phosphorex

*microspheres, nanoparticles & drug delivery*

# Drug Delivery Solutions for Pharmaceutical Development

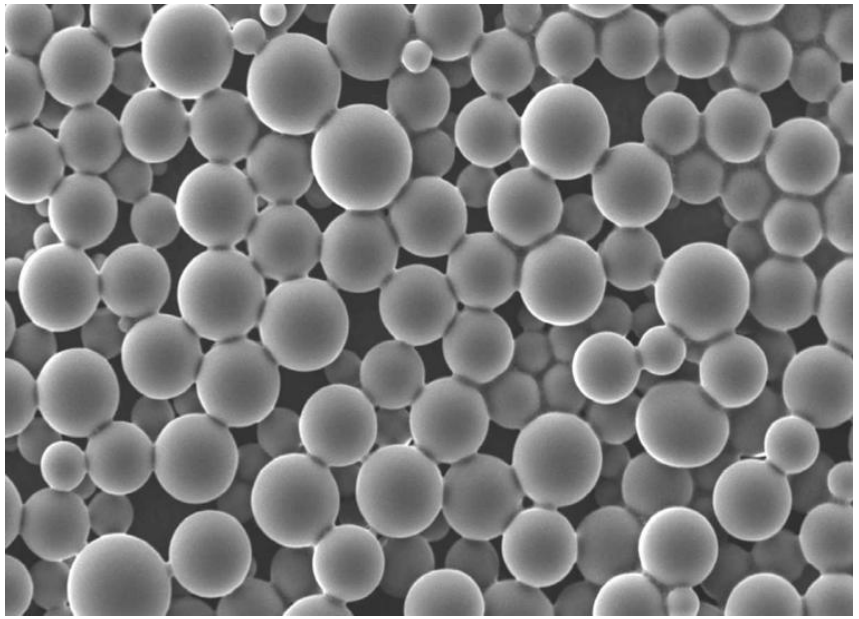
Updated on June 1, 2021

# Company snapshot

- A contract development and manufacturing (CDMO) founded in 2005
- Located in Hopkinton, MA
- 30,000+ $ft^2$ state-of-the-art facility
  - Wet chemistry, formulation, cell culture and analytical labs
  - Pilot and process development labs with cleanroom suites
  - Good laboratory practice (GLP) capability
  - Capability of GMP batch production through partnership
- Focus on particle technology and formulation development for pharmaceuticals and devices
- Experienced team composed of experts in formulation technologies with broad cross-functional skills
- Fee-for-service model for contract work
- Mission is to help clients to reduce cost and shorten the time to clinic

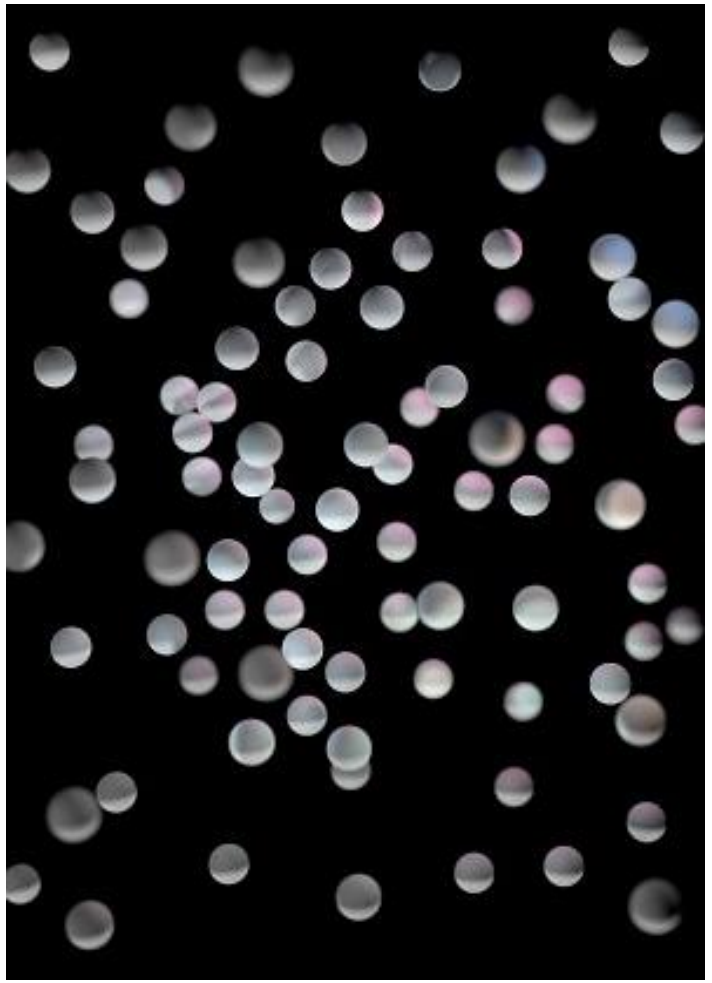
# Sustained release, long-acting injectables

- Reduce dose frequency
  - API is released to environment slowly to maintain therapeutic level for extended period
  - Long-acting microsphere formulations can be potentially dosed weekly, monthly, every 3 months, or even every 6 months
  - Improve patient compliance and enhance efficacy
- Extend biological half-lives of API
  - Protect APIs from enzymatic degradation or hydrolysis
- Biocompatible and biodegradable material
  - PLGA, PLA and PCL are used extensively as drug delivery carriers
  - Low toxicity and high drug encapsulation capabilities enabled multiple sustained release products in marketplace
- Flexible administration method
  - SC or IM
  - Topical administration within specific tissue/organ
- Suitable for delivery of broad therapeutics
  - Small molecule, peptide, protein, nucleic acid, etc.



# Polymeric Nanoparticles

- Prolong circulation and decrease dosing frequency
- Deliver drug to desired organ, tissue or cell
- Concentrate API within targeted tissue and extend half life
- Enhance blood-brain barrier crossing
- Protect drug from premature degradation
- Increase potency and decrease systemic toxicity
- Enhance intracellular uptake of macromolecular therapeutics



# Nucleic Acid Delivery

- Lipid-based nanoparticles (LNP)
- Formulation of mRNAs and DNAs
- siRNAs and anti-sense oligonucleotides (ASO)
- Vaccine development
- Applications in immunology and immuno-oncology
- Gene delivery
- Targeted delivery

# Fully integrated approach: from formulation design to clinic

| Formulation Design and Prototyping | Scale Up and GLP | GMP via Tech Transfer |
|---|---|---|
| • Interactively work with partner to identify critical parameters, discuss pros/cons<br>• Design, fabricate and characterize prototype particles<br>• Generate formulations for animal POC studies<br>• Optimize small-scale formulation. | • Scale up optimized formulation<br>• Conduct process development and optimization of large-scale formulation<br>• Develop and prepare GLP batches to support IND-enabling, pre-clinical studies<br>• Finalize pilot process and prepare for tech transfer | • Strategic partnership with CMO<br>• Technology transfer to CMO partner<br>• Oversight and technical support during manufacturing of clinical batch<br>• Troubleshooting as needed |

# Phosphorex is a Partner in Pharmaceutical Development

- Over 16 years of experiences in developing and manufacturing microparticles and nanoparticles, advancing products to clinic
- Helped over 70 life sciences companies (16 large pharma & biotech) developing their preclinical and clinical formulations
- Completed 40 preclinical and clinical projects
- Integrated approach shortens the time to clinic
- Experiences, know-hows and innovation

# Examples of Projects Phosphorex Completed

- ✓ Developed a growth factor loaded microsphere for a melanoma vaccine implant and supported the Phase I clinical trial.
- ✓ Developed protein-loaded nanoparticles and supported clinical trials.
- ✓ Developed a microsphere-based peptide formulation for a biotech with high (~50%) drug loading and a sustained release profile; scaled up and generated GLP materials to support IND filing; successfully transferred process to GMP site; clinical materials produced and phase I trial scheduled.
- ✓ Developed and scaled up several LNP/mRNA formulations for IO applications to support preclinical animal studies.
- ✓ Formulated an antisense oligonucleotide (ASO) into nanoparticles for preclinical studies.
- ✓ Facilitated IP filing for several partners.