Primary completion of the trial is expected in 2029.
- **AUR-112 (Aurigene) -** An oral MALT1 protease inhibitor, with Phase I trial (AUR112-101) ongoing for relapsed advanced lymphoma. Initial results were reported at December 2025 press release, which showed limited Gr3 hyperbilirubinemiand 64% response rate (6 PR, 1CR) across B-cell lymphomas.

Other assets that have been discontinued or have a different strategic focus includes:

- **CTX-177/ONO-7018 (Chordia/ONO) -** An oral MALT1 inhibitor that was in Phase 1 trial for patients with R/R NHL/CLL which has recently been discontinued with the company looking to out license the asset.
- **RB-201 (Rarefied Biosciences) -** An oral MALT1 inhibitor currently in a healthy volunteer's study, with a strategic focus on autoimmune diseases.

REC-4539 for Solid Tumors and Hematology Oncology – Phase 1

REC-4539 is an orally bioavailable, highly potent and selective, CNS penetrant, and potential best-in-class inhibitor under development for the treatment of solid tumors and hematological malignancies. LSD1 is an epigenetic regulator that removes methyl groups from histones, thereby controlling the expression of tumor suppressors and oncogenes. By inhibiting LSD1, REC-4539 promotes the reactivation of tumor suppressor pathways and may slow tumor growth or enhance sensitivity to cytotoxic agents. There are currently no LSD1 inhibitors approved by the FDA. In January 2025, the FDA cleared an IND application for ENLYGHT, a Phase 1 open-label multicenter study evaluating REC-4359. In May 2025, the program was placed on strategic pause, to allow review of emerging clinical data and to ensure the program has a competitive Target Product Profile. Following completion of this review, we now expect to initiate a Phase 1 trial in the first half of 2026, with the dose escalation study evaluating REC-4539 in patients with SCLC or other select solid tumors. We expect to share early safety and PK data in the second half of 2027.

Disease Overview

LSD1 is abnormally overexpressed in a broad spectrum of solid tumors including lung, breast, prostate, esophageal, and bladder cancers, as well as acute myeloid leukemia (AML), with evidence suggesting that LSD1 is a promising therapeutic target. One indication of focus is SCLC, a poorly differentiated neuroendocrine tumor, representing roughly 15% of all lung cancer diagnoses. The majority of SCLC patients present with metastatic (extensive) or unresectable disease and, notably, over 50% of patients eventually develop brain metastases. Despite some improvements in frontline therapy such as chemotherapy plus immunotherapy, treatment options after progression remain limited. Median survival in ES-SCLC is poor, with a 5-year overall survival rate of approximately 3%. Across the US and EU5, approximately 45,000 patients have a treatable Stage III/IV SCLC each year.

Within SCLC, LSD1 plays a key epigenetic role by demethylating histones that regulate critical tumor suppressor genes. Inhibiting LSD1 can reverse this epigenetic repression, upregulating pathways such as NOTCH, that promote differentiation of neuroendocrine tumor cells into a more quiescent state, potentially sensitizing them to cytotoxic therapies. However, effective LSD1 inhibition requires a reversible, brain-penetrant molecule with a short half-life to minimize risks such as thrombocytopenia. Many LSD1 inhibitors have failed to achieve these parameters, particularly brain penetration and controlled on-target effects, highlighting the unmet need that REC-4539 aims to address.

A second indication of focus is acute myeloid leukemia (AML), which is the most prevalent adult leukemia. The disease accounts for approximately 80% of cases and is characterized by the aggressive expansion of immature "blast cells." While advancements in management have improved outcomes for younger patients, the prognosis for the elderly population remains poor, with cure rates as low as 15%. At the molecular level, LSD1 is abnormally overexpressed, acting as an epigenetic master regulator that complexes with GFI1 to arrest myeloid differentiation and drive the self-renewal of leukemic stem cells.

While the therapeutic potential of LSD1 inhibition is well-documented across various genetic profiles, the broader clinical field has been limited by significant safety hurdles. REC-4539 addresses this critical unmet need with an optimized profile designed to maximize anti-leukemic efficacy while mitigating the systemic risks that have hindered previous candidates, offering a highly differentiated solution for a patient population with few remaining options.

Insight from Recursion OS

Developing a selective LSD1 inhibitor for solid tumor indications requires a reversible mechanism, a short half-life to minimize on-target toxicity (e.g. thrombocytopenia), and the ability to penetrate the blood-brain barrier to address frequent metastases seen in indications such as SCLC. Many existing LSD1 agents fail to meet these criteria, resulting in dose-limiting toxicity and poor CNS exposure. Using our AI-driven, multi-parameter optimization approach, we generated and screened diverse chemical scaffolds for potency, selectivity, ADME properties, and CNS penetration. Active learning identified counterintuitive yet informative compounds, enabling a rapid design breakthrough. As a result, we created REC-4539 – a potent, selective, reversible, brain-penetrant, and potential best-in-class LSD1 inhibitor with a short predicted half-life and potential improved therapeutic index through better management of on-target toxicities such as reduced impact on platelets. We believe these key attributes provide competitive differentiation for REC-4539 versus prior LSD1-targeted molecules.

Preclinical

REC-4539 demonstrated potent anti-tumor activity across multiple preclinical models, including the NCI-H1417 human SCLC xenograft. In this model, dose-dependent tumor growth inhibition correlated with a corresponding decrease in the neuroendocrine tumor biomarker progastrin-releasing peptide (proGRP). Additionally, REC-4539 treatment was well-tolerated, with minimal impact on platelet counts.

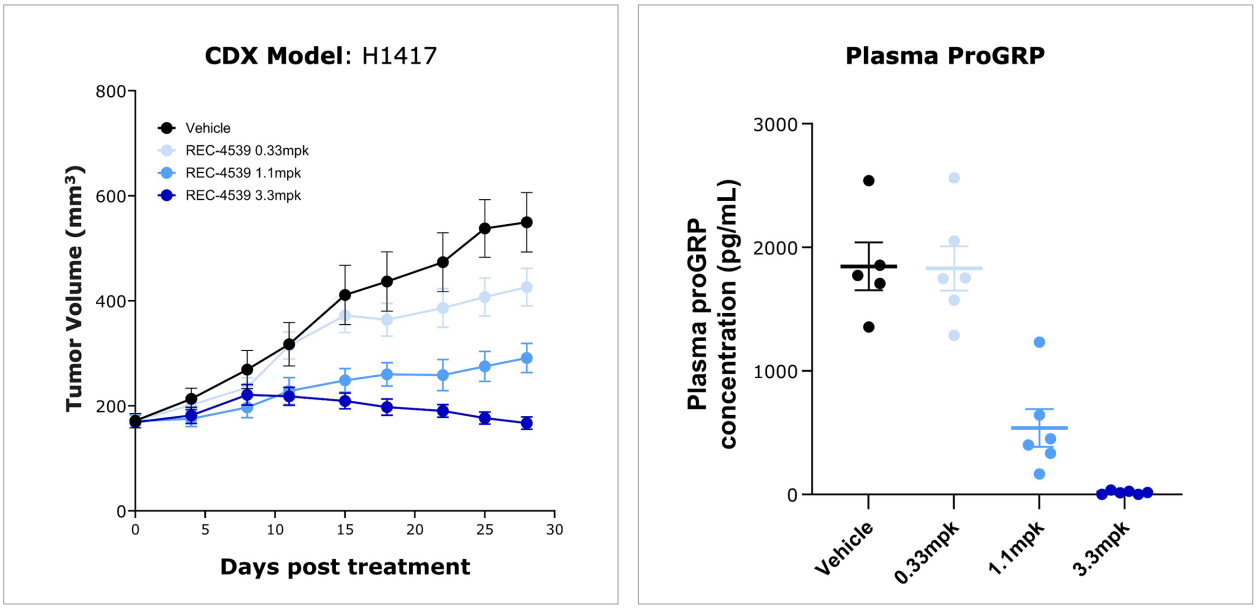


Figure 28. REC-4539 preclinical assessment in SCLC xenograft model. BALB/c mice, REC-4539 dosed BID, 28 day study (Left) REC-4539 induces dose-dependent tumor growth inhibition in the NCI-H1417 SCLC cell line derived xenograft mouse model. (Right) REC-4539 induces dose dependent reductions in plasma proGRP.[19,20]

[19] *Payne, et al. (2023). Characterizing Antitumor Responses to EXS74539, a Novel, Reversible LSD1 Inhibitor with Potential in Small-cell Lung Cancer [poster]. American Association for Cancer Research (AACR) Annual Meeting: 6290.*
[20] *Data on file.*

Clinical

ENLYGHT is a Phase 1, open-label, multicenter dose escalation study designed to evaluate the safety, tolerability, and preliminary efficacy of REC-4539 monotherapy in patients with select solid tumors. The FDA cleared an IND application in January 2025; the program was then placed on strategic pause in May 2025. While the broader field has faced safety challenges, REC-4539 remains highly differentiated by its optimized profile, and we now expect to initiate a Phase 1 trial in the first half of 2026. The Phase 1 study will evaluate REC-4539 as a monotherapy in patients with SCLC and select other solid tumors, to assess safety and tolerability, PK/PD, to establish the MTD, and to evaluate preliminary efficacy as per the study design diagram below. We expect to share early safety and PK monotherapy data in the second half of 2027.

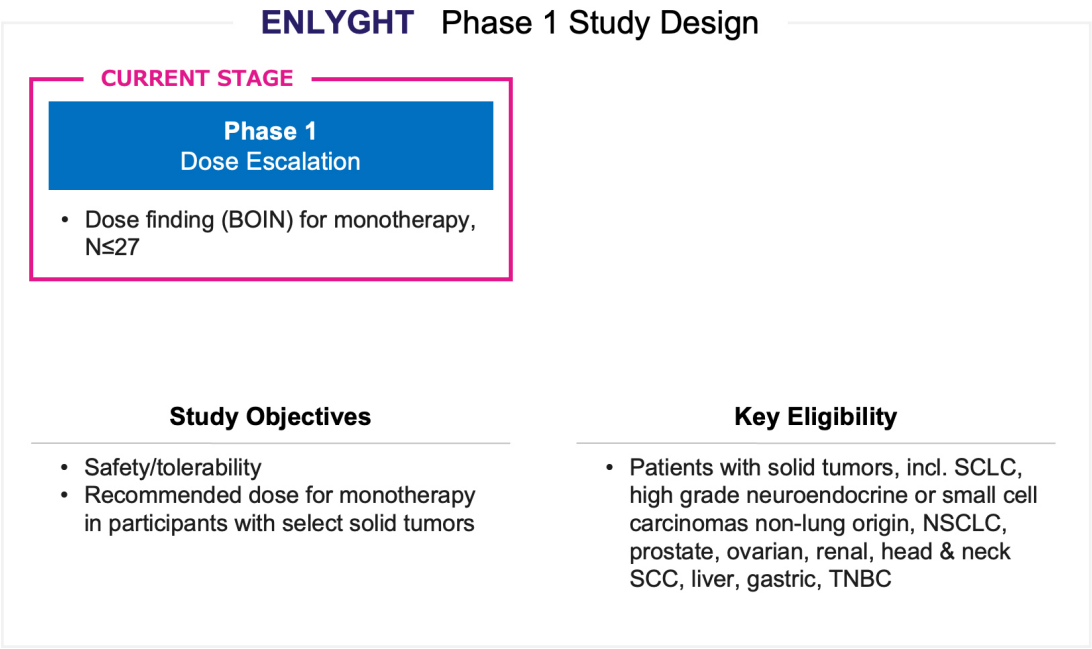


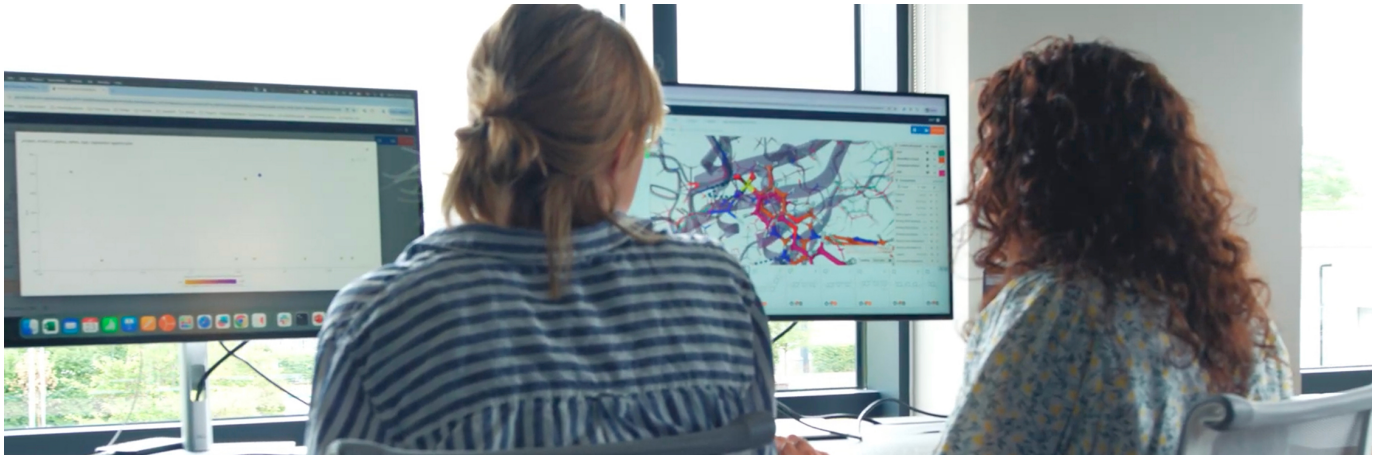
Figure 29. ENLYGHT study design. Phase 1 trial design to assess the safety, tolerability, and preliminary efficacy of REC-4539 monotherapy.

Competitors

The LSD1 inhibitor competitor landscape is limited to a small number of programs currently advancing in active clinical development. These programs vary by indication of interest, combination strategy, and development priority.

Active LSD1i clinical development programs:

- **Bomedemstat (Merck) -** Merck is focusing on myeloproliferative neoplasms (MPNs) as a route to market for bomedemstat. Bomedemstat is being investigated in a Phase 3 trial in essential thrombocythemia (ET), a Phase 2 study in myelofibrosis (MF) and polycythemia vera (PV), and a Phase 1 IIT study in AML (in combination with venetoclax). Merck terminated a Phase 1/2 SCLC trial in combination with PD-L1 maintenance in 2024 due to low accrual rates.
- **Iadademstat (Oryzon) -** Iadademstat is being investigated in AML and SCLC patient populations. It is in an ongoing Ph1b study for R/R AML with FLT3 mutation in combination with gilteritinib and in a Ph1b study for newly-diagnosed unfit AML in combination with venetoclax and azacitidine. It is also in a Phase 2 IIT for relapsed/refractory (R/R) SCLC and extrapulmonary high-grade NETs (in combination with paclitaxel), as well as a Phase 1b/2 IIT in first-line extensive-stage SCLC (ES-SCLC) in combination with a checkpoint inhibitor.
- **JBI-802 (Jubilant Life Sciences) -** JBI-802 is in a Phase 1/2 basket study, with expansion cohorts planned in SCLC, neuroendocrine prostate cancer (NEPC), and other NETs, as well as a Phase 2 study for patients with advanced NSCLC tumors harboring an STK11 Mutation in combination with pembrolizumab.
- **TAS1440 (Benz Sciences/ Taiho Pharmaceuticals) -** Benz Sciences are preparing for a Phase 1b/2 study for MPN patients, after in-licensing TAS1440 from Taiho Pharmaceuticals in June 2025. Taiho recently completed a Phase 1 trial targeting AML in the US population.



Partnered Discovery

Driving Innovation Across Multiple Diseases

At the core of Recursion's mission is the pursuit of breakthrough therapeutics for patients. Recursion collaborates with leading pharma partners to identify novel targets and therapeutic candidates across a wide range of disease areas, including neuroscience, oncology, immunology, and inflammation.

Each partnership is designed to advance therapeutic development, with multiple pathways to success:

- Novel Targets: Combining our multi-modal (phenomics, RNA sequencing) maps of human biology with real-world clinical-genomic data, we can identify novel druggable targets with potential therapeutic benefit. Validated targets may be optioned by our partners or advance within the collaborations as a therapeutic program.
- Novel Therapeutics: Using our precision chemistry platform, we can design differentiated molecules across a wide variety of targets. Resulting molecules may be optioned by our partners and advanced for further clinical development.

To date, Recursion has secured over $500 million in upfront milestone payments, with the potential to unlock over $20 billion in additional milestones before royalties. These high-impact collaborations not only generate near-term financial value but also leverage Recursion's combined capabilities in biology and precision chemistry to accelerate the development of transformative therapies. By collaborating with top-tier biopharmaceutical companies, Recursion gains access to invaluable knowledge from some of the most experienced teams in the industry. Together, we continuously drive innovation and have the potential to expand patient impact, and revolutionize the treatment of complex diseases. Below are some of the latest milestones reflecting this exciting momentum.

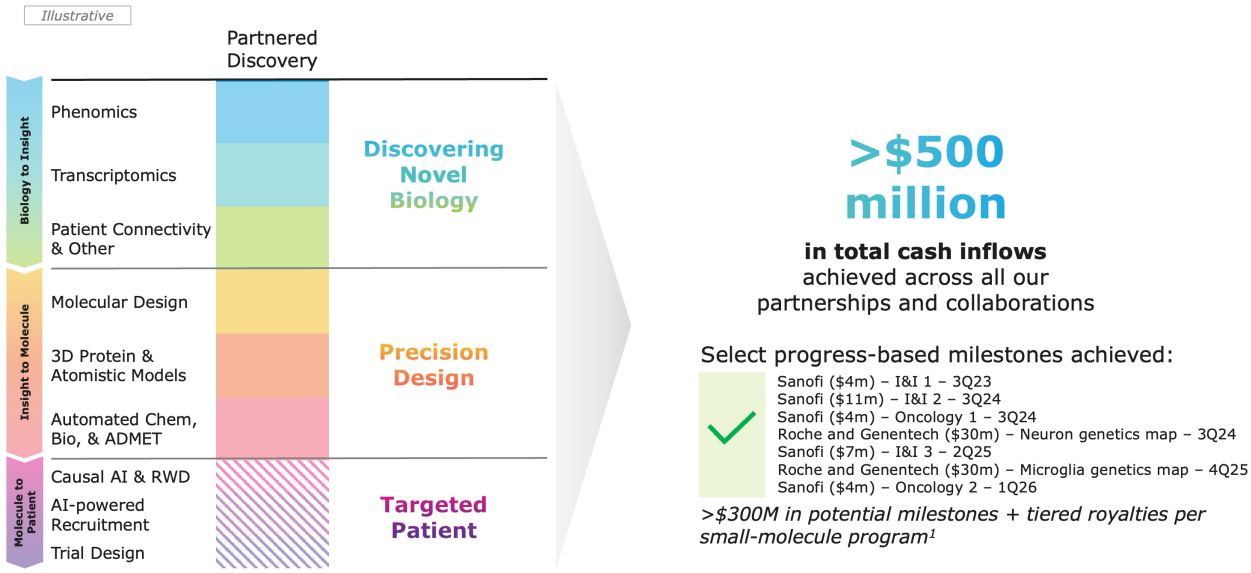


Figure 30. Recursion leveraging its OS across its partnerships. 1. Milestones: Potential Roche and Genentech and Sanofi milestones per small molecule program. Royalties: Recursion is eligible for tiered royalties up to high single digits (Roche and Genentech) and up to double digits (Sanofi)

Roche and Genentech

In December 2021, we entered a multi-year, strategic collaboration with Roche and Genentech in the field of neuroscience and a single oncology indication. Through the partnership, we are leveraging the Recursion OS and extensive single-cell perturbation screening data from Roche and Genentech, to rapidly identify novel biological relationships and advance therapeutic programs. Together, we may initiate up to 40 small molecule programs over a decade or longer. As part of this agreement, we received an upfront cash payment of $150 million, with the potential to receive milestones of more than $300 million per small molecule program plus tiered royalties.

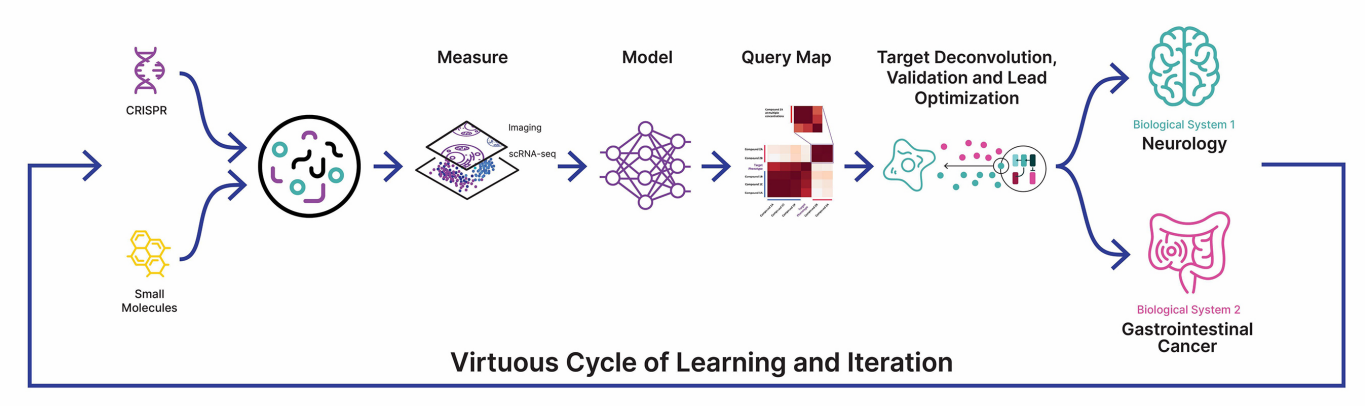


Figure 31. Under our collaboration with Roche and Genentech, we are creating multimodal maps of cellular biology to elucidate novel targets and starting points.

Sanofi

In January 2022, we entered a strategic research collaboration with Sanofi to develop an AI-driven pipeline of precision-engineered, small molecule medicines. Through this collaboration, we are using our end-to-end integrated platform to discover and advance up to 15 novel targets in the oncology and immunology therapeutic areas. As part of this agreement, we received an upfront cash payment of $100 million, with the potential to receive up to $5.2 billion in total aggregate milestone payments plus tiered royalties.

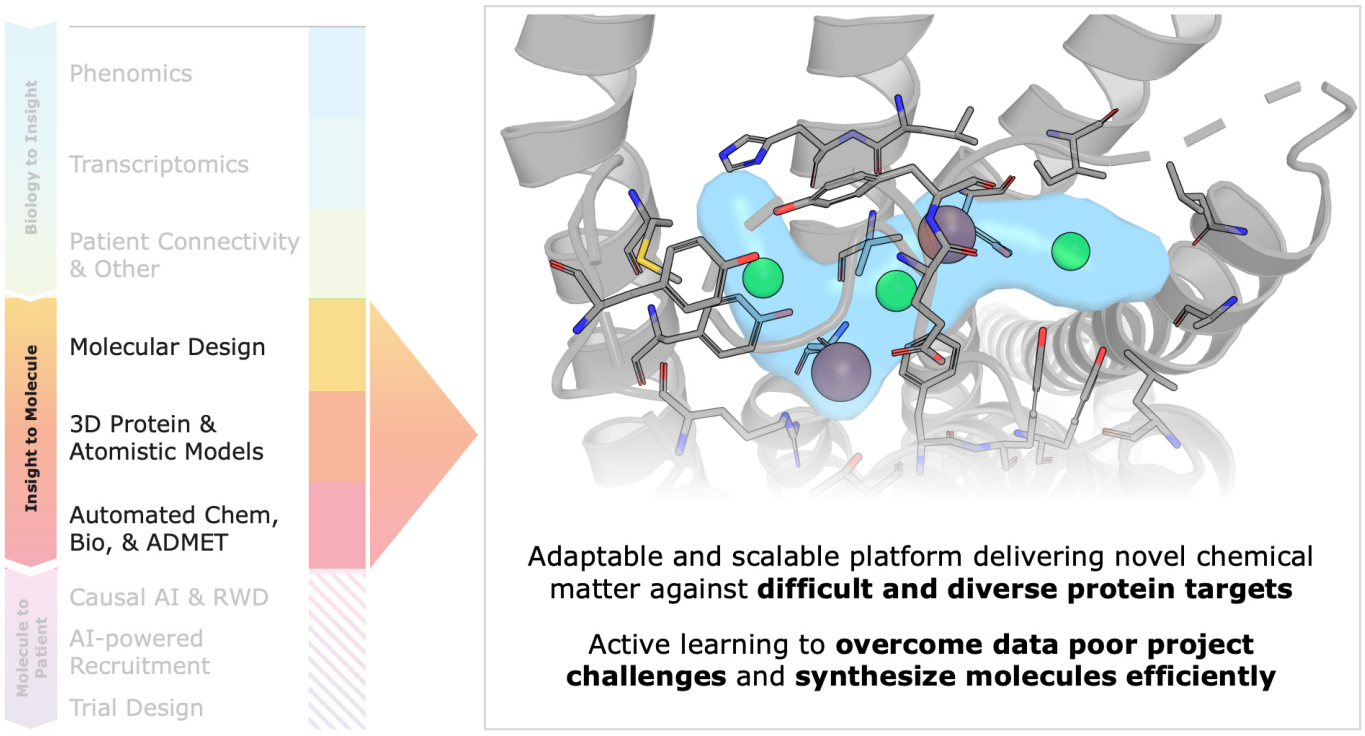


Figure 32. Leveraging the Recursion OS with Sanofi to design small molecules against challenging targets using AI

Bayer

In November 2023, we announced an amended and restated collaboration with Bayer. We are using the Recursion OS to identify and advance up to 7 therapeutic targets for challenging oncology indications with high unmet need. Under the terms of the agreement, Recursion is eligible to receive potential, success-based, future payments of up to $1.5 billion plus royalties on net sales.

Merck KGaA (Darmstadt, Germany)

In September 2023, we entered into a collaboration with Merck KGaA, Darmstadt, Germany. This multi-year collaboration utilizes our AI-driven precision drug design and discovery capabilities while leveraging Merck KGaA, Darmstadt, Germany's disease expertise in oncology and immunology, clinical development capabilities, and global footprint.

Case Study 1: Delivering the World's First Neuromap

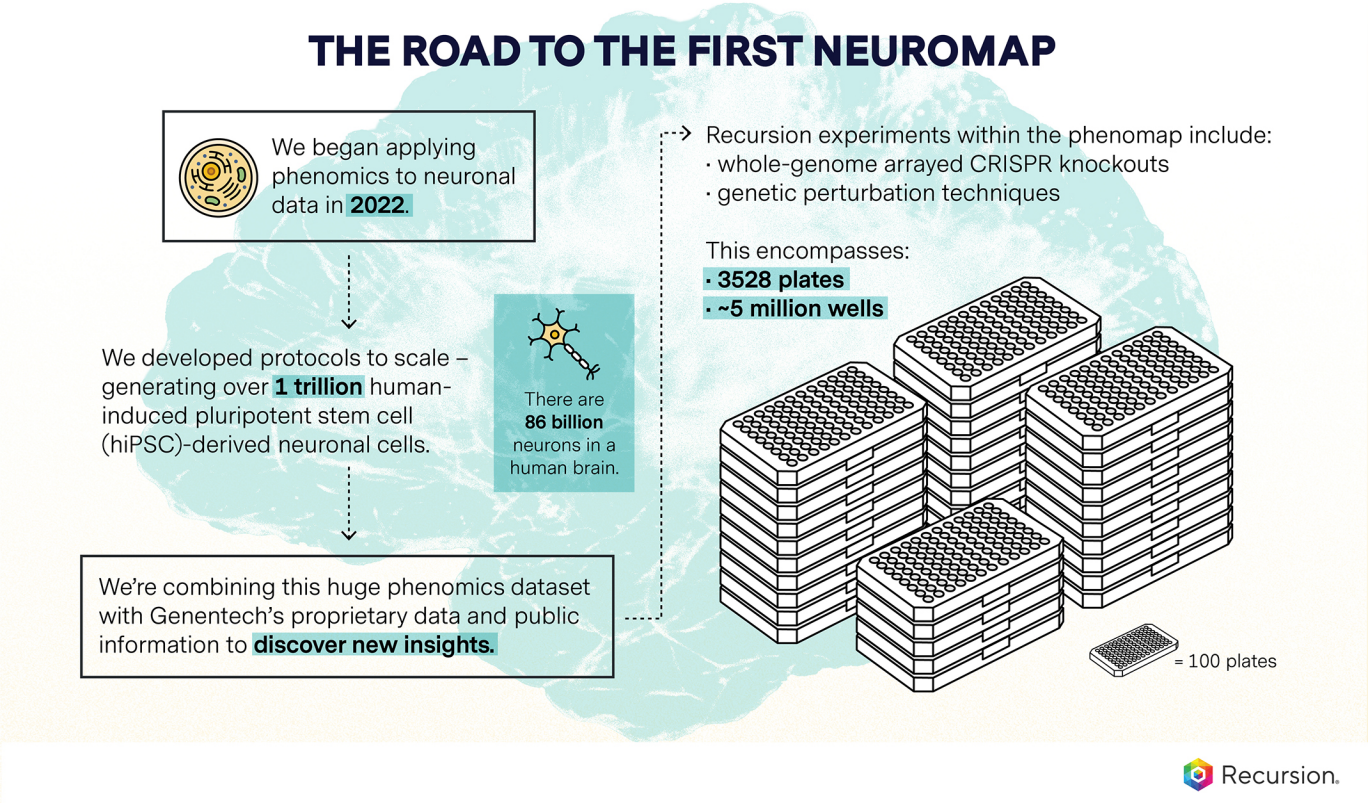


Figure 33. Recursion launched a transformational collaboration with Roche and Genentech, delivering the world's first whole-genome neuromap in 2024.

Overview

In 2021, Recursion launched a transformational collaboration with Roche and Genentech to create the world's first neuromap—a comprehensive and scalable neuronal data model powered by machine learning. This effort aimed to uncover novel insights into neurodegenerative diseases, a category of illnesses that has long been difficult to tackle using traditional drug discovery methods. With a dedicated team of 50 people, Recursion set out to overcome numerous technical and biological challenges, all with the goal of driving innovation in neuroscience.

The Challenge

When the project began, the team faced significant uncertainty. The goal was ambitious: produce enough neurons, knock out genes, and generate a reliable signal from machine learning models to guide the development of potential drug programs. This challenge was particularly daunting given the complexity of neuronal cells, which do not divide or proliferate like other cell types. Unlike other cell types, such as human umbilical vein endothelial cells (HUVECs), which Recursion had previously worked with to create large-scale disease maps, neuronal cells posed a unique set of hurdles due to their limited ability to be produced at scale.

Neurodegenerative diseases had long been a difficult area for drug development. Traditional approaches had yielded limited breakthroughs, and the complexity of the biological system presented a higher bar for success. Recursion needed to develop new technologies and methodologies to produce and analyze neuronal data on a scale not attempted before in drug discovery.

Recursion had already proven its ability to create large-scale cell maps in other disease areas, notably in gastrointestinal oncology, as part of its partnership with Roche and Genentech. The success of this collaboration demonstrated the power of Recursion's phenotypic screening platform, which uses high-throughput technologies to produce vast amounts of biological data. However, creating a neuromap would require more than just expanding on previous work - it required adapting the process to handle the unique challenges posed by neuronal biology.

Execution

To tackle this challenge, Recursion collaborated with Roche and Genentech to develop and refine a model using human-induced pluripotent stem cells (hiPSCs), which could be differentiated into neurons. This protocol enabled Recursion to produce large quantities of neurons, ultimately generating over 1 trillion hiPSC-derived neuronal cells. These neurons served as the foundation for the neuromap, a data-rich resource that Recursion, Roche and Genentech could use to gain deeper insights into the genetic underpinnings of neurodegenerative diseases. In addition to the joint development of the neuronal cell context, Recursion's machine learning team played a pivotal role in developing algorithms capable of processing the massive amounts of data generated by the neuromap. The combination of scalable cell production and cutting-edge computational models allowed Recursion to generate the first whole-genome neuronal phenomap that can be utilized by the partnership to uncover new relationships between genes and the phenotypes associated with neurodegeneration.

Outcome

Our work led to the exercise of a $30 million option by Roche and Genentech in August 2024 with the neuromap offering an unbiased view of the genetic relationships related to neurodegenerative diseases and providing insights that could pave the way for development of novel therapies in neuroscience. Unlike traditional approaches that are often guided by pre-existing hypotheses, researchers in the collaboration can now explore new biological pathways and identify potential therapeutic targets that may not have been considered before. Together, Recursion, Roche and Genentech have identified a number of biological insights from this first neuroscience-focused phenomap, that could become novel targets of interest.

Case Study 2: Delivering the World's First Microglia Map

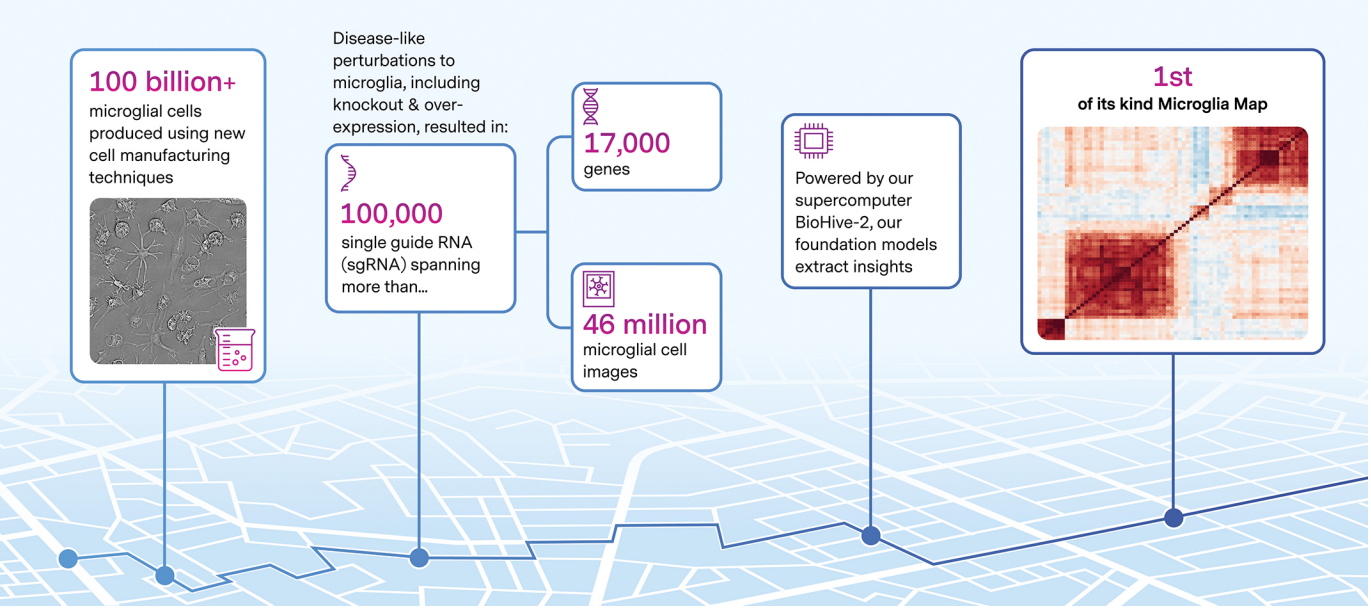


Figure 34. Recursion launched a transformational collaboration with Roche and Genentech, delivering the first-of-its-kind microglia map in 2025.

Overview

In 2025, building on the success of the original neuromap, Recursion reached another milestone in its collaboration with Roche and Genentech by launching the world's first microglia map. Microglia are the resident immune cells of the brain and play a central role in neuroinflammation and the progression of neurodegenerative diseases. By mapping the whole genome within these complex cells, the microglia map represents a completely new approach to explore the cellular mechanisms underlying neurodegenerative diseases, offering a new approach to explore novel targets and pathways.

The Challenge

Despite decades of research, FDA approvals for neuroscience drugs are less than half of those for other therapeutic areas, and drugs targeting the CNS have some of the highest failure rates in medicine. Attrition rates are high, and traditional approaches can be biased to dominating hypotheses e.g. the "Amyloid Hypothesis" in Alzheimer's disease. This is the idea that a build-up of the amyloid protein is a major contributor to the disease, and while this hypothesis has historically guided research and led to deep insights into the condition, the underlying biology is both extremely complex and still poorly understood.

To provide an unbiased approach to explore novel targets and pathways, the team studied microglia. However, microglia are very difficult to work with, proving difficult to grow and keep alive and stable outside of the body, in a laboratory setting. Because microglia are the resident immune cells of the brain, they can be highly sensitive to their environment, changing states from relatively stable to becoming more reactive and inflammatory, and they are also highly variable from batch to batch. To create a reliable map, Recursion had to overcome the technical hurdle of producing these sensitive immune cells at a massive, industrial scale while ensuring they remained stable enough to provide a clear biological signal for machine learning models.

Execution

Tackling this effort was a multi-year collaboration that required Recursion and the Roche and Genentech microglia team to develop new protocols for the manufacture of microglial cells. Starting with human-induced pluripotent stem cells (hiPSCs), the team developed a protocol that allowed the most phenotypically active cell Recursion has ever tried to map to be grown at massive scale. Over 100 billion microglial cells were grown in a standardized way and confirmed to be as stable as possible for the start of the mapping process. The collaborative team also worked together to determine the most interesting disease-like perturbations to the microglia from a neuroscience perspective, to generate a rich dataset containing some novel knockdowns and overexpressions not previously tried in other maps. This resulted in 100,000 single guide RNA being used spanning more than 17,000 genes, 46 million microglial cell images, and thousands of chemical compound perturbations. Recursion foundation models, powered by the supercomputer BioHive-2, extracted insights to generate the first-of-its-kind microglia map, allowing scientists to use AI to systematically explore how different genes and compounds may be implicated in a wide range of neurological diseases.

Outcome

The successful completion of the microglia map led to a $30 million milestone payment from Roche and Genentech in October 2025. The microglia map provides a holistic, unbiased approach to drug discovery for neurodegenerative diseases compared with the slow traditional approach, which has yielded very few new therapeutic targets. The map allows for the systematic, unbiased evaluation of thousands of gene targets at once, allowing AI to uncover novel biological connections that humans might miss. Overall, this offers a new approach to exploring novel targets and pathways, addressing a major challenge in neuroscience drug discovery. Following on from development of the map, it will be mined for novel biological insights, which will move forward to robust experimental validation from Recursion in partnership with Roche and Genentech. This could lead to program selection and development, and potential new therapeutic approaches in neurological diseases.

Our Platform

A Unified, AI-Native Platform for Drug Discovery & Development

Recursion is leading the evolution of how medicines are discovered and developed with the Recursion OS: a unified, AI-native intelligence platform designed to translate complex science into medicines that matter — faster, better, and at scale for the patients who are waiting.

Our approach combines proprietary experimental data, purpose-built computational models, and scaled compute infrastructure to support decision-making across the full lifecycle of drug discovery and development. Rather than optimizing isolated tools or workflows, we organize our platform around three tightly connected stages of value creation: **novel biological discoveries, precision design, and next-generation clinical development.** Together, these stages enable us to initiate programs with stronger biological grounding, design differentiated molecules more efficiently, and advance medicines into the clinic with improved patient relevance.

Across all three stages, Recursion integrates automated wet-lab experimentation with in-house computational analysis. Our laboratories generate large volumes of standardized, high-quality biological and chemical data, while our dry-lab capabilities apply machine learning, physics-based modeling, and statistical inference to extract actionable insights from those data. This tight integration allows experimental results to directly inform computational models, and model outputs to guide subsequent experiments, enabling faster iteration and more consistent decision-making across programs. Additionally, the integration of agentic and automated systems underpins our approach at Recursion and enables us to accelerate learning and decision-making throughout the R&D process.

The Recursion OS

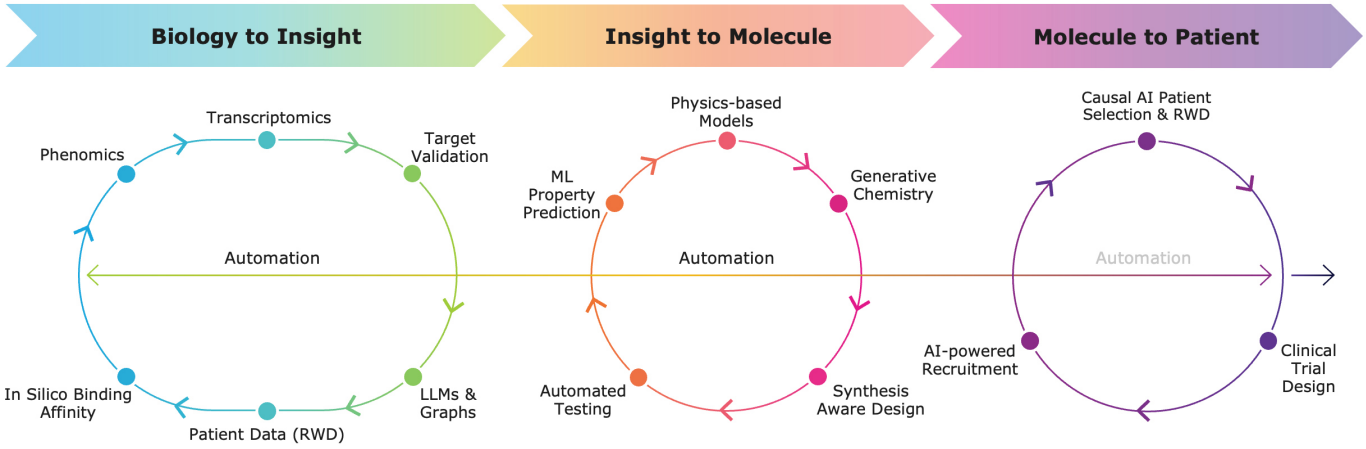


Figure 35. The Recursion OS. The Recursion OS is designed to use AI to advance and accelerate decision-making and insight across the entire R&D value chain with the end goal to make novel medicines that matter. The Recursion OS generates value by advancing a pipeline of differentiated investigational medicines, in addition to building pipelines for our partners.

By leveraging the Recursion OS to explore and advance our programs, we have shown leading indicators of improvement when compared to the traditional drug discovery process, particularly with respect to cost and time. We also use AI/ML tools to better understand which molecules to make and test and ultimately design better quality molecules that can solve complex problems – on average, the industry synthesizes about 2,500 molecules to candidate, compared to the approximately 330 we synthesize per program to advanced candidate.

Biology to Insight

The first stage of the Recursion OS focuses on translating complex biological signals into actionable insights that support program initiation. Recursion combines large-scale cellular phenomics, high-throughput transcriptomics, in silico binding affinity predictions, and real-world patient data to identify disease-relevant mechanisms, validate targets, and prioritize opportunities with stronger biological grounding and patient relevance. These capabilities allow us to systematically interrogate biology at scale and reduce biological uncertainty earlier in the discovery process.

A core differentiator of this approach is the integration of complementary data modalities. Patient-derived data are the most directly relevant to human disease but are often noisy, heterogeneous, and limited in scale. In contrast, cellular phenomics data can be generated reproducibly, at scale, with high completeness and consistency. By integrating these and other modalities through joint forward- and reverse-genetics approaches, Recursion can connect robust experimental signals with patient biology, enabling more confident identification and prioritization of translatable targets.

- Generated and aggregated >50 petabytes of high-quality, multimodal data
- Over 100 novel insights triaged into ~10 actionable and translatable targets for experimental validation within a matter of weeks
- ~1.9B-parameter phenomics foundation model delivers ~25–30% gains in biological signal accuracy
- New transcriptional foundation model delivers a 70% improvement in operational efficiency

Deep Dive: Phenomics-based Discovery

Phenomics is Recursion's large-scale, image-based cellular profiling capability that measures functional cellular responses to genetic and chemical perturbations and serves as a foundational input to biological discovery and program initiation. Using high-content microscopy, automated experiment design and execution, and purpose-built machine learning models, we generate rich, high-dimensional phenotypic data that capture cellular behavior across diverse biological contexts. Our platform is differentiated by its scale, precision, and breadth, operating both Cell Painting and live-cell brightfield microscopy across nearly 50 distinct cell types, including differentiated iPSC-derived neuronal and microglial cells. These experimental capabilities directly enhance our advanced computer vision and foundation models, including our Phenom-2 model series, by enabling our models to learn true biology as opposed to experimental design patterns. The impact of this capability is reflected in both our internal pipeline and strategic partnerships, including the development of two first-of-their-kind whole-genome neuronal and microglia phenotypic maps as part of our collaboration with Roche and Genentech. More broadly, phenomics has enabled Recursion to initiate and advance multiple internal and partnered programs by supporting unbiased discovery, rapid hypothesis triage, and identification of novel biological insights that may translate into new therapeutic opportunities.

Deep Dive: Transcriptional Foundation Model (TxFM)

TxFM is Recursion's self-supervised transcriptomics foundation model designed for representation learning of complex gene expression data. Built on a transformer-based architecture optimized for biological structure rather than natural language analogies, TxFM harmonizes diverse transcriptomic datasets—including bulk and single-cell RNA sequencing across multiple assays, cell types, and translational systems—into a unified embedding space.

Many transcriptomic models rely on large, heterogeneous public atlases that limit cross-experimental comparability and translational consistency. TxFM leverages Recursion's proprietary data strategy and architecture decisions to improve cross-sample and cross-experiment relatability, enabling consistent integration of in vitro experiments, in vivo models, and patient-derived samples. This not only captures a more universal biological grammar but also allows us to **outperform larger models trained on datasets up to 50x larger in size.** By representing experimental perturbations and patient transcriptomes within the same high-dimensional space, we can begin to perform in silico perturbations on digital patient representations, serving as a practical translational bridge between laboratory biology and human disease.

TxFM has demonstrated state-of-the-art performance across multiple zero-shot benchmarks, outperforming existing foundation models and classical baselines. Within the Recursion OS, TxFM improves batch correction and multi-dataset integration, enhances signal recovery from low-read-depth transcriptomic data, and enables consistent mapping of gene–gene and gene–compound relationships. By improving data consistency and reducing the need for experimental re-runs, **TxFM has delivered an approximate 70% improvement in operational efficiency for transcriptomics-driven workflows.** Furthermore, the model's learned gene-specific parameters recover known protein complexes and pathways without supervision, providing a non-perturbational gene-gene map for over 40,000 genes, including non-coding RNAs. These capabilities strengthen target discovery, accelerate hypothesis validation, and improve the biological and patient relevance of programs entering the pipeline.

Insight to Molecule

Once we have nominated a program, either through insights derived from our phenomics and multiomics platforms or through the careful selection and validation of a high-potential target, we transition from biological discovery to precision molecular design. Our precision design platform, anchored by Centaur Chemist, represents a transformative shift from traditional trial-and-error drug discovery to a fully integrated, AI-first industrialized process. By fusing massive, high-dimensional biological and chemical datasets with advanced generative AI and automated synthesis, the platform enables the rapid design, prioritization, and physical testing of novel small molecules. This modular end-to-end engine is designed to navigate trillions of biological and chemical relationships with unprecedented speed and efficiency, aiming to deliver higher-quality drug candidates to the clinic while significantly reducing development timelines and costs. Centaur Chemist serves as a critical component of our unified operating system, driving a continuous "design-make-test-learn" or DMTL cycle that refines its predictive capabilities with every successive iteration.

- 100 million+ molecules generated virtually using synthetically aware design in 2025
- ~90% of synthesized molecules are AI-generated, scored, and prioritized – all patentable
- On average, only ~330 compounds are synthesized per program to achieve an advanced candidate in ~17 months, compared to industry average of over 2,500 compounds and 42 months, respectively,
- To date, the platform has designed >10 development candidates that address a wide variety of previously unsolved biological or chemistry problems

Deep Dive: Centaur Chemist Methods and Models

At its core, Centaur Chemist is an AI-first learning system that automates the design, prioritization, and optimization of novel small molecules. It is not a single piece of software but an integrated platform within the Recursion OS that enables the development and deployment of a vast number of design tools that have been developed in-house, including the following proprietary models:

- **Generative AI and Evolutionary Models:** These create novel chemical structures based on target profiles
- **Synthesis-Aware Methods:** The platform employs an expansive synthesis-driven design toolkit that couples advanced billion-scale search algorithms (e.g. SALSA) and accurate chemo- and regioselectivity models with up-to-date vendor logistics to rigorously generate synthetically feasible compounds and expedite their reduction to practice
- **Protein and Target Tractability predictions.** These methods predict protein structures with and without the presence of ligands, enabling ligandability and druggability of targets.

- **Property Prediction and Scoring:** Our industry leading advanced models, including our proprietary version of Boltz-2 that allows us to fine-tune the model on internal program data, predict potency (see figure below), selectivity, and ADMET (absorption, distribution, metabolism, excretion, and toxicity).
- **Physics Methods:** A toolkit of physics-based methods that apply molecular dynamics and quantum mechanics, which enables us to more accurately predict target-ligand interactions and properties, fully integrated with our generative design capabilities.

The platform not only incorporates our in-house proprietary methods and algorithms but makes it simple to deploy open-source and licensed software, ensuring that we are using state-of-the-art methods developed by the community as well.

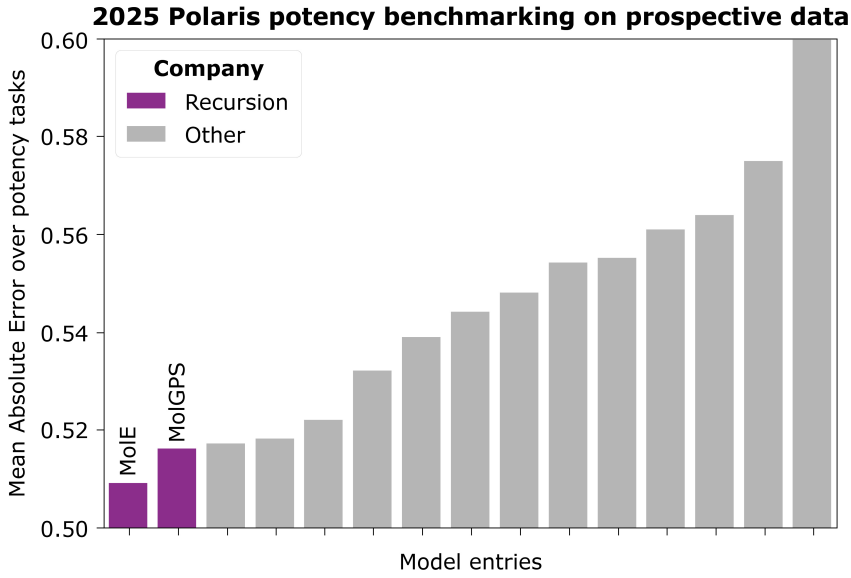


Figure 36. Recursion potency models MolE and MolGPS outperform (lower is better on the Y-axis in figure) all other entrants in the 2025 blind challenge for potency predictions[21]

Deep Dive: DMTL (Design-Make-Test-Learn) and Automation

With these tools in place, our DMTL procedure begins by defining program objectives via a Target Product Profile (TPP), which is encoded using a multi-parameter optimization (MPO) function. This ensures that potency and affinity are balanced with other critical ADMET properties, such as clearance, solubility, stability, and permeability. Every generated molecule is scored by an integrated function called Merit, allowing us to monitor the quality of chemical matter across the program lifecycle in an unbiased, holistic manner. This allows us to focus our efforts from the start on high-quality molecules that meet the needs of our drug discovery programs, optimizing for both cost and operational efficiency.

Once the Design phase is complete, synthesis (Make) is triggered through the platform, which can be routed through to our in-house chemistry automation studio or dedicated CROs. Because our generative tools prioritize synthesizability from the outset, the platform utilizes property prediction models to guide design toward compounds that are both biologically optimized and amenable to efficient synthesis. To achieve this "synthesis awareness," we account for building-block availability and logistics across different CROs, ensuring the system suggests the most cost- and time-effective synthetic routes. A critical enabler of this physical execution is our in-house chemistry automation studio located in Milton Park, shown in the figure below, designed to support high-throughput DMTL cycles with minimal manual intervention (see Figure 40). The modular, automated lab is designed to accelerate DMTL cycles by utilizing automation flexibly across the full Make workflow, with over 1000 compounds having now been made and tested at Milton Park. The core mission of this DMTL procedure is to automate processes that reduce costs, optimize efficiency, and deliver high quality results to drive program success, not just making compounds that can easily be synthesized with automation. Through 2025 there was a 4-fold increase in reaction classes executed with automation, including 14 reactions that are not typically automated.

[21] *Polaris hub competition results. Source: https://polarishub.io/competitions/asap-discovery/antiviral-drug-discovery-2025#competiton-results 12 February 2026*

Figure 37. Recursion's automated chemistry wet lab, a modular system for chemical synthesis preparation, execution, analysis, work-up, and purification.

Following the Make phase, an assay cascade is initiated (Test). Depending on program needs, this includes ADMET, affinity, and phenomic responses via our proprietary -omics platform in either Salt Lake City or Milton Park facilities. Once an assay is completed, results are ingested back into the platform for analysis alongside all other relevant program data. This data automatically updates our ML models, ensuring the most accurate information informs the next cycle and closes the Learning loop. An example of this improvement is shown in Figure 38, which demonstrates that iterative learning has led to an approximately 50% improvement in a property prediction model. Our models improve over time, not by chance, but by learning.

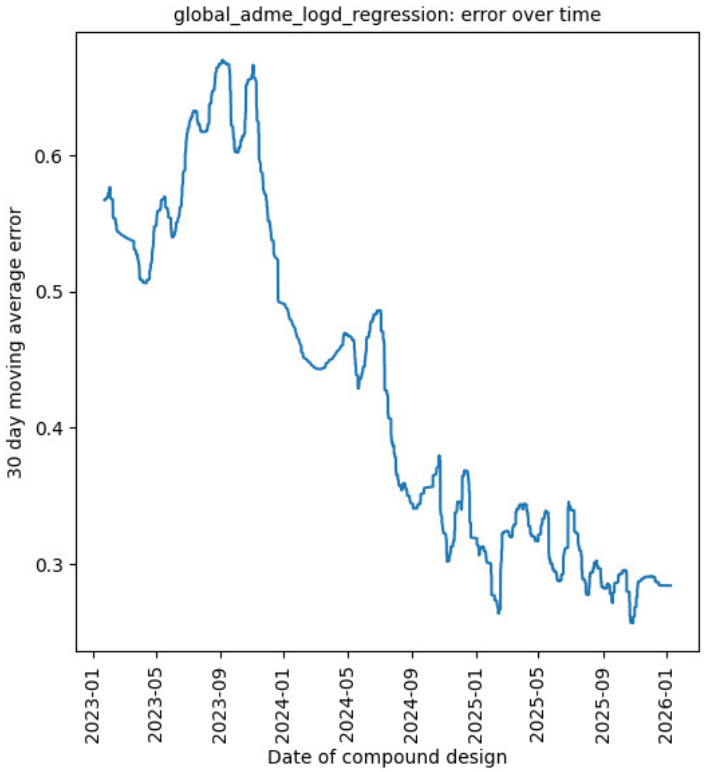


Figure 38. LogD model improvement over time as DMTL cycles progress, showing an approximately 50% increase in accuracy over time.

By tracking all data centrally we can monitor Design, Make, and Test durations, as well as lag times between phases. Streamlining these workflows, both in-house and with CROs, allows us to identify and resolve bottlenecks in real time. This continuous monitoring has driven significant productivity gains: in 2025, our Design-to-Test times improved by 20% over 2024 benchmarks.

To further support our learning system, we also employ our RADME-01 platform. This platform performs high-throughput ADME evaluations through intelligent software prioritization and automation. The system generated over 35,000 total data points across >15,000 novel compounds, including >13,500 human and >5,000 mouse microsomal stability results, alongside thousands of points for PAMPA, protein binding, and rat stability. RADME data is integrated into our proprietary datasets and automatically fed into our suite of ML models for comprehensive ADMET property prediction, which drives drug discovery during Nominations and Design. We employed Active Learning with RADME to generate thousands of datapoints, expanding model training sets and boosting accuracy across design programs. Additionally, new multi-task models optimally combine RADME and CRO assay data for related properties, delivering enhanced predictions to our design programs.

Molecule to Patient

The final stage of the Recursion OS focuses on translating molecules into clinical impact. Recursion utilizes large scale multi-modal datasets to rigorously design and execute clinical trials. As an example, by applying causal AI on human genomics, we select the indications and patient sub-populations most likely to benefit from our investigational therapies. Our AI-driven study planning algorithms applied to our operational data recommend site selection to enhance enrollment in minutes. Our clinical trials incorporate advanced statistical methods across several design elements from selecting optimal doses to forming external control arms to expanding the eligible patient population for our studies.

These capabilities form Recursion's Clinical Development Technology (ClinTech) platform, an AI-enabled clinical development system that unifies molecule-to-patient decisions within an integrated workflow. It combines global site intelligence data, real-world patient data—including ~300 million real world lives and 1 million molecularly profiled lives—with causal inference, simulation, and agentic automation to continuously inform trial strategy and execution. By embedding patient relevance and operational feasibility earlier in development, ClinTech supports more disciplined trial design and execution at portfolio scale.

- ~1 million molecularly profiled lives between Tempus, Helix, and UK Biobank. Used across our clinical and preclinical portfolio for target validation and patient selection. Impact includes but not limited to:
  - Expansion into ovarian cancer for the CDK7 program
- De-identified records covering ~300 million real-world lives, including electronic health records, diagnostics, and medical & pharmacy, leading to.
  - 10-40% increase in eligible population
  - ~1.5X improvement in enrollment rates
- Global clinical trial site intelligence database covering a wide swath of historical clinical trials
  - Data driven country & site selection in hours vs. months

In practice, ClinTech shortens the cycle from protocol to site activation and enrollment by turning fragmented clinical operations data into actionable, real-time recommendations. For example, the platform can **shorten the time to prioritize countries and sites from months (industry standard) to hours** using multimodal site intelligence data. It can forecast enrollment trajectories as criteria evolve—enabling benefit-risk tradeoffs that can meaningfully expand the eligible population and improve enrollment performance. It can reinforce upstream portfolio decisions through genetically informed target validation and patient selection. Across the trial lifecycle, these capabilities translate into increased probability of success and timely execution of our clinical studies.

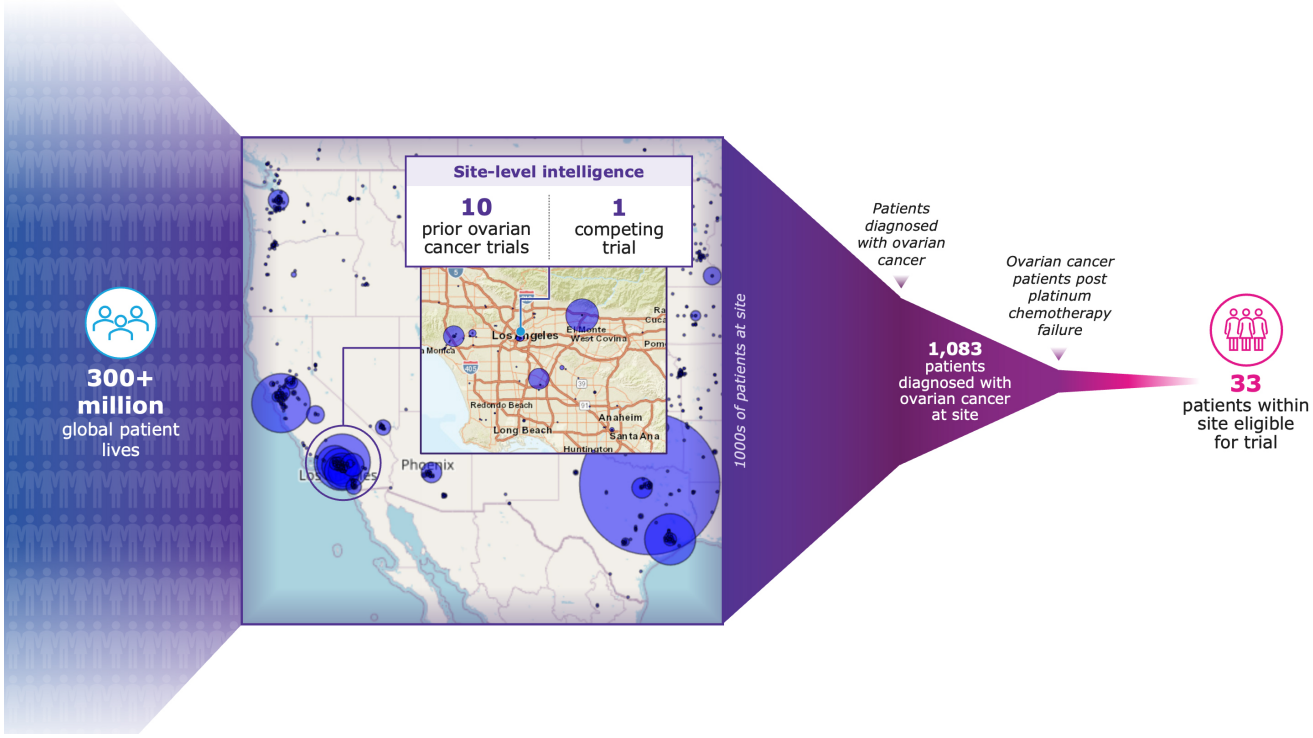


Figure 39. AI-driven clinical development platform for trial design and execution

Deep Dive: Natural History Data in Familial Adenomatous Polyposis (FAP)

Recursion applied its ClinTech platform to generate high-quality natural history evidence to contextualize the single-arm efficacy of REC-4881 in the TUPELO study. Natural history data are increasingly important to regulators in rare diseases, yet for FAP there has historically been limited quantified evidence describing disease progression outside of clinical trials. To address this gap, Recursion leveraged real-world evidence analytics and AI-enabled data extraction to build a comprehensive view of the lived FAP patient experience across routine clinical practice and long-term registry data.

Using ClinTech's real-world data capabilities, Recursion analyzed records from more than 1,000 US patients with FAP, including over 250,000 unstructured physician notes processed using a custom large language model–based workflow. This analysis enabled systematic characterization of disease burden, intervention frequency, and the progressive nature of polyp growth in everyday clinical care. Recursion extended this work through an academic collaboration with Amsterdam UMC, analyzing nearly 20 years of longitudinal follow-up data from approximately 200 patients enrolled in one of the largest and longest running FAP registries globally. Together, these datasets enabled a level of real-world disease characterization that is rarely available in rare disease development.

Across both real-world and registry datasets, the findings were consistent and clinically meaningful: untreated FAP is characterized by predictable, year-over-year progression of polyp burden in 87% of the trial-relevant patient populations, with a mean annualized increase of 60%. These insights provided a robust, data-driven benchmark for contextualizing therapeutic impact and directly informed the clinical development strategy for REC-4881, including support for a single-arm study design aligned with regulatory expectations. More broadly, this work illustrates how ClinTech augments clinical development with unbiased real-world insight, strengthens the translational path from molecule to patient, and enables more confident engagement with regulators in rare disease programs.

Processing and Data Storage Infrastructure

The need to understand pathways, targets, compounds, and mechanisms of action requires obtaining, synthesizing, or predicting large volumes of data. To store this data in an efficient and low-risk way, Recursion makes use of a combination of cloud storage, and on-premises storage. To process this data efficiently, we bring it close to where the compute will run – either in our HPC datacenter (BioHive) or to our cloud (partnering with Google Cloud). To make this more seamless for our scientists, we have invested in a hybrid storage and compute platform, which enables replication of data and locality of compute to allow us to use these resources as efficiently as possible.

People and Culture

Essential to leading and defining TechBio is our team of close to 600 employees, comprising of life scientists, such as chemists and biologists (approximately 35% of employees) and computational and technical experts such as data scientists and software engineers (approximately 43% of employees). Together our team creates an environment where empirical data, statistical rigor and creative thinking is brought to bear on the problems we address. While we are united in a common mission, Decoding Biology to Radically Improve Lives, our strength lies in our differences: expertise, gender, race, disciplines, experience and perspectives. Deliberately building and cultivating this culture is critical to achieving our audacious goals.

In 2025, we made significant progress to deploy agentic and automated AI solutions across the workforce to enhance enterprise productivity and efficiency. In our technology organization, approximately 91% of employees are actively using AI coding tools to accelerate their work. As a result, 35% of our code is authored by AI, allowing our teams to focus on solving the problems and trusting AI to accelerate creating the solution. This saves an average of 4.3 hours of work per week, per employee.

Employee Recruitment, Development and Training

At Recursion, we believe a diversity of experiences, backgrounds, ideas and expertise will create high performing teams. We are intentional about the employee experience at Recursion, with a fit-for-purpose system that finds, grows and retains top talent to deliver our mission. We employ a targeted approach to identify, attract and hire diverse employees across highly technical scientific disciplines including biology, chemistry, data science, machine learning, engineering, robotics, clinical development and more. People stay at Recursion because of the opportunity to impact the world and grow in a place where they feel challenged, supported, and connected.

Employee Health and Safety

We have dedicated Standard Operating Procedures to manage occupational health and safety, safety training and injury, and illness and incident reporting. Every employee is responsible to ensure these procedures and policies are followed. We offer extensive training to ensure understanding and compliance. Compliance is mandatory for all laboratory employees per requirements of the Occupational Safety and Health Administration standard on Hazardous Chemicals in Laboratories. Our Chemical Hygiene Officer and Lab Manager oversees the day-to-day management of institutional chemical hygiene.

Read more about how we invest in and motivate our people to achieve our mission in Recursion's latest Environmental, Social and Governance Report, available at our corporate website.

Facilities

Recursion's global footprint is architected around two primary pillars: industrialized wet lab infrastructure that powers platform operations and offices that allow us to attract and retain top talent.

Industrialized Wet Lab & Platform Operations Hubs

Our two heavy-infrastructure sites in Salt Lake City, Utah and Milton Park, Oxfordshire are designed for the massive-scale data generation that drives our platform. These facilities house our robotics, automation, biology, and chemistry capabilities. Our Salt Lake City site has capacity to generate phenomics and transcriptomics data, and at Milton Park, the automated lab assembles the vision of autonomous DTML loops.

- Salt Lake City, Utah: We utilize 140,000 square feet of laboratory and office space in downtown Salt Lake City. This campus houses our high throughput screening labs, generating large volumes of standardized high quality biological data across phenomic and transcriptomic endpoints.
- Milton Park, Oxfordshire: This 20,151 square foot laboratory and office space serves as our primary European wet lab, focused on DMTL, quantitative pharmacology, complex bioassays, target validation, and automation engineering.

Strategic Talent and Office Hub

Our office locations in New York City, Montreal, and London are positioned in global centers for AI, scientific innovation, clinical development, and executive leadership.

- New York City: In January 2025, we opened a new 11,655 square foot office in New York City's Hudson Yards neighborhood. This office serves as a key location for our executive leadership, strategy and clinical development teams,

- Montreal: We have a 8,367 square foot site in Montréal that houses our semi-autonomous artificial intelligence research engine, Valence Labs
- London: Located in the knowledge quarter and heart of King's Cross neighborhood, our 6,792 square foot office serves as a magnet for Europe's top AI and computational talent.

Commercialization

We retain significant development and commercial rights to some of our drug candidates. If marketing approval is obtained, we may commercialize our drug candidates on our own, or potentially with a partner, in the US and other geographies. We currently have no sales, marketing, or commercial product distribution capabilities. Decisions to create this infrastructure and capability will be made following further advancement of our drug candidates and based on our assessment of our ability to build the necessary capabilities and infrastructure with competitive advantage. Clinical data, the size of the addressable patient population, the size of the commercial infrastructure, manufacturing needs and major trends as to how value is accrued in the industry may all influence or alter our commercialization plans.

Manufacturing

We currently utilize contract development and manufacturing organizations to produce drug substance and investigational drug product in support of the assets within our pipeline. To date, we have obtained drug substance and drug product for our drug candidates from third party contract manufacturers.

Strategic Partnership and Collaboration Agreements

To achieve our mission, we may partner with leading biotechnology companies, pharmaceutical companies and academic research institutions to access datasets, molecules, or other intellectual property.

Roche and Genentech Collaboration and License Agreement

On December 5, 2021, we entered into a Collaboration and License Agreement with Genentech, Inc. and F. Hoffmann-La Roche Ltd, pursuant to which we will construct, using our imaging technology and proprietary machine learning algorithms, unique maps of the inferred relationships amongst perturbation phenotypes in a given cellular context (each a "phenomap") and together with Roche and Genentech will create multimodal models and maps to further expand and refine such inferred relationships, in both cases, with the goal to discover and develop therapeutic small molecule and target programs in a gastrointestinal cancer indication and neuroscience (each an "Exclusive Field").

Upfront Payment. In January 2022, Roche and Genentech paid us an upfront cash payment of $150.0 million.

Phenomap Creation, Acceptance and Access. Under the Collaboration Agreement, we are responsible for creating a certain number of phenomaps in each of the Exclusive Fields. We will also provide Roche and Genentech results to requested queries, at Recursion's discretion, of our pre-existing human umbilical vein endothelial cells (HUVEC) phenomap. Roche and Genentech will have specified rights to request queries or have direct access to the phenomaps to generate novel inferences that may lead to the discovery or development of therapeutic products.

Phenomap-Related Options in neuroscience. Each of the neuroscience phenomaps requested by Roche and Genentech and created by Recursion may be subject to either an initiation fee, acceptance fee or both. Such fees could exceed $250.0 million for sixteen (16) accepted phenomaps. In addition, for a period of time after Roche and Genentech's acceptance of certain phenomaps, Roche and Genentech will have the option to obtain, subject to payment of an exercise fee, rights to use outside the collaboration the raw images generated in the course of creating those phenomaps. If Roche and Genentech exercises its External Use Option for all twelve (12) eligible phenomaps, Roche and Genentech's associated exercise fee payments to Recursion could exceed $250.0 million.

Collaboration Programs and Roche and Genentech Options. Roche and Genentech and Recursion will collaborate to select certain novel inferences with respect to small molecules or targets generated from the phenomaps for further validation and optimization as collaboration programs. There can be up to 40 programs initiated as part of this collaboration. Roche and Genentech and Recursion may also combine sequencing datasets from Roche and Genentech with Recursion's phenomic imaging data and collaborate to generate new algorithms to produce multimodal maps from which additional collaboration programs may be initiated. For every collaboration program that successfully identifies potential therapeutic small molecules or validates a target, Roche and Genentech will have an option to obtain an exclusive license to develop and commercialize such potential therapeutic small molecules or to exploit such target.

Payments if Roche and Genentech Exercises Option for a Collaboration Program. Under the collaboration, Roche and Genentech may initiate up to forty (40) small molecule programs. Each small molecule collaboration program, if optioned and successfully developed and commercialized by Roche and Genentech, could yield more than $300.0 million in research, development, commercialization and net sales milestones for Recursion, as well as mid- to high-single digit tiered royalties on net sales. Recursion is also eligible for research, development, commercialization and net sales milestones for target collaboration programs optioned by Roche and Genentech.

Recursion Programs. If Roche and Genentech does not exercise its options in the Collaboration Agreement for certain collaboration programs, we may, with Roche and Genentech's prior consent, choose to independently validate, develop and commercialize products in a limited number of such programs, subject to agreed milestones and royalties to Roche and Genentech. Roche and Genentech will have rights to obtain an exclusive license to exploit such products by providing notice and paying us an opt-in fee and economics exceeding those that would otherwise be applicable if Roche and Genentech had exercised its option for such program.

Exclusivity. During an agreed period of time after the Collaboration Agreement's effective date, we are subject to certain exclusivities that limit our ability to conduct certain research and development activities with respect to compounds and targets in the Exclusive Fields, other than pursuant to the collaboration with Roche and Genentech. However, we may continue pursuing products that we are researching and developing in the Exclusive Fields as of the effective date of the Collaboration Agreement.

Termination. The Collaboration Agreement includes standard termination provisions, including for material breach or insolvency and for Roche and Genentech's convenience. Certain of these termination rights can be exercised with respect to a particular Exclusive Field or exclusive license, as well as with respect to the entire Collaboration Agreement.

Sanofi License Collaboration and License Agreement

In January 2022, we entered into a Collaboration and License Agreement, with Sanofi, or the CLA, and in July 2023 and December 2023, we amended the Collaboration and License Agreement, with such as amended CLA referred to as the Amended CLA. Pursuant to the Amended CLA, we will use our artificial intelligence-driven, end-to-end integrated platform to discover and validate novel targets in the oncology and immunology therapeutic areas. We will collaborate with Sanofi to advance certain of these targets into small molecule inhibitor drug research projects and accelerate the identification of certain small molecule development candidates.

Sanofi made an upfront cash payment of $100 million to us on signing the CLA and made an additional payment of $4 million in connection with the expansion of the collaboration pursuant to the December 2023 amendment. Under the Amended CLA, Recursion and Sanofi may initiate up to 15 novel small molecule programs. Each program, if successfully researched, developed and/or commercialized, will yield research, clinical development, regulatory, and commercial milestone payments of up to approximately $343 million including up to $193 million in the aggregate for certain specified research, development and regulatory milestones, and up to $150 million in the aggregate for certain specified commercial milestones. The Amended CLA could potentially provide us with up to approximately $5.2 billion in aggregate milestone payments across all 15 potential programs.

In the case that a therapeutic product resulting from the research collaboration is commercialized, we will also be eligible to receive tiered royalties on net sales ranging from high-single-digits to mid-teens. We also have an option for clinical co-investment which, if exercised, would increase the tiered royalty rates to up to 21% on net sales of co-funded products.

The collaboration may utilize Recursion's AI-based capabilities and precision medicine platform from target identification through patient selection. Once a target is identified, Recursion will be responsible for leading the design, translational and early preclinical studies to determine development candidates. Upon Sanofi's selection of a compound as a development candidate, Sanofi will be solely responsible for the IND-enabling studies and clinical development, manufacturing and commercialization of such development candidate at its own cost and expense. Under the Amended CLA, Sanofi has agreed to use commercially reasonable efforts to obtain regulatory approval for at least one qualifying small molecule product in at least one agreed upon major market.

The research component of the collaboration will be overseen by a joint steering committee comprised of an equal number of representatives from each of Recursion and Sanofi. Recursion and Sanofi may agree to utilize our precision medicine platform for patient enrichment in Sanofi's non-small molecule programs.

Pursuant to the Amended CLA, Recursion granted to Sanofi an exclusive license (with the right to grant sublicences through multiple tiers) to the intellectual property that is the subject of each small molecule research program for all purposes, throughout the world. Sanofi has the right to control the prosecution and maintenance of any patent rights related to intellectual property that is the subject of each small molecule research program.

After the CLA's effective date, we are subject to varying exclusivity arrangements for specified periods of time which limit our ability to conduct research and development, manufacturing or commercialization activities (whether ourselves or in conjunction with a third party) with respect to compounds and targets which are within the scope of the Amended CLA and with respect to certain agreed pathways of interest.

The Amended CLA contains standard termination provisions, including for material breach or insolvency and for Sanofi's convenience. Certain of these termination rights can be exercised in respect of a given target, or in respect of the CLA as a whole. In certain circumstances, upon termination, we have the right to terminate the licenses granted to Sanofi and to pursue the development, manufacture and commercialization of the product candidates.

Bayer AG Amended and Restated Research Collaboration and Option Agreement

On August 28, 2020, Recursion and Bayer entered into a Research Collaboration and Option Agreement, which was subsequently expanded on December 1, 2021, for research and collaboration on a certain number of projects related to fibrosis. On November 8, 2023, the parties amended and restated the original Bayer Agreement to re-align the collaboration with Bayer's strategic shift in focus to oncology. As a result, the parties wound down their joint work in fibrosis and the exclusivities with respect to the field of fibrosis were terminated.

Under the Restated Agreement, Recursion will collaborate with Bayer for the remainder of the five-year period under the original Agreement (extendable by up to 2 years to enable completion of certain research activities), to initiate up to seven programs in oncology. During certain agreed time periods within the collaboration term, Recursion is prohibited from conducting certain research and development activities with respect to certain identified genes of relevance in oncology outside of the collaboration, either by itself or together with third parties. However, Recursion may continue research and development activities for any such identified genes that it has initiated prior to the date of identification of such gene.

Under each oncology project, Recursion will work with Bayer to identify potential lead candidates for development. Under the Restated Agreement, Bayer has the first option to license potential candidates; each such license could potentially result in option exercise fees and development and commercial milestones paid to Recursion with an aggregate value of up to approximately $210.0 million for one license and up to approximately $1.5 billion if each program is licensed, as well as tiered royalties for each such license, ranging from low- to mid-single digit percentages of sales, depending on commercial success. Royalty periods for each license are on a country-by-country basis, and the duration of each such period is tied to the duration of patent or regulatory exclusivity in each country (with a minimum term of 10 years each).

If Bayer does not exercise its option with respect to a lead candidate or otherwise discontinues a project prior to completion, within a specified period of time, Recursion may exercise an option to negotiate with Bayer in good faith to obtain an exclusive license under Bayer's interest in any lead series developed pursuant to the project and backup compounds related thereto, as well as a non-exclusive license under Bayer's background intellectual property necessary for Recursion's use of the project results related to such compounds.

Bayer may terminate the collaboration at any time without cause. Either party may terminate the agreement for a material breach by the other party. The term of each license agreement continues on a product-by-product and country-by-country basis until the later of (a) the expiration of the last to expire valid claim of the licensed patents covering such product in such country, (b) the expiration of any applicable regulatory exclusivity period for such product in such country and (c) ten years after the first commercial sale of such product in such country. Bayer may terminate each such license agreement at any time without cause. Either party may terminate each such license agreement for the other party's uncured material breach.

Merck KGaA, Darmstadt, Germany Research Collaboration Agreement

In September 2023, we entered into a Research Collaboration Agreement, or the RCA, with the Healthcare Business of Merck KGaA, Darmstadt, Germany, referred to as Merck KGaA, Darmstadt, Germany, pursuant to which we will be responsible for the design process, as well as translational and early non-clinical studies to discover development candidates based on the initial agreed targets. Upon Merck KGaA, Darmstadt, Germany's selection of a compound as a development candidate, Merck KGaA, Darmstadt, Germany will be solely responsible for the non-clinical studies and clinical development, manufacturing and commercialization of such development candidate at its own cost and expense. Under the RCA, Merck KGaA, Darmstadt, Germany has agreed to use commercially reasonable efforts to obtain regulatory approval for at least one product candidate in certain major markets and to commercialize such product if it receives any such regulatory approval.

The research component of the collaboration will be overseen by a joint steering committee comprised of an equal number of representatives from us and from Merck KGaA, Darmstadt, Germany. The collaboration will also have an IP sub-committee comprised of an equal number of patent attorneys from each party that will be the liaison for intellectual property matters that arise in connection with the collaboration.

The RCA allows Merck KGaA, Darmstadt, Germany and us to identify additional targets in oncology and immunology or other mutually agreed disease areas. Should we identify additional targets for the collaboration, we would be responsible for target validation in addition to drug design.

Merck KGaA, Darmstadt, Germany made an upfront cash payment of $20 million to us on signing the RCA, and we remain eligible to receive up to $674 million in discovery, development, regulatory and sales-based milestones, if all milestones for all three initial programs are achieved. Of this amount, up to $113 million is potentially payable on milestones achieved in the discovery phase of development. In addition, we will receive royalty payments ranging from mid-single-digits to low-double-digits on net sales of any products resulting from the initial three targets that are commercialized. If any additional target is identified for the collaboration, we would be eligible to receive additional milestone payments on such target. Pursuant to the RCA, we granted to Merck KGaA, Darmstadt, Germany a worldwide, exclusive, transferable license (with the right to grant sublicenses through multiple tiers) to the intellectual property that is necessary or reasonably useful for development or commercialization of the target compounds and resulting products, if any, in order to develop, manufacture, commercialize and sell the target compounds and resulting products, if any. Merck KGaA, Darmstadt, Germany has the right to control the prosecution and maintenance of any patent rights related to intellectual property that is the subject of each program.

The RCA will remain in effect from September 20, 2023 until such date that no milestone payments or royalties are, or may become, payable under the RCA, unless the RCA is terminated earlier in accordance with its terms. The RCA contains standard termination provisions, including termination by either party for material uncured breach or insolvency of the other party, by us if Merck KGaA, Darmstadt, Germany breaches certain obligations with respect to regulatory and commercialization activities, and by Merck KGaA, Darmstadt, Germany for convenience. Certain of these termination rights can be exercised in respect of a given target, or in respect of the RCA as a whole. In certain circumstances, upon termination, we have the right to terminate the licenses granted to Merck KGaA, Darmstadt, Germany and to pursue the development and commercialization of the target compounds and resulting products, if any.

During the term of the RCA, we are subject to exclusivity obligations that limit our ability to conduct research and development or commercialization activities (whether ourselves or in conjunction with a third party) with respect to the compounds and targets which are within the scope of the RCA.

The RCA contains standard confidentiality provisions and representations and warranties made by each party to the agreement. The parties also provide mutual indemnification under the agreement and the RCA excludes liability of either party for consequential or similar damages, except to the extent prohibited by law.

Tempus Master Agreement

On November 3, 2023, Recursion Pharmaceuticals, Inc., or the Company, and Tempus Labs, Inc., or Tempus entered into a Master Agreement, or the Tempus Agreement pursuant to which Tempus may provide certain services and deliverables to the Company and/or license certain data to the Company. The term of the Tempus Agreement is five years from the effective date of the Tempus Agreement, or the Term.

Under the terms of the Tempus Agreement, the Company is granted a limited right to access Tempus's proprietary database of de-identified clinical and molecular data for certain therapeutic product development purposes, including to develop, train, improve, modify, and create derivative works of the Company's machine learning/artificial intelligence models for the purposes of therapeutic product development. The Company is permitted to download a maximum number of de-identified records at any one time, subject to an aggregate cap in the total unique records that can be downloaded over the course of the Term, and to retain each downloaded record for a period of 180 days from the date of download. After such 180-day period, The Company may elect to license such downloaded records for a longer period subject to additional terms and the payment of additional fees.

In exchange for these rights, the Company paid Tempus an initial license fee in an amount equal to $22.0 million, or the Initial License Fee and agreed to pay annual license fees during the Term ranging between $22.0 million and $42.0 million, which, together with the Initial License Fee, totals up to $160.0 million over the Term, subject to the Company's early termination, which may be triggered only following the third anniversary of the Master Agreement's effective date, and payment by the Company of an early termination fee (as further discussed below). The Initial License Fee and each annual license fee shall be payable at the Company's option either in the form of (x) cash, (y) shares of Class A common stock of the Company or (z) a combination of cash and shares of Class A common stock in such proportion as is determined by the Company in its sole discretion; provided

that (a) the aggregate number of shares of Class A common stock that the Company may issue in connection with all payments under this Agreement shall not exceed 19.9% of the aggregate total of shares of Class A common stock and the Company's Class B common stock outstanding on November 2, 2023 or the date immediately preceding the date of any shares of Class A common stock issued pursuant to the Tempus Agreement, whichever is less (the "Share Maximum").

In the event that all or any portion of the Initial License Fee or any annual license fee is payable in the form of shares of Class A common stock, the Company shall, subject to the Share Maximum, issue to Tempus a number of shares of Class A common stock equal to (1) the amount of such fee divided by (2) the volume weighted average price of Class A common stock for the seven trading day period ending on the trading day immediately preceding (and including) the date that is five business days before the date on which such fee is paid (any shares so issued, the "Tempus Shares").

The Company has agreed to use commercially reasonable efforts to prepare and file a registration statement (or a prospectus supplement to an effective registration statement on Form S-3ASR that will become automatically effective upon filing with the SEC pursuant to Rule 462(e)) with the Securities and Exchange Commission as soon as practicable but in no event later than 30 days after each issuance of Tempus Shares under the Tempus Agreement, and to use its commercially reasonable efforts to have the registration statement declared effective as promptly as possible but in any event within 30 days following initially filing (or up to 90 days in the event of full SEC review). After such registration, the Company has agreed to use commercially reasonable efforts to keep such registration statement effective until such date that all Tempus Shares covered by such registration statement have been sold thereunder or may be sold without restriction or volume limitation under Rule 144 as promulgated by the SEC under the Securities Act of 1933, as amended.

The Tempus Agreement also grants the Company the right to access and use Tempus' LENS software that permits the viewing and analysis of clinical, molecular, and other health data maintained by Tempus. Company will pay Tempus a six-figure annual license fee for the duration of the Term for the use of such software.

In addition to mutual rights to terminate for an uncured breach of the Tempus Agreement, the Company may terminate the Tempus Agreement for convenience after three years upon 90 days prior notice, subject to payment by the Company of an early termination fee equal to (a) an amount per unique record that Company has downloaded prior to termination less (b) the sum of any annual license fees paid prior to termination, which could result in early payment of the aggregate annual license fees contemplated by the Tempus Agreement to the extent all records made available under the Tempus Agreement have been downloaded.

Either party may assign its rights under the Tempus Agreement subject to limited restrictions, but the Company may not assign the Tempus Agreement without Tempus's consent if the proposed assignee is a large pharmaceutical company.

REC-4881: Takeda License Agreement

In May 2020, we entered into a License Agreement, or the Takeda In-License, with Takeda Pharmaceutical Company Limited, or Takeda, pursuant to which we obtained an exclusive (even as to Takeda and its affiliates), worldwide, sublicensable under certain conditions, transferable, royalty-bearing license to certain Takeda patents, know-how and materials related to develop, manufacture and commercialize Takeda's clinical-stage compound known as TAK-733, a non-ATP-competitive allosteric inhibitor of MEK1 and MEK2, subject to a non-exclusive, royalty-free, irrevocable, fully paid up, license back to Takeda to use the licensed compounds for non-clinical research purposes. We are currently developing the compound REC-4881 for the treatment of FAP, and patients with spontaneous APC-mutant tumors. We are also evaluating the utility of the compound in additional disease states using our platform.

We are required to use commercially reasonable efforts to develop and commercialize at least one licensed product in each of (a) the US, (b) at least three of the following European countries: the United Kingdom, France, Germany, Italy and Spain and (c) Japan.

Upon execution of the agreement, we paid an upfront fee of $1.5 million to Takeda. Under the Takeda In-License, we are obligated to pay Takeda milestones amounts totaling up to $39.5 million upon achievement of specified development and regulatory milestone events. In addition, we are obligated to pay Takeda low-to-mid single-digit royalties based on net sales of products containing the licensed compounds by us, our affiliates or sublicensees, subject to specified reductions. Our obligation to pay royalties continues on a country-by-country basis until the latest of expiration of the last to expire patent licensed by Takeda that covers the product, expiration of any regulatory exclusivity period for the product and ten years after the first commercial sale of the product, in such country.

Each party has the right to terminate the license agreement for the other party's material uncured breach, insolvency or bankruptcy. In addition, we may terminate the agreement without cause any time after May 2023, and Takeda may terminate the agreement if we have not conducted any material activities in support of the development or commercialization of the licensed compounds or any product containing a licensed compound and have not demonstrated that we used commercially reasonable efforts towards the development of such compounds or products for a period of 12 consecutive months and such failure is not due to events beyond our reasonable control. Further, Takeda may terminate the license agreement if we challenge the validity or enforceability of a licensed patent. Upon termination for any reason other than for Takeda's breach of the license agreement, upon Takeda's request we are obligated to negotiate in good faith, for a period of 120 days, terms and conditions of a license to Takeda under certain technology developed by us during the term of the agreement for the purpose of developing, commercializing and otherwise exploiting the licensed compounds and products containing the licensed compounds.

REC-102: Rallybio Purchase Agreement

In July 2025, we entered into a Membership Interest Purchase Agreement (the "Purchase Agreement") with RallyBio Corporation and certain of its affiliates ("RallyBio"). Pursuant to the Purchase Agreement, we acquired 50% of the issued and outstanding membership interests (the "Membership Interests") of RE Ventures I, LLC ("ENPP1 JV") from RallyBio in exchange for cash and shares of Class A common stock of the Company (the "RallyBio Shares") with a value of $7.5 million. Prior to the closing of the acquisition, we indirectly held 50% of the membership interests of ENPP1 JV. As a result of the acquisition, ENPP1 JV is an indirect wholly-owned subsidiary of Recursion.

In August 2025, following the satisfaction of certain milestones with respect to the compound developed by the ENPP1 JV, we paid to RallyBio a milestone payment with a value of $12.5 million. The Purchase Agreement also provides that Recursion will make additional cash payments to the Seller contingent upon the occurrence of certain future events, including based on the amount of the proceeds received by the Seller from the sale of the RallyBio Shares under certain circumstances and the occurrence of certain milestones or other events with respect to the compound developed by the ENPP1 JV.

REC-617: Apeiron Asset Purchase Agreement

In July 2024, Exscientia and GT Apeiron Therapeutics Inc. ("Apeiron") announced that they had entered into an Asset Purchase Agreement, IP Assignment Agreement, Subscription Agreement and Share Surrender Agreement, pursuant to which Exscientia owned the full rights to the intellectual property in REC-617 as well as took full control of the CDK7 inhibitor program (the "IP Rights") for the purpose of continuing independent research, development and commercialization efforts. Concurrent to the transaction, Exscientia AI and Apeiron terminated the Collaboration Agreement, dated July 1, 2021, by and between Exscientia and Apeiron.

As consideration for the IP Rights, Exscientia made an upfront payment to Apeiron in the amount of $10 million and forgave Apeiron of all outstanding debt. The Company also issued Apeiron $10 million of the Company's equity in the form of restricted American Depositary Shares. In addition, Exscientia AI surrendered 9,173,021 ordinary shares and 1,549,942 Series Pre-A preferred shares that Exscientia then held in Apeiron with no consideration being due from Apeiron to Exscientia or the Company.

Pursuant to the Asset Purchase Agreement, we shall pay Apeiron a single digit royalty, net of any applicable withholding taxes, if we or a third party commercializes REC-617. We will take on all development costs and shall also pay Apeiron a single digit percentage of any outlicensing income received by us or our affiliates if we enter into an outlicensing agreement with a third party.

Technology Partnerships

As Recursion continues to generate and leverage highly relatable and reliable datasets to support our internal pipeline and therapeutic partnerships, we continue to invest in advanced compute capabilities and data-centric solutions to strengthen our drug discovery and development efforts. Expanding on our previous release of select datasets and models, we are exploring additional opportunities to make more datasets and foundational models available to the broader scientific community. Our technology and data collaborations underline our commitment to implementing data- and technology-enabled solutions to support our efforts to bring better medicines to patients faster.

NVIDIA

In July 2023, we entered a strategic collaboration with NVIDIA to accelerate the development of our groundbreaking AI foundation models for biology and chemistry using our supercomputer, BioHive-1, and priority access on NVIDIA DGX™ Cloud. In May 2024, we completed BioHive-2, Recursion's new NVIDIA DGX SuperPOD AI supercomputer, powered by 63 DGX H100 systems with a total of 504 NVIDIA H100 Tensor Core GPUs increasing the computational capacity by over 4X. The BioHive-2 supercomputer was ranked as number 76 in the top supercomputers globally by the Top500 list in 2025.

Google Cloud

In October 2024, we announced an expanded collaboration with Google Cloud leveraging their technologies to accelerate drug discovery research and further enhance our ability to bring new medicines to patients faster. Through this strategic partnership, we will explore generative AI capabilities, including Gemini models, to support the Recursion OS. We will improve data search and access from our proprietary dataset with BigQuery and facilitate the scaling of compute resources to run large inference workflows effectively. Additionally, in November 2024, we announced the release of OpenPhenom-S/16 in Google Cloud's Vertex AI Model Garden. OpenPhenom, a non-commercial, publicly available foundation model built on microscopy data, sets a new "gold standard" for the industry, outperforming CellProfiler. This model offers the potential for researchers to replace their existing workflows with an off-the-shelf model that outperforms traditional microscopy analysis pipelines without requiring any additional tuning or training.

Helix

In May 2024, we entered into a multi-year agreement with Helix to access hundreds of thousands of de-identified records including Helix's Exome+® genomic data and data from longitudinal health records. Recursion continues to use this data to train causal AI models and design biomarker and patient stratification strategies across broad disease areas. The Helix dataset expands Recursion's integration of real-world patient data and complements Recursion's access to Tempus' oncology data.

HealthVerity

In April 2025, we entered into a license agreement with HealthVerity to access de-identified records for over 340M covered lives in the US. Recursion is leveraging this real-world data to enhance clinical development by enabling smarter clinical trial design, accelerating patient recruitment and generating evidence to support clinical and regulatory decisions.

Competition

Our efforts to date have resulted in several clinical-stage programs, an expansive pipeline of differentiated programs in early discovery and preclinical development, several partnerships with large pharma and technology companies, as well as an intellectual property portfolio comprising patents, trademarks, software and trade secrets. We believe that our differentiated approach provides us with a significant competitive advantage. We are a hybrid company, competing within multiple categories of the pharmaceutical, biotechnology, and technology industries where companies are similarly working to integrate rapidly advancing technologies into their drug discovery and development activities and/or are creating scalable scientific platforms. Notable competitors include:

- ***TechBio Companies.*** Such companies apply computational tools to unlock novel insights or accelerate drug discovery and development across different points in the value chain. Representative examples include Relay Therapeutics, Isomorphic Labs, Schrodinger, and AbCellera.
- ***Scalable Platform Companies.*** Such companies are applying novel scientific approaches or engineering novel therapeutic modalities with the potential to seed large numbers of therapeutic candidates. These companies may compete directly with our pipeline of predominantly small molecule therapeutics. Representative companies include Moderna, BioNTech, and Roivant Sciences.
- ***Traditional Biopharma Companies.*** Such companies, while primarily engaged in late-stage clinical development and product commercialization, are increasingly making their own investments in the application of ML and advanced computational tools across the drug discovery and development value chain. Such investments may include partnerships with other biotechnology companies (including Recursion) from which we may benefit. Representative companies include Janssen (a subsidiary of Johnson & Johnson), Merck, and Pfizer.
- ***Large Technology Companies.*** Large technology companies constantly seek growth opportunities. Technology-enabled drug discovery may represent a compelling opportunity for these companies, some of which have research groups or subsidiaries focused on drug discovery and others of which have signed large technology partnerships with biopharma companies. Representative companies include Alphabet, Microsoft, and Amazon.

Intellectual Property

Patents

As of February 2026, the Recursion patent portfolio is balanced between Platform IP and Program IP.

- ***Platform IP:*** Approximately one-half of the patents and patent applications that we own or license worldwide relate to the Recursion platform, including patents and applications related to the Recursion OS IP, as well as many other inventions related to Recursion's machine learning and artificial intelligence capabilities, cell perturbations, gene editing, drug discovery, drug development and hardware solutions. We also pursue a strategy of seeking patent protection on

smaller discrete inventions throughout the breadth of our pipeline, ranging from experiment design, operations within our labs, data collection and analysis (including deep learning insights).

- ***Recursion Program IP:*** A breakdown of our Program IP portfolio is below:
    - REC-4881: We own patent applications, or exclusively license Takeda's interest in patents and patent applications from Takeda, related to composition of matter and methods of reducing polyp burden in people living with FAP using REC-4881. Currently, we expect our licensed issued patents related to REC-4881 to generally expire in 2029, excluding any patent term extension, or other mechanisms for effecting patent term, and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fee. With respect to FAP, orphan drug exclusivity in the U.S. would run seven years from marketing authorization.
    - REC-3964: We own a patent and patent applications related to the composition of matter and methods of inhibiting the toxin produced by Clostridioides difficile in the gastrointestinal tract using REC-3964. Currently, we expect our issued patent related to REC-3964 to expire no earlier than 2042, excluding any patent term adjustment or patent term extension, or other mechanisms for effecting patent term, and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fee.
    - REC-617: We own patent applications related to REC-617; these patent applications relate to composition of matter and methods of treatment of multiple advanced solid tumor indications for REC-617. Upon issuance, we expect our patents resulting from these patent applications will expire no earlier than 2041, excluding any patent term extension, or other mechanisms for effecting patent term, and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fee.
    - REC-1245: We own patent applications related to the composition of matter and methods of treating biomarker-enriched solid tumors and lymphoma using REC-1245. Upon issuance, we expect our patents resulting from these patent applications will expire no earlier than 2043, excluding any patent term adjustment or patent term extension, or other mechanisms for effecting patent term, and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fee.
    - REC-3565: We own patent applications related to the composition of matter and methods of treating multiple hematology indications using REC-3565. Upon issuance, we expect our patents resulting from these patent applications will expire no earlier than 2041, excluding any patent term adjustment or patent term extension, or other mechanisms for effecting patent term, and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fee.
    - REC-4539: We own a Patent Cooperation Treaty (PCT) application related to the composition of matter and methods of treating multiple hematology and solid tumor indications using REC-4539. Upon issuance of a national phase patent from our PCT application, we expect the resulting patents to expire no earlier than 2043, excluding any patent term adjustment or patent term extension, or other mechanisms for effecting patent term, and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fee.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of biotechnology has emerged in the United States and in Europe, among other countries. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, importing, or otherwise commercializing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending and enforcing patent claims that cover our technology, inventions and improvements. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our platform and drug candidates and the methods used to manufacture them. Moreover, our issued patents and those that may issue in the future may not guarantee us the right to practice our technology in relation to the commercialization of our drug product candidates. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, which may prevent us from commercializing our drug candidates and future drug candidates and practicing our proprietary technology.

Our issued patents and those that may issue in the future may be challenged, narrowed, circumvented, or invalidated, which could limit our ability to stop competitors from marketing related platforms or drug candidates or limit the length of the term of patent protection that we may have for our drug candidates, future drug candidates and platforms. In addition, the rights granted under any issued patents may not provide us with complete protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that achieve similar outcomes but with different approaches. For these reasons, we may have competition for our drug candidates. Moreover, the time required for the development, testing and regulatory review of our candidate products may shorten the length of effective patent protection

following commercialization. For this and other risks related to our proprietary technology, inventions, improvements, platforms and drug candidates, please see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Our commercial success will also depend in part on not infringing upon the intellectual property and proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies for our products or processes or to obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future products may have an adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, please see “Risk Factors—Risks Related to Our Intellectual Property.”

Some of our pending patent applications in the United States are provisional patent applications. Provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a nonprovisional patent application related to the patent. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent. A U.S. patent also may be accorded patent term adjustment, or PTA, under certain circumstances to compensate for delays in obtaining the patent from the USPTO. In some instances, such a PTA may result in a U.S. patent term extending beyond 20 years from the earliest date of filing a non-provisional patent application related to the U.S. patent. In addition, in the United States, the term of a U.S. patent that covers an FDA-approved drug may also be eligible for patent term extension (PTE), which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. However, with respect to patent term extensions granted as a result of the FDA regulatory review period, the restoration period cannot be longer than five years, the total patent term including the restoration period must not exceed 14 years following FDA approval, only one patent applicable to each regulatory review period may be extended and only those issued claims covering the approved drug or a method for using it may be extended. We may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. There can be no assurance that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents.

Rapidly evolving patent laws in the United States and elsewhere make it difficult to predict the breadth of claims that may be allowed or enforced in our patents. Moreover, patent offices in general can require that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we are able to obtain patents, the patents may be substantially narrower than anticipated.

Our ability to maintain and defend our intellectual property and proprietary position for our drug product candidates, methods of their use, and other proprietary technologies will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of the patent applications that we may file or license from third parties will result in the issuance of any patents. The issued patents that we own, may receive in the future, or license from third parties may be challenged, invalidated, held unenforceable, narrowed or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against third parties, including our competitors, with similar technology. Furthermore, third parties, including our competitors, may be able to independently develop and commercialize similar drugs or products, or duplicate our technology, business model or strategy without infringing our patents.

Trademarks

As of February 2025, our trademark portfolio comprises more than 70 registered trademarks or active trademark applications worldwide, among which we have issued trademarks in the U.S. for “Recursion” and “Recursion Pharmaceuticals.”

Trade Secrets

In addition to our reliance on patent protection for our inventions, drug candidates and programs, we also rely on trade secrets, know-how, confidentiality agreements and continuing technological innovation to develop and maintain our competitive position.

For example, some elements of manufacturing processes, proprietary assays, analytics techniques and processes, knowledge gained through clinical experience such as approaches to dosing and administration and management of patients, as well as computational-biological algorithms, and related processes and software, are based on unpatented trade secrets and know-how that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees, advisors and consultants, these agreements may be breached, and we may not have adequate remedies for any breach. In addition, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. As a result, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived of by the individual during the course of employment, and which relate to or are reasonably capable or being used in our current or planned business or research and development are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against the misappropriation of our proprietary technology by third parties. However, such agreements and policies may be breached, and we may not have adequate remedies for such breaches. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Related to Our Intellectual Property."

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the relevant regulatory authority.

U.S. Drug Development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA. Drugs also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

- Our drug candidates are considered small molecule drugs and must be approved by the FDA through the new drug application, or NDA, process before they may be legally marketed in the United States. The process generally involves the following: completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP;
- submission to the FDA of an investigational new drug, or IND, application, which must become effective before human clinical trials in the U.S. may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish substantial evidence of the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to accept the filing for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the preclinical study and/or clinical trial sites that generated the data in support of the NDA filing;
- payment of user fees for FDA review of the NDA;

- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

The data required to support an NDA is generated in two distinct developmental stages: preclinical and clinical. The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for any current and future drug candidates will be granted on a timely basis, or at all.

Preclinical Studies and IND

Before testing any drug product candidate in humans, the product candidate must undergo rigorous preclinical testing. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP and ICH regulations for safety/toxicology studies. The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials, which are generally required for FDA approval of an NDA, to commence. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development along with any subsequent changes to the investigational plan. Some long-term nonclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB must also approve the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA. The FDA will generally accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP and GMP requirements, and the FDA is able to validate the data through an onsite inspection, if deemed necessary, and the practice of medicine in the foreign country is consistent with the United States.

Clinical trials in the United States generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the drug candidate. The primary purpose of these clinical

trials is to assess the metabolism, pharmacologic action, tolerability and safety of the drug, the side effects associated with increasing doses, and if possible to gain early evidence on effectiveness.

- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose and dosing schedule required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information are collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, are conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. The sponsor is also responsible for submitting written IND safety reports, including reports of serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or in vitro testing that suggest a significant risk for human subjects, and any clinically significant increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal safety studies and also must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process, as performed by the manufacturing facility, must be capable of consistently producing quality batches of our drug candidates. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that our drug candidates do not undergo unacceptable deterioration over their labeled shelf life.

NDA Review Process

Following completion of the clinical trials, data is analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling, chemistry, and manufacturing information to ensure product quality and other relevant data. In short, the NDA is a request for approval to market the drug in the United States for one or more specified indications and must contain proof of safety and efficacy for a drug.

The application must include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of an NDA must be obtained before a drug may be legally marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for each marketed human drug. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the

submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months, from the filing date, in which to complete its initial review of a new molecular-entity NDA and respond to the applicant, and six months from the filing date of a new molecular-entity NDA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies and/or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. Further, FDA's "real-time" release of newly issued Complete Response Letters associated with withdrawn or abandoned applications, if applicable to any of our product candidates, can materially impact our business and competitive advantage.

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant an orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are

seeking approval, or if a drug candidate is determined to be contained within the scope of the competitor's product for the same indication. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting with the FDA.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, which is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. FDA may withdraw drug approval or require changes to the labeled indication of the drug if confirmatory post-market trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product.

Additionally, a drug may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast track designation, priority review, accelerated approval and breakthrough therapy designations do not change the standards for approval, but may expedite the development or approval process.

Post-approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, requirements to report adverse events and comply with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations, known as "off-label promotion," and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for REMS, to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. Manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to

expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, its manufacturer or the NDA holder, including recalls.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- suspension or revocation of product approvals;
- product seizure or detention;
- refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

FDA Regulation of Companion Diagnostics

Safe and effective use of a therapeutic product may rely upon an in vitro companion diagnostic for use in selecting the patients that will be more likely to respond to that therapy. If an in vitro diagnostic is essential to the safe and effective use of the therapeutic product and if the manufacturer wishes to market or distribute such diagnostic for use as a companion diagnostic, then the FDA will require separate approval or clearance of the diagnostic as a companion diagnostic to the therapeutic product. According to FDA guidance, an unapproved or uncleared companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational medical device unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will likely be considered a significant-risk device, which requires the sponsor to obtain an Investigational Device Exemption, or IDE, from FDA before commencing any testing in humans. The sponsor of a significant-risk diagnostic device will be required to comply with the IDE regulations for clinical studies involving the investigational diagnostic device. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same clinical trial, if the trial meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the clinical trial protocol, the investigational product(s), and subjects involved, a sponsor may seek to submit an IDE alone (e.g. if the drug has already been approved by FDA and is used consistent with its approved labeling), or both an IND and an IDE.

Pursuing FDA approval/clearance of an in vitro companion diagnostic would require either a pre-market notification, also called 510(k) clearance, or a pre-market approval, or PMA, or a de novo classification for that diagnostic. The review of companion diagnostics involves coordination of review with the FDA's Center for Devices and Radiological Health.

510(k) Clearance Process

To obtain 510(k) clearance, a pre-market notification is submitted to the FDA demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet required the submission of a PMA application. The FDA's 510(k) clearance process may take three to 12 months from the date the application is submitted and filed with the FDA, but may take longer if FDA requests additional information, among other reasons. In some cases, the FDA may require clinical data to support substantial equivalence. In reviewing a pre-market notification submission, the FDA may request additional information, which may significantly prolong the review process. Notwithstanding compliance with all these requirements, clearance is never assured.

After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or require a PMA. In addition, the FDA may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, which may significantly affect the process.

De Novo Classification Process

If a new medical device does not qualify for the 510(k) pre-market notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. The Food and Drug Administration Modernization Act of 1997 established a different route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification process. This process allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents a low or moderate risk, rather than requiring the submission and approval of a PMA. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk and requires PMA or that general controls would be inadequate to control the risks and special controls cannot be developed.

Obtaining FDA marketing authorization, de novo down-classification, or approval for medical devices is expensive and uncertain, may take several years and generally requires significant scientific and clinical data.

PMA Process

The PMA process, including the gathering of clinical and nonclinical data and the submission to and review by the FDA, can take several years or longer. The applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness, including information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for medical devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality Management System Regulation, or QSMR, which went into effect in February 2026, replacing the former Quality System Regulation. The QSMR imposes extensive testing, control, documentation and other quality assurance and GMP requirements.

After a device is placed on the market, it remains subject to significant regulatory requirements. Among other requirements, medical devices may be marketed only for the uses and indications for which they are cleared or approved, device manufacturers must establish registration and device listings with the FDA and a medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSMR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA and the FDA also may inspect foreign facilities that export products to the U.S.

Other U.S. Regulatory Matters

- Our current and future arrangements with healthcare providers, third-party payors, customers and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to: the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug or medical device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the ACA (as defined below) provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- The federal criminal False Claims Act and Civil Monetary Penalties Laws, and the civil False Claims Act that can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are

false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government and/or impose exclusions from federal health care programs and/or penalties for parties who engage in such prohibited conduct;

- The Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations also impose obligations on covered entities such as health insurance plans, healthcare clearinghouses and certain health care providers and their respective business associates, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the FD&C Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to Centers for Medicare & Medicaid Services, or CMS, information regarding certain payments and other transfers of value to physicians, certain non-physician healthcare professionals, and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their sales representatives, state laws that require biotechnology companies to report information on the pricing of certain drug products and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"). If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical and/or medical device products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical and/or medical device products. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act as well as other applicable consumer safety requirements.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

U.S. Patent-Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of any future drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug, a method for using it, or a method of manufacturing it, is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, if and when our products receive FDA approval, we may apply for restoration of patent term for our currently owned or licensed patents covering products eligible for patent term extension to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA. Similar provisions are available in Europe and certain other jurisdictions to extend the term of a patent that covers an approved drug. We may seek patent term extension for any of our issued or licensed patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for an NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness or generate such data themselves.

European Union Drug Development

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated, it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The Clinical Trials Regulation EU No 536/2014 repealed the Clinical Trials Directive No. 2001/20/EC and harmonizes the processes for assessment and supervision of clinical trials throughout the European Union. From January 31, 2023, all initial clinical trial applications in the European Union must be submitted via the Clinical Trials Information System (CTIS), which provides a single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data.

European Union Drug Review and Approval

In the European Economic Area, or EEA, which is composed of the 28 Member States of the European Union and three European Free Trade Association States (Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific, or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SOPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SOPC, labeling or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e. in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Similar to the U.S. patent term-restoration, Supplementary Protection Certificates, or SPCs, serve as an extension to a patent right in Europe for up to five years. SPCs apply to specific pharmaceutical products to offset the loss of patent protection due to the lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval.

Coverage and Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical drug candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific drug candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow the price structures of the United States and generally prices tend to be significantly lower.

Healthcare Reform

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private third-party payors often follow Medicare coverage policy and payment limitations in setting their own payment rates.

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was passed which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the U.S. Department of Health and Human Services, or HHS, Secretary as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and adding a rebate calculation for "line extensions" (i.e. new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have passed.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032 unless additional congressional action is taken. The American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. In August 2022, Congress passed the Inflation Reduction Act of 2022 (IRA), which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various stakeholders, including pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of HHS to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the U.S. In November 2025, CMS announced a voluntary initiative called the GENEROUS Model (GENErating cost Reductions for U.S. Medicaid Model) to introduce the option of most-favored-nation pricing to the Medicaid program, whereby a drug manufacturer may voluntarily offer supplemental rebates to participating state Medicaid programs for a manufacturer's covered outpatient drugs. Government agreements with pharmaceutical companies and other measures that use most-favored-nation pricing targets for prescription drugs or that increase generic and biosimilar drug entry sooner than expected can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future, or the pricing of our approved product in the U.S. and in foreign countries. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the current administration on us and the pharmaceutical industry as a whole is unclear. Similarly, at the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Available Information

Our principal executive office is located at 41 S Rio Grande Street, Salt Lake City, UT 84101. Our telephone number is (385) 269-0203.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, or the Exchange Act, are available free of charge on our website as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Our website is www.recursion.com. Investors and others should note that we announce material financial and other information to our investors using our investor relations website (https://ir.recursion.com/), SEC filings, press releases, public conference calls and webcasts. We use these channels as well as social media and blogs to communicate with our stakeholders and the public about our company, our services and other issues. It is possible that the information we post on social media and blogs could be deemed to be material information. Therefore, we encourage investors, the media and others interested in our company to review the information we post on the social media channels and blogs listed on our investor relations website. Information contained in, or that can be accessed through, our website is not a part of, and is not incorporated into, this report.

This report includes citations to information published by third parties, including academic and industry research, publications, surveys, and studies. While we believe that such information is reliable, we have not separately verified such information, and such information is not a part of, and is not incorporated into, this report.