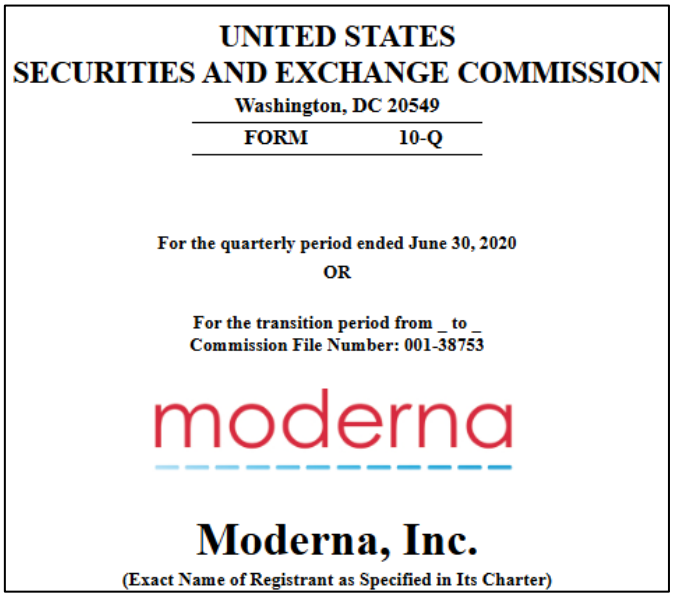
Vax or Gene Therapy?



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

For the quarterly period ended June 30, 2020
OR

For the transition period from _ to _
Commission File Number: 001-38753

moderna

Moderna, Inc.
(Exact Name of Registrant as Specified in Its Charter)

https://www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm

No previous Phase 3 Trial (because it always failed in Phase 2?)

> *"As a potential new class of medicines,* ***no mRNA medicines have been approved to date by the FDA or other regulatory agency."*** ***P68***
>
> *"Prior to the Phase 3 trial for mRNA-1273 [that would be 'the Moderna Covid-19 jab'] and that of one other company****, there had never been a Phase 3 trial in which mRNA is the primary active ingredient****, and there has never been and there may never be a commercialized product in which mRNA is the primary active ingredient."* ***P68***

A Gene Therapy:

> ***"Currently, mRNA is considered a gene therapy product by the FDA."*** ***P69***
>
> ***Some of our investigational medicines are classified as gene therapies by the FDA and the EMA****, and the FDA has indicated that our investigational medicines will be reviewed within its Center for Biologics Evaluation and Research, or CBER. Even though our mRNA investigational medicines are designed to have a different mechanism of action from gene therapies,* ***the association of our investigational medicines with gene therapies could result in increased regulatory burdens, impair the reputation of our investigational medicines, or negatively impact our platform or our business****.* ***P76***

Gene therapies cause significant adverse effects:

> *"****Unlike certain gene therapies that irreversibly alter cell DNA and could act as a source of side effects****, mRNA-based medicines are designed to not irreversibly change cell DNA; however, side effects observed in gene therapy could negatively impact the perception of mRNA medicines despite the differences in mechanism."* ***P69***
>
> *"There have been few approvals of gene therapy products in the United States or foreign jurisdictions, and there have been well-reported significant adverse events associated with their testing and use.* ***Gene therapy products have the effect of introducing new DNA and potentially irreversibly changing the DNA in a cell. In contrast, mRNA is highly unlikely to localize to the nucleus, integrate into the DNA, or otherwise make any permanent changes to cell DNA****."* ***P76***

May require same testing as a gene therapy:

> ***"The number and design of the clinical trials and preclinical studies required for the approval*** *of these types of medicines have not been established, may be different from those required for gene therapy products, or* ***may require safety testing like gene therapy products****."* ***P69***

There is no assurance that we will meet safety or efficacy standards. There is expected to be wide variation in effects and in biodistribution.

> ***there can be no assurance that we will observe acceptable safety or efficacy profiles*** *in later-stage trials required for approval of these programs. …In general, several biological steps are required for delivery of mRNA to translate into therapeutically active medicines. These processing steps may differ between individuals or tissues, and this could lead to variable levels of therapeutic protein, variable activity, immunogenicity, or variable distribution to tissues for a therapeutic effect.* ***P72***

Potential auto-immune reactions:

> *"Gene therapies and mRNA-based medicines may activate one or more immune responses against any and all components of the drug product (e.g., the mRNA or the delivery vehicle, such as an LNP) as well as against the encoded protein, giving rise to potential* ***immune reaction related adverse events****."* ***P72***

Our primary motivation is the ability to conduct our business

> *"mRNA medicines are a novel approach, and negative perception of the efficacy, safety, or tolerability of any investigational medicines that we develop could adversely affect our ability to conduct our business, advance our investigational medicines, or obtain regulatory approvals."* ***P75***

World Health Summit: Video

Amount of DNA Contamination in Different Batches Sampled:

BioNTech Batch	Expiry Date	DNA ng/µl	DNA ng/Dose	Multiple of 10 ng	Plasmids
GH9715	06/2023	9,45	2835	284-times limit	YES
FW1374	09/2022	7,78	2334	233-times limit	YES
343961B	10/2022	3,38	1014	101-times limit	YES
ACB5517	04/2022	11,80	3540	354-times limit	YES
FP1972	04/2022	2,78	834	83-times limit	YES

Logic:

The Covid jab contained:

- Contaminant DNA, Spike DNA (from plasmid production)
- mRNA code for SV40, which carries it into the nucleus, and reverse transcribes it
- mRNA code for amyloidogenic proteins