## Q3 2019 Quarterly Report



Joey Bose, President joey.bose@cytonics.com

## KEY UPDATES & HIGHLIGHTS

proud We are to announce the successful purification of our lead drug candidate, CYT-108. This is a major milestone for the company as it allows us to commence pre-clinical trials in large animal models of osteoarthritis. Our pre-clinical trial strategy is two-fold: (1) We will conduct a *pilot* study to optimize our experimental design and methods on a small scale before (2) Committing to a *large-scale* pre-clinical trial in accordance with the FDA's GLP standards. We initiated the pilot pre-clinical trial on September 30, 2019 at Sinclair Medical, a Contract Research Organization specializing in pre-clinical investigation of novel drugs. Dr. Scuderi and I visited their facilities on October 4th and impressed with their were very competence and capabilities. We anticipate safety and efficacy results from this pilot study in early Q2 2020. Following data analysis and discussion with the FDA, we expect to start the large-scale, GLP-compliant pre-clinical trial bv Q1 2021. This data will support our Investigational New Drug (IND) application and allow us to proceed into Phase 1 human clinical trials upon review by the FDA.

CYT-108 In addition to our R&D, we have been aggressively pursuing new market entry and further market penetration for our autologous APIC products. We recently executed an out-licensing agreement with a medical device distributor specializing in the veterinary markets, receiving \$400,000 for the sale of the exclusive license as well as royalties on gross sales. We are currently negotiating an out-licensing agreement with medical device distributor who has operational capacity the European and Canadian human markets. We expect to close this deal by year end.

2019 US patents In we were issued two covering both APIC formulation the autologous our CYT-108 drug. APIC The treatment and is filtration method produced bv a proprietary that enriches selectively for the naturally-occurring Alpha-2-Macroglobulin (A2M) molecule found in blood, concentrating the A2M by at least 10%. Our patents provide us with intellectual property protection against other regenerative medicine groups who claim to enrich A2M by methods of filtration. Our CYT-108 drug is specific mutations to an A2M variant that contains efficacy over the naturally-occurring lend increased A2M. The design of this protein and its method of use are protected by our patents and prevent other research groups from creating a recombinant A2M-variant therapy.

The successful raise of over \$463,000 during the Regulation CF round, along with the out-licensing of our APIC products, have provided us with enough capital to fully fund our pre-clinical studies and data needed pursue generate the scientific to Phase human clinical trials. Once we have data 1 support CYT-108's safety and efficacy in animal to models of osteoarthritis, we will conduct a followon Regulation A+ IPO (Q2 2020) to raise the \$10M needed to get through Phase 2 clinical trials and find a strategic partner or acquirer.

## CHALLENGES & PATH FORWARD

Purification of CYT-108 was a daunting scientific feat, but through careful engineering and process development we managed to develop a purification procedure that produces high concentrations of CYT-108 while removing a large percentage of possible contaminants. Further optimization needs to be done to efficiently produce a high-quality product at large scale for human clinical trials.

The next major milestone is the completion of our pilot preclinical study and pre-IND meeting with the FDA. Upon completion of the pilot study and analysis of the data, we will discuss the results and procedures with the FDA to gather their input and optimize our study protocol. A major hurdle in the clinical trial process is study design. Often times trials fail not because the underlying science is poor, but because the study design is flawed. The FDA's guidance is crucial to designing an appropriately controlled study with acceptable measurements of safety and efficacy. We have established a strong relationship with the FDA's Center for Biologics Evaluation and Research (CBER), the reviewing entity for biologic therapies such as our CYT-108 drug, and will continue to remain in close contact to ensure that our studies are welldesigned and will yield definitive results as per FDA guidelines.

## UNAUDITED FINANCIALS

(Nine Months - Sept 30, 2019)

| Revenue             | \$309,168   |
|---------------------|-------------|
| R&D Expenses        | \$406,291   |
| G&A Expenses        | \$366,287   |
| Interest Exp, net   | \$55,211    |
| Net Income (Loss)   | \$(518,621) |
| Ending Cash Balance | \$647,718   |

The vast majority of our discretionary funding has been directed towards research and development for CYT-108, in alignment with the company's primary mission of completing Phase 2 clinical trials and finding a strategic partner or acquirer to purchase our intellectual property portfolio. We intend to raise future capital at a higher valuation supported by the issuance of new patents protecting both the autologous APIC and recombinant CYT-108 technologies, pre-clinical data for the safety and efficacy of CYT-108, and other business development activities such as the licensing of our APIC technologies and FDA approval of our APIC "Mini" system.

This communication contains forward-looking statements by third-parties. These statements reflect current views with respect to future events based on information currently available and are subject to risks and uncertainties that could cause actual results to differ materially. You are cautioned not to place undue reliance on these forward-looking statements as they are meant for illustrative purposes and they do not represent guarantees of future results, levels of activity, performance, or achievements, all of which cannot be made. Moreover, no person nor any other person or entity assumes responsibility for the accuracy and completeness of forward-looking statements, and is under no duty to update any such statements to conform them to actual results.