# 2019 Year in Review & Q1 2020 Quarterly Report



#### **KEY UPDATES & HIGHLIGHTS**

#### Year in Review

2019 was a transformational year for the company. Having struggled with the purification of our recombinant A2M variant (CYT-108) for over a year and a half, we found ourselves in a precarious situation. As often experienced by early-stage R&D companies, the development of a proof-of-concept technology is capital intensive and relies on the confidence of early investors in the market potential of the product(s) and in the management team. Small biotechnology companies often find themselves in a Catch 22, wherein the successful development of their technology requires significant capital outlay, while those investment dollars are secured by the demonstrable success of the technology. To break this cycle, R&D companies must secure enough cash to achieve the next key development milestone, upon which they can go out and raise additional capital with confidence and at a higher valuation. 2019 was a make or break year for the company. And we made it.

Two key R&D milestones were accomplished in 2019: (1) the successful purification of the recombinant A2M variant (CYT-108) and (2) the initiation of a *pilot* pre-clinical trial. These accomplishments allowed us to launch a public capital raise (via Regulation CF - crowdfunding) to fund the next phase of our drug development program. This was a risky strategy as we were marketing the investment opportunity to a general audience - a tough sell unless the crux of the technology can be effectively communicated and the value of the company adequately explained. The crowdfunding campaign paid off with ~\$460,000 in proceeds raised, enough to fully fund the upcoming pre-clinical study (2021). Furthermore, the crowdfunding campaign was demonstrable proof that we can raise capital from a retail market, and that the public understands the potential of our technology and has faith in our company.

#### Q1 2020 Updates

- We have commenced GMP development of CYT-108 for pre-clinical and human clinical trials. GMP product is required to enter human studies.
- We have **concluded our** *pilot* **pre-clinical trial** and await a summary report containing (1) Evidence of the cartilage-protecting properties of CYT-108, (2) Immunogenicity data regarding a potential immune response due to the injection of CYT-108 into the joint, and (3) Safety data regarding the accumulation of CYT-108 in the major organs and if any pathology was reported. This data will be used to inform our upcoming *large* pre-clinical study (under FDA supervision), which we expect to start by Q1 2021.
- This pre-clinical 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.
- We are aggressively pursuing new market entry for APIC, and anticipate signing a new licensing agreement for international distribution in the human market for \$500,000 upfront and 10% royalties on sales.
- We are preparing to raise \$19M via Regulation A+, through the issuance of preferred stock. Similar to our 2019 crowdfunding campaign, we will issue public securities on the SeedInvest platform.
- The Regulation A+ campaign is set to go-live in early Q3 2020. Proceeds will be used to complete GMP drug development for CYT-108 and for Phase 1/2 human clinical trials.

#### CHALLENGES & PATH FORWARD

Cytonics' path towards exit (sale of the company) involves surmounting three distinct sets of challenges: (1) Regulatory - we must ensure that CYT-108 is produced according to FDA guidelines and that our clinical trials are designed to satisfy the FDA's requirements, (2) Research - R&D and clinical trials are fraught with potential missteps. We are still in the process of developing and testing CYT-108 to ensure that it is fit for human use. We intend to mitigate this risk by conferencing with the FDA prior to beginning our clinical trials and using their input to optimize the study design, and (3) Financing - our cash runway is limited and we rely on continued support from our investors, as well as royalties on APIC sales, to support our R&D initiative. We intend to raise \$19M in our upcoming Regulation A+ IPO A significant portion of the Regulation A+ funds will be allocated to GMP purification and Phase 1/2 human clinical trials.

#### AUDITED FINANCIALS

(Twelve Months - Dec 31, 2019)

| Revenue             | \$365,169   |
|---------------------|-------------|
| R&D Expenses        | \$544,223   |
| G&A Expenses        | \$161,934   |
| Interest Exp, net   | \$96,119    |
| Net Income (Loss)   | \$(976,922) |
| Ending Cash Balance | \$537,592   |
|                     |             |

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. Funds raised in the Regulation A+ public offering will be allocated to GMP production of CYT-108, pre-clinical trials, Phase 1/2 trials, and general working capital.

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.

# **Cytonics Corporation**

# Audited Financial Statements End of Year 2019

## **Balance Sheet**

As of Dec 31, 2019

| Cash                       | \$<br>537,592   |
|----------------------------|-----------------|
| Accounts Receivables, net  | 18,417          |
| Prepaid Expenses           | <br>28,354      |
| Total Current Assets       | 584,363         |
| Fixed Assets, net          | 9,753           |
| Deferred IPO Costs         | 59,186          |
| Patents, net               | 413,059         |
| Total Assests              | \$<br>1,056,608 |
| Accounts Payable           | \$<br>157,633   |
| Convertible Notes          | 961,904         |
| Stockholder's Equity       | (162,929)       |
| Total Liabilities & Equity | \$<br>1,056,608 |

### **Income Statement**

Twelve Months Ended Dec 31, 2019

| Total Revenues              | \$<br>365,169   |
|-----------------------------|-----------------|
| Operating Expenses          |                 |
| Research and Development    | 544,223         |
| General, and administrative | <br>161,934     |
| Total Operating Expenses    | <br>1,119,923   |
| Loss from operations        | (754,754)       |
| Interest Expense, net       | <br>96,119      |
| Net Loss                    | \$<br>(976,922) |