Q3 2019
Quarterly Report

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KEY UPDATES & HIGHLIGHTS

We are proud 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 were very impressed with their 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 by 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.

In addition to our CYT-108 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 a medical device distributor who has operational capacity in the European and Canadian human markets. We expect to close this deal by year end.

In 2019 we were issued two US patents covering both the autologous APIC formulation and our CYT-108 drug. The APIC treatment is produced by a proprietary filtration method that selectively enriches 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 an A2M variant that contains specific mutations to lend increased efficacy over the naturally-occurring 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 generate the scientific data needed to pursue Phase 1 human clinical trials. Once we have data to support CYT-108's safety and efficacy in animal models of osteoarthritis, we will conduct a follow-on 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 pre-clinical 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 well-designed 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.