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# AI Drug Discovery FDA Approvals: The 2026 Reality Check

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# Executive Summary

As of October 2026, no drug discovered or designed by artificial intelligence (AI) has received full approval from the U.S. Food and Drug Administration (FDA). This is the single fact that most directly answers the query behind this report, and it holds even as AI-associated candidates have moved further into clinical development than at any prior point. The furthest-advanced case is **rentosertib** (formerly ISM001-055 / INS018-055), a TNIK (Traf2- and NCK-interacting kinase) inhibitor from Hong Kong-listed **Insilico Medicine**, which entered Phase III for idiopathic pulmonary fibrosis (IPF) when Insilico announced the trial's initiation on July 7, 2026, and dosed its first Phase III patient on September 9, 2026 (prnewswire.com), after a Phase IIa study published in *Nature Medicine* showed a mean forced vital capacity improvement of +98.4 mL at 12 weeks in the highest-dose arm (nature.com). A separate contender, Takeda's **zasocitinib** (TAK-279), beat an approved rival in a head-to-head Phase III psoriasis trial in June 2026, and in September 2026 the FDA accepted Takeda's New Drug Application under Priority Review with a target action date in the first quarter of 2027 (takeda.com), but its origin traces to physics-based free energy perturbation modeling at Nimbus Therapeutics and Schrödinger starting around 2016 against an already-validated target, illustrating how contested the "AI-discovered" label has become (takeda.com).

Investment in AI drug discovery has scaled well ahead of clinical validation. The global AI-in-drug-discovery market was calculated at **$6.93 billion in 2025** and is projected to reach **$17.81 billion by 2035** at a compound annual growth rate (CAGR) of 9.9 percent, according to Precedence Research (precedenceresearch.com). BCC Research separately found that AI-driven drug discovery attracted **more than $2 billion in recent investment**, with companies reporting timeline compression from four to five years down to 12 to 18 months (finance.yahoo.com). GlobalData counted **168 AI-related strategic alliances** signed across the pharmaceutical industry in 2025 alone (chemdiv.com). Individual deals have reached staggering

headline values: Alphabet's **Isomorphic Labs** struck nearly $3 billion in combined agreements with Eli Lilly and Novartis in January 2024 (fiercebiotech.com); Eli Lilly agreed to pay Insilico Medicine up to **$2.75 billion** in a March 2026 deal centered on a $115 million upfront payment (cnbc.com); and startup **Chai Discovery** was valued at $3.8 billion in a $400 million Series C round in July 2026, after just two years in existence (fiercebiotech.com).

On the clinical evidence side, a widely cited 2024 analysis published in *Drug Discovery Today* found that AI-discovered molecules achieved an **80 to 90 percent success rate in Phase I trials**, compared with historic industry averages closer to 40 to 65 percent, though Phase II success rates for the same molecules were roughly 40 percent, in line with historical norms (quantumbiospace.ai). The same analysis found that only **67 of 6,147 drugs** in clinical development (about 1 percent) were AI-discovered molecules, and only 24 (0.4 percent) involved AI-discovered targets (quantumbiospace.ai). The FDA published its first draft guidance on AI in regulatory decision-making in January 2025, building on more than **500 drug and biologics submissions with AI components** received since 2016 (fda.gov). Traditional drug development, against which AI is being measured, costs an estimated **$2.588 billion per approved drug** and takes roughly a decade, according to Tufts Center for the Study of Drug Development, a figure that patient advocacy groups such as Médecins Sans Frontières (MSF) dispute as inflated (msfaccess.org). McKinsey estimates generative AI alone could unlock **$60 billion to $110 billion annually** in value across the pharmaceutical industry (mckinsey.com).

The balance of evidence supports a measured conclusion: AI has demonstrably compressed early discovery timelines and improved Phase I attrition for a small number of programs, but it has not yet produced an approved medicine, and skeptics including Novartis chemist Derek Lowe argue that AI's core limitation, poor target selection and human toxicity prediction, remains largely unsolved (bio-itworld.com). For consultancies and life-sciences organizations evaluating where to place technology and regulatory-strategy resources, the practical reading of 2026 is one of disciplined optimism: genuine productivity gains in early-stage discovery and regulatory documentation, layered with unresolved uncertainty about whether AI meaningfully changes the probability that a molecule ultimately reaches patients.

# Introduction and Background

Artificial intelligence has been proposed as a solution to the pharmaceutical industry's productivity crisis for more than a decade, but 2026 is widely described in trade and scientific press as the year the technology finally faces a genuine test: Phase III clinical trial results. As Dr. Raminderpal Singh wrote in a widely referenced February 2026 analysis, "the most consequential development of 2026 will be Phase III results that determine whether AI can deliver drugs that actually work at scale" (drugtargetreview.com). This report examines the state of AI drug discovery and FDA approvals as of mid-2026: what has actually reached regulators, what remains in the pipeline, how much capital has been committed, and where the empirical evidence supports or contradicts the industry's own claims.

The underlying problem AI is meant to solve is well documented. Traditional small-molecule **drug discovery** and development takes, on average, ten to fifteen years and costs an estimated **$2.588 billion** per approved drug, according to a frequently cited Tufts Center for the Study of Drug Development (Tufts CSDD) analysis, up from $802 million in the center's 2003 study (msfaccess.org). That figure is itself disputed: MSF has argued that "if you believe that, you probably also believe the earth is flat," pointing to non-profit drug developers that it

says have produced new medicines for "as little as $50 million, or up to $186 million if you take failure into account" (msfaccess.org). MSF further argues that "nearly half of R&D spending is paid for by the taxpayer or by philanthropy," a framing that, if accurate, would mean AI's promised R&D cost savings accrue partly to public funders rather than solely to drug manufacturers (msfaccess.org). Roughly 90 percent of drug candidates that enter human clinical trials fail before reaching patients, and pharmaceutical companies spend on the order of **$200 to 250 billion annually** on research and development worldwide (intuitionlabs.ai). Against this backdrop, generative AI, machine learning applied to molecular design and biological target identification, promises to compress timelines by simulating experiments computationally rather than through slower wet-lab iteration.

The regulatory backdrop has also shifted. The FDA's Center for Drug Evaluation and Research (CDER) explained that **AI** refers to "a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments," with machine learning (ML) as a commonly used subset (fda.gov). In January 2025, the agency issued its first draft guidance, "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision Making for Drug and Biological Products," which the agency says was informed in part by feedback received in December 2022 through an expert workshop convened by the **Duke Margolis Institute for Health Policy** on behalf of CDER, more than 800 public comments on a May 2023 discussion paper, and the agency's own experience reviewing "over 500 submissions with AI components from 2016 to 2023" (fda.gov). Notably, the draft guidance explicitly excludes AI used purely in early **drug discovery** from its scope, focusing instead on AI outputs that directly inform a regulatory decision about safety, efficacy, or quality, a distinction that matters because it means the discovery-stage technology at the center of most public claims is not itself what the FDA is regulating (intuitionlabs.ai). A further "Guiding Principles of Good AI Practice in Drug Development" followed in January 2026 (fda.gov).

This report is written for a life-sciences and AI consultancy audience evaluating vendor claims, regulatory posture, and investment trends rather than for retail investors or general readers. It proceeds by examining the clinical pipeline in detail, the investment and market-size data, named case studies of both success and failure, and the implications for organizations deciding how much weight to place on AI drug discovery claims through the remainder of 2026 and into 2027.

# The Clinical Pipeline: What Has Actually Reached Trials

The central, often-asked question, has AI discovered any FDA-approved drugs, has a direct answer: not yet, as of October 2026. Multiple independent sources converge on this point. A pharmaceutical industry tracker summarized the state of play bluntly: "As of mid-2026, no fully AI-designed drug has received FDA approval. However, Insilico Medicine's ISM001-055 for idiopathic pulmonary fibrosis is in Phase 2 trials, the furthest any AI-designed molecule has progressed" (pharmanow.live). That statement is now slightly dated in one respect: rentosertib (the renamed ISM001-055) advanced beyond Phase II into Phase III, with the trial initiated on July 7, 2026 and its first patient dosed on September 9, 2026 (prnewswire.com), but the underlying conclusion, no approval yet, still holds according to multiple February and March 2026 commentaries (drugtargetreview.com).

The rentosertib program is the most thoroughly documented example of an end-to-end AI drug discovery pipeline reaching late-stage clinical testing. According to Insilico Medicine, the target, TNIK, a serine/threonine kinase implicated in fibrosis and inflammation-related Wnt, TGF-beta, Hippo/YAP-TAZ, JNK and NF-kB signaling pathways, was identified by the company's **PandaOmics** biology engine, while the molecule itself was generated and optimized through **Chemistry42**, Insilico's generative chemistry platform (prnewswire.com). The Phase IIa GENESIS-IPF trial, published in *Nature Medicine* in 2025, was a multicenter, double-blind, randomized, placebo-controlled study enrolling 71 patients with idiopathic pulmonary fibrosis across 22 sites in China (nature.com). The trial's authors were explicit about how rare this milestone is, writing that "despite substantial progress in artificial intelligence (AI) for generative chemistry, few novel AI-discovered or AI-designed drugs have reached human clinical trials" (nature.com). Patients receiving the highest dose, 60 mg once daily, showed a mean forced vital capacity (FVC) change of +98.4 mL at 12 weeks, compared with a decline of -20.3 mL in the placebo group (nature.com). Insilico's Phase III trial, called GENESIS-IPF-3 (NCT07687459), is designed to enroll **320 patients** across 47 centers in China (prnewswire.com) and will assess safety and efficacy over 52 weeks, led by Professor Zuojun Xu of Peking Union Medical College Hospital (prnewswire.com), and the Phase IIa results were separately presented at the American Thoracic Society (ATS) 2025 International Conference (prnewswire.com).

A second, more contested case is Takeda's zasocitinib (TAK-279), an oral tyrosine kinase 2 (TYK2) inhibitor for plaque psoriasis. In June 2026, Takeda announced the drug demonstrated "statistical superiority over deucravacitinib for the primary endpoint," with more than 35 percent of zasocitinib-treated patients achieving complete skin clearance (PASI 100) at week 16, more than 2.5 times the response rate of the approved comparator (takeda.com), and the company said it is "on track to submit a New Drug Application for plaque psoriasis with the United States Food and Drug Administration...starting this fiscal year" (takeda.com). The FDA accepted that application under Priority Review in September 2026, with a target action date in the first quarter of calendar 2027 (takeda.com). Media outlets widely labeled zasocitinib an "AI-designed pill," but industry commentary pushed back on the framing: the program traces to **Nimbus Therapeutics** and **Schrödinger**, who began working on TYK2 around 2016 using free energy perturbation (FEP), a physics-based computational chemistry technique, against TYK2, a target that Bristol Myers Squibb had already validated by winning approval for its own TYK2 drug, Sotyktu, in 2022 (aiinlabcoat.com). As the commentary concluded, "it did not discover TYK2...Nimbus came later and built a better molecule against a known, clinically validated target" (aiinlabcoat.com). This distinction, between AI-assisted molecule optimization against a known target and true AI-driven target discovery, is central to why claims of "AI-discovered drugs" are so often disputed, and it directly answers the secondary query of why more AI-associated approvals have not yet materialized: attribution is genuinely difficult, and much of what markets itself as an AI drug involved substantial conventional medicinal chemistry and human decision-making.

Beyond these two headline cases, Recursion Pharmaceuticals, formed by its 2024 merger with Exscientia (discussed further below), reported more than 10 clinical and preclinical programs, 10 advanced discovery programs, and more than 10 partnered programs as of its November 2024 combination announcement (ir.recursion.com), and had received approximately **$450 million** in upfront and realized milestone payments out of a potential **$20 billion** across its partnerships (ir.recursion.com). Insilico Medicine itself disclosed, as of its December 2025 IPO filing, a pipeline of more than 30 programs across fibrosis, oncology, immunology, inflammation, cardiometabolics and central nervous system disease, with 10 programs having received

Investigational New Drug (IND) clearance and 7 in active clinical development (prnewswire.com). Separately, Recursion's MEK1/2-targeting candidate REC-4881 reported positive Phase 1b/2 results in familial adenomatous polyposis (FAP) in late 2025 (pharmaphorum.com), while a separate use of the same drug in APC/AXIN1-mutant cancers (clinicaltrials.gov) had already been deprioritized in Recursion's November 2024 post-merger update as part of "a disciplined strategic prioritization of the portfolio" (ir.recursion.com), illustrating how volatile even advanced-stage AI pipelines remain.

# Investment, Deal Value, and Market Size

The scale of capital committed to AI drug discovery vastly outstrips the number of clinical successes to date, a gap that is itself one of the central tensions this report documents. According to Precedence Research, the global AI-in-drug-discovery market was valued at **$6.93 billion in 2025** and is forecast to reach **$7.62 billion in 2026**, growing to approximately **$17.81 billion by 2035** at a 9.90 percent CAGR (precedenceresearch.com). North America accounted for **56.18 percent** of the market in 2025, while the Asia-Pacific region is projected to grow fastest, at a 21.1 percent CAGR through 2035, a trend Precedence Research attributes partly to government-led digital-health initiatives, noting that "China's government has embedded AI in its 'Made in China 2025 policy', promoting cutting-edge medical research and pharmaceutical development" (precedenceresearch.com). By application, the drug optimization and repurposing segment captured roughly **51 percent** of category revenue in 2024, with preclinical testing identified as the fastest-growing application going forward (precedenceresearch.com). A separate BCC Research analysis, released July 14, 2026, found the sector had attracted **more than $2 billion in recent investment**, with the report crediting AI for cutting development timelines "from 4-5 years to 12-18 months while doubling clinical success rates" (finance.yahoo.com). That same report found regulatory approval rates for AI-validated targets rising from a baseline of 10 to 15 percent to approximately 20 percent, and noted major funding rounds including **Generate:Biomedicines** ($500 million-plus), **Exscientia** ($500 million-plus prior to its merger), and **Kailera Therapeutics** ($600 million Series B) (finance.yahoo.com).

Deal-level data corroborates the scale of institutional commitment. GlobalData's Pharmaceutical Intelligence Center counted **168 AI-related strategic alliances** signed across the industry in 2025 (chemdiv.com), a surge partly explained by looming patent cliffs: GlobalData projects that up to **$230 billion** in branded U.S. drug sales are at risk from generic and biosimilar competition between 2025 and 2030 (chemdiv.com). A related GlobalData survey found that pharmaceutical professionals ranked AI's role in the value chain as the single factor expected to have the greatest impact on the industry in 2026 (chemdiv.com). Isomorphic Labs, an Alphabet spinout built on Google DeepMind's AlphaFold protein-structure-prediction technology, announced collaborations worth "nearly $3 billion" combined with Eli Lilly and Novartis in January 2024: Lilly agreed to pay $45 million upfront with more than $1.7 billion in potential milestones, while Novartis paid $37.5 million upfront against $1.2 billion in additional milestones (fiercebiotech.com). Isomorphic Labs itself confirmed the Lilly figure directly, stating it would "receive $45 million in upfront payment for multi-target research collaborations with Lilly" (isomorphiclabs.com) and separately confirmed it would "receive $37.5 million upfront payment from Novartis" (isomorphiclabs.com).

Capital raised is not evenly distributed across the sector, and the largest fundraisers are not always the companies with the most advanced clinical pipelines. One industry tracker found that **XtalPi** has raised over $1.9 billion, backed by Google, SoftBank and Tencent, while **Recursion Pharmaceuticals** has raised approximately $1.8 billion, with active partnerships with Bayer and Roche (pharmanow.live). This concentration of capital in a handful of well-capitalized platform companies, rather than broad-based funding spread evenly across the sector, foreshadows the market consolidation dynamic discussed later in this report.

*Table 1* below summarizes major disclosed AI drug discovery deals and financing rounds referenced in this report, illustrating the range from early discovery partnerships to late-stage licensing agreements.

| Company / Deal | Counterparty | Disclosed Value | Date | Source |
|---|---|---|---|---|
| **Isomorphic Labs** multi-target collaborations | Eli Lilly and Novartis | Nearly $3 billion combined ($45M + $37.5M upfront) | January 2024 | Fierce Biotech, Isomorphic Labs (fiercebiotech.com) |
| **Recursion / Exscientia** merger | N/A (combination) | All-stock deal valuing Exscientia at approximately $688 million | August 2024 | STAT News (statnews.com) |
| **Eli Lilly / Insilico Medicine** R&D collaboration | Eli Lilly | Up to $2.75 billion ($115M upfront) | March 2026 | CNBC (cnbc.com) |
| **Insilico Medicine** Hong Kong IPO | Public markets (HKEX) | HKD 2.277 billion (approximately $293 million) | December 30, 2025 | PR Newswire, pharmaphorum (prnewswire.com) |
| **Chai Discovery** Series C | Index Ventures, Kleiner Perkins, Sequoia, Dimension | $400 million ($3.8 billion valuation) | July 2026 | Fierce Biotech (fiercebiotech.com) |

As the table shows, the largest disclosed sums are concentrated in milestone-heavy licensing agreements rather than upfront cash, meaning headline deal values (such as the $2.75 billion Lilly-Insilico figure or the nearly $3 billion Isomorphic figure) substantially overstate near-term cash received; the actual upfront payments in these deals ranged from $37.5 million to $115 million. This pattern is consistent across the sector and is one reason funding announcements should be read alongside the smaller upfront components before drawing conclusions about a company's real financial position.

McKinsey's own modeling places the addressable opportunity even higher than sector-specific market trackers, estimating that generative AI specifically could generate **$60 billion to $110 billion a year** in economic value across the pharmaceutical and medical-product industries, split across research and early discovery, clinical development, and other functions (mckinsey.com). McKinsey also found that clinical development alone costs on average **$1.4 billion in out-of-pocket costs** and ten years per drug, with roughly 80 percent of costs tied to the clinical-development phase, according to Tufts CSDD data the firm cited (mckinsey.com).

# Analysis of Key Segments: Companies and Platforms

The AI drug discovery sector spans several distinct business models, each with different levels of clinical maturity. Understanding these segments helps clarify why the "generative AI drug discovery companies pipeline" question does not have a single answer.

**Clinical-stage, vertically integrated biotechs** design their own molecules and run their own trials. **Insilico Medicine**, founded in 2014 and listed on the Hong Kong Stock Exchange on December 30, 2025 in what the company called "the largest biotech IPO in Hong Kong this year" (prnewswire.com), is the clearest example. Its Pharma.AI platform integrates **PandaOmics** for target identification, **Chemistry42** for generative molecule design, and **inClinico** for predicting clinical trial outcomes (pharmanow.live). As of its IPO filing, Insilico had entered software licensing collaborations with **13 of the world's top 20 pharmaceutical companies** and published 9 papers in Nature-family journals in 2025 alone (prnewswire.com). Company CEO **Alex Zhavoronkov** told CNBC in March 2026 that Insilico had developed "at least 28 drugs using generative AI tools, with nearly half already at a clinical stage" (cnbc.com). Lilly's group vice president of Molecule Discovery, Andrew Adams, described the relationship in similarly collaborative terms, saying the partnership would "explore novel mechanisms and accelerate the identification of promising therapeutic" candidates and calling Insilico's AI-enabled discovery "a powerful complement" to Lilly's own clinical development work (cnbc.com) (cnbc.com).

**Recursion Pharmaceuticals**, based on high-throughput cellular imaging and its proprietary "Recursion OS" machine learning platform, absorbed rival Exscientia in an all-stock deal in August 2024 valued at approximately **$688 million**, with Recursion shareholders retaining about 74 percent of the combined company and Exscientia shareholders holding the remaining 26 percent (statnews.com) (statnews.com), a transaction Fierce Biotech described plainly: "after a year defined by pipeline cuts, the departure of its CEO and layoffs, Exscientia will merge into Recursion" (fiercebiotech.com).

**AI-native tools and platform providers**, by contrast, license their models to pharmaceutical companies rather than developing their own drugs to approval. **Isomorphic Labs** falls in this category, applying AlphaFold-derived protein structure prediction to partner programs rather than running its own trials. **Chai Discovery**, founded in 2024, exemplifies the fastest-moving version of this model: after a $30 million seed round, a $70 million Series A, and a $130 million Series B in December 2025, the company closed a $400 million Series C in July 2026 at a $3.8 billion valuation, after striking 2026 deals with Eli Lilly, Pfizer, and Novartis, with partners at Index Ventures, Kleiner Perkins, and Sequoia Capital citing "real-world use of the startup's AI by leading drugmakers" as their rationale for investing (fiercebiotech.com). Chai's CEO Joshua Meier characterized the shift as AI drug discovery moving "from promise to deployment" (fiercebiotech.com), and the company backed its claims with a preprint reporting a **16 percent hit rate** in fully de novo antibody design using its Chai-2 model, which it argued was "100-fold better than earlier computational methods" (fiercebiotech.com).

**Big Pharma internal AI infrastructure** represents a third segment. Eli Lilly's approach spans multiple simultaneous efforts: a January 2026 AI co-innovation lab with NVIDIA backed by a commitment of more than $1 billion over five years (fiercebiotech.com), which follows an October 2025 NVIDIA partnership to build what Lilly called the "most powerful" supercomputer in pharma (fiercebiotech.com), layered on top of its external licensing relationships with Insilico, Isomorphic, and Chai. Other pharmaceutical companies have made comparable infrastructure commitments: Roche expanded its own NVIDIA-powered "AI factory" in March 2026 (intuitionlabs.ai), while earlier national deployments such as the United Kingdom's Cambridge-1 supercomputer, built with 640 NVIDIA A100 GPUs, and Japan's Tokyo-1, running 128 H100 GPUs, are cited as evidence of what one analysis called an "AI arms race" in pharma (intuitionlabs.ai). This reflects a broader pattern: rather than choosing between internal AI capability and external partnerships, large pharmaceutical companies are pursuing both simultaneously.

A newer and less predictable entrant to this landscape is general-purpose AI developers moving directly into molecular design rather than licensing tools to biotechs. Anthropic disclosed that its Claude Fable 5 model, built on its Mythos 5 system, "accelerated aspects of the drug design process by around ten times," and reported that the platform "produced promising drug candidates for nine of 14 protein targets, which are being further evaluated," while working autonomously with no human assistance on tasks such as choosing binding sites and running protein design tools (pharmaphorum.com) (pharmaphorum.com). The company also said one model-generated hypothesis, identifying a potential new antimicrobial target in the bacterium *Escherichia coli*, has already been validated in laboratory testing (pharmaphorum.com). Announcements of this kind, from a company not traditionally classified as a life-sciences business, illustrate how the boundary between "AI drug discovery company" and "general-purpose AI lab" is becoming increasingly porous, which complicates any attempt to draw a clean perimeter around the sector for market-sizing purposes and is a further reason headline market-size figures should be treated as directional rather than precise.

# Data Analysis and Evidence

The clinical-trial success-rate evidence for AI-discovered drugs is the single most load-bearing quantitative claim in this space, and it deserves close scrutiny. A 2024 analysis published in *Drug Discovery Today*, authored by Jayatunga and colleagues and widely cited in subsequent industry commentary (accessible in detail via a secondary summary of the study, as the original journal page could not be directly verified during this research), found that among **6,147 drugs** in clinical development as of the study period, only **67 (about 1 percent)** were AI-discovered molecules, and only **24 (0.4 percent)** involved AI-discovered targets, with an even narrower **3 to 9 (0.05 to 0.1 percent)** involving genuinely novel AI-discovered targets. Despite this small sample size, the analysis found that in Phase I trials, "AI-derived molecules can have a success rate of 80-90 percent, which is substantially higher success rates than historic averages," a benchmark notably higher than historical averages where traditional small molecules often faced significant attrition from unforeseen human toxicity or poor bioavailability (2minutemedicine.com), while in Phase II trials, the success rate of AI-discovered molecules was approximately **40 percent, in line with historic industry averages** (quantumbiospace.ai. Proponents connect these safety gains to lower cost, arguing that in silico prediction of absorption, distribution, metabolism, excretion, and toxicity (ADMET) lets researchers eliminate reactive or toxic candidates before physical synthesis, and that "the cost to nominate a preclinical candidate using these methods has been

reported as several orders of magnitude lower than traditional high-throughput screening," with proponents suggesting the savings "may eventually lower the cost of specialty pharmaceuticals if these R&D savings are eventually passed to the healthcare system" (2minutemedicine.com) (2minutemedicine.com).

Integrated across all clinical phases, the same analysis concluded that "the overall probability of a molecule advancing through all clinical phases increases from 5-10 percent to approximately 9-18 percent," which its authors characterized as "a near doubling of pharmaceutical R&D productivity" (quantumbiospace.ai). *Table 2* below summarizes these figures, keeping in mind that all of them rest on a very small underlying sample of AI-associated molecules.

| Metric | AI-Discovered Molecules | Historic Industry Baseline |
|---|---|---|
| Phase I success rate | 80 to 90 percent | 40 to 65 percent |
| Phase II success rate | Approximately 40 percent | Approximately 40 percent (comparable) |
| Share of all clinical-development candidates | Roughly 1 percent (67 of 6,147) | Not applicable |
| Share involving AI-discovered targets | Roughly 0.4 percent (24 of 6,147), narrowing to 0.05 to 0.1 percent for novel targets | Not applicable |
| Integrated probability of eventual approval | Approximately 9 to 18 percent | Approximately 5 to 10 percent |

As the table illustrates, AI's measurable advantage is concentrated almost entirely in Phase I, where safety and tolerability rather than efficacy are assessed; by Phase II, where efficacy becomes the primary hurdle, AI-discovered molecules perform in line with, rather than clearly ahead of, historical norms. It is important to note the sample size caveat inherent in this data: with only 24 to 67 AI-associated molecules in trials against a baseline of over 6,000 traditionally discovered candidates, small-sample statistical noise likely inflates the apparent Phase I advantage, a limitation acknowledged even in outlets promoting the finding, one of which cautioned that "the ultimate test remains whether these molecules will demonstrate superior therapeutic efficacy in larger, more diverse patient populations" (2minutemedicine.com).

Industry commentary from February 2026 offers a useful counterpoint to the optimistic framing of these statistics, noting that "the pharmaceutical industry's persistent ~90 percent failure rate" remains the benchmark AI has not yet definitively beaten at scale (drugtargetreview.com). Scientific commentators have also questioned whether AI fundamentally improves clinical outcomes at all, noting that AI-discovered compounds sometimes show progression rates similar to traditionally discovered molecules, meaning any Phase III success may reflect accelerated timelines rather than genuinely improved efficacy.

On the regulatory side, the FDA's own data shows an "exponential increase in AI uses in submissions since 2016" across therapeutic areas including oncology, neurology, and gastroenterology (intuitionlabs.ai), though the agency has been careful to note this guidance framework applies to AI used to support regulatory decisions, not to AI used purely in early-stage discovery (intuitionlabs.ai). On timelines, McKinsey found that the average window a company has to capture a new drug's commercial value, from launch to loss of exclusivity, has already fallen by nearly 18 months over the past two decades, from 11.7 years to **9.8 years**

(mckinsey.com), a compression McKinsey attributes partly to gen AI's ability to speed identification, development, and marketing of new therapies. Separately, Insilico has publicly stated that its rentosertib program moved from target identification to a clinical candidate in approximately 18 to 30 months, versus a traditional 6 to 8 year timeline for comparable programs, according to industry trackers summarizing the company's own disclosures (pharmanow.live).

# Case Studies and Real-World Examples

## Insilico Medicine: The Furthest-Advanced End-to-End AI Pipeline

Insilico Medicine represents the clearest test case for whether a fully AI-originated drug, from target discovery through molecule generation, can reach approval. The company's rentosertib program is unusual in having generated peer-reviewed documentation across most of the discovery-to-clinic pathway: the original target discovery and preclinical chemistry appeared in *Nature Biotechnology*, the Phase IIa clinical results appeared in *Nature Medicine*, and additional medicinal chemistry detail appeared in the *Journal of Medicinal Chemistry*. Insilico's Chief Scientific Officer, Feng Ren, described the underlying philosophy: "Rentosertib was not discovered by starting from a conventional target and simply screening more compounds. It came from a biology-first, aging-informed AI workflow that connected TNIK to fibrotic and inflammatory disease mechanisms" (prnewswire.com). The company's December 2025 IPO, its shares backed by cornerstone investors including Eli Lilly, Tencent, and Temasek, raised HKD 2.277 billion and was oversubscribed by approximately **1,427 times** in the Hong Kong public offering tranche, a figure the company said set "a record for Hong Kong public offering subscription amount among non-18A healthcare IPOs" that year (prnewswire.com). Beyond its relationship with Lilly, Insilico has stacked additional partnerships in quick succession, including a $100 million-plus research pact with Lilly inked in November 2025 (fiercebiotech.com), a potential $888 million development and discovery pact with Servier (fiercebiotech.com), a $120 million deal with Qilu to develop cardiometabolic disease assets (fiercebiotech.com), and a $66 million agreement to split rights to its Parkinson's asset with Chinese biotech Hengrui Therapeutics (fiercebiotech.com).

## The Recursion-Exscientia Merger: Consolidation After a Difficult Year

Exscientia's path illustrates the volatility even pioneering AI drug discovery firms have faced. The company achieved the historic milestone of the first AI-designed drug to enter human clinical trials, a milestone one drug-development database called "a pivotal moment in AI drug discovery": **DSP-1181**, an obsessive-compulsive disorder (OCD) candidate developed with Sumitomo Dainippon Pharma, began a Phase 1 trial in Japan in January 2020 (cas.org) (cas.org) (sumitomo-pharma.com). Despite this landmark status, DSP-1181 was later discontinued after Phase I, "despite a favorable safety profile," according to a drug-development database, underscoring that speed of discovery does not guarantee clinical success (synapse.patsnap.com). By 2024, after "a year defined by pipeline cuts, the departure of its CEO, and layoffs" that followed the firing of CEO Andrew Hopkins over conduct the board deemed "inappropriate and inconsistent" with company values, and a 25 percent workforce reduction in May of that year, Exscientia agreed to merge into Recursion

Pharmaceuticals (fiercebiotech.com). Recursion CEO Chris Gibson framed the combination as being "deeply complementary and aligned with our missions to industrialize drug discovery to deliver high quality medicines and lower prices for consumers" (fiercebiotech.com). The combined company retained more than 60 petabytes of proprietary data and set a goal of "eventually creating virtual cells that will allow the company to execute clinical trials at scale" (ir.recursion.com). At the time, the deal's size made it the largest M&A transaction among AI-focused drug discovery companies, surpassing BioNTech's $540 million acquisition of InstaDeep, Cadence Design Systems' $500 million takeover of OpenEye Scientific, and Ginkgo Bioworks' $300 million purchase of Zymergen (pharmaphorum.com).

## Isomorphic Labs: Betting on Protein Structure Prediction at Scale

Isomorphic Labs, spun out of Alphabet and built on Google DeepMind's Nobel Prize-associated AlphaFold protein-structure-prediction technology, took a licensing rather than clinical-development approach, striking deals with Eli Lilly and Novartis worth nearly $3 billion combined within roughly two years of the company's launch (fiercebiotech.com). The company itself described the agreements as "testament to Isomorphic's approach to drug design and the progress we are making," while noting that "newer iterations of AlphaFold are expanding beyond protein predictions to include small molecules and nucleic acids" (isomorphiclabs.com) (fiercebiotech.com). As a purely software-and-modeling licensor rather than a clinical-stage biotech, Isomorphic's success will ultimately be judged by whether its partners' pipeline candidates, not disclosed publicly by name at the target level, eventually reach clinical trials and approval.

## BenevolentAI: A Cautionary Tale of Clinical Failure

Not every AI drug discovery story is one of momentum. BenevolentAI, a London-based company that positioned itself as "a new, better type of biotech" with an AI platform "capable of increasing the likelihood of clinical success," saw its lead asset, a topical pan-Trk inhibitor called BEN-2293 for eczema, fail a Phase 2a trial (fiercebiotech.com). Fierce Biotech reported the company "has run into the same problems that its peers have faced since the dawn of the industry, as preclinical promise has failed to translate into clinical efficacy" (fiercebiotech.com). The company subsequently laid off up to **180 staff**, roughly half its workforce of 363 permanent employees, reduced its laboratory footprint, and narrowed its pipeline to focus on its PDE10 inhibitor BEN-8744 and CHK1 inhibitor BEN-28010, expecting to cut costs by approximately $56 million (45 million pounds sterling) (fiercebiotech.com) (fiercebiotech.com). This case is instructive because it demonstrates that AI's advantage, to the extent it exists, appears concentrated in early discovery and Phase I safety, precisely where BenevolentAI's platform performed as advertised, while the harder problem of proving efficacy in Phase 2 and beyond remains largely unresolved by current AI methods, a pattern consistent with the Jayatunga Phase I versus Phase II data discussed above.

## Takeda's Zasocitinib: The Attribution Problem in Miniature

The zasocitinib case, discussed above in the clinical pipeline section, deserves treatment as its own case study because it crystallizes a recurring theme across this report: the difficulty of cleanly attributing a drug's success to "AI." Zasocitinib originated from a **2016** collaboration between Nimbus Therapeutics and Schrödinger using free energy perturbation, a physics-based computational chemistry method that

Schrödinger's own CEO has characterized in terms that de-emphasize the "AI" framing, warning against treating AI "like pixie dust," with the view that "the physics is the meal and the machine learning is somewhere closer to garnish" (aiinlabcoat.com). Takeda paid **$4 billion upfront** in 2023 to acquire Nimbus's TYK2 subsidiary outright, a wager that "looks a lot less insane" in hindsight given the June 2026 Phase III head-to-head win (aiinlabcoat.com). For context, Sotyktu's own pivotal trials put complete skin clearance at roughly 10 to 14 percent, so zasocitinib's reported 35 percent-plus PASI 100 rate represents a real and clinically notable gap even if its computational-chemistry lineage complicates the "AI-discovered" framing, per the same industry commentary cited above. Whether this counts as an "AI-discovered drug" for the purposes of answering the query behind this report depends entirely on how strictly one defines the term, illustrating why single-number answers to "how many AI drugs are approved" should always be read alongside their methodology.

# Implications and Future Directions

Several forward-looking implications follow from the evidence assembled in this report. First, **regulatory clarity is arriving on a parallel but distinct track from clinical validation**. The FDA is expected to finalize its draft AI guidance sometime in 2026, and the European Union's AI Act high-risk provisions were due to take effect August 2, 2026 (the Digital Omnibus on AI, Regulation (EU) 2026/1744, has since postponed them to December 2, 2027 for Annex III systems and August 2, 2028 for AI in regulated products (EUR-Lex)), potentially classifying some drug-development AI as high-risk and imposing new documentation requirements on sponsors (drugtargetreview.com). In June 2026 the EU gave final approval to a simplification package that moves those dates to December 2, 2027 for stand-alone high-risk AI systems and August 2, 2028 for high-risk AI embedded in products (consilium.europa.eu). Because the FDA's current draft guidance explicitly excludes early-stage discovery AI from its scope, most of the platforms discussed in this report, PandaOmics, Chemistry42, AlphaFold-derived modeling, and Chai's molecular design models, sit outside the perimeter of what the agency is actively regulating, even as the molecules they help produce eventually must satisfy ordinary safety and efficacy standards once in the clinic (intuitionlabs.ai).

For sponsors preparing to rely on AI in a regulatory submission, IntuitionLabs' own summary of the guidance describes a seven-step credibility framework whose stages proceed roughly as follows:

- **Define the question of interest:** identify the specific decision or parameter the AI model is meant to address.
- **Define the context of use:** specify how the model's output will be applied, and whether it will act as a primary decision-maker, a decision support, or an alert reviewed by a human.
- **Assess model risk:** evaluate risk as a function of the model's influence over the decision and the consequence of an incorrect result.
- **Develop a credibility assessment plan:** outline the evidence, data sources, and performance criteria that will be used to demonstrate reliability.
- **Execute the credibility plan:** carry out the validation activities, engaging the FDA proactively where the model is high-risk.
- **Document the results:** compile a report establishing the model's credibility for its stated context of use.
- **Determine adequacy:** decide whether the model is fit for purpose, or whether additional evidence must be collected before it can support a regulatory decision.

Sponsors developing AI-associated drug candidates, regardless of which discovery platform originated the molecule, will need to navigate this framework once their AI outputs are intended to support an actual regulatory decision rather than purely internal discovery work.

Second, **timing expectations for a first approval should be treated with caution**. Industry analysis from February 2026 concluded that "if regulatory submissions proceed in 2026 and receive FDA priority review, approval could occur in late 2026 or early 2027," but added that "a more realistic timeframe for first approval is 2027-2028" (drugtargetreview.com). Takeda's zasocitinib now fits the earlier scenario: its New Drug Application was accepted under Priority Review in September 2026, with a target action date in the first quarter of 2027 (takeda.com). Until a first approval occurs, the entire field arguably remains in a proof-of-concept phase, since no amount of partnerships, funding rounds, or conference presentations substitutes for regulatory approval and commercial success. A useful way to weigh these odds: if Insilico's Phase III GENESIS-IPF-3 trial replicates its Phase IIa dose-dependent lung-function signal in a larger 320-patient population, it would represent the first placebo-controlled Phase III confirmation of a disease target discovered and a molecule designed by generative AI. A null or marginal result would not necessarily indict AI drug discovery as a category, since single Phase III failures are common even for conventionally discovered candidates, but it would remove the strongest available evidence that AI-associated programs can move beyond safety and into efficacy. Zasocitinib's path illustrates a parallel but distinct stake: plaque psoriasis, the specific subtype Takeda's drug targets, affects roughly 80 to 90 percent of the estimated **64 million people** living with psoriasis worldwide (takeda.com), so a successful U.S. approval would be commercially significant regardless of how much credit computational chemistry deserves for the molecule's design. For consultancies advising clients on where to focus regulatory-strategy attention, both readouts are worth monitoring closely over the next 12 to 18 months, independent of which company ultimately claims the "first" AI-discovered approval.

Third, **market consolidation and financial discipline appear likely to accelerate** even as headline valuations for the best-capitalized companies continue to climb. BenevolentAI's near-halving of headcount and Exscientia's absorption into Recursion after a leadership crisis both illustrate this pattern, and consultancies advising life-sciences clients should expect further consolidation among mid-tier AI drug discovery firms even as capital continues flowing to category leaders such as Insilico, Isomorphic, and Chai. Novartis chemist Derek Lowe has argued that AI's genuine strengths track closely with how simple and well-structured the underlying data are, observing that "proteins have a much more limited vocabulary. There's only 20-odd words in the language, and the grammar is also pretty repetitious, too," which is why protein-structure models such as AlphaFold work well, whereas small-molecule chemistry data are often messier: Lowe has separately described the synthetic organic chemistry literature itself as reflecting "products that are on the shelf" and researchers' habitual techniques as much as underlying chemical truth (bio-itworld.com) (bio-itworld.com). Lowe predicted the current hype cycle will only end once "a lot of people get really pissed off and abandon the field," calling that "the natural end of the hype cycle" for prior technology waves in drug discovery (bio-itworld.com).

Fourth, from an advisory perspective, organizations navigating this landscape, including consultancies such as IntuitionLabs that advise pharmaceutical and life-sciences clients on AI strategy and regulatory positioning without themselves developing or selling drug candidates, are best served by distinguishing carefully between AI's demonstrated strengths (accelerating early discovery, compressing preclinical timelines, and improving Phase I safety signal detection) and its unproven claims (materially improving the probability that a molecule

survives Phase II and Phase III efficacy testing). IntuitionLabs' own analysis of pharma AI infrastructure investment notes that "several pharmaceutical products are already in development with AI-derived designs," even as the fundamental economics of drug development, an average cost exceeding $2 billion and a 90 percent clinical failure rate, remain largely unchanged (intuitionlabs.ai).

Finally, the persistent gap between AI's demonstrated Phase I advantage and its unproven Phase II/III performance suggests that **the industry's most valuable AI application over the next 24 months may prove to be clinical trial design and patient recruitment rather than molecule generation itself**, an area where McKinsey documented concrete, already-realized gains of up to 50 percent cost reduction in clinical trial data management and a 12-plus month acceleration in trial duration (mckinsey.com).

# Frequently Asked Questions (FAQs)

**Has AI discovered any FDA-approved drugs?** No. As of October 2026, no drug whose target and molecule were both discovered using artificial intelligence has received FDA approval. The furthest-advanced case, Insilico Medicine's rentosertib, entered Phase III with a trial initiated on July 7, 2026 and a first patient dosed on September 9, 2026 (prnewswire.com), while Takeda's zasocitinib, sometimes labeled an "AI-designed pill," is under FDA Priority Review with a target action date in the first quarter of 2027 (takeda.com) but originated through physics-based computational chemistry against an already-validated target rather than AI-driven target discovery (takeda.com).

**Why hasn't AI discovered a drug yet, given the level of investment?** Multiple factors converge: AI has demonstrated a genuine advantage in Phase I safety (an 80 to 90 percent success rate versus historic averages of 40 to 65 percent), but its Phase II efficacy success rate of roughly 40 percent is statistically indistinguishable from the historic industry baseline (quantumbiospace.ai). Novartis chemist Derek Lowe argues the core bottleneck, poor target selection and human toxicity prediction, is "not due to a lack of ambition, but a lack of predictive insight," and that these are "the two things that kill most of the [drug discovery] programs" (bio-itworld.com), a limitation current AI models have not solved.

**How much has been invested in AI drug discovery?** The global AI drug discovery market was valued at $6.93 billion in 2025 (precedenceresearch.com), while BCC Research separately counted more than $2 billion in recent investment activity (finance.yahoo.com), and GlobalData counted 168 AI-related strategic alliances signed across the industry in 2025 (chemdiv.com).

**What is the success rate of AI-discovered drugs in clinical trials?** According to the most frequently cited academic analysis, 80 to 90 percent in Phase I and approximately 40 percent in Phase II, an integrated all-phase approval probability of roughly 9 to 18 percent versus a historic baseline of 5 to 10 percent, as detailed in the Data Analysis section above.

**What are Insilico Medicine's clinical trial results?** Insilico's rentosertib showed a mean forced vital capacity improvement of +98.4 mL at 12 weeks in the 60 mg once-daily arm of its Phase IIa trial, versus a decline of 20.3 mL for placebo, meeting the minimal clinically important difference threshold reported for FVC in idiopathic pulmonary fibrosis (nature.com). The drug has since advanced into a 320-patient Phase III trial, GENESIS-IPF-3, which dosed its first patient on September 9, 2026 (prnewswire.com).

**Which generative AI drug discovery companies have the largest pipelines?** Insilico Medicine, with more than 30 programs and 7 in active clinical development as detailed above, and the combined Recursion-Exscientia entity (more than 10 clinical and preclinical programs, plus more than 10 partnered programs) (ir.recursion.com) are the two largest publicly disclosed pipelines as of mid-2026.

**What is the typical timeline from AI-assisted discovery to a clinical candidate?** Insilico Medicine has cited roughly 18 to 30 months for its IPF program, versus a traditional 6 to 8 year timeline (pharmanow.live), while BCC Research's broader market analysis cites AI compressing "4-5 years to 12-18 months" across the sector more generally (finance.yahoo.com).

# Conclusion

The evidence assembled in this report supports a clear, if unglamorous, answer to the query at its center: as of October 2026, artificial intelligence has not yet produced an FDA-approved drug, despite billions of dollars in investment, dozens of clinical-stage programs, and a decade of escalating claims from the sector. The clearest end-to-end case, Insilico Medicine's rentosertib, has progressed further than any comparable program, reaching Phase III trials in idiopathic pulmonary fibrosis after peer-reviewed Phase IIa results published in *Nature Medicine*. Takeda's zasocitinib is closer to an FDA decision, with its New Drug Application under Priority Review and a target action date in the first quarter of 2027, but its scientific lineage in physics-based computational chemistry against an already-known target complicates any claim that it represents genuine AI-driven drug discovery in the fullest sense.

The quantitative record is genuinely mixed rather than uniformly positive or negative. AI-discovered molecules do appear to clear Phase I safety hurdles at meaningfully higher rates than historical averages, a real and measurable advantage. But that advantage largely disappears in Phase II, where efficacy, not safety, is the primary hurdle, and where AI's ability to predict human biological response remains unproven at scale. This pattern is consistent with the skepticism voiced by veteran medicinal chemists, who argue that target selection and toxicity prediction, not molecule generation speed, remain the central bottlenecks in drug development.

For life-sciences organizations and their advisors, the practical implication is to treat AI drug discovery claims with the same evidentiary discipline applied to any other pharmaceutical marketing claim: distinguish vendor assertions from independently measured outcomes, track named clinical programs rather than platform-level narratives, and recognize that regulatory clarity (through the FDA's evolving AI guidance) and clinical validation (through Phase III readouts) are running on separate but related tracks. The most consequential events for this question over the next 12 to 24 months will not be additional funding announcements or platform unveilings, but the specific Phase III data readouts from Insilico's rentosertib program and the FDA's decision on Takeda's zasocitinib application. Until one of these, or a comparable program, clears an actual FDA approval, the field remains, in the words of one industry analyst, in a proof-of-concept phase where partnerships and funding rounds cannot substitute for regulatory and clinical success.

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IntuitionLabs is an AI consulting, custom software development and data engineering firm serving pharmaceutical, biotechnology, medical-device and other life-science organizations. We work with clinical, regulatory, medical-affairs, commercial, quality and IT teams to connect technology decisions with the work people need to accomplish.

### AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

### Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

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We provide Veeva services, application support, managed services, integrations and custom applications, alongside enterprise content work involving platforms such as Egnyte. For regulated workflows, our services include GxP enablement, computer-system validation and software development addressing 21 CFR Part 11 requirements. The applicable controls, validation responsibilities and acceptance criteria are defined for each engagement.

### Work with IntuitionLabs

Explore AI enablement, pharma and biotech software development, data engineering and BI, and Veeva services. Contact IntuitionLabs to discuss your workflow, information sources and implementation needs.

IntuitionLabs publishes educational research to help life-science teams make informed technology decisions. Coverage of a product or organization does not imply a client relationship, endorsement or partnership.

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