

RNA therapeutics have entered a defining phase.

What began as a scientific breakthrough has evolved into a highly competitive, capital-intensive space. The success of mRNA vaccines has accelerated global investment, expanded pipelines, and positioned RNA as a transformative modality across multiple therapeutic areas.

Critical Challenge:

Many RNA programs fail not due to weak science, but because of an incomplete understanding of how therapies behave in the human body.

1 The Shift: From Molecular Design to Biological Performance

Past Focus:

- Sequence optimization
- Stability improvements
- Protein expression efficiency

Current Question:

How does RNA behave in real biological systems?

Biological Realities:

- Dynamic protein environments
- Immune system interactions
- Organ-specific barriers

Key Insight:

The success of an RNA therapy is defined less by its design and more by how it performs inside the body.

2 The Biological Layer Most Teams Underestimate

RNA delivery systems, particularly lipid nanoparticles (LNPs), evolve after administration.

Interactions can:

- Modify surface properties
- Influence tissue distribution
- Trigger or suppress immune responses

Implications:

- Preclinical results may not translate directly
- Small formulation differences can lead to major outcome changes
- Predictability remains a major industry gap

3 The Translation Gap: Why Promising Programs Stall

Challenges moving from controlled environments to human systems:

- Variability in patient biology
- Inconsistent delivery efficiency
- Limited understanding of in vivo behavior

Impact:

- Delayed clinical timelines
- Increased development costs
- Repeated reformulation cycles

Key Insight:

The biggest bottleneck in RNA is not discovery, it is translation.

4 Delivery Remains the Defining Challenge

Current delivery systems perform well in limited contexts.

Challenges expanding beyond conventional use:

- Tissue-specific targeting
- Controlled biodistribution
- Minimizing off-target effects

Industry Reality:

Achieving consistent and precise delivery across multiple tissues remains one of the most critical challenges in RNA therapeutics.

5 The Next Frontier: Beyond Conventional Targets

Future RNA applications require:

- Access to immune cells
- Penetration into solid tumors
- Delivery across complex biological barriers

Resulting challenges:

- Greater design complexity
- Higher regulatory scrutiny
- Need for advanced delivery strategies

Key Insight:

The next wave of RNA innovation will be defined by where therapies can reach—not just what they encode.

6 Strategy Shift: Integration Over Isolation

Traditional Model:

Discovery → Development → Manufacturing → Regulatory

Emerging Model:

Integrated, parallel decision-making with early collaboration and cross-functional alignment

Key Insight:

Success depends on aligning science, strategy, and execution from the very beginning.

7 Asia's Growing Role in RNA Advancement

Key Drivers:

- Strong government investment
- Expanding biotech infrastructure
- Faster clinical execution timelines
- Growing number of specialized partners

Key Insight:

Asia is emerging as a critical hub for RNA development and commercialization.

8 What Leading Companies Are Doing Differently

Shared Strategies:

- Building integrated platforms
- Prioritizing delivery and clinical outcomes
- Investing in scalable systems
- Aligning early with partners and regulators

Examples:

- **Moderna** – Platform-driven development
- **BioNTech** – End-to-end RNA capabilities
- **Alnylam Pharmaceuticals** – Sustained clinical success

Key Insight:

Competitive advantage is shifting from innovation alone to execution capability.



Norihiko Shiraishi
Chief Scientific Officer,
NANO MRNA Co., Ltd., Japan



Janya Grainok
Chief Scientific Officer,
PYC Therapeutics, Australia



Dr. Ya-Shan Chuang
Director of Medical Affairs,
Immunwork, Taiwan



Adam Zhao
Chairman & CEO,
Anlong Bio Inc., China



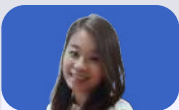
Bo Ying
Founder, Chairman & CEO,
Abogen Biosciences, China



Jia-Ming Chang
CEO, Vacino Biotech, Taiwan



Jagadish Sankaran
Senior Scientist,
A*STAR, Singapore



Crystal Lau
Senior Director CMC,
MSD, Singapore



Madhavan Nallani
Founder & CEO,
ACM Biolabs, Singapore



Dr. Tomoya Takenaka
Principal Scientist, Drug Product
and Device Development, Takeda
Pharmaceutical Company, Japan



Mohamed ElSayed
Executive Director,
Nucleic Acid Therapeutics
Initiative (NATI), Singapore



Prof. Rakesh Veedu
Professor, Murdoch University, Founder
& CTO, SynGenis Pty Ltd. Co-Founder
& MD/CEO, ProGenis Pharmaceuticals



Volker Patzel
Assistant Professor,
National University of Singapore,
Singapore



Xuezhi Bi
Senior Principal Scientist,
Group Leader (Protein Analytics),
Bioprocessing Technology Institute,
A*STAR, Singapore



Janise Chevrier-Lee
Country Medical Director Singapore,
Roche Singapore Pte Ltd to ebock.



Yasumasa Ota
mRNA technology Leader,
Meiji, Japan



Kim Seokjoong
CSO, BreezeBio



Wonil Kim
CSO, Aston Sci.



Poon Hung Fai
CEO, Sirnaomics



Xian Zeng
CEO & Founder,
Byterna Therapeutics



Jin Li
Head of Research Department,
CanSino (Shanghai) Biological
Research Co., Ltd, China



Arvind K Jain
Deputy General Manager,
R&D – mRNA Vaccines,
Biological E. Limited, India

Focus Areas: > Delivery technologies > Clinical translation > Strategic partnerships

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Investment Landscape: A Shift Toward Execution

Capital is flowing toward:

- > Delivery technologies
- > Scalable platforms
- > Late-stage development programs
- > AI-enabled optimization

Deprioritized:

Early-stage, non-differentiated approaches

Key Insight:

Investors are prioritizing execution readiness over theoretical innovation.

Implications for Biopharma

To remain competitive:

- > Design with biological performance in mind
- > Integrate delivery strategy early
- > Align regulatory pathways from the start
- > Collaborate across the ecosystem

Critical Gap:

Treating delivery as a secondary step rather than a core strategy

Implications for CDMOs

Beyond manufacturing, companies now seek:

- > Formulation expertise
- > Development guidance
- > Faster clinical readiness
- > Integrated service offerings

Key Insight:

The most valuable CDMOs are those that contribute to outcomes, not just capacity.

The Road Ahead

RNA therapeutics will expand across:

- > Oncology
- > Rare diseases
- > Vaccines
- > Genetic disorders

Success will depend on:

- > Precision in delivery
- > Consistency in outcomes
- > Speed of development
- > Strength of partnerships

Key Insight:

The future of RNA will be defined by the effectiveness of translating science into real-world impact.

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CONFIRMED SPEAKERS



Norihiko Shiraishi

Chief Scientific Officer,
NANO MRNA Co., Ltd., Japan



Janya Grainok

Chief Scientific Officer,
PYC Therapeutics, Australia



Dr. Ya-Shan Chuang

Director of Medical Affairs,
Immunwork, Taiwan



Adam Zhao

Chairman & CEO,
Anlong Bio Inc., China



Bo Ying

Founder, Chairman & CEO,
Abogen Biosciences, China



Jia-Ming Chang

CEO, Vacino Biotech, Taiwan



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Dr. Tomoya Takenaka

Principal Scientist, Drug Product
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Mohamed ElSayed

Executive Director,
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Prof. Rakesh Veedu

Professor, Murdoch University; Founder
& CTO, SynGenis Pty Ltd; Co-Founder
& MD/CEO, ProGenis Pharmaceuticals



Volker Patzel

Assistant Professor,
National University of Singapore,
Singapore



Xuezi Bi

Senior Principal Scientist,
Group Leader (Protein Analytics),
Bioprocessing Technology Institute,
A*STAR, Singapore



Kim Seokjoong

CSO, BreezeBio



Wonil Kim

CSO, Aston Sci.



Poon Hung Fai

CEO, Sirnaomics



Xian Zeng

CEO & Founder,
Byterna Therapeutics



Jin Li

Head of Research Department,
CanSino (Shanghai) Biological
Research Co., Ltd, China



Arvind K Jain

Deputy General Manager,
R&D – mRNA Vaccines,
Biological E. Limited, India



Jagadish Sankaran

Senior Scientist,
A*STAR, Singapore



Janise Chevrier-Lee

Country Medical Director Singapore,
Roche Singapore Pte Ltd to ebook.



Yasumasa Ota

mRNA technology Leader,
Meiji, Japan



Crystal Lau

Senior Director CMC,
MSD, Singapore

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