Exosomes are extracellular vesicles that are secreted by cells for cellular communication. They carry bioactive cargo like nucleic acids, proteins, and other metabolites and can precisely deliver them to recipient cells, making them an effective vehicle for targeted drug delivery and disease diagnostics. Currently, clinical trials are exploring their use in various diseases, such as diabetes, stroke, and cancer. However, current exosome production methods are cost-ineffective, labour-intensive, and lack scalability. This is where EXOVIA comes in, as we are designing an economically viable process for producing exosomes on a large scale, in our facility based in Calgary.

### INTRODUCTION

Exosomes are produced at a large scale for various applications, including targeted drug delivery and disease diagnostics. Current methods are labor-intensive and lack scalability. EXOVIA aims to design an economically viable process for producing exosomes on a large scale, with a focus on cost-effectiveness and efficiency.

### PROCESS OVERVIEW

#### UPSTREAM

- Two stirred-tank bioreactors are run in batch mode to multiply the cells and reach the target cell count for seeding onto the hollow fiber bioreactor. This process takes 9.17 days to reach 9.10 × 10^8 cells.

#### EXOSOME PRODUCTION

- The hollow fiber bioreactor will take 22.2 days to process one batch with a total of 6 collections, each containing 2.72 × 10^10 exosomes. One full batch will produce 1.633 × 10^14 exosomes.

#### DOWNSTREAM

- Tangential Flow Filtration
- This ultrafiltration device provides the final removal of any contaminants less than 20 nm, purifying the exosome product. One sample from this unit creates 34 doses.

### ECONOMICS

- **After-Tax NPV:** $580M CAD
- **Internal Rate of Return:** 118%
- **Plant Lifetime:** 15 years
- **10 Batches produced annually**

### PRODUCT

EXOVIA produces 10 high-quality annual batches using a Quality by Design approach and adheres to Good Manufacturing Practices, supplying 14,500 vials for 57 clinical trials across the U.S. and China, capturing a major share of the global exosome trial market.

### ENVIRONMENT, HEALTH, AND SAFETY

- **Key Safety Hazards:**
  - Contamination
  - Equipment Failure or Misfunction
  - Operator Error
  - Deviations in Operating Conditions
  - Biohazardous Materials & Waste

- **Safeguards & Mitigations:**
  - Operator Training & PPE
  - Controls, Sensors, & Alarms
  - Equipment Maintenance & Inspection
  - HVAC Ventilation
  - cGMP Practices
  - Clean Rooms

### ACKNOWLEDGEMENT

We thank Dr. Michael Kallos for his consistent guidance and support for the duration of this project. We would also like to extend our gratitude to our industry sponsor, Dr. Krishna Panchalingam, from Lonza for his time, expertise, and industrial insights.

### REFERENCES