

# ACCELERATE YOUR PRODUCT DEVELOPMENT

WITH

# ROOSTERBIO PRODUCTS AND SERVICES

RUO

## LATE DISCOVERY AND R&D

- Define product quality characteristics
- Find clinically relevant and scalable manufacturing system
- Estimate cost of goods
- Outline expected manufacturing process



1M Cells



>150 Cells



>1.5E12 EVs

### RoosterBio can:

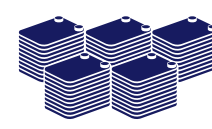
- ▶ Transfer your current research protocol to RoosterBio's platform in 2D/small scale
- ▶ Support genetic engineering
- ▶ Perform MSC priming

## PROCESS DEVELOPMENT AND PRECLINICAL STUDIES

- Scale up production and ensure robust manufacturing system
- Refine product quality characteristics
- Prepare preclinical doses and tech transfer preclinical models to CRO proficient in IND enabling and tox studies using qualified materials
- Tech transfer manufacturing process to a qualified GMP facility with finalized manufacturing process



10M Cells



>1.5B Cells



1E13 EVs

### RoosterBio can:

- ▶ Move your process to small-scale bioreactors
- ▶ Screen GMP donors
- ▶ Scale to appropriate bioreactor size for clinical trial phase
- ▶ Finalize and transfer batch records to a GMP facility

DEV

## IND APPLICATION

- Pre-IND meeting with FDA or other regulatory authority
- IND file preparation 2-3 months prior to IND submission. If in the U.S., fill out RoosterBio's request for Letters of Authorization (LoAs)
- RoosterBio reviews and asks for the Master Files to be amended. RoosterBio provides you with LoAs
- Customer submits IND referencing specific Master Files

### RoosterBio can:

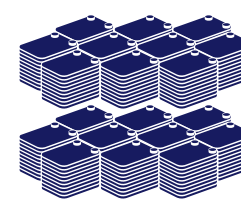
- ▶ Provide regulatory support by issuing Letters of Authorization allowing clients to cross-reference our Master Files for trials under the FDAs purview or by providing regulatory dossiers for trials conducted outside of the US

## PHASE I

- ~20 patients/healthy volunteers
- Determine if there are dose-limiting toxicities
- Determine biodistribution of the therapy
- Monitor signals of potential efficacy via secondary endpoints
- Design and stratify Phase II Trial according to data and biomarkers via Phase I results
- Consider a route to Orphan Drug approval



20M Cells



>3B Cells



>3E13 EVs

### RoosterBio can:

- ▶ Provide training and technical support to assist clinical manufacturing
- ▶ Perform media comparability, bridging, and optimization studies

GMP

## PHASE II

- ~50-100 patients
- Validate safety and spectrum of adverse events with effective dose window likely zeroed in
- May use interim reporting to determine go/no-go manufacturing advance to Phase III, return to Phase II, or earlier
- Meet with regulatory agencies to discuss large-scale studies
- Design Phase III Trial according to patient responders and key monitored biomarkers



100M Cells



>25B Cells



>3E14 EVs

### RoosterBio can:

- ▶ Establish a supply agreement to secure key materials for production
- ▶ Work on scaling the process if needed
- ▶ Perform media comparability, bridging, and optimization studies

## PHASE III

- ~100s of patients
- Here, may use interim reporting for proactive go/no-go manufacturing scale up plans for post-BLA & market phase
- Consider prospective "off label" uses and/or new trials directed at different clinical indications or expanded patient cohorts
- Strategize pipeline based on successful cell tech platform
- Implement plans for long-term patient monitoring



500M Cells



>100B Cells



>1E15 EVs

### RoosterBio can:

- ▶ Establish or continue the supply agreement to secure key materials for production
- ▶ Work on scaling the process if needed
- ▶ Perform media comparability, bridging, and optimization studies

