



E L E G E N

INNOVATION IS OUR DNA

Elegen is breaking new ground in the biotech industry with its cell-free manufacturing approach to synthetic DNA production. By manufacturing made-to-order DNA with an unprecedented combination of sequence length, complexity, accuracy, and speed, Elegen is accelerating upstream research and discovery as well as downstream clinical scaleup workflows to revolutionize genetic medicine development.

In January 2024 the company announced a collaboration and licensing agreement with pharmaceutical giant GSK. This partnership underscores the recognition of Elegen's cell-free DNA manufacturing technology as a transformative tool in drug and vaccine development. By leveraging Elegen's capabilities, GSK aims to accelerate the development of its medicines and vaccines, validating Elegen's vision to revolutionize genetic medicine and mRNA vaccine development.

More recently (May 2024), the company closed on a Series B financing round of \$35 million, which included strategic investment by GSK and John Ballantyne, co-founder of Aldevron, a CDMO focused on scaleup of high-quality DNA for clinical applications. The new funds will accelerate the extension of the company's ENFINIA™ DNA product line to clinical DNA manufacturing with turnkey production of GMP-compliant DNA for genetic medicine development. Said Founder and CEO Matthew Hill, Ph.D., "The investment validates the differentiation of Elegen's platform, which enables a significant increase in throughput and scalability while eliminating conventional DNA synthesis limitations, cell-based contamination, and days to weeks of hands-on cloning time for researchers."

What makes Elegen's DNA synthesis platform unique?

Elegen's next-gen DNA manufacturing platform is entirely cell-free and represents a disruptive shift forward from the conventional decades-old cell-based synthesis and cloning methods that have been a cornerstone of the DNA synthesis industry.

Elegen's platform combines systems engineering principles with innovations in molecular biology, chemistry, and microfluidics. This enables the company to produce long, complex, high-accuracy DNA on a much faster timeline than traditional manufacturers. Elegen's novel cell-free manufacturing process yields long, complex DNA with 95% sequence-perfect purity, eliminating the need for additional cloning and purification steps.

Conventional gene synthesis using DNA made either chemically or enzymatically requires researchers to compromise on length, complexity, and accuracy for speed. While the compromise provides researchers with DNA quickly, it forces them to compensate for the lower quality by adding days or weeks of their own

time and resources cloning to arrive at the sequence-perfect DNA they really need.

The ability to receive custom DNA at the length, complexity, and accuracy needed within just 6 to 8 business days, requiring no or very minimal cloning, is a game-changer in the biopharma industry. In fields like mRNA vaccines, gene therapies, and personalized medicines, Elegen's high-quality synthetic DNA and rapid delivery can significantly accelerate the pace of discovery and development.



**Matt Hill, PhD/Founder
& Chief Executive Officer**



Elegen and GSK Sign Collaboration and Licensing Agreement to Further Develop Elegen's Cell-Free DNA Production Technology. -Elegen Press Release, Jan 24, 2024

Tell us more about your ENFINIA™ DNA product

Elegen commercially launched ENFINIA™ DNA in March 2023. Customers currently can order DNA at lengths up to 7,000 base pairs, though the company has successfully synthesized DNA more than double that length and shipped it to early access customers. Elegen's DNA synthesis platform technology has an accuracy that is 20 times higher than competitors, which is verified by NGS prior to shipment to ensure reliability. The company began offering options for higher synthesis scale—or mass—in early Q4 2023.

In March 2024, Elegen further expanded its ENFINIA™ DNA synthesis service to tackle even the most challenging sequences, including those with high or low GC content, long hairpins, and long repeat regions. These sequences, often rejected by other suppliers or taking months to synthesize, can now be obtained in as few as 10 days through Elegen's innovative process.

By drastically reducing the time and resources required for DNA synthesis, assembly, and cloning, ENFINIA™ DNA accelerates the design-build-test-learn (DBTL) cycle at the heart of molecular biology workflows.

Unlike conventional DNA suppliers that may focus on metrics like cost per base or turnaround time, Elegen recognizes that the real value lies in streamlining the entire workflow. ENFINIA™ DNA not only shortens the "build" phase of the DBTL cycle but also eliminates the need for additional assembly, cloning, or manipulation, saving researchers weeks or even months of development time, resources, and costs.

How are Elegen's innovations leading your industry forward?

Elegen's ENFINIA™ DNA is not just a product—it's a catalyst for innovation, empowering researchers to focus more on research and less on the logistics of DNA synthesis and cloning. By reducing barriers to accelerate the pace of development, Elegen is helping to bring groundbreaking discoveries to market faster, benefitting both research and clinical development.

Research and Discovery. A description of the typical research lab paradigm helps highlight the challenges inherent in the traditional methods of obtaining synthetic DNA: third-party providers, relying on outdated or limited synthesis technologies, often deliver DNA with shortcomings in sequence length, complexity, and accuracy. To overcome these limitations and obtain longer, higher quality DNA constructs, labs have resorted to costly and time-consuming alternatives such as custom clonal DNA synthesis services or internal "biofoundry" teams. These approaches add weeks of time plus additional costs to the research and discovery process.

Elegen's ENFINIA™ DNA disrupts this paradigm by delivering DNA with the required length, complexity, accuracy, purity, and speed for immediate use in workflows. Unlike DNA supplied by conventional third-party suppliers, ENFINIA™ DNA typically requires no further assembly, cloning, or purification, enabling labs to iterate faster and advance innovations more quickly. This not only improves efficiency but also reduces development costs and accelerates time-to-market.

Pre- / Clinical Development. There's a bottleneck in DNA supply not only in the upstream discovery stage of genetic medicines but also in the downstream processes of pre-clinical and clinical development.

Traditional large-scale production of DNA involves fermentation in *E. coli* strains, which is a labor-intensive, time-consuming, and expensive bottleneck for all advanced genetic medicines.

Here too the industry uses a decades-old technology of cell-based vat fermentation to scale up master cell banks of DNA for preclinical and clinical use. *E. coli* strains introduce tons of variability and dangerous contaminants, endotoxins, infection agents, etc.

Master cell banks require 6-12 months of careful process development



Marc Unger, PhD
Chief Scientific Officer



Dan La Caze
Chief Business Officer

Where do you envision Elegen in the next five years?

Elegen’s strategic roadmap for the future outlines several key initiatives aimed at furthering their impact and expanding their reach in the industry.

Partnerships with Big Pharma:

Building on the success of its collaboration with GSK, Elegen plans to partner with other biopharmaceutical companies. These relationships not only support the development of enhancements and new products but also validate Elegen’s technology and capabilities on a larger scale.

Manufacturing Expansion:

Elegen intends to scale ENFINIA™ DNA production to support their rapid growth in the US and expansion into the EU and APAC regions. Additionally, the company is exploring opportunities to embed their manufacturing technology within partnering organizations.

Cell-Free Clinical Therapeutics Scale-Up:

Elegen’s cell-free DNA production process offers significant advantages for biopharmaceutical companies, CDMOs, and CMOs involved in clinical therapeutics scale-up.

In gene therapy development, for example, scaling DNA candidates for preclinical testing traditionally involves a lengthy and expensive process in a dedicated cGMP facility. Elegen’s cell-free process eliminates the need for bacterial cell clean-up, ensuring a safer, more efficient, and faster production process. This streamlined approach promises to accelerate the pace of genetic therapy development,

ultimately leading to faster deployment of personalized genetic therapies.

Elegen’s future initiatives demonstrate its commitment to advancing genetic medicine on a global scale.

More about the leadership

Matt Hill, CEO, holds a Ph.D. in genetics from Stanford and was previously Vice President of Research and Development at Natera, where he co-invented their core technology and led the commercialization of five precision molecular diagnostic products, which enabled Natera’s 2015 IPO. He founded Elegen in 2017 to solve DNA writing and unlock the synthetic biology revolution.

Marc A. Unger, CSO, received his Ph.D. in physical chemistry at Caltech. During a postdoc he invented Multilayer Soft Lithography, the foundational technology of Fluidigm Corporation, where he served in multiple roles growing the company, including CSO. During his tenure the company did an IPO and achieved product revenues greater than \$100M per year.

Dan La Caze, CBO, has an MS in Biology from UCSD and an MBA from London Business School. His corporate and business development roles at life science and molecular diagnostics companies have led to over 100 strategic transactions on both the buy- and sell-side, where he has developed successful corporate strategies for small- and medium-sized biotechnology companies with disruptive technologies.

and characterization test runs with intensive process monitoring and GMP-based quality control, and cost from \$500,000 to millions of dollars depending on batch size.

Elegen’s technology manufactures long, complex, NGS-verified synthetic DNA without the use of cells, providing the opportunity for a faster and smoother scale-up of GMP-compatible DNA production for clinical testing.

As it stands now, Elegen is the only DNA manufacturer with the potential to supply biopharma with a reliable supply of gram-scale DNA produced entirely cell-free, from raw nucleotides to scaled-up, ready-to-use, full-length linear DNA.

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