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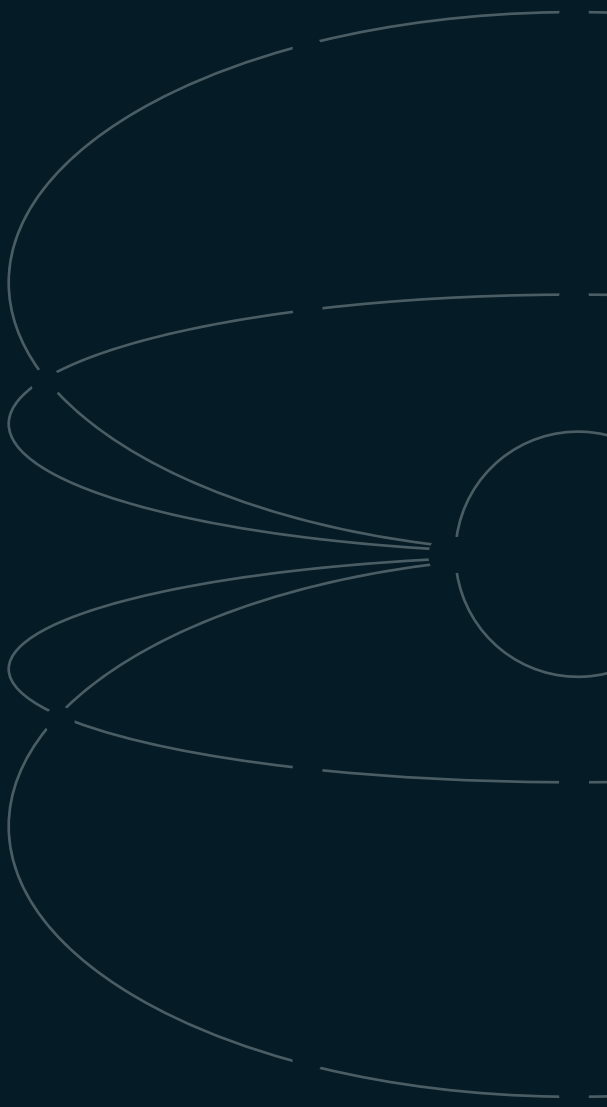
The Next Frontier For RNA May Not Be Another Injection



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The Next Breakthrough in RNA Therapeutics May Come From Formulation Scientists

The success of mRNA vaccines transformed how the industry thinks about medicine. For the first time, we could instruct cells to manufacture therapeutic proteins directly inside the body. The implications were enormous. Nearly overnight, RNA moved from a promising technology to one of the most important platforms in biotechnology.

Since then, most of the industry's attention has focused on the biology. New targets, new constructs, new payloads, and new therapeutic applications have dominated the conversation.

Yet biology may no longer be the primary bottleneck.

The next breakthrough in RNA therapeutics may come from formulation scientists.

The Industry Has Learned How to Make RNA

A decade ago, simply manufacturing mRNA at scale was a significant challenge. Today, that problem is largely solved. Companies can reliably design, synthesize, and manufacture increasingly sophisticated RNA constructs.

As the technology has matured, the industry's challenge has shifted. The question is no longer whether we can make RNA.

The question is whether we can deliver it.

Every RNA therapeutic faces the same fundamental challenge. The payload must reach the right tissue, enter the right cells, avoid degradation, escape the endosome, and remain intact long enough to produce a therapeutic effect.

For respiratory diseases, that challenge becomes even more complex.

The Lung Is an Attractive Target and a Difficult One

For diseases that originate in the lung, systemic delivery has always carried an inherent inefficiency. Large quantities of therapeutic material are administered throughout the body in order to reach a localized site of disease.

Inhaled delivery offers an elegant alternative. Deliver the therapeutic directly to the tissue where it is needed.

The logic is compelling. The execution is not.

RNA must survive aerosolization. Particles must navigate mucus barriers and pulmonary clearance mechanisms. The formulation must deposit in the appropriate region of the lung while maintaining biological activity. Even after successful deposition, the therapeutic still faces the intracellular barriers that challenge every RNA platform.

The science is difficult enough that only a handful of companies have advanced inhaled mRNA programs into clinical development.

That is precisely why the field has become so interesting.

The Real Opportunity May Be in the Powder

Most inhaled RNA programs today rely on liquid formulations administered through nebulizers. This approach has enabled important clinical progress, but it also carries limitations.

Cold-chain logistics remain challenging. Administration times can be lengthy. Devices can be cumbersome. Manufacturing and distribution costs remain significant.

Spray drying introduces a different possibility.

Rather than treating RNA as a fragile liquid formulation, scientists can engineer inhalable particles with defined aerodynamic properties, controlled moisture content, and the potential for significantly improved stability.

At first glance, this sounds like a manufacturing discussion.

It is not.

It is a product strategy discussion.

Because the ability to transform an RNA therapeutic into a stable inhaled powder could ultimately be the difference between a promising clinical program and a commercially viable medicine.

The Future May Depend on Particle Engineering

Historically, biotechnology breakthroughs have been associated with biology. New targets. New mechanisms. New molecular designs.

The next wave of innovation may come from a different discipline.

Particle engineering is rapidly becoming one of the most important enablers of advanced therapeutics. The ability to control where a particle deposits, how it disperses, how it

interacts with biological barriers, and how it maintains stability may ultimately determine which RNA therapies reach patients.

In many ways, this mirrors the evolution of poorly soluble small molecules. Once the biology was understood, formulation became the limiting factor.

RNA appears to be following a similar path.

What Comes After Cystic Fibrosis

Many of today's inhaled mRNA programs are focused on cystic fibrosis, where the therapeutic rationale is clear and the unmet need is substantial.

But cystic fibrosis is unlikely to be the endpoint.

If inhaled RNA delivery becomes reliable, the implications extend far beyond a single disease. The technology could enable localized protein expression for a wide range of pulmonary disorders, potentially reducing systemic exposure while improving therapeutic effectiveness.

That possibility is what makes the field so compelling.

The industry is understandably excited about what RNA can do.

The more important question may be whether we can reliably get it where it needs to go.

And if that challenge is solved, the next chapter of RNA therapeutics may be written not by molecular biologists, but by formulation scientists.

About Forma

Forma Life Sciences is a U.S. based contract development and manufacturing organization (CDMO) specializing in oral solid dosage formulation development, clinical manufacturing, and commercial drug product manufacturing. Headquartered in Irvine, California, Forma operates two cGMP facilities totaling more than 100,000 square feet and 27 GMP manufacturing suites, with capacity to produce over two billion tablet and capsule units annually. The company supports pharmaceutical and biotechnology partners from early clinical development through commercial scale production and offers expertise in spray-dried dispersion, amorphous solid dispersion systems, fluid bed granulation, and modified-release formulation technologies.