
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2021

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 0-21990

Oncotelic Therapeutics, Inc.

(Formerly Mateon Therapeutics, Inc.)
(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

13-3679168

(I.R.S. Employer
Identification No.)

29397 Agoura Road, Suite 107
Agoura Hills, CA

(Address of principal executive offices)

91301

(Zip Code)

Registrant's telephone number, including area code: (650) 635-7000

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of Each Class

Name of Each Exchange on Which Registered

None

Securities registered pursuant to Section 12(g) of the Exchange Act:

Common stock, par value \$0.01 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements

incorporated by reference in Part III of this Form 10-K, or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold, as of June 30, 2020 was approximately \$34,739,000.

As of March 20, 2022 the aggregate number of outstanding shares of common stock of the registrant was 378,630,104.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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FORWARD-LOOKING STATEMENTS

This 2021 Annual Report on Form 10-K (this “*Annual Report*” or “*Report*”) contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934 (the “*Exchange Act*”) that involve substantial risks and uncertainties. We generally identify forward-looking statements by terminology such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “would,” “intend,” “target,” “aim,” “project,” “believe,” “estimate,” “predict,” “potential,” “seek,” “indicate,” or “continue” or the negative of these terms or other similar words, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements regarding our or our management’s expectations, hopes, beliefs, intentions or strategies regarding the future, such as our estimates regarding anticipated operating income or losses, future performance, future revenues and projected expense, including that to fund our clinical and other development programs; our liquidity and our expectations regarding our needs for and ability to raise additional capital; our ability to continue as a going concern; our ability to select and capitalize on commercially desirable product opportunities as a result of limited financial resources; our ability to manage our expenses effectively and raise the funds needed to continue our business; our ability to retain the services of our current or future executive officers, directors and principal consultants; the competitive nature of our industry and the possibility that our products or product candidates may become obsolete or may not generate revenues as expected or at all; our ability to obtain and maintain regulatory approval of our existing products and any future products we may develop; the development of and the process of commercializing AI/Blockchain and other technologies for supporting the development of OT-101 and Artemisinin for COVID-19, OT-101, including development of OT-101, Artemisinin, OX14503, CA4P and our 2021 in-licensing of apomorphine; the initiation, timing, progress and results of our preclinical and clinical trials, research and development programs; regulatory and legislative developments in the United States and foreign countries; the timing, costs and other limitations involved in obtaining regulatory approval for any product; the further preclinical or clinical development and commercialization of our product candidates; the entering into any corporate transactions to develop our products through partnerships, joint ventures or other corporate transactions; our ability to make a proposed initial public offering between us and our potential joint-venture partners for the proposed joint venture; our ability to obtain and maintain orphan drug exclusivity for some of our product candidates; the potential benefits of our product candidates over other therapies; our ability to enter into and maintain any collaboration with respect to product candidates; our ability to continue to develop or commercialize our products or product candidates in the event any license agreements in place with third parties expire or are terminated; the performance and conduct of third parties, including our third-party manufacturers and third party service providers used in our clinical trials; our ability to obtain and maintain intellectual property protection for our products and operate our business without infringing upon the intellectual property rights of others; the potential liability exposure related to our products and our insurance coverage for such exposure; our ability to form alliances with other third parties to develop the products in our pipeline through partnerships, joint ventures, mergers or acquisitions; the successful development of our sales and marketing capabilities; the size and growth of the potential markets for our products and our ability to serve those markets; the rate and degree of market acceptance of any future products; the volatility of the price of our common stock; the ability to achieve secondary trading of our stock in certain states; the dilutive effects of potential future equity issuances; our expectation that no dividends will be declared on our common stock in the foreseeable future; our ability to maintain an effective system of internal controls; the payment and reimbursement methods used by private or governmental third-party payers; our ability to retain adequate staffing levels; unfavorable global economic conditions; unfavorable global epidemic and pandemic conditions; a failure of our internal computer systems or those of our contractors and consultants; potential misconduct or other improper activities by our employees, contractors or consultants; the ability of our business continuity and disaster recovery plans to protect us in the event of a natural disaster; and other factors discussed elsewhere in this document or any document incorporated by reference herein or therein:

The forward-looking statements contained in this document are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve several risks, uncertainties (many of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these “forward-looking statements.” Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. The sections captioned “Risk Factors” as well as other sections in this document or incorporated by reference into this document discuss some of the factors that could contribute to these differences.

The forward-looking statements made in this document relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events.

This Annual Report also contains market data related to our business and industry. These market data include projections that are based on a number of assumptions. While we believe these assumptions to be reasonable and sound as of the date of this Annual Report, if these assumptions turn out to be incorrect, actual results may materially differ from the projections based on these assumptions. As a result, the markets for our product candidates may not grow at the rates projected by these data, or at all. The failure of these markets to grow at these projected rates may have a material adverse effect on our business, results of operations, financial condition and the market price of our common stock.

PART I

ITEM 1. BUSINESS

Company Background

Oncotelic Therapeutics, Inc. (f/k/a Mateon Therapeutics, Inc.) (“Oncotelic”), was formed in the State of New York in 1988 as OXiGENE, Inc., was reincorporated in the State of Delaware in 1992, and changed its name to Mateon Therapeutics, Inc. in 2016, and Oncotelic Therapeutics, Inc. in November 2020. Oncotelic conducts business activities through Oncotelic and its wholly-owned subsidiaries, Oncotelic, Inc., a Delaware corporation, PointR Data, Inc. (“PointR”), a Delaware corporation, and EdgePoint AI, Inc. (“Edgepoint”), a Delaware Corporation for which there are non-controlling interests, (Oncotelic, Oncotelic Inc., PointR and Edgepoint are collectively called the “Company” or “We”). The Company is currently developing OT-101 for various cancers and COVID-19, Artemisinin for COVID-19 and AI technologies for clinical development and manufacturing. The Company has acquired apomorphine for Parkinson’s Disease, erectile dysfunction and female sexual dysfunction. In addition, the Company is evaluating the further development of its product candidates OXi4503 as a treatment for acute myeloid leukemia and myelodysplastic syndromes and CA4P in combination with a checkpoint inhibitor for the treatment of advanced metastatic melanoma. Our principal corporate office is in the United States at 29397 Agoura Road, Suite 107, Agoura Hills, CA 91301 (telephone: 650-635-7000). Our internet address is www.oncotelic.com.

Amendments to Certificate of Incorporation

In November 2020 the Company filed an amendment to its Certificate of Incorporation with the Secretary of State for the State of Delaware changing its name from “Mateon Therapeutics, Inc.” to “Oncotelic Therapeutics, Inc.” A notice of corporate action had been filed with the Financial Industry Regulatory Authority (“FINRA”), requesting confirmation to change its name and approval for a new ticker symbol. On March 29, 2021, the Company received approval from FINRA on its notice of corporate action, and effective March 30, 2021, the Company’s ticker symbol has changed from “MATN” to “OTLC”.

In January 2021, the Company filed an additional amendment to its Certificate of Incorporation, as amended (the “*Charter Amendment*”), with the Secretary of State for the State of Delaware, which Charter Amendment went effective immediately upon acceptance by the Secretary of State for the State of Delaware. As approved by the Company’s stockholders by written consent on August 10, 2020, the Charter Amendment increased the number of authorized shares of Common Stock from 150,000,000 shares to 750,000,000 shares.

In addition, the Company registered an additional total of 20,000,000 shares of its Common Stock, which may be issued pursuant to the Company’s Amended and Restated 2015 Equity Incentive Plan (the “*Plan*”). Such additional shares were approved by the shareholders of the Company on August 10, 2020 and as reported to the Securities and Exchange Commission (the “SEC”) on a Current Report on Form 8-K on August 14, 2020. As such, the total number of shares of the Company’s Common Stock available for issuance under the 2015 plan is 27,250,000.

Overview

We are a clinical-stage biopharmaceutical company developing drugs for the treatment of orphan oncology indications, developing antisense and small molecule injectable drugs for the treatment of cancer. After the acquisition of Mateon Therapeutics, Inc through a reverse merger in 2019, we realigned the company pipeline to focus on rare pediatric cancers. The United States Food and Drug Administration (“FDA”) has granted us Rare Pediatric Designations (“RPD”) for pediatric Diffuse Intrinsic Pontine Glioma (“DIPG”) for OT-101, pediatric melanoma for CAP4 and acute myeloid leukemia (“AML”) for Oxi4503. This strategy aims to capitalize on a voucher program in the United States (“US”). By focusing on RPD we anticipate: 1) reducing the cost of clinical development by way of a smaller and faster clinical trial, 2) acceleration of the approval process and final approval, 3) obtaining regulatory/ marketing exclusivity for up to 12 years as a biologic, and 4) obtaining vouchers worth a significantly large value on regulatory approval, which can be upwards of several million dollars. Approval in US would allow for approval in the rest of the world (“ROW”) using the US dossier. Phase 3 clinical trials for approval in adult indications will be conducted following the positive interim read of the pediatric trials. This approach maximize return on investment for the shareholders.

Concurrently we also explore opportunity to create values for shareholders by forming strategic alliances and/or licensing our product portfolio. As of August 2021, we have been working on the formation of a joint venture (“JV”) with Golden Mountain Partners (“GMP”) to transfer the developmental cost of our product(s) onto the JV, while still participating in potential upside through ownership of the JV. The Company entered into a JV with Dragon Overseas Capital Limited (“Dragon Overseas”) and GMP Biotechnology Limited (“GMP Bio”), affiliates of GMP on March 31, 2022. GMP Bio and the Company are also looking to take the JV into an initial public offering (“IPO”) of the JV and which is anticipated to be a liquidity event for Company, especially if the IPO is successful. While we believe that the JV and the IPO can be completed and be successful, we cannot provide assurance for either of the events to occur; or if they occur, then they would be successful.

As a result of the reverse merger of Oncotelic and Oncotelic Inc.in April 2019 and the acquisition of PointR in November 2019, respectively, we believe we are well positioned as a biotech company with: (1) Oncotelic Inc.’s antisense platform with our

drug candidate OT-101- targeting high value TGF- β 2 target for various cancers and COVID-19, (2) PointR artificial intelligence (“AI”) for clinical trials, research and development, (3) Edgepoint for developing technologies for manufacturing and for developing technologies for supporting our COVID-19 programs, (4) Artemisinin for COVID-19, (5) the Company’s vascular disruptor proven safe in more than 500 patients capable of causing massive antigen release which would stimulate immune response against the cancerous tumor and (6) apomorphine, which we in-licensed in 2021, for developing against Parkinson’s Disease (“PD”), erectile dysfunction (“ED”) and female sexual dysfunction (“FSD”). Since the JV is formed with GMP Bio, we will now plan to accelerate the development of apomorphine as our flagship drug candidate.

We are also developing OT-101, an antisense against TGF- β 2 – for the treatment of various viruses, including the severe acute respiratory syndrome (“SARS”) and the current coronavirus (“COVID-19”), on its own and in conjunction with other compounds. Viral replication cannot occur without TGF- β ; and TGF- β surge and a cytokine storm cannot occur without TGF- β . A Phase 2 trial was completed for OT-101 in South America. Based on the final results of the trial, the trial can expand into a Phase 3 trial if the data supports the safety of the drug. This was a randomized, double-blind, placebo-controlled Phase 2 study is intended to evaluate the safety and efficacy of OT-101 in adult patients hospitalized with positive COVID-19 and pneumonia.

In addition, during 2020 and 2021, the Company was developing Artemisinin as a potential therapy for the virus causing COVID-19 (“SARS-CoV-2”). Artemisinin, purified from a plant *Artemisia annua*. It can inhibit TGF- β activity and is able to neutralize COVID-19. The Company initially conducted a study and the test results during an in vitro study at Utah State University showed Artemisinin having an EC50 of 0.45 ug/ml, and a Safety Index of 140. Artemisinin can target multiple viral threats, including COVID-19, by suppressing both viral replication and clinical symptoms that arise from viral infection. Viral replication cannot occur without TGF- β . In a clinical study undertaken in India called ARTI-19, clinical consequences related to the TGF- β surge, including ARDS and cytokine storm, were suppressed by targeting TGF- β with Artemisinin. The ARTI-19 trials were conducted in India by Windlas Biotech Limited (“Windlas”), the Company’s business partner in India. Windlas had applied for regulatory approval for it’s Artemisinin based product, ArtiShield™, but has not been able to obtain regulatory approval for use of ArtiShield™ as a COVID-19 therapy and as such, no significant revenues have been reported by Windlas nor have we accrued any royalties on Artemisinin due from Windlas. We intend to focus future development on Artemisinin against other respiratory viruses with unmet needs.

In September 2021, Oncotelic entered into an exclusive License Agreement (the “Agreement”) with Autotelic, Inc. (“Autotelic”), pursuant to which Autotelic granted Oncotelic, among other things: (i) the exclusive right and license to certain Autotelic Patents (as defined in the Agreement) and Autotelic Know-How (as defined in the Agreement); and (ii) a right of first refusal to acquire at least a majority of the outstanding capital stock of Autotelic prior to Autotelic entering into any transaction that is a financing collaboration, distribution revenues, earn-outs, sales, out-licensing, purchases, debt, royalties, merger acquisition, change of control, transfer of cash or non-cash assets, disposition of capital stock by way of tender or exchange offer, partnership or any other joint or collaborative venture, research collaboration, material transfer, sponsored research or similar transaction or agreements. In exchange for the rights granted to Oncotelic, Autotelic will be entitled to earn the milestone payments. This transaction brings in AL-101 - an intranasal apomorphine asset with clear 505(b)2 pathway to approval for PD as well unique mechanism of action for treatment of ED and FSD.

We currently have eight primary drug and AI technology programs we are seeking to advance:

- Intranasal drug and delivery system for intra-nasal Apomorphine for the treatment of PD, ED and FSD.
- OT-101 - an antisense against TGF- β 2 – for the treatment of solid tumors with focus on brain cancer in adult and DIPG in children. A RPD for pediatric DIPG has been granted by US FDA.
- OT-101 - an antisense against TGF- β 2 –for the treatment of various viruses, including the SARS and the current COVID-19, on its own and in conjunction with other compounds.
- Artemisinin – a natural derivative from an Asian herb *Artemisia Annua* - Artemisinin has shown to be highly potent at inhibiting the ability of the COVID-19 causing virus to multiply while also having an excellent safety index as well as against hepatitis B and C viruses, human herpes viruses, HIV-1, influenza virus A, and bovine viral diarrhea virus in the low micromolar range.
- CA4P- a vascular disrupting agent (“VDA”) - in combination with Ipilimumab for the treatment of solid tumors with focus on melanoma in adult and pediatric melanoma. A RPD has been granted to the Company by the FDA for pediatric melanoma.
- Oxi4503- a second generation VDA - for the treatment of liquid tumors with focus on childhood leukemia. A RPD has been granted to the Company by the FDA for AML.
- Backoffice support using PointR fabric cluster computing grids for blockchain/AI for pharmaceutical manufacturing and clinical trials and monitoring; and PointR AI for drug development through various stages of development.
- Developing AI based technologies to enhance the development and commercialization of our Artemisinin based products and support technologies.

AL-101: PD/ ED/FSD

Oncotelic acquired AL-101 for the intranasal delivery of apomorphine for the treatment of PD. Over 60,000 new patients being diagnosed with PD in the United States and currently there are over 1 million patients in the US and expected to increase to over 1.2 million by 2030. In addition, approximately 10 million suffer from this disease globally. <https://www.parkinson.org/Understanding-Parkinsons/Statistics>. AL-101 is also being developed for ED. ED is the most prevalent male sexual disorder globally. The percentages of men affected by ED are as follows: 14.3-70% of men aged 60 years, 6.7-48% of men aged 70 years, and 38% of men aged 80 years (Geerkens MJM et al. (2019). Eur Urol Focus. pii: S2405-4569(19)30079-3). However, with the increasing administration of PDE5 inhibitors in clinical practice, it was found that approximately 30-35% of ED patients are treatment failures (McMahon CN et al. (2006). BMJ, 332: 589-92). AL-101 is designed to target treatment failure ED patients who do not respond to PDE5 inhibitors. Through similar mechanism of action, AL-101 is being developed for FSD. FSD is a prevalent problem, afflicting approximately 40% of women and there are few treatment options. FSD is more typical as women age and is a progressive and widespread condition. (Allahdadi, KJ et al. (2009) Cardiovascular & hematological agents in medicinal chemistry, 7(4), 260-269). There is no available drug for the treatment of FSD. In June 2019, the FDA approved Vyleesi (bremelanotide) to treat acquired, generalized hypoactive sexual desire disorder ("HSDD") in premenopausal women. This is the only available drug treatment. Vyleesi has essentially replaced the only other drug for HSDD, however, it has a long list of drug-drug interactions, including commonly used antidepressants, such as fluoxetine and sertraline. In addition, it has a black box warning regarding its use with alcohol, a combination that has been associated with hypotension and syncopal episodes. Therefore, there is an urgent need for effective therapy against FSD and HSDD.

OT-101: An Antisense Against TGF- β 2

Trabedersen (AP12009, OT-101) is a novel antisense oligodeoxynucleotide ("ODN") developed by Oncotelic Inc. for the treatment of patients with pancreatic carcinoma, malignant melanoma, colorectal carcinoma, high-grade glioma ("HGG"), and other transforming growth factor beta 2 ("TGF- β 2") overexpressing malignancies (e.g. prostate carcinoma, renal cell carcinoma, etc.). Trabedersen is a synthetic 18-mer phosphorothioate oligodeoxynucleotide ("S-ODN") complementary to the messenger ribonucleic acid ("mRNA") of the human TGF- β 2 gene.

TGF- β is a multifunctional cytokine with a key role in promoting tumor growth and progression including cell proliferation, cell migration, and angiogenesis. Above all, TGF- β is a highly potent immunosuppressive molecule. Inhibition of TGF- β overexpression in tumor tissue represents a novel multimodal treatment principle leading to the reduction of tumor growth, inhibition of metastasis, and restoration of host antitumor immune responses. Despite its recognized pivotal role in cancer, therapeutics targeting TGF- β have not been successful and many have failed due to toxicity issues possibly due to inhibition of TGF- β 1 essential functions. The high level of homology between the various TGF- β isoforms is making it impossible to create mAb or small molecule inhibitor without TGF- β 1 cross-inhibition. Therefore, Oncotelic Inc. chose to target TGF- β 2 only using OT-101 antisense approach. The sequence of OT-101 can only target TGF- β 2 and does not have any impact on other TGF- β isotypes. However, suppression of TGF- β 2 directly by OT-101 would also result in suppression of TGF- β 2 indirectly, but not TGF- β 3.

Trabedersen is believed to reverse TGF- β 's immunosuppressive effects, rendering the tumor visible to a patient's immune system and resulting in priming and specific activation of the patient's anti-tumor immune response. OT-101 has completed multiple clinical trials with promising outcomes. OT-101, is being developed as a broad-spectrum anti-cancer drug that can also be used in combination with other standard cancer therapies to establish an effective multi-modality treatment strategy for difficult-to-treat cancers. Oncotelic plans to initiate phase 3 clinical trials for OT-101 in both high-grade glioma and pancreatic cancer. During phase 2 clinical trials in pancreatic cancer, melanoma, and colorectal cancers (Study P001) and in high-grade gliomas (Study G004), meaningful single agent activity with meaningful tumor reduction was observed, and OT-101 exhibited a favorable safety profile. Both partial and complete responses have been observed in the G004 Phase 2 clinical trial of OT-101 as a single agent in patients with aggressive brain tumors.

Oncotelic Inc.'s self-immunization protocol (SIP[©]) is based on the novel and proprietary sequential treatment of cancers with OT-101 (antisense against TGF- β 2) and chemotherapies. Proper Sequencing of treatments is key to optimal immunotherapy. Leveraging from its in-depth knowledge of TGF- β immunotherapy, Oncotelic Inc. ordered the various treatments in the following sequence: (1) expand immune reserve through IL-2 treatment or infusion of immune cells; (2) prime immune response with TGF- β inhibitor OT-101; (3) boost immune response with chemotherapy; and (4) revitalize the exhausted of immune response with checkpoint inhibitors. This sequential treatment strategy is aimed at achieving effective self-immunization against a patients' own cancer, resulting in robust therapeutic immune response and consequently better control of the cancer and improved survival. Prolonged states of being cancer-free have been observed in some patients with the most aggressive forms of cancer, raising a renewed hope for a potential cure. The use of OT-101 lifts the suppression of the patient's immune cells around the cancer tissue, providing the foundation for an effective initial priming, which is critical for a successful immune response. The subsequent chemotherapy results in the release of neoantigens that result in a robust boost of the immune response. This process is termed Xenogenization process and can be: (1) hypermutation by temozolomide in the treatment of brain cancer, (2) immunogenic cell death by taxanes and 5FU in pancreatic cancer, or (3) necrotic cell death by VDA (vascular disrupting agent) in melanoma and MDS. Additionally, the Company believes that a rational combination of the Oncotelic Inc. SIP platform with immune-modulatory drugs like interleukin 2 (IL-2) and/or immune checkpoint inhibitors has the potential to help achieve sustained and robust immune responses in patients with the most difficult-to-treat forms of cancer. The combinations with IL-2 and NK are already partnered with external corporate partners. The Company entered into a JV with Dragon Overseas Capital Limited ("Dragon Overseas") and GMP Biotechnology Limited ("GMP Bio"), affiliates of GMP on March 31, 2022. GMP Bio and the Company will focus to further expand the development of OT-101 for various oncology indications like pancreatic cancer, melanomas, gliomas etc. as also for viral infections like COVID-19. This path is being evaluated as a monotherapy, as well as combination therapies in conjunction with other drugs like checkpoint inhibitors.

Pancreatic Cancer

Pancreatic cancer is associated with the poorest prognosis of gastrointestinal cancers and is expected to become the second leading cause of cancer-related mortality in the USA by 2030. Pancreatic cancer is traditionally considered to be an immune-resistant disease. There is a lack of effector T cells, an abundance of myeloid-derived suppressor T cells, and a dearth of key immune effector and regulatory cells. This may be part of the reason why single-agent checkpoint inhibitors are not as effective in comparison to other diseases. Here is where breaking immune tolerance by inhibiting TGF- β with OT-101 will have a significant impact.

The P001 trial was an open-label, multicenter dose-escalation study to evaluate the safety and tolerability of OT-101 (TGF- β 2-specific Phosphorothioate Antisense Oligodeoxynucleotide) in adult patients with advanced tumors known to overproduce TGF- β 2, which are not or no longer amenable to established therapies. The primary objective of the study was to determine the maximum tolerated dose (MTD) and the dose-limiting toxicities (DLTs) of two cycles of trabedersen administered intravenously (i.v.) on a 7-days-on/7-days-off or 4-days-on/10-days-off schedule. Secondary objectives included were: (1) determining the safety and tolerability of OT-101 administered intravenously at weekly intervals for four days every other week; (2) assessing the plasma pharmacokinetic profile of OT-101 administered intravenously at weekly intervals and for four days every other week; (3) establishing a suitable determination method and to assess the urine pharmacokinetic profile of OT-101 administered intravenously for four days every other week; (4) determining the effect of OT-101 administered intravenously at weekly intervals and for four days every other week on TGF- β 2 plasma concentration levels; and (5) Assessing the potential antitumor activity of OT-101 administered intravenously at weekly intervals and for four days every other week, as assessed by the effect on tumor size and tumor markers.

Of the 61 patients treated, 37 had advanced treatment failure pancreas cancer, a very difficult-to-treat cancer with an overall survival rate that is measured in months even with the best available chemotherapy regimens. Globally, over 400,000 people die of pancreatic cancer each year. MTD was not reached for the 4-days-on/10-days-off schedule, which became the schedule adopted for the phase 2 expansion phase of the trial. Disease control (complete response (CR)), partial response (PR) or stable disease (SD)) was achieved in 19 of 35 evaluable pancreas cancer patients (54%). Among liver mets only patients, there are exceptional single-agent activity and survival. Patient 1006 was pushed to complete response (CR) and survived as far out as 77 mos. This patient failed multiple lines of therapies: (1) surgery: Whipple's procedure, (2) 1st line: 5-FU/LV, Dose 425 mg/m², (3) 2nd line: 5-FU/LV, Dose 2600 mg/m²/24hr, (4) 3rd line: Gemcitabine, Dose 1000 mg/m²/week, and (5) went on to OT-101with liver mets and complete response. Patient 1022 was pushed to stable disease ("SD") with overall survival of 40 months. This patient had also failed multiple lines of therapies: (1) surgery: Whipple's procedure, (2) 1st line: radiation therapy (50 Gy), (3) 2nd line: 5FU, and (4) went on to OT-101 with liver mets and SD.

OT-101 treatment more than doubled the ratio of patients being able to go onto subsequent chemotherapy versus not being able, and consistent with the expected immunization boost coming from Xenogenization with subsequent chemotherapies (taxanes and 5FU/Cisplatin) as discussed for SIP, those with subsequent chemotherapy exhibited increased mOS and more than doubled their 1-year survival. Patients treated with the non-SIP agent did not exhibit these properties.

Gliomas

Brain tumors in the United States are rare and only accounted for 2% of all adult cancers. However, the rate of brain tumors on the rise for the last 30 years. The more common and most malignant form of brain tumors – glioblastoma (“GBM”) has more than doubled from 2.4 to 5.0 per 100,000. In the face of this increase, treatment remained essentially unchanged during the last decade. And despite aggressive surgery followed by radiation and/or chemotherapy, GBM has the worst five-year survival rates among all human cancers, with an average survival from diagnosis of only about 1 year and less than 5% of the patient survived after 5 years. On top of it all, GBM will recur or regrow in most patients. Treatment of recurring a high-grade GBM that has recurred does not always improve survival compared with hospice care alone and deciding when to stop treating the cancer and entering into hospice care is frequently recommended when the patient is unlikely to live longer than six months.

GBM resilience and persistence is in stark contrast with the recent excitement in oncology where Immuno Oncology (“IO”) agents have shown promise to be curative by driving the immune cells to attack the tumors. Though extraordinarily effective against the growing number of tumors, IOs have been ineffective against GBM. GBM is generally considered immunologically “cold” with few immune effector cells needed for successful immunotherapy. The overexpression of transforming growth factor-beta 2 (“TGF- β 2”) is associated with poor prognosis of tumors and plays a key role in malignant progression of various tumors including GBM by inducing proliferation, metastasis, angiogenesis, and immunosuppression. Oncotelic Inc. is developing a novel TGF- β 2 antisense agent OT-101 as immunotherapy against GBM.

G004 is a multinational, multicenter, open-label, randomized, active-controlled, parallel-group study in adult patients with either recurrent or refractory AA (WHO grade III) or recurrent or refractory GBM (WHO grade IV). There were 3 treatment groups: (1) 10 μ M Trabedersen, (2) 80 μ M Trabedersen, and (3) standard chemotherapy (mostly temozolomide). Tumor control rate at 6 months was the primary endpoint. Response assessment included the tumor control rate and the overall response rate, which were assessed at 6, 12, and 14 months by central MRI reading. The tumor control rate was defined as the percentage of patients with either CR, PR, or SD and the overall response rate was defined as percentage of patients with either CR or PR. An independent blinded central MRI reading was performed to obtain a standardized response assessment for the efficacy analysis. Central reading was performed by 2 independent neuroradiologists with an additional adjudicator deciding in case of conflicting opinions.

All patients had previous tumor surgery, almost all patients had previous radiation therapy, and more than half of the patients had received previous chemotherapy. A total of 134 patients, 89 patients in the OT-101 test group and 45 patients in the standard chemotherapy control group were assessed. The findings of a randomized Phase II study further confirmed the feasibility of intratumoral application of OT-101 via convection enhanced delivery (CED) for up to 6 months and showed that it results in early disease control at 6 months at a rate comparable to that achieved with temozolomide. OT-101 was administered to 89 R/R high-grade glioma (HGG) (Anaplastic Astrocytoma/AA:27; Glioblastoma multiforme/GBM: 62) patients with an intratumoral catheter using a convection enhanced delivery (CED) system. 77 patients (Efficacy population; GBM: 51; AA: 26) received at least the intended minimum number of 4 OT-101 treatment cycles. Response determinations were based on central review of MRI scans according to McDonald criteria. Standard statistical methods were applied for the analysis of data. Nineteen patients had a complete response (CR) or partial response (PR) following a slow but robust size reduction of their target lesions. In addition, 7 patients had stable disease (SD) lasting \geq 6 months. For the combined group of 26 AA/GBM patients with favorable responses, the median PFS was >3 years and OS was >3.5 years (16, 17). Hence, OT-101 administered intratumorally exhibits clinically meaningful single-agent activity and induces durable CR/PR/SD in R/R HGG patients. These results provided the proof of concept that targeting TGF β 2 with intratumoral OT-101 therapy can result in a favorable survival outcome for R/R HGG patients (AA, WHO grade 3 and GBM, WHO Grade 4).

OT-101: Pediatric DIPG

DIPG, the second most common malignant pediatric brain tumor, has a dismal outcome with available standard treatment modalities. No significant therapeutic advances have been accomplished in the treatment of this poor prognosis brain tumor and the average overall survival has remained <1 year with a 2-year survival rate of <10%. In solid tumors, the expression level of the TGF β has been identified as a significant contributor to disease progression and poor prognosis as well as resistance to standard therapy and metastasis. In particular, TGF β has been implicated in treatment resistance to targeted therapeutics, chemotherapy as well as immune-oncology drugs. Importantly, TGF β restrains anti-tumor immunity by restricting cytotoxic T-cell infiltration, recruiting regulatory T cells and inhibiting the maturation as well as function of natural killer (“NK”) cells. Amplified activity of the TGF β -Smad signaling pathway enhances tumor growth, invasion, as well as angiogenesis and has been implicated in the malignant phenotype and poor prognosis of high-grade gliomas in adults. Therefore, TGF- β has emerged as an attractive target for the therapeutic intervention of high-grade gliomas.

We recently performed a meta-analysis of TGF β 2 gene expression in primary tumor specimens from 29 pediatric DIPG patients in the publicly available archived datasets. Our data provided unprecedented evidence that TGF β 2 is expressed at high levels in pediatric DIPG. Three TGF β 2 probesets exhibited 1.8-2.5-fold increased levels of expression in DIPG patients. Our meta-analysis provided new evidence that TGF β 2 gene and its interactome are expressed in pediatric DIPG at significantly higher levels than in normal tissues or low-grade gliomas. Hence, TGF β 2 is an attractive molecular target for immunotherapy of pediatric DIPG.

The US FDA has granted the Company a RPD for pediatric DIPG.

OT-101 for Treatments of Corona Viruses

When COVID-19 emerged in China, the Company and GMP contemplated a collaboration to develop drug candidates for COVID-19. Oncotelic Inc. and GMP entered into a research and services agreement (the “*GMP Agreement*”) in February 2020 memorializing their collaborative efforts to develop and test COVID-19 antisense therapeutics. In March 2020, Oncotelic reported the anti-viral activity of OT-101 – its lead drug candidate currently in phase 3 testing in pancreatic cancer and glioblastoma. In an in vitro antiviral testing performed by an independent laboratory, OT-101 showed that it was highly active against COVID-19. Further, in March 2020, the Company, Oncotelic Inc. and GMP entered into a supplement to the Agreement (the “*Supplement*”) to confirm the inclusion of OT-101 within the scope of the GMP Agreement, pending positive confirmatory testing against COVID-19. In consideration for the financial support provided by GMP for the research, pursuant to the terms of the GMP Agreement (as amended by the Supplement), GMP is entitled to obtain certain exclusive rights to the use of the Product in the field of the treatment of COVID-19 on a global basis, and an economic interest in the use of the Product in the field of the treatment of COVID-19 including 50/50 profit sharing. In March 2020, the Company reported the anti-viral activity of OT-101, in an in vitro antiviral testing performed by an independent laboratory, OT-101 has an 50% effective concentration (EC50) of 7.6 μ g/mL and is not toxic at the highest dose of 1000 μ g/mL giving a safety index (SI) value of >130, which is considered highly active and on par or superior to Remdesivir- a Gilead’s drug. Unlike Remdesivir- OT-101 targets not only the virus replication but also the virus induced pneumonia and fibrosis.

A Phase 2 C001 Covid Study: “A Double-Blind, Randomized, Placebo Controlled, Multi-Center Study of OT-101 in Hospitalized COVID-19 Subjects” was completed for OT-101 in South America, that can expand into a Phase 3 trial if the data supports the safety of the drug. This was a randomized, double-blind, placebo-controlled Phase 2 study intended to evaluate the safety and efficacy of OT-101 in adult patients hospitalized with positive COVID-19 and pneumonia. By suppressing TGF- β , OT-101 suppresses COVID-19 replication directly and has the potential to also suppressed viral induced pneumonia and fibrosis. In October 2021, Data lock and Study Data and Analysis Data Models (SDTMs & ADaMS Databases) were generated for the trial. The trial compares OT-101 in combination with Standard of Care (“SOC”) versus Placebo plus SOC (N= 32 pts at 2:1 randomization ratio). SOC includes dexamethasone, the only drug known to improve outcomes in severe cases of COVID-19. The top line data was:

- 1) Safety endpoints met. OT-101 as a TGF- β inhibitor was safe to administer to COVID-19 patients including severe/critical COVID-19 patients.
- 2) Efficacy signals were obtained. End of treatment (Day 7) mortality for the entire study population was 4.5% OT-101 versus 20% for placebo.
- 3) Incidence of >96% viral load knockdown on End of Treatment (Day 7) was 89% for OT-101 versus 67% for placebo.
- 4) Overall survival improved 3X for critical COVID-19 pts (4 days for placebo versus 14 days for OT-101, p < 0.0166).

Artemisinin for Treatment of COVID-19

Artemisinin derived from Chinese herb *Artemisia annua* L. (Sweet wormwood) has been used medicinally to treat fevers for centuries in China. Like other potential COVID-19 therapeutic agents such as Hydrochloroquine and Remdesivir, the efficacy of Artemisinin remains to be tested in well controlled and sufficiently powered clinical trials.

We discovered that Artemisinin was highly potent at inhibiting the ability of SARS-CoV-2 to multiply while also having an excellent safety index. The Company’s test results during an in vitro study at Utah State University showed Artemisinin having an EC50 of 0.45 ug/ml, and a Safety Index of 140. Artemisinin has the potential to target multiple viral threats, including COVID-19, by suppressing both viral replication and clinical symptoms that arise from viral infection. Viral replication cannot occur without TGF- β . Artemisinin also has been reported to have antiviral activities against hepatitis B and C viruses, human herpes viruses, HIV-1, influenza virus A, and bovine viral diarrhea virus in the low micromolar range. TGF- β surge and cytokine storm cannot occur without TGF- β . Clinical consequences related to the TGF- β surge, including ARDS and cytokine storm, are suppressed by targeting TGF- β with Artemisinin.

The availability of Artemisinin as a pre-existing dietary supplement may allow it to be deployed in many countries, including developing countries where the healthcare system can easily be overwhelmed. Its safety was clearly superior to chloroquine and remdesivir. The Company’s ARTI-19 trial in India was conducted by Windlas, the Company’s business partner in India, as part of the Company’s effort at deploying ArtiShield™ across India, and a variation of that in Asia, Africa, and Latin America. No adverse events were reported that required discontinuation of treatment. When ARTIVeda™ / PulmoHeal™ was added to the SOC, more patients recovered faster than SOC alone. 31 of 39 (79.5%) of patients taking became asymptomatic after 5-day of therapy. In comparison, only 12 of 21 control patients (57.1%) treated with SOC alone became asymptomatic on day 5. For the sicklier patients (WHO scale 4), the median time to becoming asymptomatic was only 5 days for the ARTIVeda™ / PulmoHeal™ + SOC group, as compared to 14 days for the SOC alone group. These data sets provided clinical support that targeting the TGF- β pathway with ARTIVeda™ / PulmoHeal™ may contribute to a faster recovery of patients with mild to moderate COVID-19 patients. The Company has published the results of the trial in certain renowned publications. The Company is intending to continue developing Artemisinin as pharmaceutic for tropical viral diseases. Windlas had applied for regulatory approval for its Artemisinin based product, ArtiShield™, but has not been able to obtain regulatory approval for use of ArtiShield™ as a COVID-19 therapy and as such, no significant revenues have been reported by Windlas nor have we accrued any royalties on Artemisinin due from Windlas.

CA4P as an Immuno-Oncology Agent

Radiation therapy, recognized for its potent cytotoxic effect on cancer cells by inducing direct DNA damage, can sometimes elicit a systemic antitumoral response. Irradiation releases a plethora of neoantigens and pro-inflammatory cytokines, acting like an in-situ vaccine, resulting in tumor regression within the primary site, but may also occasionally result in regression of distant secondary lesions. This regression of distant cancer metastases when the primary tumor is irradiated is defined as the abscopal effect. Yet, an abscopal effect with radiotherapy alone occurs infrequently, signifying that the antitumor immunity caused by radiation is not sufficient enough to abolish the tumor and its metastases nor able to prevent the metastatic process or the immunosuppressing effect the cancer exhibits on the host’s systemic macroenvironment. Recently, several studies have confirmed the synergistic antitumoral immunity caused by the combination of radiation with immunotherapy, which has demonstrated a durable abscopal effect in patients with advanced malignancies. Postow, et al, Golden, et al, Hinicker, et al and others have all described early findings of a reproducible abscopal effect when combining irradiation with Ipilimumab and/or Nivolumab.

Similarly, CA4P causes rapid and widespread tumor cell necrosis. A number of laboratories have shown that the type of tumor cell death induced by ischemic necrosis not only controls the presence or absence of specific tumor antigens, but also can result in immunological responses ranging from immunosuppression to anti-tumor immunity. The terms “immunogenicity of cell death” or “immunogenic cell death” (ICD) is often used by scientists to describe the ability of dead/dying cells (especially of tumor cells) to mount antigen-specific and particularly CD8 + T-cell-mediated adaptive immune responses and not simply lead to innate inflammation. CD8 + T-cells play significant role in tumor protection and development of this type of immunity. A modernized concept has emerged which defines immunogenic cell death in general because of mutual or consequent processes including endoplasmic reticulum stress release of “find-me” signals (e.g., ATP), exposure of “eat-me” signals (e.g., calreticulin, phosphatidylserine) and damage-associated molecular patterns (DAMPs [HMGB1, F-actin]). These molecular changes might occur in the cells undergoing necrotic death. These and other signals appear to be relevant to the potential for CA4P to increase immunogenicity following induction of ischemic necrosis.

Preclinical studies in which CA4P was combined with an anti-CTLA4 antibody using an EMT-6 mammary tumor model showed that 7 out of 8 mice receiving a combination of CA4P and an anti-CTLA4 antibody experienced complete remission of their tumors, compared to only 1 of 8 in the CA4P monotherapy arm and 2 of 8 in the anti-CTLA4 antibody monotherapy.

Three of four follow-up preclinical studies confirmed that CA4P combined with immuno-oncology agents could delay tumor growth. Follow-up studies were conducted in a CT26-32 colon cancer model, a larger tumor EMT-6 mammary cancer model, and a C3H mammary cancer model. Studies in a CT-26-32 colon cancer animal model using CA4P combined with anti-CTLA4 antibodies demonstrated a 77% reduction in tumor size compared to immuno-oncology agents alone, and an 89% reduction in tumor size compared to control. This large tumor model also showed a survival benefit for the animals receiving combination therapy, with all animals in the combination therapy group surviving to the end of the study, compared to no animals surviving on the control and only half of the animals surviving that received immuno-oncology agents alone.

Additional analyses of changes induced within tumors following combination therapy have shown that CA4P increases the immunogenic effect of checkpoint inhibitors when used alone as monotherapy. Tumor-fighting white blood cell counts, T-cells and cytotoxic T-cells compared to immuno-oncology agents alone. Tumor necrosis with the combination of CA4P and immuno-oncology agents is nearly double the necrosis with only immuno-oncology agents (63.9% compared to 32.8%, control = 25.8%).

The overall data from all these studies provides evidence that CA4P may enhance the activity of immuno-oncology agents for the treatment of cancer, including anti-CTLA4 antibodies. Furthermore, CA4P has clinical activity in melanoma in early clinical testing and repeated demonstration of CA4P mediated necrotic tumor cell death across 17 completed clinical trials and >500 patients. During various phase 1 studies, we found that CA4P treatment resulted significant disease control among patients with solid tumors who progressed on standard therapies. CA4P treatment resulted in 2 Stable Disease (SD) of 5 melanoma patients treated. The combination of CA4P with carboplatin and paclitaxel was well tolerated in the majority of patients with adequate premedication and had antitumor activity in patients who were heavily pretreated. Patients with advanced cancer refractory to standard therapy were treated with CA4P as a 10-min infusion, 20 h before carboplatin, paclitaxel, or paclitaxel, followed by carboplatin. Responses were seen in 10 of 46 (22%) patients with ovarian, esophageal, small-cell lung cancer, and melanoma. One Partial Response (PR) was observed of 6 melanoma patients treated follow progressing during first-line trial therapy with dacarbazine and sorafenib. In melanoma animal model- B16-F10 murine melanoma experimental tumors- seventy-four hours after drug administration, a decrease in the number of tumor blood vessels was apparent and necrotic areas within tumors were visible. Building on the single agent activity of CA4P, we are expecting that combination of CA4P with Ipilimumab or other immuno-oncology drug would result in improved tumor control for these patients above the 2 PR out of 17 patients treated with Ipilimumab alone which supported the approval of Ipilimumab in pediatric melanoma.

CA4P: Pediatric Melanoma

Until the recent approval of ipilimumab as the first immunotherapy agent approved for children, metastatic or nonresectable pediatric melanoma did not have any FDA-approved therapies available. As for adult melanoma patients, the mainstay of care is surgical excision. Studies also show that children treated for melanoma should be closely monitored as they are at increased risk of recurrence later in life. However, there are only very limited data on the efficacy of systemic therapy in children and adolescents with advanced melanoma and new effective therapies are urgently needed. There are only very limited data on the efficacy of systemic therapy in children and adolescents with advanced melanoma. Several phase I/II trials have been designed to evaluate therapies for pediatric cancer patients that included subsets of patients with advanced melanoma.

Ipilimumab was evaluated in a phase I clinical study in children with unresectable stage IIIC or IV melanoma and in a pediatric phase II trial (NCT01696045) that included children aged 12 years or older with previously treated or untreated, unresectable stage III or IV malignant melanoma. Of the 17 melanoma patients older than 12 years treated with ipilimumab across both studies, two experienced objective responses. Immune-related adverse events included pancreatitis, pneumonitis, endocrinopathies, colitis, and transaminitis, with dose-limiting toxicities observed at 5 mg/kg. No grade 2 or higher immune-related toxicities were identified at doses of 3 mg/kg or less. Based upon the results of these studies and evidence from studies in adult patients, in July 2017, the FDA approved ipilimumab for the treatment of unresectable or metastatic melanoma in children aged 12 years and older.

It is expected that combination of CA4P with Ipilimumab or other immune-oncology drugs would result in improved tumor control for these patients above the 2 PR out of 17 patients treated with ipilimumab.

The FDA has granted Rare Pediatric Disease Designation for CA4P/ Fosbretabulin tromethamine for the treatment of stage IIB–IV melanoma due to genetic mutations that disproportionately affect pediatric patients as a drug. Preclinical studies in which CA4P was combined with an anti-CTLA4 antibody using an EMT-6 mammary tumor model showed that 7 out of 8 mice receiving a combination of CA4P and an anti-CTLA4 antibody experienced complete remission of their tumors, compared to only 1 of 8 in the CA4P monotherapy arm and 2 of 8 in the anti-CTLA4 antibody monotherapy. This application is based on observed CA4P activity in melanoma in early clinical testing. During various phase 1 studies, we found that CA4P treatment resulted significant disease control among patients with solid tumors who progressed on standard therapies. CA4P treatment resulted in 2 Stable Disease (SD) of 5 melanoma patients treated. One Partial Response (PR) was observed of 6 melanoma patients treated follow progressing during first-line trial therapy with dacarbazine and sorafenib. Building on the single agent activity of CA4P, we are expecting that combination of CA4P with Ipilimumab or other immune-oncology drug would result in improved tumor control for the target pediatric population above the 2 PR out of 17 patients treated with Ipilimumab alone which supported the approval of Ipilimumab in pediatric melanoma.

OXi4503 for Acute Myeloid Leukemia

OXi4503 (combretastatin A1-diphosphate; CA1P) is a novel investigational VDA that has been shown to have a significant in vitro cytotoxic as well as chemo-sensitizing activity against human AML cells. OXi4503 also exhibited in vivo anti-leukemic activity in xenografted mice with human AML.

OXi4503 employs a new, broader strategy against AML than currently exists for standard chemotherapy, as it provides a dual mechanism of action involving both anti-vascular effects and direct cytotoxicity to AML cells. Vascular and/or Bone marrow endothelial cells (“ECs”) appear to provide a protective effect for AML cells, keeping them dormant within the bone marrow. VDAs may target these ECs and reverse their chemo protective effect, providing a novel approach to the treatment of AML which may otherwise be resistant to other chemotherapeutic therapies. Preclinical data indicate that OXi4503 alone and in combination with traditional AML treatments such as cytarabine may provide significant benefit in eliminating AML cells. Results from two completed Phase I clinical trials demonstrated the clinical impact potential of OXi4503 against relapsed AML when it is alone or in combination with the standard chemotherapy drug cytarabine (“ARA-C”) can induce complete remissions in relapsed AML patients. Notably, OXi4503 showed single agent activity in a clinical Phase I trial and resulted in complete remission of a relapsed AML patient. Sustained complete remissions were also achieved in relapsed AML patients who were treated with OXi4503 in combination with ARA-C.

OXi4503 has received orphan designation for AML in both the United States (Designation No. 12-3824) and the European Union (Designation No. EU/3/15/1587 - EMA/OD/144/15). In 2017, the FDA has granted fast-track designation to OXi4503 for the treatment of relapsed/refractory AML. Oxi4503 met the qualifying criteria for the Fast Track designation since AML is a serious and life-threatening condition, and a large unmet medical need exists for additional treatment strategies for this disease.

The Investigator-Sponsored trial (IST) UF OXi4503 AML MDS Ph 1 (UF4503), “A Phase 1 Clinical Trial of OXi4503 for Relapsed and Refractory AML and Myelodysplastic Syndromes (“MDS”) was designed to evaluate the safety profile and the maximum tolerated dose (“I”) as well as a recommended Phase 2 dose (RP2D) of OXi4503 in patients with recurrent/refractory (R/R) AML and MDS (ClinicalTrials.gov NCT01085656) (14, 50). The clinical single agent activity of OXi4503 was also assessed within the confines of a Phase 1 clinical trial setting. A total of 18 patients enrolled in the study from February 2011 to January 2016. The patients were predominantly male (78%) and the median age was 62.5 years. Of the 15 patients with AML, 4 (27%) had primary refractory AML, 2 (13%) were in first relapse, and 9 (60%) had refractory AML beyond CR1.

Eight patients (44%) completed at least one cycle of CA1P and were evaluable for efficacy assessments. Of the eight patients evaluable, one achieved morphologic remission with incomplete blood count recovery (“CRi”) after 1 cycle but came off study in cycle 2 due to fungal pneumonia. Three patients had stable disease after at least one cycle of CA1P. Three patients experienced progressive disease after 1 cycle of CA1P and were withdrawn from the study.

The Phase 1 dose-escalation combination of the Company sponsored study OX1222 (NCT02576301) was a Phase 1b dose escalation study of OXi4503 as a single agent and in combination with Cytarabine with subsequent combination Phase 2 cohorts for subjects with relapsed/refractory (R/R) AML and MDS. 29 subjects were treated with OXi4503 in combination with Cytarabine.

Of these 29 patients, one was evaluable for safety analysis, but no EFS/OS data or response data were available for activity evaluations. Of the 28 patients evaluable for EFS/OS outcome analyses, 26 had AML and 2 had MDS. For the 26 AML patients, there were 4 CRs. The CR responses were associated with prolonged overall survival substantially better than the median OS time: One patient who became eligible for allogeneic PBSCT remains alive, free-of-leukemia at 720+ days. The overall survival times were 434 days, 521 days, 535 days and 720 days, respectively. The median OS time for the 4 patients who achieved a CR/CRi was 528 (95% CI: 434 - NA) days which was significantly better than the median OS time of 113 (95% CI: 77 - 172) days for the remaining 22 AML patients who did not achieve a CR (Log Rank = 11.8, P-value = 0.0006).

Three of the 4 CR/CRis were achieved in 1st relapse patients while one patient with CRi had failed 5 previous regimens, including 7:3, HiDAC, and PBSCT. Patients who achieved a CR/CRi went on to receive other treatments after receiving 4-6 cycles of OXi4503. The median OS for all 26 AML patients who received therapy was 119 (95% CI: 87 - 232) days. Patients who had rapidly progressive disease or developed toxicity could not get as many OXi4503 doses as patients who responded to their treatment favorably. The median OS time for 18 patients receiving 1-3 doses Of OXi4503 was 82 (95% CI: 66 - 135) days and these patients exhibited a worse survival outcome compared to 9 patients receiving 4-6 doses which was recorded at 434 (95% CI: 191 - NA) days (Log Rank = 12.3, P-value = 0.0004).

OXi4503: Pediatric AML

Pediatric AML is most common during the first 2 years of life and during the teenage years. In the United States, about 730 people under age 20 are diagnosed with AML each year. The number of deaths was 0.6 per 100,000 children per year. These rates are age-adjusted and based on 2012-2016 cases.

Compared with pediatric acute lymphoblastic leukemia (“ALL”), the outlook for pediatric AML patients is far worse. Even though pediatric AML cases are far fewer than pediatric ALL, the mortality rate is about the same, illustrating that AML is a devastating disease and the need for continuing research to identify effective treatments for these children. The prognosis for AML in children remains relatively poor, with a 5-year survival rate of 64% compared with 90% in ALL.

Patients with poor-risk cytogenetics include those that lack any favorable changes and harbor any of the following cytogenetic abnormalities: monosomy 7, monosomy 5, deletion of 5q, abnormalities of 3q, t(6;9)(p23;q34), and complex karyotype which is defined as three or more cytogenetic abnormalities. Children and adolescents harboring these unfavorable features have survival of less than 50 percent, and in many cases less than 20 percent.

The standard of care for management of pediatric AML involves predominantly induction therapy intended to put the patient into remission and consolidation chemotherapy designed to eradicate leukemia cells that may have escaped front line induction therapy. Whereas, >80% of pediatric AML patients will achieve remission, only about half will remain disease-free for an appreciable period of time. Approximately 30 percent of children with AML will experience relapse and only one third of them become long-term survivors after salvage therapy. Although cure rates for children and adolescents with AML have improved, outcomes for pediatric AML patients with adverse prognostic biologic features (e.g. high risk genetic mutations or chromosomal abnormalities) and refractory or relapsed disease who failed or did not respond to their initial standard induction chemotherapy remains poor and limited treatment options are available for these patients. Novel therapies for these high-risk patients are urgently needed. OXi4503 shows clinical potential and promise for this indication based on the proof-of-concept data obtained from nonclinical and clinical studies.

The FDA has granted a RPD for OXi4503 for the treatment of pediatric AML.

AI/Blockchain: PointR/EdgePoint

PointR, an acquisition made in November of 2019, develops, and deploys high performance cluster computers and artificial intelligence (“AI”) technologies for inference processing of a camera-grid that are interconnected to create 360-degree vision-grid to track men and materials indoors. The scope has expanded to include the entire life cycle of a drug: discovery, clinical trials, and manufacturing. These grids provide real-time, localized decision-making harvesting complex data from structured and unstructured sources. Originally intended to be used exclusively for operator tracking in manufacturing, the AI is broadened to automate surveillance and inspections in processing lines. In addition, AI is being targeted to provide support for clinical trials and pre-clinical research.

The deployment of this supercomputing grid enables data capture and insight extraction in real time in blocks which are chained into blockchain ledger records serving as immutable transactions for stakeholders such as regulatory agencies, caretakers, insurers, payers, and manufacturers. The vision grid can integrate and fuse data from any type of sensors or collection devices. For example, the platform is a network of activity detection cameras and proximity beacons functionalized with AI algorithms to monitor, evaluate, and archive real time visual data as a series of metadata entries in a Blockchain ledger.

The use of AI and machine learning will streamline operations, enhance efficiency, and create immutable audit records for regulators while reducing labor overhead and source of human errors. The deployment of this supercomputing grid enables data capture and insight extraction in real time in blocks which are chained into blockchain ledger records serving as immutable transactions for stakeholders such as regulatory agencies, caretakers, insurers, payers, and manufacturers. The PointR grid can integrate and fuse data from any type of sensors or collection devices. For example, the platform is a network of activity detection cameras and proximity beacons functionalized with AI algorithms to monitor, evaluate, and archive real time visual data as a series of metadata entries in a Blockchain ledger.

In the pharmaceutical industry PointR’s AI combined with Blockchain will be used in the entire life cycle of a drug: discovery, clinical trials and manufacturing. Leveraging its deep partnership with IBM, the PointR team will combine its own AI Vision technology with industry standard Blockchain to transform drug manufacturing and real-world evidence monitoring for clinical trials. The combined system has the potential to automatically record individual key steps in cGMP manufacturing operations including the flow of people, raw materials and operations in trusted perpetual blockchain ledgers that are indisputable. This has the potential to create much more efficient GMP manufacturing operations while simultaneously improving reliability and data security.

Data integrity is a large and unsolved problem within drug development and manufacturing. Data from 5 1/2 years of FDA inspection records, from 2014 to 2020, for four major markets: China, India, Europe, and the United States, revealed endemic data integrity issues including data manipulation. These stipulate that all manufacturing data must be preserved — unaltered — and made available to regulators. For example- out of more than 12,000 FDA inspections of drug plants in the United States, about 7% uncovered violations of the FDA’s data integrity rules including data manipulation. In India, about 24% of the plants inspected committed some sort of data violation, while in China, that figure is 31%. The consequences of data manipulation would be the invalidation of clinical data based on the adulterated drug product, safety concerns and liabilities to the patients, and FDA sanction and legal action.

Country	Number of inspections	Number (percentage) of violation forms (Form 483) issued	Percentage of Form 483s that cite data integrity violations	Percentage of Form 483s that cite data manipulation
China	916	617 (67.4%)	48%	31%
India	1,693	976 (57.6%)	44%	24%
Europe	2,969	1,445 (48.7%)	36%	18%
USA	13,650 (estimated)	6,794 (49.8%)	26%	7%

The local real time AI processing of the data through grid computing allows for flexibility in data processing and AI training. Federated learning through grid supercomputing is inherently faster and more effective than mainframe supercomputing. In general, AI methods excel at automatically recognizing complex patterns in imaging data and providing quantitative assessments of the underlying characteristics. PointR AI deep learning algorithms have the capability of detecting meaningful relationships in image-recognition tasks in radiology and pathology. The coupling of image algorithm with Vision allows us to integrate imaging data frequently encountered during patient care into coherent metadata for blockchain ledgers. This can transform the design and implementation of clinical trials and accelerate outcomes. Combined with Blockchain the technologies will create trusted irrefutable ledgers which track real world monitoring and evidence gathering.

The Company's non-controlling interest subsidiary, EdgePoint, is working to bring a solution that addresses both issues using proven technology. We intend to solve this problem with AI "machine vision" based on our proprietary technology, which is integrated with IBM and re-sold by IBM and its partners. We address the data integrity problem in a stepwise fashion. We start with streamlining the warehouse supply chain component. Later we add modules that spread across the plant in a comprehensive manner. We may spin-off Edgepoint as a separate publicly traded entity.

We expect our warehouse modules will streamline many labor issues in a manner very similar to Amazon-Go stores that run without cashiers. Monitored by a camera grid, shoppers simply enter, grab items and leave. A shopper can grab a sandwich and soda and leave within few minutes without checkout lines and delays. Amazon's AI machine vision automation identifies the shoppers, the items they picked-up, consummates the transaction and sends receipt. Sounds like science fiction but there are 11 such stores nationwide and disrupting the retail industry.

Clinical AI Deployment: Oncotelic is anticipating a series of investigator led studies for its flagship product, OT-101. Investigator led studies are conducted by physicians in academic institutional settings. The university settings of clinical studies provide several benefits including their neutrality (appreciated by regulators), high quality (enhanced research corpus) and reduced expense (in-house resources). However, in data-collection, cleansing and analysis the investigator studies can be resource starved so resort to unconventional techniques such as spreadsheets on laptops which can affect the study. To offset the deficiency Oncotelic will deploy AI to streamline its clinical trials. By creating a data lake based on and in partnership with Amazon Web Services ("AWS") data will flow directly from patient's hospital electronic medical records (EMR) into the clinical trial data-store called EDC. AI processes will extract relevant information from the records and populate the clinical database without any human intervention ensuring accuracy of the study-data transfer. Later the data can be analyzed by a number of machine learning tools that are attached to AWS frameworks for submission to regulators. The entire data workflow and storage will be under AWS regulation compliance practices satisfactory to any regulator.

Leveraging its partnerships with industry leaders, the AI team will combine its own AI technology with industry standard Blockchain to transform drug manufacturing. The combined system has the potential to automatically record individual key steps in cGMP manufacturing operations including the flow of people, raw materials, and operations in trusted perpetual blockchain ledgers that are indisputable. This has the potential to create much more efficient GMP manufacturing operations while simultaneously improving reliability and data security.

The company is designing a nanoparticle manufacturing plant to produce its own as well as 3rd party products. The plant will be paperless incorporating integrated computer automation with a real-time dashboard that includes AI for predictive maintenance and control of its fill-finish lines. Also, AI-based machine vision will inspect final vials for quality control before labeling, packing and distribution. The cost-benefit for AI is clear when it replaces labor-intensive and error-prone manual process of vial-inspections to detect inconsistencies for example accidental particulates in the mix, level-of the fill and damaged stoppers. The AI promises to replace labor-intensive and error-prone manual processes.

The deployment of this supercomputing grid enables data capture and insight extraction in real time in blocks which are chained into blockchain ledger records serving as immutable transactions for stakeholders such as regulatory agencies, caretakers, insurers, payers, and manufacturers. The vision grid can integrate and fuse data from any type of sensors or collection devices. For example, the platform is a network of activity detection cameras and proximity beacons functionalized with AI algorithms to monitor, evaluate, and archive real time visual data as a series of metadata entries in a Blockchain ledger.

The use of AI and machine learning will streamline operations, enhance efficiency, and create immutable audit records for regulators while reducing labor overhead and source of human errors.

Taking Retail AI to Drug Manufacturing

Using its Amazon-Go-like cashier-less AI proprietary technology, EdgePoint intends to address the human element in the drug manufacturing industry. Its TrustPoint product is designed to track men and materials with a camera grid and commit each transaction to a series of immutable blockchain records that are irrefutable permanent record of men and materials. The addition of blockchain technology, specifically our partner IBM's version called Hyper-Ledger, enables manufacturers to conduct audits in a reliable and streamlined manner in a trustworthy system.

This automation of manual verification eliminates wasted and indeterministic human cycles. The product is a novel and potentially disruptive application of AI neural networks and blockchain to ensure compliance with drug sponsors and the FDA while ensuring a return on investment ("ROI") for manufacturers by slashing labor costs.

The EdgePoint technology is already proven in the retail sector and generating revenues at a US east-coast, convenience store chain in partnership with IBM and its business partner Meridian IT. Meridian is a \$0.5 billion systems conglomerate that ranked top-25 of managed services providers with 775 employees worldwide. The ceiling of the Amazon-Go retail store is a few hundred camera grid that track and shoppers with precision and monitor products they collect from shelves. When the shopper leaves the store, the AI automatically recognizes the shopper and items retrieved to issue a receipt. No human cashier is involved.

TrustPoint is a re-deployment of this type of tested technology for GMP drug manufacturing relieving human errors in supply chain and increasing compliance with warehouse operating procedures. For example, the warehouse module of TrustPoint will automatically create a shopping list from standard templates and alert supply chain personnel to collect and deliver a list of raw materials to manufacturing.

TrustPoint will track personnel authorized to collect materials of the shelves in compliance with picklist and generate alerts if the wrong materials are picked. It will commit the data to an immutable block chain ledger for later retrieval in case of compliance issues. Blockchain records are irrefutable and can be reproduced to trace with fidelity operating activities, e.g. authorized personnel, what they picked, who they delivered to with date and timestamps of each action.

In manufacturing plants, the implementation is even simpler Amazon-Go. The shoppers (supply chain personnel) are limited in number, not random and the raw materials are stable, and their shopping-list is automated by the machines that track the “shopping”. In this simplified version of Amazon-Go TrustPoint tracks supply chain personnel and monitors list of items collected from shelves. The automation is designed to reduce the overall human error element and increase compliance with standard operating procedures of the manufacturer, its customers and governmental oversight agencies.

Market

Human labor costs represent the most expensive element in drug manufacturing. In the \$70.0 billion CDMO (contract development manufacturing operations) industry, personnel costs of \$30 billion are ripe for computer automation. Until now, computer technologies like MRP and ERP created more problems than resolved. The labor problem is compounded by the cost of personnel onboarding and turnover. It takes 6-9 months to train a quality control employee only to lose them to a competitor.

The market is large. Approximately 10,000 drug manufacturing facilities worldwide are FDA and EMA (European FDA) registered, representing a significant addressable market for EdgePoint. Many such facilities run on paper-based, handwritten forms ripe for modernization by the TrustPoint product. The \$70.0 billion CDMO industry is poised to grow to \$123.0 billion by 2025 according to industry experts. EdgePoint has first mover advantage and expects to lead the industry’s transition. It expects to garner significant share of the labor automation market. Addressing the \$30.0 billion labor market and more specifically the \$12.0 billion supply-chain segment, EdgePoint expects to improve efficiencies and create additional value for shareholders. EdgePoint intends to address the \$12.0 billion market with AI Vision, BlockChain and NLP.

Go-to-Market: IBM

The Company’s go-to-market plan is to execute a proof-of-concept project with a biologic substance manufacturer called iBIO Inc. based in Texas. The expected outcome is a re-sellable product for materials release deployed by iBIO with production level data to attract a rich pipeline of paying customers. The company has partnered with IBM in multiple areas including sales and distribution. The significant value to IBM in this partnership is the enrichment EdgePoint provides to the IBM product suites vertically targeting cGMP manufacturing. There are three areas of technology enrichment and technology collaboration.

1. **AI Vision:** IBM has developed data center hardware and software for machine vision training. While EdgePoint complements IBM products with its in-plant, on-premises low profile cluster computers called BRICKs and cameras. The integration between EdgePoint and IBM machine vision products (IBM Power AI Vision software running on state-of-the-art IBM AC922 GPU cluster computer) and EdgePoint enables continuous updates to the AI models.
2. **Blockchain:** IBM has created an open source product called Hyper-Ledger which has been endorsed by multiple vertical markets including Life Sciences and Financial industries. Integrating AI machine vision and Hyper-ledger will enrich the IBM’s offerings in the cGMP manufacturing market.
3. **Warehouse Management Software:** IBM’s Sterling software is an industry leader in warehouse management and supply-chain optimization. In addition, IBM is in the process of integrating its Power AI Vision software (PAIV) with Sterling. Since EdgePoint AI vision is integrated with PAIV it will enable EdgePoint to extend the Sterling platform for GMP in an easy and flexible manner.

The technology enrichment and integration by EdgePoint extends the already committed relationship with IBM. The main benefits of the IBM relationship are three-fold: (1) Sales: IBM direct sales focus enables penetration into top 10 large pharma companies, while IBM value-added-sellers (“VARs”), (2) focus on smaller CDMOs by region, and IBM and partners provide turnkey cloud managed services with high reliability, availability and monitoring and (3) trust, as the industry relies on the core reputation of IBM’s backing to deploy EdgePoint.

EdgePoint is addressing an unsolved problem with a proprietary technology and first mover advantage to capture a significant share of the GMP manufacturing market. The product is a novel and potentially disruptive application of AI neural networks and block-chain to ensure compliance with drug sponsors and the FDA while ensuring ROI for manufacturers by slashing labor costs. The side benefit is that it brings this industry into the fourth industrial revolution which includes AI, cloud computing, blockchain, and IoT sensor fusion.

In addition to ARTIVeda™ / PulmoHeal™, the Company has also developed and launched a mobile application called ArtiHealth and a post marketing survey that have been included with ArtiVeda, which along with ArtiHealth is called PulmoHeal™. PulmoHeal™ is a full evaluation package of drug and assessment platforms for COVID-19, and other respiratory disease patients. Windlas has launched PulmoHeal™ on Amazon.in and a couple other websites. The platform has been powered by the Company’s AI supercomputing and AI platform in conjunction with IBM. Initially, the cough assessment will be powered by Salcit AI module. Per Salcit, their AI module has overall accuracy in predicting the pattern of the disease at 91.97%, sensitivity at 87.2%, and specificity at 93.69%.

Our Strategy and Development Plan

We have been operating with significant capital constraints since the reverse merger between the Company and Oncotelic Inc, and for this time period we have been seeking to secure sufficient funding to continue our operations while we simultaneously seek to advance our all our investigational drugs for the treatment of cancer, coronaviruses, AI technology and more recently for PD, ED and FSD. Subject to our ability to secure additional capital, we would seek to further develop our product candidates. However, our inability to access capital historically has and may significantly impairs our ability to develop these compounds. If we are able to advance any or all of our drug candidates, we would seek to develop them till commercialization, however, there is no guarantee that we would be able to fully develop our products, obtain regulatory approvals and successfully commercialize them.

We continue to discuss collaboration opportunities with other biopharmaceutical companies, although to date have not secured any agreements with companies that are willing to purchase the products from us or license the development and commercialization rights. We intend to continue to seek a partner to acquire the marketing rights to our product candidates and to finance further clinical studies and will seek to complete a transaction if we are able to reach mutual agreement on terms. We were in discussions with GMP to further the development of OT-101, primarily for oncology indications and COVID-19, as well as CA4P and Oxi4503. The Company entered into a JV with Dragon Overseas Capital Limited (“Dragon Overseas”) and GMP Biotechnology Limited (“GMP Bio”), affiliates of GMP on March 31, 2022. GMP Bio and the Company will work together to further the development of OT-101, wherein the Company would provide the technology and technical expertise and GMP Bio would fund the development expenses.

In addition to entering into a transaction that would provide funding for the further development of our product candidates, other elements of our development strategy would currently include:

- Initiating clinical trials of OT-101 in various cancers: We have yet to initiate any trials but we are evaluating conducting such trials in the US as well as other countries like China in conjunction with GMP Bio. We are looking to conduct such trials in combination with other drugs like checkpoint inhibitors.
- Conducting follow up clinical trials of OT-101 for COVID-19: The Company planned and initiated a Phase 2 trial for OT-101 in Latin America and reported preliminary results in October 2021. Data lock and Study Data and Analysis Data Models were generated for the Phase 2 COVID-19 Study. The trial compared OT-101 plus SOC versus Placebo plus SOC in a total of 32 patients at a 2:1 randomization ratio. We are considering expanding the study into China and other countries. For China, we could conduct such trials in conjunction with our development partners GMP.
- We have completed a 120-patient trial for Artemisinin. We continue to further develop Artemisinin as pharmaceutical against respiratory viral infections.
- Initiating a clinical trial of CA4P in combination with an immuno-oncology agent: Based on preclinical data generated to date and support of two well-known immuno-oncology clinical investigators, we have developed a protocol for a clinical trial that would be the first human clinical trial combining CA4P and an approved immuno-oncology agent. This trial is designed to make initial determinations of whether the combination results in improved patient outcomes, including safety, overall survival, progression free survival, objective response rate, tumor size and other parameters.
- Continuing to evaluate OXi4503 in a clinical trial: We have completed six ascending dose cohorts of OXi4503 in combination with cytarabine in Study OX1222 in patients with relapsed/refractory AML and/or MDS. In the highest dose cohort, the sixth cohort of the study, we observed potential safety signals which triggered stopping rules for the study and resulted in a partial clinical hold from the FDA until we and the FDA assess additional safety data, particularly at the fifth dose cohort level. In the fifth dose cohort of OX1222, we have observed the best potential signs of efficacy to date in the trial and believe treatment of additional patients would provide additional evidence regarding the efficacy of OXi4503 in these indications
- Ramping up the apomorphine development program and initiating noninferiority trial comparing AL-101 against subcutaneous apomorphine for the treatment of PD. We are also considering to ramp up the apomorphine development programs for ED and FSD/HSDD.

REGULATORY MATTERS

Government Regulation and Product Approval

Government authorities in the United States and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. Our drug candidates must be approved by the FDA through the New Drug Application (“NDA”), process before they may be legally marketed in the United States.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (“FDCA”), and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to review or approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusal of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices (“GLP”) or other applicable regulations;
- submission to the FDA of an Investigational New Drug Application, or IND, which must be first approved by the FDA before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices (“GCP”) to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of FDA inspections of clinical sites and GLP toxicology studies; and
- FDA review and approval of the NDA.

The testing and approval process require substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Preclinical testing continues even after the IND is submitted. The IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent. Further, an institutional review board, or IRB, must review and approve the plan for any clinical trial before it commences at any institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative and must monitor the clinical trial until completed.

Each new clinical protocol must be submitted to the IND for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and efficacy in Phase 2 and 3 clinical trials.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The drug is initially introduced into human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- Phase 2: Involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to evaluate preliminary efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population. These studies are intended to establish the overall risk-benefit ratio of the product and provide, if appropriate, an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. IND Safety Reports must be submitted to the FDA, IRBs and the investigators for (a) any suspected adverse reaction that is both serious and unexpected; (b) any findings from epidemiological studies, pooled analysis of multiple trials, or clinical trials (other than those already reported in (a)); (c) any findings from animal or *in vitro* testing, whether or not conducted by the sponsor, that suggest a significant risk in humans exposed to the drug, such as reports of mutagenicity, teratogenicity, or carcinogenicity or reports of significant organ toxicity at or near the expected human exposure; and (d) any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, phase 2, and phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances, which may include orphan drug status and the first NDA application for a company.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA also may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The approval process is lengthy and difficult and the FDA may refuse to approve an NDA at its discretion or the FDA may require additional clinical or other data and information. Even if such additional data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy its criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we or others may interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to obtain approval of the NDA. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will generally inspect the facility or facilities where the product is manufactured. The FDA will also generally inspect selected clinical sites that participated in the clinical studies and may inspect the testing facilities that performed the GLP toxicology studies cited in the NDA.

NDAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Priority review and accelerated approval do not change the standards for approval but may expedite the approval process.

If a product receives regulatory approval, the approval may be limited to specific diseases or patient subpopulations and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, approval by the FDA may include a requirement for phase 4 testing, which involves clinical trials designed to further assess a drug's safety and effectiveness, and the FDA may require testing and surveillance programs to monitor the safety of approved products which have been commercialized.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in very limited circumstances.

In the European Union and Japan, orphan drug exclusivity regulations provide for 10 years of market exclusivity.

CA4P has been awarded orphan drug status by the FDA for the treatment of anaplastic, medullary, Stage IV papillary and Stage IV follicular thyroid cancers, ovarian cancer, neuroendocrine tumors and glioma. OXi4503 has been awarded orphan drug status by the FDA for the treatment of acute myelogenous leukemia. CA4P has been awarded orphan drug status by the FDA for the treatment of pancreatic cancer, melanoma, and glioblastoma.

CA4P has also been awarded orphan drug status by the European Commission in the European Union for the treatment of anaplastic thyroid cancer, ovarian cancer and neuroendocrine tumors. OXi4503 has been awarded orphan drug status by the European Commission in the European Union for the treatment of acute myelogenous leukemia. OT-101 has been awarded orphan drug status by European Commission in the European Union for the treatment of pancreatic cancer, melanoma, and glioblastoma.

Rare Pediatric Disease Designation

The FDA grants rare pediatric disease designation for diseases with serious or life-threatening manifestations that primarily affect people aged from birth to 18 years, and that affect fewer than 200,000 people in the U.S. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, a sponsor who receives an approval of a new drug application or biologics license application for a product for the prevention or treatment of a rare pediatric disease may be eligible for a voucher, which can be redeemed to obtain priority review for any subsequent marketing application and may be sold or transferred. Such vouchers can be valued at several millions of dollars, sometimes in excess of \$100 million.

The FDA granted Rare Pediatric Disease Designation for OT-101/Trabedersen for the treatment of DIPG as a drug for a rare pediatric disease.

The FDA granted Rare Pediatric Disease Designation for CA4P/ Fosbretabulin tromethamine for the treatment of stage IIB–IV melanoma due to genetic mutations that disproportionately affect pediatric patients as a drug.

The FDA granted Rare Pediatric Disease Designation for Oxi4503 for the treatment of AML as a drug for a rare pediatric disease.

Expedited Review and Approval

The FDA has various programs, including Fast Track, priority review, accelerated approval and breakthrough therapy, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints. Even if a drug qualifies for one or more of these programs, the FDA may subsequently decide the drug no longer meets the conditions for qualification or the FDA may not shorten the review or approval time period. Generally, drugs that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast-Track designated drug and expedite review of the application for a drug designated for priority review. Drugs that receive an accelerated approval may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials.

OXi4503 has been awarded Fast Track designation for the treatment of AML.

Foreign Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and if any of our product candidates are approved, we will be subject to additional regulations regarding commercial sales and distribution. Whether or not we obtain FDA approval to test a product candidate in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence testing any product candidate in those countries. Likewise, whether or not we obtain FDA approval to market a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence marketing of any product candidate in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, a company may submit marketing authorization applications, or MAAs, either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders or diabetes and optional for those medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessments report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

As in the United States, the European Medicines Agency, or EMA, may grant orphan drug status for specific indications if the request is made before an MAA is submitted. The EMA considers an orphan medicinal product to be one that affects less than five of every 10,000 people in the European Union. A company whose application for orphan drug designation in the European Union is approved is eligible to receive, among other benefits, regulatory assistance in preparing the marketing application, protocol assistance and reduced application fees. Orphan drugs in the European Union receive up to ten years of market exclusivity for the approved indication.

Reimbursement

Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. These third-party payors are increasingly challenging the prices charged for health care products and services. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption or application of price controls and cost-containment measures could limit our revenue. If third-party payors do not consider our products to be cost-effective, they may not pay for our products even if we receive approval, or their level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposes requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D (the Medicare prescription drug benefit), Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs not covered under Medicare Part B. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs. Each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. Federal regulations require Part D prescription drug formularies to include drugs within each therapeutic category and class of covered Part D drugs, although not necessarily all the drugs in each category or class.

In general, government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA or other Medicare regulations may result in a similar reduction in payments from non-governmental payors.

The Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the “*Affordable Care Act*” or “*ACA*”) mandated prescription drug coverage as one of ten essential health benefits that most health plans must offer, requiring coverage of at least one drug in every category and class. The ACA increased in the number of individuals covered by insurance and as a result commercial insurers and government programs have increased their emphasis on cost controls to reduce overall spending. A number of federal government leaders have expressed their intentions to repeal and replace the ACA. If full or partial repeal is enacted, many if not all of the provisions of the ACA may no longer apply to prescription drugs. As a result, we expect that there will continue to be uncertainty regarding drug product pricing, reimbursement and other factors impacting the revenue we may receive if our product candidates are ultimately approved, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and tend to be significantly lower.

PATENTS AND PROPRIETARY RIGHTS

We actively seek to protect the proprietary technology that we consider important to our business, including chemical species, compositions and forms, their methods of use and processes for their manufacture, as well as modified forms of naturally-expressed receptors, in the United States and other jurisdictions internationally that we consider key pharmaceutical markets. We also rely upon trade secrets and contracts to protect our proprietary information.

As of May 12, 2020, we were the exclusive licensee, sole assignee or co-assignee of fifteen granted U.S. patents, one pending U.S. patent application, and granted patents and/or pending applications in several other major markets, including the European Union, Canada and Japan. Our policy is to file U.S. and foreign patent applications to protect technology, inventions and improvements to inventions that are commercially important to the development of our business. There can be no assurance that any of these patent applications will result in the grant of a patent either in the United States or elsewhere, or that any patents granted will be valid and enforceable, or will provide a competitive advantage or will afford protection against competitors with similar technologies. We also intend to rely upon trade secret rights to protect other technologies that may be used to discover and validate targets and that may be used to identify and develop novel drugs. We seek protection, in part, through confidentiality and proprietary information agreements.

We consider the following U.S. patents and applications owned by or exclusively licensed to us to be particularly important to the protection of our most advanced product candidates.

Product Candidate	Patent Scope	Patent Expiration
CA4P	Use of VDAs to Enhance Immunomodulating Therapies Against Tumors	August 2036
OXi4503	Method for Treating Myeloid Neoplasm by Administering OXi4503	November 2028
OT-101	Combination of A Chemotherapeutic Agent and An Inhibitor of the TGF- β System Combination Therapy for Treatment of Pancreatic Cancer Compositions and Methods for Treating Cancer	July 2030 to February 2036 February 2036

In addition to these patents, for some of our product candidates, we have patents and/or applications that cover a particular form or composition, use for a particular indication, use as part of combination therapy or method of preparation or use, as well as other pending patent applications. These issued patents, including any patents that issue from pending applications, could provide additional or a longer period of protection. We also have patent applications pending that seek equivalent or substantially comparable protection for our product candidates in jurisdictions internationally that we consider key pharmaceutical markets.

The patent expiration dates referenced above do not reflect any potential patent term extension that we may receive under the federal Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act. The Hatch-Waxman Act generally permits a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years. The patent term restoration period is generally one-half of the time between the effective date of an investigational new drug application, or IND, and the submission date of a new drug application, or NDA, plus the time between the submission date and approval date of an NDA. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves applications for patent term extension.

As previously noted, the FDA and European Union have granted CA4P and OXi4503 orphan drug status for certain indications. We are also pursuing, and may continue to in the future to pursue, orphan drug status for other product candidates and indications. Our ability to obtain and maintain the exclusivity for our products and product candidates by virtue of their orphan drug status is an important part of our intellectual property strategy. Also as previously noted, we emphasizing on Rare Pediatric Designation to leverage on the regulatory exclusivity and voucher program associated with these designations.

COMPETITION

The industry in which we are engaged is characterized by rapidly evolving technology and intense competition. Our competitors include, among others, major pharmaceutical, biopharmaceutical and biotechnology companies, nearly all of which have financial, technical and marketing resources significantly greater than ours. In addition, many of the small companies in our industry have also formed collaborative relationships with large, established companies to support research, development and commercialization of products that may be competitive with ours. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and patenting new technologies in our line of business and any of these entities may commercialize products that may be competitive with ours.

We expect that, if any of our products gain regulatory approval for sale, they will compete primarily on the basis of product efficacy, safety, patient convenience, reliability, price and patent protection. Our competitive position will also depend on our ability to attract and retain qualified scientific and other personnel, develop effective proprietary products and implement joint ventures or other alliances with large pharmaceutical companies in order to jointly market and manufacture our products.

EMPLOYEES

We had sixteen full-time employees as of December 31, 2021. We rely on external consultants or outsource nearly all our research, development, preclinical testing and clinical trial activity, although we maintain managerial and quality control over our clinical trials. We also rely on external consultants for various administrative tasks that are required for a public company. We expect to continue to rely on external service providers and to maintain a small number of executives and other employees. Our relations with our employees are good and we do not have any unions for the Company.

COSTS OF COMPLIANCE WITH ENVIRONMENTAL REGULATIONS

We have not incurred any costs associated with compliance with environmental regulations, nor do we anticipate any future costs associated with environmental compliance; however, no assurances can be given that we will not incur such costs in the future.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our financial statements and the related notes thereto and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, operating results, and growth prospects. In such an event, the market price of our common stock could decline, and you may lose part or all of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

RISKS RELATED TO OUR BUSINESS AND INDUSTRY

If we are unable to obtain additional funding, we may be forced to cease operations.

We have experienced net losses every year since inception. In April 2019, the Company entered into an Agreement and Plan of Merger with Oncotelic Inc. for developing investigational drugs for the treatment of orphan oncology indications. The Company completed the Merger and Oncotelic Inc. became a wholly-owned subsidiary of the Company. The Merger was treated as a recapitalization and reverse acquisition for financial accounting purposes. Oncotelic was considered the acquirer for accounting purposes, and the Company’s historical financial statements before the Merger were replaced with the historical financial statements of Oncotelic Inc. prior to the Merger in the financial statements and filings with the Securities and Exchange Commission.

Even though Oncotelic Inc. is considered as the acquirer for accounting purposes, the Company, as of December 31, 2021, had an accumulated deficit of approximately \$31.0 million, including a net loss of approximately \$10.5 million in 2021. We have no source of product revenue and do not expect to receive any product revenue in the near future, except if we generate product revenues from Artemisinin in countries around the globe other than India and which at the current time is not anticipated. We may generate revenues from services rendered in the future, but we cannot expect that to be a regular and of recurring nature. If we remain in business, we expect to incur additional operating losses over the next several years, principally as a result of our plans to continue clinical trials for our investigational drugs. As of December 31, 2021, we had approximately \$0.6 million in cash and current liabilities of approximately \$15.5 million, of which \$1.3 million pertains to Oncotelic’s liabilities prior to the Merger and \$2.6 million of contingent liabilities, incurred upon our merger with PointR Data, Inc. in November 2019, that would be issuable in shares of common stock of the Company to the PointR shareholders upon satisfaction of certain conditions. Based on our planned operations, we expect our cash to only support our operations for a short period of time. Therefore, we will need to secure near-term funding, or we would be forced to curtail or terminate operations. Because we do not currently have a guaranteed source of capital that will sustain operations for at least the next twelve months, Management has determined that there is substantial doubt about our ability to continue as a going concern.

The principal source of our working capital to date has been the proceeds from the sale of equity and debt, a substantial portion of which has been provided by officers and certain insiders. If we are unable to access additional funds in the near term, whether through the sale of additional equity, debt or another means, we may not be able to continue in business. We also may not be able to continue the development of our investigational drugs. Any additional equity or debt financing, if available to us, may not be available on favorable terms and would most likely be dilutive to stockholders. Any debt financing, if available, may involve restrictive covenants and also be dilutive to current stockholders. If we obtain funds through collaborative or licensing arrangements, we may be required to relinquish rights to some of our technologies or product candidates on terms that are not favorable to us. Our ability to access capital when needed is not assured.

In their audit report with regard to our financial statements as of December 31, 2021, we as well as our independent registered public accountants have expressed an opinion that substantial doubt exists as to whether we can continue as a going concern. Because we have limited cash resources, we believe that it will be necessary for us to either raise additional capital in the near term or to enter into a license or other agreement with a larger pharmaceutical company. If we do not succeed in doing so, we may be required to suspend or cease our business, which would likely materially harm the value of our common stock.

Due in part to our limited financial resources, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates, and we may be unable to pursue and complete the clinical trials that we would like to pursue and complete.

We have limited financial and technical resources to determine the indications on which we should focus the development efforts for our product candidates. Due to our limited available financial resources, we have curtailed clinical development programs and activities that might otherwise have led to more rapid progress of our product candidates through the regulatory and development processes. We currently have insufficient financial resources to complete any additional drug development work.

If we are able to raise funds and continue developing investigational drugs for cancer, we may make incorrect determinations with regard to the indications and clinical trials on which to focus the available resources that we do have. Furthermore, we cannot assure you that we will be able to retain adequate staffing levels to run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish. The decisions to allocate our research, management and financial resources toward particular indications or therapeutic areas for our product candidates may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate drug development programs may also cause us to miss valuable opportunities. In addition, from time to time, we may in-license or otherwise acquire product candidates to supplement our internal development activities. Those activities may use resources that otherwise would have been devoted to our internal programs, and with research and development programs there is no way to assure that the outcome of any trials or other activities will be positive, whether the program was internally generated or in-licensed.

We may encounter difficulties in expanding our operations successfully if and when we evolve from a company that is primarily involved in clinical development to a company that is also involved in commercialization.

As we advance our product candidates through later stages of clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with such third parties, as well as additional collaborators, distributors, marketers and suppliers.

Maintaining third party relationships for these purposes will impose significant added responsibilities on members of our management and other personnel. We must be able to manage our development efforts effectively, manage our participation in the clinical trials in which our product candidates are involved effectively, and improve our managerial, development, operational and finance systems, all of which may impose a strain on our administrative and operational infrastructure.

If, following any approval of our product candidates, we enter into arrangements with third parties to perform sales, marketing or distribution services, any product revenues that we receive, or the profitability of these product revenues to us, are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or in doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our products.

If we were to submit an NDA for our drug candidates in the United States or a marketing application in the EU, we would need to undertake commercial scale manufacturing activities at significant expense to us in order to proceed with the application for approval for commercialization. We or our external vendors may encounter technical difficulties that preclude us from successfully manufacturing the required registration and validation batches of active pharmaceutical ingredient, or API, and/or drug product and we may be unable to recover any financial losses associated with the manufacturing activities. Further, our research or product development efforts may not be successfully completed, any compounds currently under development by us may not be successfully developed into drugs, any potential products may not receive regulatory approval on a timely basis, if at all, and competitors may develop and bring to market products or technologies that render our potential products obsolete. If any of these problems occur, our business would be materially and adversely affected.

We may not be able to partner with other pharmaceutical companies or even form any types of alliances with third parties.

As we plan to advance our product candidates through later stages of clinical trials but with lack of adequate capital resources, we will need to form alliances or enter into partnerships with other pharmaceutical companies or even other third parties. We cannot assure you that we would be able to do so at terms beneficial to the Company or at all.

We may not be able to successfully set up an IPO with third parties.

As we plan to advance our product candidates through later stages of clinical trials but with lack of adequate capital resources, we will need to form alliances or enter into partnerships with other pharmaceutical companies or even other third parties and create shareholder value, including through IPOs. We cannot assure you that we would be able to do so at terms beneficial to the Company or at all. While the Company has formed a joint venture with Dragon Overseas and GMP Bio, and taking that through an IPO, there can be no assurances that such IPO will be made or will be successful.

We have no manufacturing capacity and have relied on, and expect to continue to rely on, third-party manufacturers to produce our product candidates.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates or any of the compounds that we are testing in our preclinical programs, and we lack the resources and the capabilities to do so. As a result, we currently rely, and we expect to rely for the foreseeable future, on third-party manufacturers to supply our product candidates. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our product candidates or products ourselves, including:

- reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of third-parties;
- the possible breach of manufacturing agreements by third-parties because of factors beyond our control; and
- the possible termination or non-renewal of the manufacturing agreements by the third-party, at a time that is costly or inconvenient to us.

If we do not maintain our developed important manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us, and there could be a substantial delay before new facilities could be qualified and registered with the FDA, EMA and other foreign regulatory authorities.

The FDA, EMA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with current good manufacturing practices, or cGMPs. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products after approval.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our ability to develop our product candidates, our ability to commercialize any products that receive regulatory approval and our potential future profit margins on these products.

Our product candidates have not completed clinical trials, and may never demonstrate sufficient safety and efficacy in order to do so.

Our product candidates are in the clinical stage of development. In order to achieve profitable operations, we alone or in collaboration with others, must successfully develop, manufacture, introduce and market our products. The time frame necessary to achieve market success for any individual product is long and uncertain. The products currently under development by us may require significant additional research and development and additional preclinical and clinical testing prior to application for commercial use. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after showing promising results in early or later-stage studies or clinical trials. Although we have obtained some favorable results to date in preclinical studies and clinical trials of certain of our potential products, such results may not be indicative of results that will ultimately be obtained in or throughout such clinical trials, and clinical trials may not show any of our products to be safe or capable of producing a desired result. Additionally, we may encounter problems in our clinical trials that may cause us to delay, suspend or terminate those clinical trials.

Adverse events observed to date and associated with CA4P and OXi4503 have generally been found to be manageable for drugs treating the indications for which we are developing our product candidates. However, we will be required to continue to test and evaluate the safety of our product candidates in additional clinical trials, and to demonstrate their safety to the satisfaction of appropriate regulatory agencies, as a condition to receipt of any regulatory approvals. In clinical trials to date, transient hypertension believed to be associated with CA4P and OXi4503 has been effectively managed through pre-treatment with anti-hypertensive medication. We cannot assure you, however, that we will be able to make the necessary demonstrations of safety to allow us to receive regulatory approval for our product candidates in any indication.

We only have a limited number of employees to manage and operate our business.

As of December 31, 2021, we had sixteen full-time employees. We rely on consultants and professionals to augment our staffing needs. Our limited financial resources require us to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to retain adequate staffing levels to run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

We depend on our executive officers and principal consultants and the loss of their services could materially harm our business.

We believe that our success depends, and will likely continue to depend, upon our ability to retain the services of our current executive officers, particularly our Chief Executive Officer, Chief Technology Officer, Chief Business Officer and Chief Financial Officer, our principal consultants and others. This increases the risk that we may not be able to retain their services. The loss of the services of any of these individuals could have a material adverse effect on our business. In addition to these key service providers, we have established relationships with universities, hospitals and research institutions, which have historically provided, and continue to provide, us with access to research laboratories, clinical trials, facilities and patients. Additionally, we believe that we may, at any time and from time to time, materially depend on the services of consultants and other unaffiliated third parties. We cannot assure you that consultants and other unaffiliated third parties will provide the level of service to us that we require in order to achieve our business objectives.

Our industry is highly competitive, and our product candidates may become obsolete.

We are engaged in a rapidly evolving field. Competition from other pharmaceutical companies, biotechnology companies and research and academic institutions is intense and likely to increase. Many of those companies and institutions have substantially greater financial, technical and human resources than we do. Many of those companies and institutions also have substantially greater experience in developing products, conducting clinical trials, obtaining regulatory approval and in manufacturing and marketing pharmaceutical products. Our competitors may succeed in obtaining regulatory approval for their products more rapidly than we do. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these competitive products may have an entirely different approach or means of accomplishing the desired therapeutic effect than products being developed by us. Our competitors may succeed in developing products that are more effective and/or cost competitive than those we are developing, or that would render our product candidates less competitive or even obsolete. In addition, one or more of our competitors may achieve product commercialization or patent protection earlier than we do, which could materially adversely affect us.

If clinical trials or regulatory approval processes for our product candidates are prolonged, delayed or suspended, we may be unable to out-license or commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay or prevent our receipt of any proceeds from potential license agreements or product sales.

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials or delay or invalidate the analysis of data derived from them. A number of events, including any of the following, could delay the completion of our other ongoing and planned clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular product candidate:

- conditions imposed on us by the FDA, EMA or another foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in obtaining, or our inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply of our product candidates or other materials necessary to conduct and complete our clinical trials;
- slow enrollment and retention rate of subjects in clinical trials;
- any compliance audits and pre-approval inspections by the FDA, EMA or other regulatory authorities;
- negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results;
- serious and unexpected drug-related side effects; and
- failure of our third-party contractors to comply with regulatory requirements or otherwise meet their contractual obligations to us.

Commercialization or licensure of our product candidates may be delayed or prevented by the imposition of additional conditions on our clinical trials by the FDA, EMA or another foreign regulatory authority or the requirement of additional supportive clinical trials by the FDA, EMA or another foreign regulatory authority. In addition, clinical trials require sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, the conduct of other clinical trials that compete for the same patients as our clinical trials, and the eligibility criteria for our clinical trials. Our failure to enroll patients in our clinical trials could delay the completion of the clinical trial beyond our expectations, or it could prevent us from being able to complete the clinical trial. In addition, the FDA and EMA could require us to conduct clinical trials with a larger number of subjects than we have projected for any of our product candidates. We may not be able to enroll a sufficient number of patients in a timely or cost-effective manner. Furthermore, enrolled patients may drop out of our clinical trials, which could impair the validity or statistical significance of the clinical trials.

We do not know whether our clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, if at all. Delays in our clinical trials will result in increased development costs for our product candidates, and our financial resources may be insufficient to fund any incremental costs. In addition, if our clinical trials are delayed, our competitors may be able to bring products to market before we do and the commercial viability of our product candidates could be limited.

If physicians and patients do not accept our future products or if the market for indications for which any product candidate is approved is smaller than expected, we may be unable to generate significant revenue, if any.

Even if any of our product candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients, and third-party payers. Physicians may decide not to prescribe our drugs for a variety of reasons including:

- timing of market introduction of competitive products;
- demonstration of clinical safety and efficacy compared to other products;
- cost-effectiveness;
- limited or no coverage by third-party payers;
- convenience and ease of administration;
- prevalence and severity of adverse side effects;
- restrictions in the label of the drug;
- other potential advantages of alternative treatment methods; and
- ineffective marketing and distribution support of our products.

If any of our product candidates is approved, but fails to achieve market acceptance, we may not be able to generate significant revenue and our business would suffer.

The uncertainty associated with pharmaceutical reimbursement and related matters may adversely affect our business.

Market acceptance and sales of any one or more of our product candidates that we develop will depend on reimbursement policies and may be affected by future healthcare reform measures in the United States and in foreign jurisdictions. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for any product candidates that we develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any product candidates that we develop.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs.

The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of any products that we develop due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

In March 2010, the Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, ACA, became law in the U.S. The goal of ACA is to reduce the cost of health care and substantially change the way health care is financed by both government and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we may charge for, any products we develop that receive regulatory approval.

More recently, the current U.S. presidential administration has made statements suggesting plans to seek repeal of all or portions of the ACA. There is uncertainty regarding the impact that the President's administration may have on matters currently governed by the ACA, if any, and any regulatory or legislative changes will likely take time to unfold. These changes could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Our business and operations could suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Furthermore, we have little or no control over the security measures and computer systems of our third-party CROs and other contractors and consultants. While we have not experienced any material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.

REGULATORY AND LEGAL RISK FACTORS

If we are unable to obtain required regulatory approvals, we will be unable to market and sell our product candidates.

Our product candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing, oversight of clinical investigators, recordkeeping and commercialization. Rigorous preclinical testing and clinical trials and an extensive regulatory review and approval process are required to be successfully completed in the United States, in the European Union and in many other foreign jurisdictions before a new drug can be sold. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain, and subject to unanticipated delays. The time required to obtain approval by the FDA or the European Medicines Agency, or EMA, is unpredictable and often takes many years following the commencement of clinical trials.

In connection with the clinical development of our product candidates, we face risks that:

- our product candidates may not prove to be safe and efficacious;
- patients may die or suffer serious adverse effects for reasons that may or may not be related to the product candidate being tested;
- we fail to maintain adequate records of observations and data from our clinical trials, to establish and maintain sufficient procedures to oversee, collect data from, and manage clinical trials, or to monitor clinical trial sites and investigators to the satisfaction of the FDA, EMA or other regulatory agencies;
- we may not have sufficient financial resources to complete the clinical trials that would be necessary to obtain regulatory approvals;
- the results of later-phase clinical trials may not confirm the results of earlier clinical trials; and
- the results from clinical trials may not meet the level of statistical significance or clinical benefit-to-risk ratio required by the FDA, EMA or other regulatory agencies for marketing approval.

Only a small percentage of product candidates for which clinical trials are initiated are the subject of NDAs and even fewer receive approval for commercialization. Furthermore, even if we do receive regulatory approval to market a product candidate, any such approval may be subject to limitations such as those on the indicated uses for which we may market the product.

If we or the third parties on which we rely for the conduct of our clinical trials and results do not perform our clinical trial activities in accordance with good clinical practices and related regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We currently use independent clinical investigators in all of our clinical trials and, in many cases, also utilize contract research organizations, or CROs, and other third-party service providers to conduct and/or oversee the clinical trials of our product candidates and expect to continue to do so for the foreseeable future. We rely heavily on these parties for successful execution of our clinical trials. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with the FDA's requirements and our general investigational plan and protocol. Currently, we have clinical trial activities involving CA4P and OXi4503 being conducted by clinical investigators who are independent of us, but with whom we have agreements for them to provide the results of their clinical trials to us. In order for us to rely on data from these ongoing clinical trials in support of a New Drug Application, or NDA, for approval of any of our product candidates by the FDA or similar types of marketing applications that are required by other regulatory authorities, the independent investigators are required to comply with applicable good clinical practice requirements.

The FDA and corresponding foreign regulatory authorities require us and our clinical investigators to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the respective trial plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates or result in enforcement action against us.

We have taken and continue to take steps to strengthen our procedures and practices, but we cannot assure you that the FDA will be satisfied with our procedures or that the FDA will not issue warning letters or take other enforcement action against us in the future. The steps we take to strengthen our procedures and conduct future clinical trials necessary for approval will be time-consuming and expensive.

The use of our products may result in product liability exposure, and it is uncertain whether our insurance coverage will be sufficient to cover all claims.

The use of our product candidates in clinical trials may expose us to liability claims in the event such product candidates cause death, injury or disease, or result in adverse effects. We may be exposed to liability claims even if our product did not cause death, injury or disease, but is merely presumed or alleged to have caused any of these. If our product candidates are ever commercially approved, the commercial use of these products may also expose us to similar liability claims. Any of these claims could be made by health care institutions, contract laboratories, patients or others using such products. Although we have obtained liability insurance coverage for our ongoing clinical trials, this coverage may not be in amounts sufficient to protect us from any product liability claims or product recalls which could have a material adverse effect on our financial condition and prospects. Further, adverse product and similar liability claims could negatively impact our ability to obtain or maintain regulatory approvals for our technology and product candidates under development.

We have been granted orphan drug status for certain of our product candidates and may seek orphan drug status for additional indications for those product candidates or for additional product candidates. We may be unsuccessful in maintaining orphan drug exclusivity for our product candidates and may be unsuccessful in our efforts to seek orphan drug status and orphan drug exclusivity.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a disease with a patient population of fewer than 200,000 individuals in the United States. Our lead product candidate, OXi4503, has been awarded orphan drug status by the FDA and the European Commission for the treatment of acute myelogenous leukemia. Our other product candidate, CA4P, has been awarded orphan drug status by the FDA for the treatment of anaplastic, medullary, Stage IV papillary and Stage IV follicular thyroid cancers, ovarian cancer, neuroendocrine tumors and glioma. CA4P has also been awarded orphan drug status by the European Commission in the European Union for the treatment of anaplastic thyroid cancer, ovarian cancer and neuroendocrine tumors.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug for the same indication during the period of exclusivity. The applicable period is seven years in the United States and ten years in the European Union. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective, if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product candidate or additional product candidates, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a different drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Our product candidates will remain subject to ongoing regulatory review even if they receive marketing approval, and if we fail to comply with continuing regulations, we could lose these approvals and the sale of any approved commercial products could be suspended.

Even if we receive regulatory approval to market a particular product candidate, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, and record keeping related to the product will remain subject to extensive regulatory requirements. If we fail to comply with the regulatory requirements of the FDA, EMA and other applicable domestic and foreign regulatory authorities or previously unknown problems with any approved product, manufacturer, or manufacturing process are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers, or manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- pressure to initiate voluntary product recalls;
- suspension or withdrawal of regulatory approvals; and
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation.

We have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

RISKS RELATED TO INTELLECTUAL PROPERTY

We depend extensively on the patents and proprietary technology we license from others, and we must maintain these licenses in order to preserve our business.

We have licensed in rights to CA4P, OXi4503 and other programs from third parties. If our license agreements terminate or expire, we may lose the licensed rights to our product candidates, including CA4P and OXi4503, and we may not be able to continue to develop them or, if they are approved, we may not be able to market or commercialize them.

We depend on license agreements with third-parties for certain intellectual property rights relating to our product candidates, including patent rights. Currently, we have licensed in certain patent rights from Arizona State University, or ASU, and the Bristol-Myers Squibb Company for CA4P and OXi4503 and from Baylor University for other programs. In general, our license agreements require us to make payments and satisfy performance obligations in order to keep these agreements in effect and retain our rights under them. These payment obligations can include upfront fees, maintenance fees, milestones, royalties, patent prosecution expense, and other fees. These performance obligations typically include diligence obligations. If we fail to pay, be diligent or otherwise perform as required under our license agreements, we could lose the rights under the patents and other intellectual property rights covered by the agreements. While we are not currently aware of any dispute with any licensors under our material agreements with them, if disputes arise under any of our in-licenses, including our in-licenses from ASU, the Bristol-Myers Squibb Company and Baylor University, we could lose our rights under these agreements. Any such dispute may not be resolvable on favorable terms, or at all. Whether or not any disputes of this kind are favorably resolved, our management's time and attention and our other resources could be consumed by the need to attend to and seek to resolve these disputes and our business could be harmed by the emergence of such a dispute.

If we lose our rights under these agreements, we may not be able to conduct any further activities with the product candidate or program that the license covered. If this were to happen, we might not be able to develop our product candidates further, or following regulatory approval, if any, we might be prohibited from marketing or commercializing them. In particular, patents previously licensed to us, such as the patents we previously licensed from Angiogene, might after termination be used to stop us from conducting activities in the patents' respective fields.

We depend on patents and proprietary technology in the course of our business, and we must protect those assets in order to preserve our business.

Although we expect to seek patent protection for any compounds we discover and/or for any specific use we discover for new or previously known compounds, any or all of them may not be subject to effective patent protection. Further, the development of regimens for the administration of pharmaceuticals, which generally involve specifications for the frequency, timing and amount of dosages, has been, and we believe, may continue to be, important to our effort, although those processes, as such, may not be patentable. In addition, the issued patents may be declared invalid or our competitors may find ways to avoid the claims in the patents. Further, our lack of access to adequate capital may cause us to curtail payment of fees necessary to maintain patents that we otherwise would seek to maintain, and we may make incorrect decisions regarding which patents to keep and which to abandon.

Our success will depend, in part, on our ability to obtain and maintain patents, protect our trade secrets and operate without infringing on the proprietary rights of others. We are the exclusive licensee, sole assignee or co-assignee on a number of granted United States patents, pending United States patent applications, and granted patents and/or pending applications in several other major markets, including the European Union, Canada and Japan. The patent position of pharmaceutical and biotechnology firms like us is generally highly uncertain and involves complex legal and factual questions, resulting in both an apparent inconsistency regarding the breadth of claims allowed in United States patents and general uncertainty as to their legal interpretation and enforceability. Accordingly, patent applications assigned or exclusively licensed to us may not result in patents being issued, any issued patents assigned or exclusively licensed to us may not provide us with competitive protection or may be challenged by others, and the current or future granted patents of others may have an adverse effect on our ability to do business and achieve profitability. Moreover, because some of the basic research relating to one or more of our patent applications and/or patents were performed at various universities and/or funded by grants, one or more of these universities, employees of such universities and/or grantors could assert that they have certain rights in such research and any resulting products. Further, others may independently develop similar products, may duplicate our products, or may design around our patent rights. In addition, as a result of the assertion of rights by a third-party or otherwise, we may be required to obtain licenses to patents or other proprietary rights of others in or outside of the United States. Any licenses required under any such patents or proprietary rights may not be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we could encounter delays in product market introductions while our attempts to design around such patents or could find that the development, manufacture or sale of products requiring such licenses is foreclosed. In addition, we could incur substantial costs in defending ourselves in suits brought against us or in connection with patents to which we hold licenses or in bringing suit to protect our own patents against infringement.

We require employees and the institutions that perform our preclinical and clinical trials to enter into confidentiality agreements with us. Those agreements provide that all confidential information developed or made known to a party to any such agreement during the course of the relationship with us be kept confidential and not be disclosed to third-parties, except in specific circumstances. Any such agreement may not provide meaningful protection for our trade secrets or other confidential information in the event of unauthorized use or disclosure of such information.

RISKS RELATED TO OUR STOCK AND FINANCING ACTIVITIES

The price of our common stock is volatile, and is likely to continue to fluctuate due to reasons beyond our control; a limited public trading market may cause volatility in the price of our common stock.

The market price of our common stock has been, and likely will continue to be, highly volatile. Factors, including our financial results or our competitors' financial results, clinical trial and research development announcements and government regulatory action affecting our potential products in both the United States and foreign countries, have had, and may continue to have, a significant effect on our results of operations and on the market price of our common stock. We cannot assure you that an investment in our common stock will not fluctuate significantly. One or more of these factors could significantly harm our business and cause a decline in the price of our common stock in the public market. Substantially all of the shares of our common stock issuable upon exercise of outstanding options and warrants have been registered or are likely to be registered for resale or are available for sale pursuant to Rule 144 under the Securities Act and may be sold from time to time. As of December 31, 2021, we had approximately 139.5 million shares of common stock underlying currently outstanding convertible debt, warrants and options. Sales of any of these shares on the market, as well as future sales of our common stock by existing stockholders, or the perception that sales may occur at any time, could adversely affect the market price of our common stock.

Our common stock is currently quoted on the OTCQB Market. The quotation of our common stock on the OTCQB Market does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is subject to this volatility. Sales of substantial amounts of common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short time and our stockholders could suffer losses or be unable to liquidate their holdings.

We will require additional capital funding, the receipt of which may impair the value of our common stock.

Our future capital requirements depend on many factors, including our research, development, sales and marketing activities. We will need to raise additional capital through public or private equity or debt offerings or through arrangements with strategic partners or other sources in order to continue to develop our product candidates. There can be no assurance that additional capital will be available when needed or on terms satisfactory to us, if at all. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution and the new equity securities may have greater rights, preferences or privileges than our existing common stock.

Our common stock is currently subject to the "Penny Stock" Rules of the SEC and the trading market in our securities is limited, which makes transactions in our stock cumbersome and may reduce the value of an investment in our stock.

As of December 31, 2021, we had net tangible assets of less than \$0.6 million and our common stock had a market price per share of less than \$5.00. As a result, transactions in our common stock are subject to the SEC's "penny stock" rules. The designation of our common stock as a "penny stock" likely limits the liquidity of our common stock. Prices for penny stocks are often not available to buyers and sellers and the market may be very limited. Penny stocks are among the riskiest equity investments. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. The document provides information about penny stocks and the nature and level of risks involved in investing in the penny stock market. A broker must also provide purchasers with bid and offer quotations and information regarding broker and salesperson compensation and make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser's written agreement to the purchase. Many brokers choose not to participate in penny stock transactions. Because of the penny stock rules, there may be less trading activity in penny stocks. Because shares of our common stock are currently subject to these penny stock rules, your ability to trade or dispose of shares of our common stock may be adversely affected.

We may not be able to achieve secondary trading of our stock in certain states because our common stock is no longer nationally traded, which could subject our stockholders to significant restrictions and costs.

Our common stock is not currently eligible for trading on the Nasdaq Capital Market or on a national securities exchange. Therefore, our common stock is subject to the securities laws of the various states and jurisdictions of the United States in addition to federal securities law. While we may register our common stock or qualify for exemptions for our common stock in one or more states, if we fail to do so the investors in those states where we have not taken such steps may not be allowed to purchase our stock or those who presently hold our stock may not be able to resell their shares without substantial effort and expense. These restrictions and potential costs could be significant burdens on our stockholders.

If we fail to maintain an effective system of internal controls over financial reporting, we may not be able to accurately report our financial results. As a result, current and potential stockholders could lose confidence in our financial reporting, which could harm our business and the trading price of our stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports. If we cannot maintain effective controls and reliable financial reports, our business and operating results could be harmed. For example, our small size and limited staffing levels do not allow for segregation of duties that exist at larger companies. We have conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2021 based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on that evaluation, our management concluded that our internal control over financial reporting were not effective as of December 31, 2021. We continue to work on remedying our weaknesses and maintaining effective internal controls over financial reporting; however, there can be no assurance that a material weakness will not occur in the future or our material weaknesses would be rectified. Any failure to implement and maintain controls over our financial reporting or difficulties encountered in the implementation of improvements in our controls, could cause us to fail to meet our reporting obligations. Any failure to maintain our internal controls over financial reporting or to address identified weaknesses in the future, if they were to occur, could also cause investors to lose confidence in our reported financial information, which could have a negative impact on the trading price of our stock.

Issuance of additional equity securities may adversely affect the market price of our common stock.

We were authorized to issue up to 750,000,000 shares of our common stock. As of December 31, 2021, we had 375,288,146 shares of common stock issued and outstanding, including 1,019,303 shares of common stock to be issued. As of December 31, 2021, we also had approximately 53,300,000 warrants outstanding, approximately 16,600,000 options and approximately 69,500,000 shares of common stock issuable upon conversion of convertible notes.

To the extent that additional shares of common stock are issued or options and warrants are exercised, holders of our common stock will experience dilution. In addition, in the event of any future issuances of equity securities or securities convertible into or exchangeable for common stock, holders of our common stock may experience dilution.

Our Board of Directors is authorized to issue preferred stock without any action on the part of our stockholders. Our Board of Directors also has the power, without stockholder approval, to set the terms of any such preferred stock that may be issued, including voting rights, conversion rights, dividend rights, preferences over our common stock with respect to dividends or if we liquidate, dissolve or wind up our business and other terms. If we issue preferred stock in the future that has preference over our common stock with respect to the payment of dividends or upon our liquidation, dissolution or winding up, or if we issue preferred stock with voting rights that dilute the voting power of our common stock, the market price of our common stock could decrease. Any provision permitting the conversion of any such preferred stock into our common stock could result in significant dilution to the holders of our common stock.

We also consider from time-to-time various strategic alternatives that could involve issuances of additional common or preferred stock, including but not limited to acquisitions and business combinations.

We have no plans to pay dividends on our common stock, and you may not receive funds without selling your common stock.

We have not declared or paid any cash dividends on our common stock, nor do we expect to pay any cash dividends on our common stock for the foreseeable future. We currently intend to retain any future earnings, if any, to finance our operations and growth and, potentially, for future stock repurchases and, therefore, we have no plans to pay cash dividends on our common stock. Any future determination to pay cash dividends on our common stock will be at the discretion of our Board of Directors and will be dependent on our earnings, financial condition, operating results, capital requirements, any contractual restrictions, and other factors that our board of directors deems relevant.

Accordingly, you may have to sell some or all of your common stock in order to generate cash from your investment in the Company. You may not receive a gain on your investment when you sell our common stock and may lose the entire amount of your investment.

The Company will require additional capital funding, the receipt of which may impair the value of our Common Stock and EdgePoint's Common Stock.

Our future capital requirements and EdgePoint's future capital requirements depend on many factors, including our research, development, sales and marketing activities as well as the development of EdgePoint's business. We and EdgePoint will need to raise additional capital through public or private equity or debt offerings or through arrangements with strategic partners or other sources in order to continue to develop our product candidates. There can be no assurance that additional capital will be available when needed or on terms satisfactory to us or EdgePoint, if at all. To the extent we and/or EdgePoint raise additional capital by issuing equity securities, our shareholders and EdgePoint's shareholders may experience substantial dilution and the new equity securities may have greater rights, preferences or privileges than our existing Common Stock and EdgePoint's Common Stock and the Securities contemplated to be issued as described in this Confidential Offering Memorandum.

GENERAL RISK FACTORS

Unfavorable global epidemic or pandemic conditions could adversely affect our business, financial condition or results of operations.

Our operations and the financial results of our operations could be adversely affected by general conditions in the global economy and in the global financial markets. Global financial concerns have caused, and may continue to cause, extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. We cannot currently anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our business may suffer from the severity or longevity of the COVID-19 Global Outbreak.

The COVID-19 is currently impacting countries, communities, supply chains and markets, as well as the global financial markets. To date, COVID-19 has not had a material impact on the Company, other than as set forth above. However, the Company cannot predict whether COVID-19 will have a material impact on our financial condition and results of operations due to understaffing, disruptions in government spending, among other factors. In addition, at this time we cannot predict the impact of COVID-19 on our ability to obtain financing necessary for the Company to fund its working capital requirements. In most respects, it is too early in the COVID-19 pandemic to be able to quantify or qualify the longer-term ramifications on our business, our customers and/or our potential investors.

We, or the third parties upon whom we depend, may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes or other natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our office is located in Agoura Hills, California, where we lease about 2,000 square feet of general office space. The lease for this office is on a month-to-month basis. We consider our office space to be adequate for our current needs. We believe that other suitable office space would be available if we move to a different location upon the expiration of our current lease.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Historically, the outcome of all such legal proceedings has not, in the aggregate, had a material adverse effect on our business, financial condition, results of operations or liquidity. Other than as set forth below, there are no additional pending or threatened legal proceedings at this time.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

The Company's common stock trades on the OTCQB market, operated by OTC Markets, under the symbol "OTLC".

Holders

As of March 20, 2022, there were approximately 83 stockholders of record of the 378,630,104 outstanding shares of the Company's common stock.

Dividends

The Company has not declared or paid any cash dividends on its common stock since its inception in 1988 and does not intend to pay cash dividends in the foreseeable future. The Company presently intends to retain future earnings, if any, to finance the growth and development of its business.

Securities Authorized for Issuance Under Equity Compensation Plans

Information relating to compensation plans under which our equity securities are authorized for issuance is presented in Part III, Item 12 of this Annual Report on Form 10-K.

Unregistered Sales of Securities

No unregistered securities were issued during the fiscal year that were not previously reported in a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (the “*Annual Report*” or “*Report*”) includes a number of forward-looking statements that reflect management’s current views with respect to future events and financial performance. Forward-looking statements are projections in respect of future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as “may,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other comparable terminology. Those statements include statements regarding the intent, belief or current expectations of us and members of our management team, as well as the assumptions on which such statements are based. For a more detailed discussion on our forward-looking statements, kindly refer to “Forward Looking Statements” prior to Item 1: Part I: Business contained in this Annual Report.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, or performance. These statements are only predictions and involve known and unknown risks, uncertainties and other factors. Some of these risks are included in the section entitled “Risk Factors” set forth in this Annual Report and in other reports that we file with the SEC. The occurrence of any of these risks, or others of which we are currently unaware, may cause our company’s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks include, by way of example and without limitation:

- our ability to successfully commercialize our products and services on a large enough scale to generate profitable operations;
- our ability to maintain and develop relationships with customers and suppliers;
- our ability to successfully integrate acquired businesses or new products, or to realize anticipated synergies in connection with acquisitions of businesses or products;
- expectations concerning our ability to raise additional funding and to continue as a going concern;
- our ability to successfully implement our business plan;
- our ability to successfully form a joint venture with Golden Mountain Partners to develop our product portfolio;
- our ability to avoid, or to adequately address any intellectual property claims brought by third parties; and
- the anticipated impact of any changes in industry regulation.

Readers are urged to carefully review and consider the various disclosures made by us in this Annual Report and in our other reports filed with the SEC. We undertake no obligation to update or revise forward-looking statements to reflect changed assumptions, the occurrence of unanticipated events or changes in the future operating results over time except as required by law. We believe that our assumptions are based upon reasonable data derived from and known about our business and operations. No assurances are made that the actual results of operations or the results of our future activities will not differ materially from our assumptions.

Corporate History

Oncotelic Therapeutics, Inc. (f/k/a Mateon Therapeutics, Inc.) (“*Oncotelic*”), was formed in the State of New York in 1988 as OXiGENE, Inc., was reincorporated in the State of Delaware in 1992, and changed its name to Mateon Therapeutics, Inc. in 2016, and Oncotelic Therapeutics, Inc. in November 2020. Oncotelic conducts business activities through Oncotelic and its wholly-owned subsidiaries, Oncotelic, Inc., a Delaware corporation, PointR Data, Inc. (“*PointR*”), a Delaware corporation, and EdgePoint AI, Inc. (“*Edgepoint*”), a Delaware Corporation for which there are non-controlling interests, (Oncotelic, Oncotelic Inc., PointR and Edgepoint are collectively called the “*Company*” or “*We*”). The Company is currently developing OT-101 for various cancers and COVID-19, Artemisinin for COVID-19 and AI technologies for clinical development and manufacturing. The Company has acquired apomorphine for Parkinson’s Disease, erectile dysfunction and female sexual dysfunction. In addition, the Company is evaluating the further development of its product candidates OXi4503 as a treatment for acute myeloid leukemia and myelodysplastic syndromes and CA4P in combination with a checkpoint inhibitor for the treatment of advanced metastatic melanoma.

Amendments to Certificate of Incorporation

In November 2020 the Company filed an amendment to its Certificate of Incorporation with the Secretary of State for the State of Delaware changing its name from “Mateon Therapeutics, Inc.” to “Oncotelic Therapeutics, Inc.” A notice of corporate action had been filed with the Financial Industry Regulatory Authority (“*FINRA*”), requesting confirmation to change its name and approval for a new ticker symbol. On March 29, 2021, the Company received approval from FINRA on its notice of corporate action, and effective March 30, 2021, the Company’s ticker symbol has changed from “*MATN*” to “*OTLC*”.

In January 2021, the Company filed an additional amendment to its Certificate of Incorporation with the Secretary of State for the State of Delaware which went effective immediately upon acceptance by the Secretary of State for the State of Delaware. As approved by the Company’s stockholders by written consent on August 10, 2020, the amendment also increased the number of authorized shares of Common Stock from 150,000,000 shares to 750,000,000 shares.

In addition, the Company registered an additional total of 20,000,000 shares of its Common Stock, which may be issued pursuant to the Company’s Amended and Restated 2015 Equity Incentive Plan (the “*Plan*”). Such additional shares were approved by the shareholders of the Company on August 10, 2020 and as reported to the Securities and Exchange Commission (the “*SEC*”) vide a Current Report on Form 8-K on August 14, 2020. As such, the total number of shares of the Company’s Common Stock available for issuance under the 2015 plan is 27,250,000.

Merger Agreement with Oncotelic, Inc.

In April 2019, the Company completed a merger with Oncotelic Inc. (the “*Merger*”), a clinical-stage biopharmaceutical company focused on the treatment of cancer using TGF- β RNA). Oncotelic and Oncotelic Inc. entered into the Merger in order to create a publicly traded company with a pipeline of immunotherapies that target several cancer markets which currently lack adequate treatment options. For a more detailed discussion on the Merger, please refer to our 2020 Annual Report on Form 10-K filed with the SEC on April 15, 2021.

Merger Agreement with PointR Data, Inc.

In November 2019, the Company consummated a merger with PointR Data, Inc. (the “*PointR Merger*”). The PointR Merger was intended to create a publicly traded AI driven immuno-oncology company with a robust pipeline of first in class TGF- β immunotherapies for late-stage cancers such as gliomas, pancreatic cancer and melanoma. For a more detailed discussion on the Merger, please refer to our 2020 Annual Report on Form 10-K filed with the SEC on April 15, 2021.

Company Overview

We are a clinical-stage biopharmaceutical company developing drugs for the treatment of orphan oncology indications, developing antisense and small molecule injectable drugs for the treatment of cancer. After the acquisition of Mateon Therapeutics, Inc through a reverse merger in 2019, we realigned the company pipeline to focus on rare pediatric cancers. The United States Food and Drug Administration (“*FDA*”) has granted us Rare Pediatric Designations (“*RPD*”) for pediatric Diffuse Intrinsic Pontine Glioma (“*DIPG*”) for OT-101, pediatric melanoma for CAP4 and acute myeloid leukemia (“*AML*”) for Oxi4503. This strategy aims to capitalize on a voucher program in the United States (“*US*”). By focusing on RPD we anticipate: 1) reducing the cost of clinical development by way of a smaller and faster clinical trial, 2) acceleration of the approval process and final approval, 3) obtaining regulatory/ marketing exclusivity for up to 12 years as a biologic, and 4) obtaining vouchers worth a significantly large value on regulatory approval, which can be upwards of several million dollars. Approval in US would allow for approval in the rest of the world (“*ROW*”) using the US dossier. Phase 3 clinical trials for approval in adult indications will be conducted following the positive interim read of the pediatric trials. This approach maximize return on investment for the shareholders.

Concurrently we also explore opportunity to create values for shareholders by forming strategic alliances and/or licensing our product portfolio. As of August 2021, we have been working on the formation of a joint venture (“JV”) with Golden Mountain Partners (“GMP”). The Company entered into a JV with Dragon Overseas and GMP Bio, affiliates of GMP on March 31, 2022. GMP Bio to transfer the developmental cost of our product(s) onto the JV, while still participating in potential upside through ownership of the JV. GMP Bio and the Company are also looking to take the JV into an initial public offering (“IPO”) of the JV and which is anticipated to be a liquidity event for Company, especially if the IPO is successful. While we believe that the IPO can be achieved and would be successful, we cannot provide assurance for either the IPO or the success thereof.

As a result of the reverse merger of Oncotelic and Oncotelic Inc. in April 2019 and the acquisition of PointR in November 2019, respectively, we believe we are well positioned as a biotech company with: (1) Oncotelic Inc.’s antisense platform with our drug candidate OT-101- targeting high value TGF- β 2 target for various cancers and COVID-19, (2) PointR artificial intelligence (“AI”) for clinical trials, research and development, (3) Edgepoint for developing technologies for manufacturing and for developing technologies for supporting our COVID-19 programs, (4) Artemisinin for COVID-19, (5) the Company’s vascular disruptor proven safe in more than 500 patients capable of causing massive antigen release which would stimulate immune response against the cancerous tumor and (6) apomorphine, which we in-licensed in 2021, for developing against Parkinson’s Disease (“PD”), erectile dysfunction (“ED”) and female sexual dysfunction (“FSD”). Since the JV is formed with Dragon Overseas Capital Limited (“Dragon Overseas”) and GMP Biotechnology Limited (“GMP Bio’), we plan to accelerate the development of apomorphine as our flagship drug candidate.

We are also developing OT-101, an antisense against TGF- β 2 – for the treatment of various viruses, including the severe acute respiratory syndrome (“SARS”) and the current coronavirus (“COVID-19”), on its own and in conjunction with other compounds. Viral replication cannot occur without TGF- β ; and TGF- β surge and a cytokine storm cannot occur without TGF- β . A Phase 2 trial was completed for OT-101 in South America. Based on the final results of the trial, the trial can expand into a Phase 3 trial if the data supports the safety of the drug. This was a randomized, double-blind, placebo-controlled Phase 2 study is intended to evaluate the safety and efficacy of OT-101 in adult patients hospitalized with positive COVID-19 and pneumonia.

In addition, during 2020 and 2021, the Company was developing Artemisinin as a potential therapy for the virus causing COVID-19 (“SARS-CoV-2”). Artemisinin, purified from a plant *Artemisia annua*. It can inhibit TGF- β activity and is able to neutralize COVID-19. The Company initially conducted a study and the test results during an in vitro study at Utah State University showed Artemisinin having an EC50 of 0.45 ug/ml, and a Safety Index of 140. Artemisinin can target multiple viral threats, including COVID-19, by suppressing both viral replication and clinical symptoms that arise from viral infection. Viral replication cannot occur without TGF- β . In a clinical study undertaken in India called ARTI-19, clinical consequences related to the TGF- β surge, including ARDS and cytokine storm, were suppressed by targeting TGF- β with Artemisinin. The ARTI-19 trials were conducted in India by Windlas Biotech Limited (“Windlas”), the Company’s business partner in India. Windlas had applied for regulatory approval for it’s Artemisinin based product, ArtiShield™, but has not been able to obtain regulatory approval for use of ArtiShield™ as a COVID-19 therapy and as such, no significant revenues have been reported by Windlas nor have we accrued any royalties on Artemisinin due from Windlas. We intend to focus future development on Artemisinin against other respiratory viruses with unmet needs.

In September 2021, Oncotelic entered into an exclusive License Agreement (the “Agreement”) with Autotelic, Inc. (“Autotelic”), pursuant to which Autotelic granted Oncotelic, among other things: (i) the exclusive right and license to certain Autotelic Patents (as defined in the Agreement) and Autotelic Know-How (as defined in the Agreement); and (ii) a right of first refusal to acquire at least a majority of the outstanding capital stock of Autotelic prior to Autotelic entering into any transaction that is a financing collaboration, distribution revenues, earn-outs, sales, out-licensing, purchases, debt, royalties, merger acquisition, change of control, transfer of cash or non-cash assets, disposition of capital stock by way of tender or exchange offer, partnership or any other joint or collaborative venture, research collaboration, material transfer, sponsored research or similar transaction or agreements. In exchange for the rights granted to Oncotelic, Autotelic will be entitled to earn the milestone payments. This transaction brings in AL-101 - an intranasal apomorphine asset with clear 505(b)2 pathway to approval for PD as well unique mechanism of action for treatment of ED and FSD.

Research Service Agreement between GMP and the Company.

When COVID-19 emerged in China, the Company and GMP contemplated a collaboration to develop drug candidates for COVID-19. Oncotelic Inc. and GMP entered into a research and services agreement (the “*GMP Research Agreement*”) in February 2020 memorializing their collaborative efforts to develop and test COVID-19 antisense therapeutics (the “*GMP Agreement Product*”). In March 2020, the Company reported the anti-viral activity of OT-101 – its lead drug candidate currently in phase 3 testing in pancreatic cancer and glioblastoma. In an in vitro antiviral testing performed by an independent laboratory, OT-101 had an 50% effective concentration (EC50) of 7.6 µg/mL and is not toxic at the highest dose of 1000 µg/mL giving a safety index (SI) value of >130, which is considered highly active. Further in March 2020, the Company and GMP entered into a supplement to the GMP Research Agreement (the “*GMP Research Supplement*”) to confirm the inclusion of OT-101 within the scope of the GMP Research Agreement as a GMP Agreement Product, pending positive confirmatory testing against COVID-19. In April 2020, the Company announced that it had delivered the requisite testing results to GMP confirming the applicability and potential use of OT-101 for the treatment of COVID-19. OT-101 exhibited potent activity against both COVID-19 and SARS with a robust safety index of >500. Also, the Company has submitted a Pre-Investigational New Drug application package to the Food and Drug Administration. GMP paid the Company fees of \$1.2 million during the year ended December 31, 2020 for the services rendered under the agreement. The Company also recorded approximately \$40,000 for reimbursement of actual costs incurred.

In consideration for the financial support provided by GMP for the research, pursuant to the terms of the GMP Research Agreement (as amended by the GMP Research Supplement) GMP is entitled to obtain certain exclusive rights to the use of the GMP Agreement Product in the COVID Field on a global basis, and an economic interest in the use of the GMP Agreement Product in the COVID-19 Field including profit sharing to be decided. As described in the GMP Research Supplement, the Company intends to license or assign intellectual property rights, including the 2020 Patent Application and any other intellectual property rights owned or controlled by the Company relating to the GMP Agreement Product, with an option to the intellectual property rights to OXi4503 and CA4P at a future time, assuming GMP or their designee wishes to include those assets as well, to a joint venture company (the “*Joint Venture Transaction*”) to be established jointly between Oncotelic Inc. and GMP (or its designee), as well as providing management services and other expertise to the joint venture company. GMP intends that it (or its designee, as the case may be) shall provide funding to the joint venture company to support its development and commercial activities in the joint venture company’s territories, and in each case, on terms to be agreed by the parties. GMP shall be entitled to use its governmental relations and local expertise in Greater China to assist with coordinating the research, development and commercialization of (i) the GMP Agreement Products in the COVID Field, (ii) the GMP Agreement Products in the OT-101 Oncology Field, and if GMP decided to include (iii) OXi4503; and (iv) CA4P, in each case in Greater China. The Company entered into a JV with Dragon Overseas Capital Limited (“Dragon Overseas”) and GMP Biotechnology Limited (“GMP Bio”), affiliates of GMP on March 31, 2022. GMP Bio and the Company will own the joint venture company in a 45/55 ratio, and its principal activities shall be to research, develop, bring to market and commercialize: (i) the GMP Agreement Products in the COVID-19 Field on a global basis, (ii) the GMP Agreement Products in the OT-101 Oncology Field in the territory set forth above, and if GMP so decides to include (iii) OXi4503 in the territory set forth above; and (iv) CA4P in the territory set forth above.

In June 2020, the Company secured \$2 million in debt financing, evidenced by a one-year secured convertible note (the “*GMP Note*”) from GMP, to conduct a clinical trial evaluating OT-101 against COVID-19 bearing 2% annual interest, and is personally guaranteed by Dr. Vuong Trieu, the Chief Executive Officer of the Company. The GMP Note is convertible into the Company’s Common Stock upon the GMP Note’s maturity one year from the date of the GMP Note, at the Company’s Common Stock price on the date of conversion with no discount. GMP does not have the option to convert prior to the GMP Note’s maturity at the end of one year. GMP has extended the maturity of the GMP Note to June 30, 2022 with no concessions granted to GMP for such extension. Such financing was utilized solely to fund the clinical trial.

In September 2021, the Company secured a further \$1.5 million in debt financing, evidenced by a one-year convertible note (the “*GMP Note 2*”) from GMP, to fund the same clinical trial evaluating OT-101 against COVID-19 bearing 2% annual interest. The GMP Note is convertible into the Company’s Common Stock upon the GMP Note 2’s maturity one year from the date of the GMP Note 2, at the Company’s Common Stock price on the date of conversion with no discount. GMP does not have the option to convert prior to the GMP Note 2’s maturity at the end of one year. Such financing will be utilized solely to fund the clinical trial. As of December 31, 2021, GMP was invoiced by the clinical research organization for \$1.0 million. GMP paid the clinical trial organization the first tranche of \$0.5 million in October 2021 and the second tranche of \$0.5 million in February 2022.

In October 2021, the Company entered into an Unsecured Convertible Note Purchase Agreement (the “*October Purchase Agreement*”) with GMP, pursuant to which the Company issued a convertible promissory note in the aggregate principal amount of \$0.5 million (the “*October 2021 Note*”), which October 2021 Note is convertible into shares of the Company’s Common Stock. The terms of the note are identical to the GMP Note 2.

License Agreement with Autotelic, Inc.

On September 30, 2021, Oncotelic Therapeutics, Inc. (the “*Company*”) entered into an exclusive License Agreement (the “*License Agreement*”) with Autotelic, Inc. (“*Autotelic*”), pursuant to which Autotelic granted Oncotelic, among other things: (i) the exclusive right and license to certain Autotelic Patents (as defined in the Agreement) and Autotelic Know-How (as defined in the License Agreement); and (ii) a right of first refusal to acquire at least a majority of the outstanding capital stock of Autotelic prior to Autotelic entering into any transaction that is a financing collaboration, distribution revenues, earn-outs, sales, out-licensing, purchases, debt, royalties, merger acquisition, change of control, transfer of cash or non-cash assets, disposition of capital stock by way of tender or exchange offer, partnership or any other joint or collaborative venture, research collaboration, material transfer, sponsored research or similar transaction or agreements. In exchange for the rights granted to Oncotelic, Autotelic will be entitled to earn certain milestone payments (collectively, the “*Milestone Payments*”). In addition to the Milestone Payments, Autotelic will be entitled to royalties equal to 15% of the net sales of any products that incorporate the Autotelic Patents or Autotelic Know-How.

Entry into MOU and Agreement with Windlas

In August 2020 the Company executed a memorandum of understanding (the “*MOU*”) with Windlas for the development and commercialization of Artemisinin as a therapeutic pharmaceutical, nutraceutical and herbal supplement against COVID-19. The development of Artemisinin against COVID-19 was dependent on the successful completion of ARTI-19 clinical trial, which was being initiated globally in Africa, India, and South America. Windlas will be our manufacturing partner for the clinical trial batches as well as commercial batches. In September 2020 the Company executed the final MOU with Windlas regarding the development and commercialization of Artemisinin as therapeutic pharmaceutical, nutraceutical and herbal supplement against COVID-19. Windlas had applied for regulatory approval for it’s Artemisinin based product, ArtiShield™, but has not been able to obtain regulatory approval for use of ArtiShield™ as a COVID-19 therapy and as such, no significant revenues have been reported by Windlas nor have we accrued any royalties on Artemisinin due from Windlas. We intend to focus future development on Artemisinin against other respiratory viruses with unmet needs.

The Company’s ARTI-19 in India was conducted in partnership by Windlas, the Company’s business partner in India, as part of the Company’s effort at deploying ArtiShield™ across India, and a variation of that in Asia, Africa, and Latin America. No adverse events were reported that required discontinuation of treatment. When ARTIVeda™ / PulmoHeal™ was added to the SOC, more patients recovered faster than SOC alone. 31 of 39 (79.5%) of patients taking became asymptomatic after 5-day of therapy. In comparison, only 12 of 21 control patients (57.1%) treated with SOC alone became asymptomatic on day 5. For the sicklier patients (WHO scale 4), the median time to becoming asymptomatic was only 5 days for the ARTIVeda™ / PulmoHeal™ + SOC group, as compared to 14 days for the SOC alone group. These data sets provided clinical support that targeting the TGF-β pathway with ARTIVeda™ / PulmoHeal™ may contribute to a faster recovery of patients with mild to moderate COVID-19 patients. The Company has published the results of the trial in certain renowned publications. The Company is intending to continue developing Artemisinin as pharmaceutical for tropical viral diseases

Agreement with Autotelic BIO

In February 2018, Oncotelic Inc. had entered into a license agreement (the “*ATB Agreement*”) with Autotelic BIO (“*ATB*”), a non-affiliated Korean Company. The ATB Agreement licensed the use of OT-101, in combination with Interleukin-2 (the “*Combined Product*”), and granted to ATB an exclusive license under the Oncotelic Inc. technology to develop, make, have made, use, sell, offer for sale, import and export the Combined Product, and the Combined Product only, in the field, throughout the entire world (excluding the United States of America and Canada) as the territory, on the terms and subject to the conditions of the ATB Agreement. The ATB Agreement requires ATB to be responsible for the development of the Combined Product. Oncotelic Inc. was responsible to provide to ATB the technical know-how and other pertinent information on the development of the Combined Product. ATB paid Oncotelic Inc. a non-refundable milestone payment in consideration for the rights and licenses granted to ATB under the ATB Agreement, and ATB was to pay Oncotelic Inc. \$500,000 within sixty days from the successful completion of the in vivo efficacy studies. This payment was made in June 2020 after the successful completion of the in-vivo study and the Company recorded the revenue during the three months ended June 30, 2020. In addition, ATB is to pay Oncotelic Inc.: (i) \$500,000 upon Oncotelic Inc.’s completion of the technology know how and Oncotelic’s technical assistance and regulatory consultation to ATB, as determined by the preparation of a Current Good Regulation Practices audit or certification by the Food and Drug Administration, with a mutual goal to obtain marketing approval of the Combined Product in the aforementioned territory; (ii) \$1,000,000 upon receiving marketing approval of the Combined Product in Japan, China, Brazil, Mexico, Russia, or Korea; and (iii) \$2,000,000 from receiving marketing approval of the Combined Product in Germany, France, Spain, Italy, or the United Kingdom. ATB paid the Company fees of \$0.5 million during the three months ended June 30, 2020 for the successful completion of the in-vivo efficacy studies.

Private Placement through JH Darbie & Co., Inc.

Between July 2020 and March 2021, the Company offered and sold certain units (“*Units*”) in a private placement through JH Darbie & Co., Inc. (“*JH Darbie*”), with each unit consisting of: (i) 25,000 shares of Edgepoint common stock, par value \$0.01 per share (“*Edgepoint Common Stock*”), for a price of \$1.00 per share of Edgepoint Common Stock; (ii) one convertible promissory note issued by the Company (the “*Unit Note*”), convertible into up to 25,000 shares of EdgePoint Common Stock at a conversion price of \$1.00 per share, or up to 138,889 shares of the Company’s Common Stock, at a conversion price of \$0.18 per share; and (iii) 100,000 warrants (the “*Warrants*”), consisting of (a) 50,000 warrants to purchase an equivalent number of shares of EdgePoint Common Stock at \$1.00 per share (“*Edgepoint Warrant*”), and (b) 50,000 warrants to purchase an equivalent number of shares of Company Common Stock at \$0.20 per share (“*Oncotelic Warrant*”) (the sale of Units is hereinafter, the “*JH Darbie Financing*”). In total, as of December 31, 2021, the Company had issued and sold a total of 100 Units. JH Darbie earned an 10 Units as fees.

The JH Darbie Financing resulted in gross proceeds of \$5 million to the Company. Placement agent fees of \$0.65 million were paid to JH Darbie pursuant to that certain Placement Agent Agreement, dated February 25, 2020 between the Company and JH Darbie (the “*Darbie Placement Agreement*”). In addition, the Company paid approximately \$39,000 as legal costs for the transaction. Under the Darbie Placement Agreement, JH Darbie had the right to sell a minimum of 40 Units and a maximum of 100 Units on a best-efforts basis.

In June 2021, the Company and the Investors agreed to extend the maturity date of the Notes from June 30, 2021, to March 31, 2022. In addition, the Company and JHDarbie identified an error in the Oncotelic Warrants and JH Darbie Financing documents which intended to have the investors to purchase \$50,000 of shares of Common Stock or Edgepoint Common Stock. However, the Company only issued 50,000 Oncotelic Warrants, with an aggregate exercise price of \$10,000. The error was corrected by the Company and the Company issued to the Investors an aggregate of 20.0 million additional Oncotelic Warrants, and 2.0 million additional Oncotelic Warrants to J.H. Darbie, as placement agent. Each Investor was entitled to receive 200,000 additional Oncotelic Warrants for each Unit purchased.

Peak One Equity Purchase Agreement

In May 2021, the Company entered into an Equity Purchase Agreement (the “*EPL*”) and Registration Rights Agreement (the “*Registration Rights Agreement*”) with Peak One Opportunity Fund, L.P. (“*Peak One*”), pursuant to which the Company shall have the right, but not the obligation, to direct Peak One, to purchase up to \$10.0 million (the “*Maximum Commitment Amount*”) in shares of the Company’s Common Stock. Under the EPL and subject to the Maximum Commitment Amount, the Company has the right, but not the obligation, to submit Put Notices (as defined in the EPL) to Peak One (i) in a minimum amount not less than \$20,000.00, and (ii) in a maximum amount up to the lesser of (a) \$1.0 million or (b) 250% of the Average Daily Trading Value (as defined in the EPL). In exchange for Peak One entering into the EPL, the Company agreed, among other things, to (A) issue Peak One and Peak One Investments, LLC, an aggregate of 250,000 shares of Common Stock, and (B) file a registration statement registering the Common Stock issued or issuable to Peak One under the EPL for resale (the “*Registration Statement*”) with the SEC within 60 calendar days of the date of the EPL, as more specifically set forth in the Registration Rights Agreement. The obligation of Peak One to purchase the Company’s Common Stock shall begin on the date of the EPL, and ending on the earlier of (i) the date on which Peak One shall have purchased Common Stock pursuant to the EPL equal to the Maximum Commitment Amount, (ii) twenty four (24) months after the initial effectiveness of the Registration Statement, (iii) written notice of termination by the Company to Peak One (subject to certain restrictions set forth in the EPL), (iv) the Registration Statement is no longer effective after the initial effective date of the Registration Statement, or (v) the date that the Company commences a voluntary case or any person commences a proceeding against the Company, a custodian is appointed for the Company or for all or substantially all of its property or the Company makes a general assignment for the benefit of its creditors (the “*Commitment Period*”). During the Commitment Period, the purchase price to be paid by Peak One for the Common Stock under the EPL shall be 91% of the Market Price, which is defined as the lesser of the (i) closing bid price of the Common Stock on the trading day immediately preceding the respective Put Date (as defined in the EPL), or (ii) lowest closing bid price of the Common Stock during the Valuation Period (as defined in the EPL), in each case as reported by Bloomberg Finance L.P or other reputable source designated by Peak One.

During the year ended December 31, 2021, the Company sold a total of 3,435,000 shares of Common Stock at prices ranging from \$0.09 and \$0.23 for total net proceeds of approximately \$420,000.

Paycheck Protection Program

In April 2020, the Company received loan proceeds in the amount of \$250,000 under the Paycheck Protection Program (“*1st PPP*”) which was established under the Coronavirus Aid, Relief and Economic Security (“*CARES*”) Act and is administered by the Small Business Administration (“*SBA*”). The 1st PPP provides loans to qualifying businesses in amounts up to 2.5 times the average monthly payroll expenses and was designed to provide direct financial incentive to qualifying businesses to keep their workforce employed during the Coronavirus crisis. The Payment Protection Plan loans (“*PPP Loans*”) are uncollateralized and guaranteed by the SBA and forgivable after a “covered period” (8 weeks or 24 weeks) as long as the borrower maintained its payroll levels and uses the loan proceeds for eligible expenses, including payroll, benefits, mortgage interest, rent and utilities. The forgiveness amount would be reduced if the borrower terminated employees or reduced salaries and wages more than 25% during the covered period. Any unforgiven portion was payable over 2 years if issued before, or 5 years if issued after, June 5, 2020 at an interest rate of 1% with payments deferred until the SBA remits the borrowers loan forgiveness amount to the lender, or if the borrower did not apply for forgiveness, 10 months after the covered period. PPP loans provide for customary events of default, including payment defaults, breach of representations and warranties, and insolvency events and may be accelerated upon occurrence of one or more of these events of default. Additionally, the PPP Loans do not include prepayment penalties.

The Company met the 1st PPP loan forgiveness requirements and on August 7, 2021 applied for forgiveness. On Aug 17, 2021, the Company received the 1st PPP loan forgiveness approval from the lender and wrote off the loan outstanding amount inclusive of interest accrued, in the amount of \$253,347. The Company recorded the amount forgiven as forgiveness income within the other income (expense) section of its statement of operations. The balance outstanding on 1st PPP loan, inclusive of accrued interest, was \$0 and \$251,733 on December 31, 2021 and December 31, 2020, respectively.

In July 2021, the Company’s wholly owned subsidiary, PointR, received loan proceeds in the amount of \$92,995 under the PPP (“*2nd PPP*”). The 2nd PPP was at terms similar to the 1st PPP. The Company met the 2nd PPP loan forgiveness requirements and received the 2nd PPP loan forgiveness approval from the lender on December 8, 2021 and wrote off the loan outstanding amount inclusive of interest accrued, in the amount of \$93,413. The Company recorded the amount forgiven as forgiveness income within the other income (expense) section of its statement of operations. The balance outstanding on the 2nd PPP loan was \$0 and \$0 on December 31, 2021 and 2020, respectively.

The SBA reserves the right to audit any PPP loan, regardless of size. These audits may occur after the forgiveness has been granted. In accordance with the CARES Act, all borrowers are required to maintain their PPP loan documentation for six years after the loan was forgiven or repaid in full and to provide that documentation to the SBA upon request.

Geneva Roth Remark Notes

In May and June 2021, the Company entered into Securities Purchase Agreement (the “*Geneva Agreement*”) with Geneva Roth Remark Holdings Inc. (“*Geneva*”), whereby the Company issued two convertible notes (collectively, the “*Geneva Notes*”) in the aggregate principal amount of \$307,500, convertible into shares of Common Stock. Under the terms of the Geneva Agreement, the Company will receive additional tranches of convertible note financing of up to \$1.2 million throughout the term of the Geneva Agreement. The Geneva Notes have an interest rate of six percent (6%), which increases to twenty-two percent (22%) in the event of a default under each respective Note, and both mature one year from issuance (the “*Maturity Date*”). Geneva has the right from time to time, and at any time during the period beginning on the date which is one hundred eighty (180) days following issuance date and ending on the Maturity Date to convert all or any part of the outstanding and unpaid amount of the applicable Geneva Note into the Company’s Common Stock at a conversion price established at sixty five (65%) percent multiplied by the lowest two (2) daily volume weighted average price over the fifteen (15) consecutive trading days. The Geneva Notes include a clause accelerating the Company’s payment obligations upon the occurrence of certain events of default whereby, at the option of Geneva, the Company will become immediately obligated to repay Geneva in an amount equal to the principal of the applicable Geneva Loan plus both accrued but unpaid interest and default interest, in cash, with premium.

The total amount outstanding under the Geneva Notes, including accrued interest thereon, as of September 30, 2021, and December 31, 2020, was \$313,472 and \$0, respectively.

Unsecured convertible notes

In August 2021, the Company entered into Note Purchase Agreements with Autotelic, the CFO, and certain other accredited investors. Under the terms of the Note Purchase Agreements, the Company issued an aggregate of \$698,500 (the “*Principal Amount*”) in debt in the form of unsecured convertible promissory notes (collectively, the “*August 2021 Notes*”). The August 2021 Notes are unsecured and provide for interest at the rate of 5% per annum. Such August 2021 Notes were issued against some of the short-term debt due as of June 30, 2021. All amounts outstanding under the August 2021 Notes become due and payable at such time as determined by the holders of a majority of the Principal Amount of the August 2021 Notes (the “*Majority Holders*”), on or after (a) the one year anniversary of the August 2021 Notes, or (b) the occurrence of an Event of Default (as defined in the Note Purchase Agreements) (the “*Maturity Date*”). The Company may prepay the August 2021 Notes at any time. Events of Default under the August 2021 Notes include, without limitation, (i) failure to make payments under the August 2021 Notes within thirty (30) days of the Maturity Date, (ii) breaches of the Note Purchase Agreement or August 2021 Notes by the Company which is not cured within thirty (30) days of notice of the breach, (iii) bankruptcy, or (iv) a change in control of the Company (as defined in the Note Purchase Agreements). The Majority Holders have the right, at any time not more than five days following the Maturity Date, to elect to convert all, and not less than all, of the outstanding accrued and unpaid interest and principal on the August 2021 Notes. The August 2021 Notes may be converted, at the election of the Majority Holders, into shares of the Company’s common stock, par value \$0.01 per share, at a fixed conversion price of \$0.18 per share.

November – December 2021 Financing

In November and December 2021, the Company entered into securities purchase agreement with five institutional investors, whereby the Company issued five convertible notes in the aggregate principal amount of \$1,250,000 convertible into shares of common stock of the Company. The convertible notes carry a twelve (12%) percent coupon and a default coupon of 16% and mature at the earliest of one year from issuance or upon event of default. Investors has the right at any time following issuance date to convert all or any part of the outstanding and unpaid amount of the note into the Company’s common stock at a conversion price established at a fixed rate of \$0.07. The Company granted a total number of 9,615,385 warrants convertible into an equivalent number of the Company common shares at a strike price of \$0.13 up to five years after issuance. The Placement agent was also granted a total amount of 125,000 as part of a finder’s fee agreement.

Short-term loans

The Company's CEO had provided a short-term loan of \$70,000 to the Company during the year ended December 31, 2020, of which \$50,000 was repaid during the three months ended March 31, 2021. As such, \$20,000 was outstanding at December 31, 2021. During the three months ended March 31, 2021, Autotelic Inc. provided a short-term funding of \$120,000 to the Company, which was repaid shortly after the three months ended March 31, 2021. In May 2021, Autotelic provided an additional short-term funding of \$250,000 to the Company, which was converted into a promissory note in the August 2021 Notes. Autotelic provided an additional \$20,000 short-term loan to the Company, and as such, \$20,000 was outstanding and payable to Autotelic at December 31, 2021.

During the fourth quarter of the year ended December 31, 2020, the Company's CFO and the Bridge Investor provided short term loans of \$25,000 and \$50,000, respectively to the Company. Such loans were repaid as of March 31, 2021. During the year ended December 31, 2021, the CFO provided a total of approximately \$120,000, of which \$75,000 was converted into the August 2021 Notes. As such, a balance of approximately \$45,000 remained outstanding as a short-term loan as of December 31, 2021. During the year ended December 31, 2021, the Company received approximately \$630,000 primarily from two bridge investors, of which \$373,500 was converted into the August 2021 Notes, and approximately \$360,000 was outstanding as short-term advances as of December 31, 2021.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of financial statements in accordance with U.S. generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expense during the reporting periods. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances at the time we make such estimates. Actual results and outcomes may differ materially from our estimates, judgments and assumptions. We periodically review our estimates considering changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in the financial statements prospectively from the date of the change in estimate. Our significant accounting policies are more fully described in Note 2 to our financial statements included elsewhere in this Annual Report.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. We believe the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments are the following:

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including definite-lived intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of these assets is determined by comparing the forecasted undiscounted net cash flows of the operation to which the assets relate to the carrying amount. If the operation is determined to be unable to recover the carrying amount of its assets, then these assets are written down first, followed by other long-lived assets of the operation to fair value. Fair value is determined based on discounted cash flows or appraised values, depending on the nature of the assets. For the year ended December 31, 2021 and 2020, there were no impairment losses recognized for long-lived assets.

Intangible Assets

The Company records its intangible assets at cost in accordance with ASC 350, Intangibles – Goodwill and Other. The Company reviews the intangible assets for impairment on an annual basis or if events or changes in circumstances indicate it is more likely than not that they are impaired. These events could include a significant change in the business climate, legal factors, a decline in operating performance, competition, sale or disposition of a significant portion of the business, or other factors.

Goodwill

Goodwill represents the excess of the purchase price of acquired business over the estimated fair value of the identifiable net assets acquired. Goodwill is not amortized but is tested for impairment at least once annually, at the reporting unit level or more frequently if events or changes in circumstances indicate that the asset might be impaired. The goodwill impairment test is applied by performing a qualitative assessment before calculating the fair value of the reporting unit. If, on the basis of qualitative factors, it is considered not more likely than not that the fair value of the reporting unit is less than the carrying amount, further testing of goodwill for impairment would not be required. Otherwise, goodwill impairment is tested using a two-step approach.

The first step involves comparing the fair value of the reporting unit to its carrying amount. If the fair value of the reporting unit is determined to be greater than its carrying amount, there is no impairment. If the reporting unit's carrying amount is determined to be greater than the fair value, the second step must be completed to measure the amount of impairment, if any. The second step involves calculating the implied fair value of goodwill by deducting the fair value of all tangible and intangible assets, excluding goodwill, of the reporting unit from the fair value of the reporting unit as determined in step one. The implied fair value of the goodwill in this step is compared to the carrying value of goodwill. If the implied fair value of the goodwill is less than the carrying value of the goodwill, an impairment loss equivalent to the difference is recorded.

Convertible Instruments

The Company evaluates and accounts for conversion options embedded in its convertible instruments in accordance with ASC 815 “Derivatives and Hedging”.

ASC 815 generally provides three criteria that, if met, require companies to bifurcate conversion options from their host instruments and account for them as free standing derivative financial instruments. These three criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur, and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument. Professional standards also provide an exception to this rule when the host instrument is deemed to be conventional as defined under professional standards.

The Company accounts for convertible instruments (when it has determined that the embedded conversion options should not be bifurcated from their host instruments) in accordance with ASC 470-20 “Debt – Debt with Conversion and Other Options.” Accordingly, the Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Original issue discounts under these arrangements are amortized over the term of the related debt to their earliest date of redemption. The Company also records when necessary deemed dividends for the intrinsic value of conversion options embedded in preferred shares based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note.

ASC 815-40 “Derivatives and Hedging – Contracts in Entity’s Own Equity” provides that, among other things, generally, if an event is not within the entity’s control could or require net cash settlement, then the contract shall be classified as an asset or a liability.

Derivative Financial Instruments Indexed to the Company's Common Stock

We have generally issued derivative financial instruments, such as warrants, in connection with our equity offerings. We evaluate the terms of these derivative financial instruments in order to determine their accounting treatment in our financial statements. Key considerations include whether the financial instruments are freestanding and whether they contain conditional obligations. If the warrants are freestanding, do not contain conditional obligations and meet other classification criteria, we account for the warrants as an equity instrument. However, if the warrants contain conditional obligations, then we account for the warrants as a liability until the conditional obligations are met or are no longer relevant. Because no established market prices exist for the warrants that we issue in connection with our equity offerings, we must estimate the fair value of the warrants, which is as inherently subjective as it is for stock options, and for similar reasons as noted in the stock-based compensation section above. For financial instruments which are accounted for as a liability, we report any changes in their estimated fair values as gains or losses in our Consolidated Statement of Income.

Variable Interest Entity (VIE) Accounting

We evaluate our ownership, contractual relationships and other interests in entities to determine the nature and extent of the interests, whether such interests are variable interests and whether the entities are VIEs in accordance with ASC 810, Consolidations. These evaluations can be complex and involve Management judgment as well as the use of estimates and assumptions based on available historical information, among other factors. Based on these evaluations, if the Company determines that it is the primary beneficiary of a VIE, the entity is consolidated into the financial statements.

Research and Development Expense

Research and development expense consists of costs we incur for the development of our investigational drugs and, to a lesser extent, for preclinical research activities. Research and development costs are expensed as incurred. Research and development expense includes clinical trial costs, salaries and benefits of employees, including associated stock-based compensation, payments to clinical investigators, drug manufacturing costs, laboratory supplies and facility costs. Clinical trial costs are a significant component of our research and development expense, and these can be difficult to accurately estimate. Included in clinical trial costs are fees paid to other entities that conduct certain research and development activities on our behalf, such as clinical research organizations, or CROs. We estimate clinical trial expense based on the services performed pursuant to contracts with research institutions such as CROs and the actual clinical investigators. These estimates are based on actual time and expenses incurred by the CRO and the clinical investigators. Also included in clinical trial expense are costs based on the level of patient enrollment into the clinical trial and the actual services performed under the related clinical trial agreement. Changes in clinical trial assumptions, such as the length of time estimated to enroll all patients, rate of screening failures, patient drop-out rates, number and nature of adverse event reports and the total number of patients enrolled can impact the average and expected cost per patient and the overall cost of the clinical trial. Based on patient enrollment reports and services provided, we may periodically adjust estimates for the clinical trial costs. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed, the length of time for these services or the costs of these services, our actual expenses could differ from our estimates.

Share-Based Compensation

We record the estimated fair value of all share-based payments issued to employees and other service providers. Our share-based payments consist primarily of stock options. The valuation of stock options is an inherently subjective process, since market values are not available for any stock options in our equity securities. Market values are also not available on long-term, non-transferable stock options in other equity securities. With no market values on options to trade in our common stock and no comparable market values on any long-term non-transferable stock options, the process of valuing our stock options is even more uncertain and subjective. Accordingly, we use a Black-Scholes option pricing model to derive an estimated fair value of the stock options which we issue. The Black-Scholes option pricing model requires certain input assumptions, including the expected term of the options and the expected volatility of our common stock. Changes in these assumptions could have a material impact on the estimated fair value that we record for share-based payments that we issue. We determine the term of the options based on the simplified method, which averages the vesting period and the contractual life of the stock option. We determine the expected volatility based on the historical volatility of our common stock over a period commensurate with the option's expected term. The Black-Scholes option pricing model also requires assumptions for risk-free interest rates and the expected dividend yield of our common stock, but we feel that these values are more objective and note that changes in these values do not have a significant impact on the estimated value of the options when compared to the volatility and term assumptions.

We are also required to estimate the level of award forfeitures expected to occur and record compensation expense only for those awards that are ultimately expected to vest. Accordingly, we perform a historical analysis of option awards that are forfeited prior to vesting, and record total stock option expense that reflects this estimated forfeiture rate.

Results of Operations

Years Ended December 31, 2021 and 2020

A comparison of the Company's operating results for the year ended December 31, 2021 and 2020, respectively, is as follows.

	2021	2020	Variance
Revenue	-	-	-
Service revenue	\$ -	\$ 1,740,855	\$ (1,740,855)
Total revenue	-	1,740,855	(1,740,855)
 Operating expense:			
Research and development	\$ 3,658,617	\$ 4,302,447	\$ (643,830)
General and administrative	5,467,266	5,023,142	444,124
Total operating expense	9,125,883	9,325,589	(199,706)
Loss from operations	(9,125,883)	(7,584,734)	(1,541,149)
Interest expense, net	(2,002,813)	(1,998,321)	(4,492)
PPP loan forgiveness	346,761	-	346,761
Change in the value of derivatives	292,149	(45,051)	337,200
Loss on debt conversion	(27,504)	(343,700)	316,196
Net loss	\$ (10,517,290)	\$ (9,971,806)	\$ (545,484)

Net Loss

We recorded a net loss of approximately \$10.5 million for the year ended December 31, 2021, compared to a net loss of approximately \$10 million for the same period in 2020. The increased loss was primarily in connection with lower loss from operations due to the reduced revenues of approximately \$1.7 million, generated during the year ended December 31, 2020 as against no revenues during the year ended December 31, 2021, offset by operational expenses of approximately \$0.2 million. In addition, the net loss of \$0.5 million was due to loss from operations of \$1.5 million, offset by the recording of approximately \$0.3 million for the PPP loan forgiveness, approximately \$0.3 million of a lower loss on conversion of debt by TFK during the year ended December 31, 2021 as compared to the same period in 2020, and approximately \$0.3 million for change in value of derivatives during the year ended December 31, 2021 as compared to the same period in 2020.

Revenue

We recorded services revenue of \$0 for the year ended December 31, 2021 as compared to approximately \$1.7 million during the year ended December 31, 2020. The services revenue recorded in 2020 primarily comprised of \$1.2 million from services provided to GMP in connection with the development of OT-101 for COVID-19 and included reimbursement of costs incurred of approximately \$41 thousand. We also recorded \$0.5 million of revenues from ATB upon the successful completion of the in-vivo efficacy studies based on the ATB Agreement.

Research and Development Expense

Research and Development ("R&D") expense decreased by approximately \$0.6 million, from approximately \$4.3 million for the year ended December 31, 2020 as compared to approximately \$3.7 million for the year ended December 31, 2021. The decrease of approximately \$0.6 million in the R&D activities is primarily due to reduced clinical trial costs of \$0.3 million for the trials for OT-101 and Artemisinin, and \$0.4 million for lower operational costs.

Now that we have formed a joint venture with GMP Bio, whereby we are able to transfer the responsibility of our drug development program to the joint venture, we expect to increase research and development activities for apomorphine, including the initiation of new clinical trials for our other oncology indications as well continuing or expanding on the trials and development of AI based tools and applications for OT-101 and Artemisinin for COVID-19 and other epidemics, and therefore believe that research and development expense may increase in the future, subject to our continuing ability to secure sufficient funding to continue planned operations.

General and Administrative Expense

General and administrative (“G&A”) expense increased by approximately \$0.4 million, from approximately \$5.4 million for the year ended December 31, 2021 as compared to \$5.0 for the same period of 2020. The increase in G&A expenses by approximately \$0.4 million for the year ended December 31, 2021 compared to same period of 2020 was primarily due to an increase of approximately \$1 million of non-cash equity-based expenses, partially offset by lower compensation costs of approximately \$0.3 million, lower legal and professional costs of approximately \$0.2 million and lower other operational costs of approximately \$0.1 million.

Now that we have formed a joint venture with GMP Bio, we may be able to transfer the responsibility of some or most of our G&A expenses to the joint venture, we may see an increase in G&A expenses, subject to our continuing ability to secure sufficient funding to continue planned operations.

Loss on Conversion of Debt

During the year ended December 31, 2021, we recorded a loss on conversion of debt by TFK of approximately \$28 thousand related to the difference in fair value to the price at which the debt was converted. We had recorded a similar loss of \$0.3 million for the debt conversion by Peak One and TFK in 2020.

Change in value of derivatives

During the year ended December 31, 2021, we recorded a gain of \$0.3 million due to the change in value of derivatives on the notes issued to our CEO and the bridge investors. Correspondingly, during the year ended December 31, 2020, we recorded a nominal loss due to the change in value of derivatives of \$45 thousand on the 2019 Peak One note, the TFK note and the notes issued to our CEO and the bridge investors (collectively, the “Convertible Notes”).

Interest Expense

We recorded interest expense, including amortization of debt costs, of \$2.0 million for the year ended December 31, 2021 in connection with debt raised from the various convertible notes and a private placement memorandum as compared to \$2.0 million on convertible notes and a portion of the private placement memorandum for the same period of 2020.

Liquidity, Financial Condition and Capital Resources (\$s in '000's)

	December 31, 2021	December 31, 2020
Cash, including restricted cash	\$ 588	\$ 494
Working capital	(14,828)	(10,567)
Stockholders' Equity	8,158	12,481

The Company has experienced net losses every year since inception and as of December 31, 2021 had an accumulated deficit of approximately \$31 million. As of December 31, 2021, the Company had approximately \$0.6 million in cash and current liabilities of approximately \$15.5 million, of which approximately \$1.3 million are net assumed liabilities of the Company as part of the Oncotelic Inc. reverse merger, \$4.1 million of debt related to debt for conducting clinical trials for OT-101 from GMP and \$2.6 million is contingent liability to issue common shares of the Company to PointR shareholders upon achievement of certain milestones. The Company does not expect to generate any meaningful revenue from product sales or licensing in the near future, and expects to incur additional operating losses over the next several years, primarily as a result of the Company's plans to continue clinical trials for its investigational drugs, if the Company is unable to form a joint venture with GMP. Since the Company successfully formed the joint venture with Dragon Overseas and GMP Bio, then all costs associated with developing the assets licensed to the JV and a substantial portion of the G&A expenses will shift over to the JV and hence the Company may be able to reduce its expenses. The Company's limited capital resources, history of recurring losses and uncertainties as to whether the Company's operations will become profitable raise substantial doubt about its ability to continue as a going concern. The financial statements contained in this report do not include any adjustments related to the recoverability of assets or classifications of liabilities that might be necessary should the Company be unable to continue as a going concern.

The principal source of the Company's working capital deficit to date has been the issuance of convertible notes, a substantial part of which has been provided by officers and certain insiders. The Company will need to raise additional capital in order to fund its operations and continue development of product candidates. The Company is evaluating the options to further the development of the Company's lead product candidate, Apomorphine for Parkinsons Disease, erectile dysfunction and female sexual dysfunction; OT-101 for both cancer and COVID-19, Artemisinin for COVID-19, developing AI technologies to support the COVID-19 therapies; in addition to evaluating the development pathway of its product candidates; OXi4503 and/or CA4P.

The Company anticipates raising substantial additional capital through the sale of equity securities and/or debt, but no new financing arrangements are in place at this time.

If the Company is unable to access additional funds when needed, it may not be able to continue the development of these investigational drugs and the Company could be required to delay, scale back or eliminate some or all of its development programs and operations. Any additional equity financing, if available, would be dilutive to the current stockholders and may not be available on favorable terms. Additional debt financing, if available, may involve restrictive covenants and could also be dilutive. The Company's ability to access capital is not assured and, if access is not achieved on a timely basis, would materially harm the Company's financial condition, the value of its common stock and its business prospects.

Cash Flows (\$s in '000s)

	Year ended December 31,	
	2021	2020
Net cash used in operating activities	\$ (4,288)	\$ (2,812)
Net cash provided by financing activities	4,383	3,224
Increase in cash	<u>\$ 95</u>	<u>\$ 412</u>

Operating Activities

Net cash used in operating activities was approximately \$4.3 million for the year ended December 31, 2021. This was due to the net loss of approximately \$10.5 million, which was partially offset by a \$1.5 million of R&D cost paid through debt from GMP, non-cash amortization of debt discounts and deferred financing costs of \$1.4 million, non-cash stock-based compensation of \$0.8 million, amortization and depreciation of intangibles and development equipment of \$0.1 million, non-cash gain on conversion of debt and change in fair value of derivatives of \$0.3 million, forgiveness of the PPP Loan of \$0.3 million and changes in operating assets and liabilities of approximately \$0.2 million.

Net cash used in operating activities was approximately \$2.8 million for the year ended December 31, 2020. This was due to the net loss of approximately \$10.0 million, which was partially offset by a \$2.0 million of R&D cost paid through debt, non-cash amortization of debt discounts and deferred financing costs of \$1.7 million, non-cash stock-based compensation of \$2.1 million, amortization and depreciation of intangibles and development equipment of \$0.3 million, non-cash loss on conversion of debt and change in fair value of derivatives of \$0.3 million and changes in operating assets and liabilities of approximately \$0.5 million.

Financing Activities

For the year ended December 31, 2021, net cash provided by financing activities was approximately \$4.4 million. Net cash provided was due to approximately \$1.6 million raised from the JH Darbie Financing, \$0.1 million received under the Payroll Protection Plan, \$0.4 million raised from sale of common stock under the equity purchase agreement with Peak One, \$2.8 million raised through issuance of convertible debt, repayment of \$0.4 million of convertible debt due to Geneva and repayment of \$0.2 million of other notes.

For the year ended December 31, 2020, net cash provided by financing activities was approximately \$3.2 million. Net cash provided was due to approximately \$2.9 million raised from a private placement memorandum, \$0.25 million received under the Payroll Protection Plan, \$20 thousand received from our CEO, net of repayment of \$50 thousand, \$75 thousand of short term loans from the CFO and a bridge investor and repayment of \$50,000 to one of our Fall 2019 investors.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Effects of Inflation

We do not believe that inflation has had a material impact on our business, revenues or operating results during the periods presented.

Contractual Obligations

Our current drug development programs are based on a series of compounds called combretastatins, which we have exclusively licensed from Arizona State University, or ASU. If our current drug candidates are approved, we will be required to pay low to mid-single-digit royalties on future net sales of products associated with the ASU patent rights until these patent rights expire.

We also have an exclusive license from Bristol-Myers Squibb, or BMS, for certain patent rights to particular combretastatins, including CA4P. If CA4P is approved, we will be required to pay low-single-digit royalties on future net sales of products associated with the BMS patent rights until these patent rights expire.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our cash is maintained in U.S. dollar accounts. We have adopted a policy for the cash that we hold, and also for any cash equivalents and investments that we may hold, the primary objective of which is to preserve principal, while also maintaining liquidity to meet our operating needs and maximize yields to the extent possible. Although our investments can be subject to credit risk, we follow procedures to limit the amount of credit exposure in any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and would be likely to decrease in value if market interest rates increase. However, due to the generally conservative nature of our investments and relatively short duration, we believe that interest rate risk is mitigated.

Although we may from time to time manufacture drugs and conduct preclinical or clinical trials outside of the United States, we believe our exposure to foreign currency risk to be immaterial.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See Item 15 for a list of our Financial Statements and Schedules and any supplementary financial information filed as part of this Annual Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Baker Tilly US, LLP resigned from the position of our Auditors in November 2021. We appointed Rose, Snyder and Jacobs, LLP as our auditors. We have no disagreements with our accountants on accounting and financial disclosure.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. In designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives.

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") our Chief Executive Officer ("CEO") and our Chief Financial Officer ("CFO") conducted an evaluation as of the end of the period covered by this Annual Report on Form 10-K, of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our CEO and our CFO each concluded that our disclosure controls and procedures are not effective to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act, (i) is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (ii) is accumulated and communicated to our management, including our CEO and our CFO, as appropriate to allow timely decisions regarding required disclosure.

Material Weaknesses in Internal Control over Financial Reporting

Management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2021 based on the framework established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has determined that the Registrant's internal control over financial reporting as of December 31, 2021 was not effective as a result of certain material weaknesses.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The ineffectiveness of our internal control over financial reporting was due to the following material weaknesses which are observed in many small companies with a small number of accounting and financial reporting staff:

- Lack of formal policies and procedures;
- Lack of adequate independent directors on the Company's board of directors and committees to oversee financial reporting responsibilities since July 2021;
- Inadequate or lack of segregation of duties;
- Lack of dedicated resources and experienced personnel to design and implement internal control procedures to support financial reporting objectives;
- Lack of risk assessment procedures on internal controls to detect financial reporting risks on a timely manner.

Management's Plan to Remediate the Material Weaknesses

Management has been implementing and continues to implement measures designed to ensure that control deficiencies contributing to the material weakness are remediated, such that these controls are designed, implemented, and operating effectively. The remediation actions planned include:

- Continue to search for, evaluate and recruit qualified independent outside directors;
- Once independent directors are on Board, to augment or replace the non-independent directors to the Audit Committee and other committees.
- Identify gaps in our skills base and the expertise of our staff required to meet the financial reporting requirements of a public company; and
- Continue to develop policies and procedures on internal control over financial reporting and monitor the effectiveness of operations on existing controls and procedures.

Changes in Internal Control over Financial Reporting

During the year ended December 31, 2021, we continued to execute upon our planned remediation actions which are all intended to strengthen our overall control environment. We have made some progress in our planned remediation efforts and we expect the Company to complete its planned execution of internal controls over financial reporting during the year ended December 31, 2022.

We are committed to maintaining a strong internal control environment and believe that these remediation efforts will represent significant improvements in our control environment. Our management will continue to monitor and evaluate the relevance of our risk-based approach and the effectiveness of our internal controls and procedures over financial reporting on an ongoing basis and is committed to taking further action and implementing additional enhancements or improvements, as necessary and as funds allow.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth certain information about our current directors and executive officers followed by individual biographies of the directors and executive officers of the Company, including their business experience and other relevant information as of December 31, 2021.

Name	Age	Position
Vuong Trieu, Ph. D.	57	Chairman of the Board and Chief Executive Officer
Amit Shah	55	Chief Financial Officer
Saran Saund	64	Chief Business Officer
Anthony E. Maida III	69	Chief Medical Officer (Consultant) & Director
Steven W. King	57	Director

*Mr. David Diamond was a member of the Board of Directors and certain committees till his resignation in July 2021. Hence, his information has not been reflected in the table above.

Vuong Trieu, Ph.D. was the founder and Chairman of the Board of Directors of Oncotelic Inc., having served in such capacity since 2014, and now serves as the Company's Chief Executive Officer ("CEO") and Chairman of the Board of Directors. Dr. Trieu has been involved in drug discovery, development, and commercialization for over 25 years, including his contributions as co-inventor of Abraxane®. He previously served as Executive Chairman and Interim CEO of Marina Biotech, Inc. from 2016 to 2018. Marina Biotech was a developer of tkRNA for the treatment of FAP/CRC (Familial adenomatous polyposis/ Colorectal Cancer). Prior to that, he also served as President and CEO of IgDraSol, Inc.— a developer of a 2nd generation Abraxane— beginning in 2012 until its acquisition by Sorrento Therapeutics, Inc. in 2013. He served as Chief Scientific Officer for Sorrento Therapeutics, Inc. and a member of that company's board of directors from 2013 until 2014. Previously, Dr. Trieu was Senior Director of Pharmacology/Biology at Abraxis Bioscience/Celgene, where he led the preclinical, clinical and PK/biomarker development of Abraxane, and was the co-inventor of the intellectual property covering Abraxane. Earlier in his career, Dr. Trieu held positions at Genetic Therapy/Sandoz (leading the adenoviral gene therapy program against atherosclerosis), Applied Molecular Evolution (AME)/Lily (leading the expression, purification, and preclinical testing of mAb therapeutics) and Parker Hughes Institute (Director of Cardiovascular Biology program that evaluated a series of small molecules and biologics against preclinical models of atherosclerosis, dyslipidemia, stroke, ALS, and restenosis). Dr. Trieu holds a PhD in Microbiology, BS in Microbiology and Botany. He is a member of ENDO, ASCO, AACR, and many other professional organizations. Dr. Trieu is published widely in oncology, cardiovascular, and drug development.

Dr. Trieu has over 100 patent applications and 39 issued U.S. patents.

The Board believes that Dr. Trieu's extensive experience as an executive at various biotechnology and biopharmaceutical companies as well as his service on private and public company boards qualifies him to serve on the Board.

Amit Shah was appointed as our Chief Financial Officer effective in July 2019. Mr. Shah has served as a senior financial officer for a number of life science companies, including Chief Financial Officer at Marina Biotech, Inc., a publicly traded biotechnology company from 2017 to 2018; Vice President of Finance & Accounting Insightra Medical Inc. from 2014 to 2015, Acting Chief Financial Officer of Insightra Medical Inc. in 2015; VP Finance and Acting Chief Financial Officer at IgDraSol Inc. in 2013; Corporate Controller & Director of Finance at ISTA Pharmaceuticals from 2010 to 2012; Corporate Controller at Spectrum Pharmaceuticals from 2007 to 2010; and as Controller / Senior Manager Internal Audits at Caraco Pharmaceuticals Laboratories from 2000 to 2007. In addition to his work with life sciences companies, Mr. Shah served as the Chief Financial Officer at Eagle Business Performance Services, a management consulting and business advisory firm from end of 2018 through March 2019 and as a consultant and ultimately Senior Director of Finance – ERP, at Young's Market Company from 2015 to 2017. Mr. Shah received a Bachelor's of Commerce degree from the University of Mumbai, and is an Associate Chartered Accountant from The Institute of Chartered Accountants of India. Mr. Shah is also an inactive CPA from Colorado, USA.

Saran Saund has served as the Chief Business Officer of the Company since November 2019. Prior to that, he was the Chief Executive Officer and Founder of PointR Data Inc. from 2016 to 2019 where the revenue generating startup developed an innovative AI for cashier-less automated retail stores. From 2013 to 2016 Saran Saund served as managing partner of Astralync LLC that specialized in open source AI frameworks and developed an industry consortium. Previously, Saran Saund held positions as General Manager, founder and CEO at various companies, including Cambridge Silicon Radio (acquired by Qualcomm), Marvell Semiconductors Inc., and PicoMobile Inc (acquired by Marvell). Mr. Saund received his MSc. Tech in Computer Science from BITS Pilani (India) and MS Computer Science from Penn State University.

Chulho Park, Ph.D. served as the Chief Technology Officer (“CTO”) of Oncotelic Inc. since its formation in 2015 and as CTO of the Company since the merger with Oncotelic Inc. Dr. Park resigned from his office of CTO in July 2021 due to health reasons but continues to be employed by the Company.

Prior to that was the Chief Executive Officer and Founder of MabPrex from 2010 to 2018, where he led the pharmaceutical development of therapeutic antibodies as well as small molecule drugs. Dr. Park served as President of Pharmaceutical Development at IgDraSol, Inc. from January 2013 through its sale to Sorrento Therapeutics, Inc. in September 2013. Dr. Park led the CMC development at IgDraSol bringing manufacturing of the drug product to FDA’s manufacturing standard. Previously, Dr. Park has held several senior management positions with Eli Lilly & Company, Applied Molecular Evolution, and aTyr Pharma Inc.

Anthony E. Maida III, Ph.D., M.A., M.B.A. was appointed to the Board in May 2020. Dr. Maida was also appointed as a consultant Chief Medical Officer of the Company in April 2020. Dr. Maida has been involved in the clinical development of immunotherapy for over 27 years in various executive management positions. Since June 2010 till June 2020, Dr. Maida served as Senior Vice President, Clinical Research for Northwest Biotherapeutics, Inc., a cancer vaccine company focused on therapy for patients with glioblastoma multiforme and prostate cancer. From June 2009 through June 2010, Dr. Maida served as Vice President of Clinical Research and General Manager, Oncology, Worldwide for PharmaNet, Inc., a clinical research organization. From 1997 through 2010, Dr. Maida served as Chairman, Founder and Director of BioConsul Drug Development Corporation and Principal of Anthony Maida Consulting International, advising pharmaceutical and investment firms, in the clinical development of therapeutic products and product/company acquisitions. From 1992 to September of 1999, Dr. Maida was President and Chief Executive Officer of Jenner Biotherapies, Inc., an immunotherapy company. Dr. Maida is currently a member of the board of directors and audit chair of Spectrum Pharmaceuticals, Inc. and Vitality Biopharma, Inc. (OTCQB: VBIO) and was formerly a member of the board of directors and audit chair of OncoSec Medical Inc. (OTCQB: ONCS). Dr. Maida holds a B.A. in Biology and History, an M.B.A., an M.A. in Toxicology and a Ph.D. in Immunology. He is a member of the American Society of Clinical Oncology, the American Association for Cancer Research, the Society of Neuro-Oncology, the International Society for Biological Therapy of Cancer and the American Chemical Society.

The Board believes that Dr. Maida is qualified to serve on the Board and as the consultant Chief Medical Officer due to his extensive experience as an executive at various biotechnology and biopharmaceutical companies as well as his service on private and public company boards.

Steven W. King was appointed to the Board in May 2020. He previously served as the CEO of Peregrine Pharmaceuticals, Inc. and its wholly owned biomanufacturing subsidiary Avid Bioservices, Inc., during which time the company advanced its lead compound through Phase 3 development, while growing revenues to over \$55 million. Prior to joining Peregrine, Mr. King was employed at Vascular Targeting Technologies, Inc., which was acquired by Peregrine in 1997. Mr. King served in a variety of executive roles at Peregrine, including Director of Research and Development from 1997 to 2000; Vice President Technology and Product Development from 2000 to 2002; Chief Operating Officer from 2002 to 2003; and Chief Executive Officer from 2003 to 2017. Mr. King served on the board of directors of Peregrine from 2003 until 2017. Mr. King previously worked at the University of Texas Southwestern Medical Center and is co-inventor on over 40 U.S. and foreign patents and patent applications in the vascular targeting agent field. Mr. King received his Bachelor’s and Master’s degrees from Texas Tech University in Cell and Molecular Biology.

The Board believes Mr. King is qualified to serve as a director because of his extensive scientific understanding of technologies in development and expertise in developing and manufacturing biologics, combined with the perspective and experience he brings from having previously served on the boards of public companies.

David Diamond was appointed to the Board on January 22, 2020. Mr. Diamond resigned from the Board in July 2021. For more information on Mr. Diamond, please refer to our 2020 Annual Report on Form 10-K filed with the SEC on April 15, 2021.

Through July 2021, the Board had three standing committees which consist of the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee (collectively, the “Committees”), each of which has the composition and responsibilities described below through that date. We discontinued the Committees since July 2021 and since that date, the full Board serves in lieu of all Committees. Once we resume the Committees, members will serve on these committees until their resignation or as otherwise determined by our Board.

Audit Committee

From January 2021 till July 2021, the members of the Audit Committee consisted of Mr. Diamond, who served as Committee Chair and Dr. Maida. The Board determined that Mr. Diamond was an independent director and an “audit committee financial expert,” as the SEC has defined that term in Item 407 of Regulation S-K. Such Committee was discontinued upon the resignation of Mr. Diamond in July 2021.

Our Audit Committee had the authority to retain and terminate the services of our independent registered public accounting firm, reviews our annual financial statements, considers matters relating to accounting policy and internal controls, and reviews the scope of our annual audits.

The Board had adopted a charter for the Audit Committee, which is to be reviewed and reassessed annually by the Audit Committee. Due to a lack of the Committee, such review and evaluation has not been done. A copy of the Audit Committee’s written charter is publicly available on our website at www.oncotelic.com.

Compensation Committee

From January 2021 till July 2021, the members of the Compensation Committee consisted of Dr. Maida who serves as Committee Chair and Mr. King. Such Committee was discontinued upon the resignation of Mr. Diamond in July 2021.

The Compensation Committee’s responsibilities include making recommendations to the Board regarding the compensation philosophy and compensation guidelines for our executives, the role and performance of our executive officers, and appropriate compensation levels for our CEO, which are determined without the CEO present, and other executives based on a comparative review of compensation practices of similarly situated businesses. The Compensation Committee also makes recommendations to the Board regarding the design and implementation of our compensation plans and the establishment of criteria and the approval of performance results relative to our incentive plans. Our Compensation Committee also administers our 2005 Stock Plan, our 2015 Equity Incentive Plan and our 2017 Equity Incentive Plan. Each member of the Compensation Committee qualifies as independent under the definition promulgated by The NASDAQ Stock Market and qualifies as a “Non-Employee Director” within the meaning of Rule 16b-3 under the Exchange Act.

The Compensation Committee reviews and assesses the three main components of each named executive officer’s compensation: base salary, incentive compensation, and equity compensation. Adjustments to base salary are generally only made when there has been a change in the scope of the responsibilities of the named executive officer or when, based on a review of the base salary component of executive officers in companies of a similar size and stage of development, the Compensation Committee members believe that an adjustment is warranted in order to remain competitive. The executive management of the Company determines and agrees with the Compensation Committee on its corporate goals and objectives for the ensuing year. At the end of each year, the attainment of each objective is assessed and incentive awards may be made to each executive based on his or her contribution to achieving the objectives. Awards are made based on either provision of an executive’s employment agreement, or an assessment of each executive’s equity compensation position relative to the Company’s other executives.

The Compensation Committee also typically reviews our director compensation on at least an annual basis. The Compensation Committee has the authority to directly retain the services of independent consultants and other experts to assist in fulfilling its responsibilities. Currently there are no independent compensation consultants retained by the Company.

Nominating and Governance Committee

From January 2021 till July 2021, the members of the Compensation Committee consist of Mr. King who serves as Committee Chair and Dr. Maida. Such Committee was discontinued upon the resignation of Mr. Diamond in July 2021.

The Nominating and Governance Committee's responsibilities include making recommendations to the full Board as to the size and composition of the Board and making recommendations as to particular nominees to the Board. All members of the Nominating and Governance Committee qualify as independent under the definition promulgated by The NASDAQ Stock Market.

Board Attendance at Board of Directors, Committee and Stockholder Meetings

Our Board met 10 times, approved certain corporate actions by unanimous written consents three times and our Audit Committee met two times during the fiscal year ended December 31, 2021. As we did not have any cash compensatory changes to the existing executives in 2021, the Compensation Committee and the Nominating and Governance Committee did not meet in 2021. Each of our directors serving during fiscal 2021 attended all the meetings of the Board and the committees of the Board upon which such director served that were held during the term of his service.

Although we do not have a formal policy regarding attendance by members of the Board at our annual meeting of stockholders, directors are encouraged to attend.

Board Leadership Structure

Our Board has the discretion to determine whether to separate or combine the roles of Chair of the Board and Chief Executive Officer. Dr. Trieu has served in both roles since his appointment to the Board after the reverse merger with Oncotelic and our Board continues to believe that his combined role is most advantageous to the Company and its stockholders. Dr. Trieu possesses in-depth knowledge of the issues, opportunities and risks facing us, our business and our industry and is best positioned to fulfill the Board Chair's responsibility to develop meeting agendas that focus the Board's time and attention on critical matters and to facilitate constructive dialogue among Board members on strategic issues.

In addition to Dr. Trieu's leadership, the Board maintains effective independent oversight through a number of governance practices, including, open and direct communication with management, input on meeting agendas, and regular executive sessions.

Risk Oversight

Our Board oversees a company-wide approach to risk management, determines the appropriate risk level for us generally, and assesses the specific risks faced by us to reviews the steps taken by management to mitigate those risks. Although our Board has ultimate oversight responsibility for the risk management process, its committees oversee risk in certain specified areas.

Specifically, our Compensation Committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements, and the incentives created by the compensation awards it administers and our Audit Committee oversees management of enterprise risks and financial risks, as well as potential conflicts of interests. The Board will be responsible for overseeing the management of risks associated with the independence of our Board.

Compensation Committee Interlocks and Insider Participation

None of the members of our Compensation Committee had been employed by us in the last completed fiscal year. In addition, none of our executive officers, except Dr. Trieu, served as a member of the Board or Compensation Committee, or other committee serving an equivalent function, of any entity that has an executive officer who serves on our Board or Compensation Committee since 2019. After the merger of the Company with Oncotelic Inc., our Chief Executive Officer, Dr. Trieu has been identified and is a control person of Autotelic, Inc.

Also, Mr. Steven King, was the CEO of Edgepoint Inc., an AI company that is a non-controlling interest subsidiary of the Company. Dr. Maida is currently consulting as the Chief Medical Officer with the Company in regards to its planned trials for OT-101 for COVID-19 and other oncology indications.

Corporate Code of Ethics

We have adopted a Corporate Code of Conduct and Ethics (the “*Code of Conduct*”) that applies to all of our employees, including our CEO and CFO. The text of the Code of Conduct has been filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 2014, and is posted on our website at www.oncotelic.com. Disclosure regarding any amendments to, or waivers from provisions of the code of conduct and ethics that apply to our directors and principal executive and financial officers will be included in a Current Report on Form 8-K within four business days following the date of the amendment or waiver.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and persons who own more than 10% of our common stock to file with the SEC and us initial reports of beneficial ownership and reports of changes in beneficial ownership of our common stock and other equity securities. For these purposes, the term “other equity securities” would include options granted under the Company’s 2005 Stock Plan (the “*2005 Stock Plan*”), the Company’s 2015 Equity Incentive Plan (the “*2015 Plan*”) and the Company’s 2017 Equity Incentive Plan (the “*2017 Plan*”). To our knowledge, based solely on a review of the forms and written representations received by us from our Section 16 reporting persons, during the fiscal year ended December 31, 2019, all Section 16(a) filing requirements applicable to the reporting persons were properly and timely satisfied.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table provides information regarding the compensation paid during the years ended December 31, 2021 and 2020 to our principal executive officer, principal financial officer and certain of our other executive officers, who are collectively referred to as “named executive officers” elsewhere in this Annual Report.

Name and Principal Position	Year	Salary \$(1)	Bonus \$	Stock Awards \$(2)	All Other Compensation \$	Total \$
Vuong Trieu, Ph. D. <i>President and Chief Executive Officer</i>	2021	189,990	—	48,341	18,750 ⁽³⁾	257,081
	2020	168,739	—	—	47,300 ⁽³⁾	216,039
Anthony E. Maida III, Ph. D., M.D. MBA <i>Chief Medical Officer (May 2020)</i> <i>Consultant</i>	2021	—	—	100,164	205,000 ⁽⁴⁾	305,164
	2020	—	—	—	120,000 ⁽⁴⁾	120,000
Chulho Park, Ph. D. <i>Chief Technology Officer (5)</i>	2021	99,644	—	26,948	—	126,592
	2020	124,493	—	—	28,000 ⁽³⁾	152,493
Saran Saund <i>Chief Business Officer</i>	2021	188,791	—	77,652	33,809	300,252
	2020	217,542	—	—	10,000 ⁽³⁾	227,542
Amit Shah <i>Chief Financial Officer</i>	2021	230,716 ⁽³⁾	—	26,948	13,333 ⁽³⁾	270,997
	2020	180,869 ⁽³⁾	—	—	46,600 ⁽⁶⁾	227,469

(1) Includes cost of healthcare benefits paid by the Company.

(2) No grants were made for the 2020 fiscal year. During the 2021 fiscal year, the Company granted certain stock awards to Dr. Trieu, Dr. Maida, Mr. Saund and Mr. Shah. The Company recorded stock-based compensation as the fair value of the awards using a Black Scholes valuation model using the following input values.

Expected Term	2.18 to 2.28 years
Expected volatility	129.9 to 131.40%
Risk-free interest rates	0.22 to 0.27%
Dividend yields	0.00%

The values of stock option grants shown in the table represent the full estimated Black-Scholes option value at the grant date, pursuant to compensation disclosure rules of the SEC. The Black-Scholes valuation for the options and stock awards for Messrs. Trieu, Maida, Park, Saund and Shah were estimated based on the date on which the options and awards were granted to the officers. However, the stock option grants in the table vest over one to ten years, and the values shown do not take into account subsequent increases or decreases in actual value to the recipient. See the Narrative Disclosure below for information regarding the number of shares granted to each of the named executive officers. See Note 11 to our Financial Statements included in this Annual Report on Form 10-K for the year ended December 31, 2021, for additional information regarding the assumptions used to determine the fair value of each of the option awards in this table. See also our discussion of stock-based compensation under “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” in our current Annual Report on Form 10-K for the year ended December 31, 2021.

(3) Represents other compensations paid to Messrs. Trieu, Saund and Shah in lieu of salary and for services rendered to the Company and its subsidiaries.

(4) Represents compensation paid to Dr. Maida in lieu of services rendered to the Company.

(5) Dr. Park resigned from the office of CTO in July 2021 on account of health-related issues. His compensation is reported through the date of his resignation.

(6) Includes \$33,436 paid to Mr. Shah for his services to Edgepoint during the year ended December 31, 2020.

Narrative Disclosure to Summary Compensation Table

Vuong Trieu, Ph. D., Chulho Park, Ph. D, Saran Saund and Amit Shah

Commencing April 2019, Drs. Trieu and Park were appointed as Executive Officers and commenced earning compensation based on the table below. Mr. Shah was appointed as a consulting CFO in July 2019 and became an Executive Officer and employee in August 2019. Subsequently, in August 2019, the Company entered into Employment Agreements and incentive compensation arrangements with each of its executive officers. The Employment Agreements provide for annual base salaries for each year of the term, subject to review and adjustment by the Board or the Compensation Committee from time to time. Each Employment Agreement provides that the executive shall be eligible for an annual discretionary cash bonus expressed as a percentage of the executive’s base salary, subject to their achievement of performance targets and goals established by the Board or the Compensation Committee. Mr. Saund was appointed as an Executive Officer in November 2019 after the PointR merger. Dr. Maida was appointed as our consultant Chief Medical Officer – Translation Medicine in May 2020 and does not have an Employment Agreement. Each of the executive officers entered into the Company’s standard form of indemnification agreement.

The initial base salaries and discretionary cash bonus amounts have been set for the executives as follows:

Executive	Title	Initial Base Salary	Discretionary Bonus (% of Base)
Vuong Trieu	Chief Executive Officer	\$ 450,000	50%
Chulho Park	Chief Technology Officer	\$ 350,000	40%
Amit Shah	Chief Financial Officer	\$ 320,000	40%
Saran Saund	Chief Business Officer	\$ 230,000	40%
Anthony E. Maida III(1)	Chief Medical Officer	\$ 180,000	NA

(1) Dr. Maida is a consultant to the Company and currently does not have an Employment Agreement.

Each of the Employment Agreements provided that the executive would receive only a portion of the base salary until the completion of a “Financing Event”, which was: (a) the closing of an equity or debt financing with gross proceeds equal to or greater than \$4,000,000; (b) the execution of a licensing or collaboration agreement with an up-front payment equal to or greater than \$4,000,000; or (c) any combination of (a) and (b) whereby the gross proceeds are equal to or greater than \$4,000,000. Messrs. Trieu and Park were to be paid 50% of their base salary, and Mr. Shah was to be paid 60% of his base salary until the completion of a Financing Event. Under the Employment Agreements, the base salary for each executive increased to 100% effective on the closing of the Financing Event and going forward thereafter. This event occurred in March 2021 when the private placement memorandum funding under JH Darbie achieved the \$4 million mark. However, Dr. Trieu and Park have been compensated at their previously agreed portion of their compensation due to the financial situation of the Company. In addition, Dr. Trieu and Park and Mr. Shah have some portion of their compensations not paid due to the financial condition of the Company.

The Employment Agreements provided for equity awards to each executive under the terms of the 2015 Plan. Each Employment Agreement provides that the executive will receive a restricted stock grant of the Company’s common stock, par value \$0.01 per share. The Company would compensate Messrs. Trieu, Uckun, Park and Shah for the taxes actually incurred on grant of the restricted shares. The restricted stock vested fully on the one-year anniversary of employment. The Employment Agreements also provided for grants of incentive stock options to purchase shares of the Company’s common stock under the Stock Plan. Such options were granted at an exercise price of \$0.21 equal to the Fair Market Value (as defined in the Stock Plan) on the date of grant and vested and become exercisable after one year of employment. Thereafter, each Employment Agreement contemplates that the executive will be eligible to receive a comparable annual grant of restricted shares or stock options as approved by the Board or Compensation Committee and which shall contain the customary terms and provisions of such grants generally to key executives under the Stock Plan.

The initial restricted stock grants and stock option grants have been set for the executives as follows:

Executive	Title	Restricted Stock (Shares)	Stock Options (Shares)
Vuong Trieu	Chief Executive Officer	209,302	313,953
Chulho Park	Chief Technology Officer	162,791	244,186
Amit Shah	Chief Financial Officer	148,837	223,256
Saran Saund	Chief Business Officer	77,520	116,279
Anthony E. Maida III	Consulting Chief Medical Officer	-	400,000

In addition, Mr. Shah earned 100,000 shares of restricted stock grants and 275,000 incentive stock options for his services as a consultant CFO from July to August 2019. Dr. Maida earned 400,000 options upon entering into his consulting agreement with the Company.

The Employment Agreements each have a term that continues until terminated by the Company or the executive. In the event that the Company terminates an executive for “Cause”, or an executive voluntarily resigns his employment, on termination the executive will be entitled to receive all accrued and unpaid base salary, any accrued and unused paid time off, and reimbursement of outstanding business expenses. If the Employment Agreements are terminated by the Company without “Cause” or the executive resigns for “Good Reason” (each as defined in the Employment Agreement) then the executive will be entitled to additional severance benefits including: (a) a lump sum payment equal to 12 months’ of the executive’s then current base salary (18 months in the case of Dr. Trieu); (b) accelerated vesting of all outstanding stock options and incentive compensation awards, and (c) insurance benefits or COBRA coverage for 12 months (18 months in the case of Dr. Trieu) in addition to payment of accrued and unpaid.

The Company did not grant any increases in cash compensation during the year ended December 31, 2021 due to the financial condition of the Company. The Company granted stock awards to the executives during the year ended December 31, 2021 as under:

Executive	Title	Restricted Stock	Stock Options
Vuong Trieu(1)	Chief Executive Officer	50,000	425,000
Amit Shah	Chief Financial Officer	50,000	200,000
Saran Saund	Chief Business Officer	25,000	775,000
	Consulting Chief Medical Officer		
Anthony E. Maida III (2)	Officer	-	600,000

(1) Granted 225,000 stock options in his capacity as a member of the Board of Directors

(2) Granted in his capacity as a member of the Board of Directors and not his capacity as the Consulting Chief Medical Officer – Translation Medicine.

The stock-based compensation on the issuance the RSUs and stock options has been reported under Summary Compensation Table above.

Outstanding Equity Awards at Fiscal Year-End

The following table shows all outstanding grants of stock options as of December 31, 2021 to each of the executive officers named in the Summary Compensation Table. The table below reflects the options and restricted shares that are issuable to Messrs. Trieu, Maida, Saund, Park and Shah.

Name	Type	Option Awards				
		Number of Securities Underlying Unexercised Options	Number of Securities Underlying Unexercised Options	Option Exercise Price	Option Expiration Date	
Vuong Trieu, Ph. D. (1) 2021 <i>Chief Executive Officer & President</i>	ISO	225,000	135,000	0.1398	7/8/2031	
	ISO	200,000	—	0.1626	9/3/2031	
2020	ISO	313,952	—	0.22	8/13/2029	
Saran Saund (1) 2021 <i>Chief Business Officer</i>	ISO	675,000	675,000	0.1398	7/8/2031	
	ISO	100,000	—	0.1626	9/3/2031	
2020	ISO	58,139	—	0.22	8/13/2029	
Anthony Maida (1) 2021 <i>Chief Medical Officer - Consultant</i>	NQSO	400,000	—	\$ 0.1398	7/8/2031	
2020	NQSO	400,000	—	\$ 0.1626	9/3/2031	
	NQSO	600,000	360,000	\$ 0.1398	7/8/2031	
Amit Shah (1) 2021 <i>Chief Financial Officer</i>	ISO	200,000	200,000	\$ 0.1626	7/8/2031	
2020	ISO	498,256(2)	—	0.22	8/13/2029	
Chulho Park, Ph.D.(1) 2021* <i>Chief Technology Officer</i>	ISO	200,000	—	\$ 0.1626	7/8/2031	
2020	ISO	244,186	—	\$ 0.1626	7/8/2031	

*Dr. Park was the Chief Technical Officer of the Company till July 2021.

- (1) The stock awards have been approved by the board. The stock compensation thereon has been computed and expensed when granted and reported in the Summary Compensation Table.
- (2) Included 275,000 incentive stock options for his services as a consultant CFO from July to August 2019 and which are fully earned as of the date of this document.

Pension Benefits

We do not have any qualified or non-qualified defined benefit plans.

Nonqualified Deferred Compensation

We do not have any non-qualified defined contribution plans or other deferred compensation plans.

Potential Payments Upon Termination or Change-In-Control

We have entered into certain agreements and maintain certain plans that may require us to make certain payments and/or provide certain benefits to Dr. Trieu, Dr. Park and Mr. Shah in the event of a termination of their employment or a change of control of the Company. The following table summarizes the potential payments to Dr. Trieu; and Messrs. Saund and Shah assuming that one of the described termination events occurs. The table assumes that the event occurred on December 31, 2021, the last day of our fiscal year and that each of the named officers were eligible to earn the full initial base compensation. On the final trading day of our fiscal year the closing price of our common stock on OTCQB Market was \$0.17 per share.

The Employment Agreements each have a term that continues until terminated by the Company or the executive. In the event that the Company terminates an executive for “Cause”, or an executive voluntarily resigns his employment, on termination the executive will be entitled to receive all accrued and unpaid base salary, any accrued and unused paid time off, and reimbursement of outstanding business expenses. If the Employment Agreements are terminated by the Company without “Cause” or the executive resigns for “Good Reason” (each as defined in the Employment Agreement) then the executive will be entitled to additional severance benefits including: (a) a lump sum payment equal to 12 months’ of the executive’s then current base salary (18 months in the case of Dr. Trieu); (b) accelerated vesting of all outstanding stock options and incentive compensation awards, and (c) insurance benefits or COBRA coverage for 12 months (18 months in the case of Dr. Trieu) in addition to payment of accrued and unpaid personal time.

Executive Benefits and Payments Upon Termination	Termination within 12 months Following Change in Control	Voluntary Termination by Executive or Death	Involuntary Not for Cause Termination or Termination by Executive with Good Reason	For Cause Termination	Disability
	\$ 675,000	\$ —	\$ 675,000	\$ —	\$ —
Base Salary	Executive entitled to Annual Bonus related to most recently completed calendar year if earned and not already paid	Executive entitled to Annual Bonus related to most recently completed calendar year if earned and not already paid	Executive entitled to Annual Bonus related to most recently completed calendar year if earned and not already paid	N/A	Executive entitled to Annual Bonus related to most recently completed calendar year if earned and not already paid
Annual Bonus (50% of Base Salary)					
Acceleration of Vesting of Equity	100%	0%	100%	0%	0%
Stock Options & RSUs:					
Number of Stock Options & RSUs	998,255	—	998,255	—	—
Value upon Termination*	\$ 169,703	\$ —	\$ 169,703	\$ —	\$ —
Vested Stock / Received:					
Number of Shares	863,255	—	863,255	—	—
Value upon Termination*	\$ 146,753	\$ —	\$ 146,753	\$ —	\$ —
Relocation Reimbursement	N/A	N/A	N/A	N/A	N/A
Deferred Compensation Payout	N/A	N/A	N/A	N/A	N/A
Post-Term Health Care	Up to 18 months	N/A	Up to 18 months	N/A	N/A
	\$ 17,671	\$ —	\$ 17,671	\$ —	\$ —
Excise Tax Gross Up	N/A	N/A	N/A	N/A	N/A

Saran Saund

Executive Benefits and Payments Upon Termination	Termination within 12 months Following Change in Control	Voluntary	Involuntary Not for Cause Termination or		
	Termination by Executive or Death	Termination by Executive with Good Reason	For Cause Termination	Disability	
Base Salary	\$ 230,000	\$ —	\$ 230,000	\$ —	\$ —
Annual Bonus (30% of Base Salary)	Executive entitled to Annual Bonus related to most recently completed calendar year if earned and not already paid	Executive entitled to Annual Bonus related to most recently completed calendar year if earned and not already paid	Executive entitled to Annual Bonus related to most recently completed calendar year if earned and not already paid	N/A	Executive entitled to Annual Bonus related to most recently completed calendar year if earned and not already paid
Acceleration of Vesting of Equity Stock Options & RSUs:	100%	0%	100%	0%	0%
Number of Stock Options & RSUs (1)	993,798	—	993,798	—	—
Value upon Termination*	\$ 168,946	\$ —	\$ 168,946	\$ —	\$ —
Vested Stock Received:					
Number of Shares (1)	318,798	—	318,798	—	—
Value upon Termination*	\$ 54,196	\$ —	\$ 54,196	\$ —	\$ —
Relocation Reimbursement	N/A	N/A	N/A	N/A	N/A
Deferred Compensation Payout	N/A	N/A	N/A	N/A	N/A
Post-Term Health Care	Up to 9 months	N/A	Up to 9 months	N/A	N/A
	\$ 10,839	\$ —	\$ 10,839	\$ —	\$ —
Excise Tax Gross Up	N/A	N/A	N/A	N/A	N/A

Executive Benefits and Payments Upon Termination	Termination within 12 months Following Change in Control	Voluntary Termination by Executive or Death	Involuntary Not for Cause Termination or Termination by Executive with Good Reason	For Cause Termination	Disability
	\$ 320,000	\$ —	\$ 320,000	\$ —	\$ —
Base Salary	Executive entitled to Annual Bonus related to most recently completed calendar year if earned and not already paid	Executive entitled to Annual Bonus related to most recently completed calendar year if earned and not already paid	Executive entitled to Annual Bonus related to most recently completed calendar year if earned and not already paid	N/A	Executive entitled to Annual Bonus related to most recently completed calendar year if earned and not already paid
Annual Bonus (50% of Base Salary)	100%	0%	100%	0%	0%
Acceleration of Vesting of Equity					
Stock Options & RSUs:					
Number of Stock Options & RSUs (1)	997,093	—	997,093	—	—
Value upon Termination*	\$ 169,506	\$ —	\$ 169,506	\$ —	\$ —
Vested Stock Received:					
Number of Shares (1)	997,093	—	997,093	—	—
Value upon Termination*	\$ 169,506	\$ —	\$ 169,506	\$ —	\$ —
Relocation Reimbursement	N/A	N/A	N/A	N/A	N/A
Deferred Compensation Payout	N/A	N/A	N/A	N/A	N/A
Post-Term Health Care	Up to 12 months	N/A	Up to 12 months	N/A	N/A
	\$ 10,486	\$ —	\$ 10,486	\$ —	\$ —
Excise Tax Gross Up	N/A	N/A	N/A	N/A	N/A

*Based on the stock price of the Company as of December 31, 2021 and assuming the number of shares granted / vested and earned.

Dr. Park resigned from the position of Chief Medical Officer effective July 2021 and as such his information has not been compiled for this table.

Dr. Maida is a consultant Chief Medical Officer and is not subject to potential payments upon termination or change-in-control, and as such his information has not been compiled for this table.

The information set forth above is described in more detail in the Narrative Disclosure to the Summary Compensation Table.

As defined in the employment agreements, a “Change in Control” means the following during the employment term:

- (1) any “Person” (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the “Beneficial Owner” (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing more than fifty percent of the total voting power represented by the Company’s then outstanding voting securities (excluding for this purpose any such voting securities held by the Company or its affiliates or by any employee benefit plan of the Company) pursuant to a transaction or a series of related transactions which the Board of Directors does not approve; or
- (2) a merger or consolidation of the Company whether or not approved by the Board of Directors, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or the parent of such corporation) at least fifty percent of the total voting power represented by the voting securities of the Company or such surviving entity or parent of such corporation, as the case may be, outstanding immediately after such merger or consolidation; or
- (3) the stockholders of the Company approve an agreement for the sale or disposition by the Company of all or substantially all of its assets; or
- (4) a change in the composition of the Board of Directors, as a result of which fewer than a majority of the directors are Incumbent Directors, and provided in each such case the Change in Control also meets the requirements of a “Change in Control Event” within the meaning of Section 409A(a)(2)(A)(v) of the Code and Treasury Regulation Section 1.409A-3(i)(5). “Incumbent Directors” mean the directors who either (A) are directors of the Company as of the date of this Agreement, or (B) are elected, or nominated for election, to the Board of Directors with the affirmative votes of at least a majority of the Incumbent Directors at the time of such election or nomination (but shall not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).

In each such case the Change of Control must also meet the requirements of a “Change of Control Event” within the meaning of Section 409(a)(2)(A)(v) of the Code.

Each of Drs. Trieu, Saund and Mr. Shah will be entitled to certain benefits as described in the table above if his employment is terminated by the Company for reasons other than cause or by him with good reason. “Cause,” as defined in the employment agreements, means:

- (1) Substantial failure to perform any of his duties or to follow reasonable, lawful directions of the Board or any officer to whom the party reports;
- (2) willful misconduct or willful malfeasance in connection with his employment;
- (3) commission of, conviction of, or plea of nolo contendere to, any crime constituting a felony under the laws of the United States or any state thereof, or any other crime involving moral turpitude;
- (4) material breach of any provision of the employment agreement, the By-laws or any other written agreement with the Company;
- (5) engaging in misconduct that causes significant injury to the Company, financial or otherwise, or to its reputation; or
- (6) any act, omission or circumstance constituting cause under the law governing the employment agreement.

“Good Reason,” as defined in the employment agreements, means the Company:

- (1) materially reduces the officer’s title or responsibilities;
- (2) relocates its headquarters more than sixty (60) miles from their current location (unless the relocation results in the headquarters being closer to the officer’s residence);
- (3) materially reduces the officer’s base salary; or
- (4) breaches a material term of the officer’s employment agreement.

Good Reason must also meet the requirements for a good reason termination in accordance with Code Section 409A, and any successor statute, regulation and guidance thereto.

Director Compensation

For the year ended December 31, 2021 and 2020, one of the non-employee directors was paid the following in cash and stock awards

	Fees Earned or Paid in			Total
	Cash⁽¹⁾	Option Awards⁽²⁾		
David Diamond - 2021	\$ 31,875	\$ 27,106	\$ 58,981	
2020	\$ 34,125	\$ 21,558	\$ 55,683	
Steven King - 2021	\$ -	\$ 86,065	\$ 86,065	

The Company paid Mr. Diamond for his services to the Board and Committees. Mr. King was compensated in stock for his services to the Board. Drs. Trieu and Maida were granted options as Board members but have been reported in the Summary Compensation Table above.

For the year ended December 31, 2021, we granted Mr. Diamond 251,467 options. For the year ended December 31, 2020, we granted 200,000 options to Mr. Diamond. Although the initial terms of the options, when granted, provide that they vest one year subsequent to grant, pursuant to rules of the SEC the fair market value for the options granted represents the full value at the grant date only and the values do not take into account subsequent increases or decreases in actual value to the recipient. See also our discussion of stock-based compensation under “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” in the Form 10-K.

For the period of May 2020 till September 2020, we granted Mr. King 357,412 options. We also granted Mr. King 500,000 options for his services through the end of fiscal year 2022. Although the initial terms of the options, when granted, provide that they vest one year subsequent to grant, pursuant to rules of the SEC the fair market value for the options granted represents the full value at the grant date only and the values do not take into account subsequent increases or decreases in actual value to the recipient. See also our discussion of stock-based compensation under “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” in the Form 10-K.

The grant date fair values of stock option grants shown in the table represent the full estimated Black-Scholes option value at the grant date, pursuant to compensation disclosure rules of the SEC. The Company recorded stock-based compensation as the fair value of the awards using a Black Scholes valuation model using the following input values.

Expected Term	2.18 to 2.28 years
Expected volatility	129.9 to 131.40%
Risk-free interest rates	0.22 to 0.27%
Dividend yields	0.00%

The following is a description of the standard compensation arrangements under which our non-employee directors have been compensated for their service as directors, including as members of the various Committees of our Board.

Fees. In October 2016, the Board amended and restated its director compensation policy. For more details on the Fees, kindly refer to our form 2020 Annual Report on 10-K filed with the SEC on April 15, 2021.

The Board intends to re-evaluate compensation, including non-employee director compensation, following the reconstitution of its Compensation Committee.

Equity Grants.

In October 2016, the Board amended and restated its director compensation policy.

The Board intends to re-evaluate compensation, including non-employee director compensation, following the reconstitution of its Compensation Committee. For more information on our prior policy, please refer to our 2020 Annual Report on Form 10-K filed with the SEC on April 15, 2021

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth information, as of March 18, 2022, regarding the beneficial ownership of our common stock by:

- each of our directors and our director nominees;
- each of our executive officers;
- our directors and executive officers as a group; and
- each person known to us to beneficially own more than 5% of our common stock.

The address for each beneficial owner listed is c/o Oncotelic Therapeutics, Inc. 29397 Agoura Road, Suite 107, Agoura Hills, California, 91301. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder, subject to community property laws where applicable.

In accordance with applicable SEC rules, the number of shares reflected as beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC. Under those rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days after the Record Date through the exercise of any stock option, warrants or other rights.

We have computed the percentage of shares beneficially owned on the basis of 375,588,146 shares of our Common Stock outstanding as of March 18, 2022. Shares of our Common Stock that a person has the right to acquire within 60 days after the Record Date through other means, such as a stock option or warrant, are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person (other than the percentage ownership of all directors and executive officers as a group).

Name of Beneficial Owner	Common Stock Beneficially Owned	Percentage of Common Stock
Directors and Officers:		
Vuong Trieu	121,533,802(1)	32.1%
Steven W. King	4,845,836(2)	1.3%
Anthony E. Maida III	2,137,314(3)	*%
Amit Shah	1,584,871(4)	*%
Saran Saund	17,347,759(5)	4.6%
All officers and directors as a group (7 persons)	146,680,893(6)	38.1%
Beneficial owners of more than 5%		
Vuong Trieu	121,533,802(1)	32.4%
Balaji Bhakta	43,575,256(7)	11.6%
Larn Hwang	25,214,324(8)	6.7%
Chao Hsiao	21,806,942(9)	5.8%

* < 1%

- (1) Includes: (a) 90,580,829 shares owned directly and beneficially by the reporting person; 3,922,218 shares of common shares issuable upon conversion of debt, 738,953 shares issuable upon exercise of stock options and 1,250,000 shares of common shares issuable upon exercise of warrants; (b) 16,780,384 shares registered in the name of Autotelic, Inc., and 1,388,889 shares issuable upon conversion of debt, and (c) 6,872,529 shares registered in the name of Dr. Trieu's spouse. Dr. Trieu is the Chief Executive Officer of Autotelic, Inc. and in that capacity has the sole authority to control the voting and the disposition of Common Stock and Preferred Stock owned by Autotelic, Inc. Dr. Trieu disclaims beneficial ownership of the shares held by Autotelic, Inc., except to the extent of his pecuniary interest therein.
- (2) Shares held in the name of Artius Bioconsulting, LLC, consists of (i) 3,988,424 shares of Common Stock and (ii) 857,412 shares issuable upon exercise of stock options granted to Mr. King.
- (3) Consists of (i) 1,137,314 shares of Common Stock and (ii) 1,000,000 shares issuable upon exercise of stock options.

- (4) Consists of (i) 358,837 shares of Common Stock, (ii) 416,667 shares of common stock issuable upon conversion of debt and (iii) 698,256 shares of common stock upon exercise of options.
- (5) Consists of (i) 16,456,480 shares of Common Stock, and (ii) 891,279 shares issuable upon exercise of stock options.
- (6) Consists of (i) 136,174,797 shares of Common Stock, (ii) 5,144,440 shares issuable upon conversion of debt, (iii) 4,185,900 shares issuable upon exercise of options and (iv) 1,250,000 shares issuable upon exercise of warrants.
- (7) Consists of (i) 41,630,811 shares of Common Stock, (ii) 694,445 shares of common stock issuable upon conversion of debt and (iii) 1,250,000 shares of common stock upon conversion of warrants.
- (8) Consists of (i) 23,455,990 shares of Common Stock, (ii) 1,208,333 shares of common stock issuable upon conversion of debt and (iii) 550,000 shares of common stock upon exercise of options.
- (9) Consists of (i) 17,073,604 shares of Common Stock, (ii) 3,883,338 shares of common stock issuable upon conversion of debt, (iii) 600,000 shares of common stock upon exercise of options, and (iv) 250,000 shares issuable upon exercise of warrants.

Equity Compensation Plan Information

The following table provides certain aggregate information with respect to all of the Company's equity compensation plans in effect as of December 31, 2021.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by security holders	14,942,620	\$ 0.32	12,108,591
Equity compensation plans not approved by security holders	1,650,000	0.30	350,000
Total	16,592,620	\$ 0.75	12,458,591

In August 2020, the shareholders of the Company approved the expansion of the number of securities to be issued upon exercise of outstanding options, warrants, restricted stock units and warrants by 20 million. The amendment to the 2015 Plan was completed in March 2021 and as such the pool under the 2015 Plan is now 27,250,000.

Brief Description of equity compensation plan not approved by security holders

In January 2017, the Board of Directors adopted and approved the 2017 Plan. The 2017 Plan allows the Company, under the direction of the Compensation Committee, to make grants of stock options, restricted and unrestricted stock awards, and other stock-based awards to employees, consultants and directors. The purpose of these awards is to attract and retain key individuals, further align employee and stockholder interests, and provide additional incentive for them to promote our success. The 2017 Plan provides for the issuance of up to 2,000,000 shares of the Company's common stock. Any stock options granted under the 2017 Plan must be non-qualified stock options, which are not intended to meet the requirements of Section 422 of the Internal Revenue code. Options generally vest over a period of time, may not be exercised unless they are vested, and no option may be exercised after the end of the term set forth in the award agreement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Our Audit Committee reviews and approves in advance all related person transactions.

Our Board of Directors has reviewed the materiality of any relationship that each of our directors has with the Company, either directly or indirectly. Based upon this review, our Board has determined that none of the directors, qualify as “independent directors” as defined under the OTC Market Rules for U.S. Companies.

Master Service Agreement with Autotelic Inc.

In October 2015, Oncotelic Inc. entered into a Master Service Agreement (the “MSA”) with Autotelic Inc. (“Autotelic”), a related party that is partly owned by Dr. Trieu. Dr. Trieu, a related party, is a control person in Autotelic. Autotelic currently owns less than 10% of the Company. The MSA stated that Autotelic will provide business functions and services to the Company and allowed Autotelic to charge the Company for these expenses paid on its behalf. The MSA includes personnel costs allocated based on amount of time incurred and other services such as consultant fees, clinical studies, conferences and other operating expenses incurred on behalf of the Company. The MSA requires a 90-day written termination notice in the event either party requires to terminate such services.

Expenses related to the MSA were \$276,763 and \$629,617 for the years ended December 31, 2021 and 2020, respectively. Amounts outstanding at the end of the year 2021 and 2020 were \$269,872 and \$0, respectively.

In September 2021, the Company entered into an exclusive License Agreement (the “Agreement”) with Autotelic, pursuant to which Autotelic granted Oncotelic, among other things: (i) the exclusive right and license to certain Autotelic Patents (as defined in the Agreement) and Autotelic Know-How (as defined in the Agreement); and (ii) a right of first refusal to acquire at least a majority of the outstanding capital stock of Autotelic prior to Autotelic entering into any transaction that is a financing collaboration, distribution revenues, earn-outs, sales, out-licensing, purchases, debt, royalties, merger acquisition, change of control, transfer of cash or non-cash assets, disposition of capital stock by way of tender or exchange offer, partnership or any other joint or collaborative venture, research collaboration, material transfer, sponsored research or similar transaction or agreements. In exchange for the rights granted to Oncotelic, Autotelic would be entitled to earn the following milestone payments (collectively, the “Milestone Payments”).

Milestones	Transaction Value	Actions
Tranche 1	\$ 1,000,000	Upon the earlier to occur of: (i) the Company receiving an investment of at least \$20 million, and (ii) the uplisting of the Company’s common stock to any NASDAQ market or the New York Stock Exchange.
Tranche 2	\$ 2,000,000	Upon approval by the United States Food and Drug Administration of the Company’s 505(b)(2) application for purposes of treating PD.
Tranche 3	\$ 2,000,000	Upon first patient in (“FPI”) for any clinical trial supporting the use of AL-101 for the treatment of PD or ED.
Tranche 4	\$ 2,500,000	Upon FPI for phase 2 clinical trials supporting the use of AL-101 to treat FSD.
Tranche 5	\$ 2,500,000	Upon FPI for phase 3 clinical trials supporting the use of AL-101 to treat FSD
Tranche 6	\$ 10,000,000	Upon Marketing approval for the use of AL-101 to treat PD.
Tranche 7	\$ 10,000,000	Upon Marketing approval for the use of AL-101 to treat ED.
Tranche 8	\$ 10,000,000	Upon Marketing approval for the use of AL-101 to treat FSD
Tranche 9	\$ 10,000,000	Upon the earlier of: (i) the Company entering into a licensing agreement with a third party for the use of AL-101 for the treatment of PD, ED or FSD with an aggregate licensing value of at least \$50 million; and (ii) the Company’s gross revenue derived from sales of AL-101 for the treatment of PD, ED or FSD reaches at least \$50.0 million.

In addition to the Milestone Payments, Autotelic will be entitled to royalties equal to 15% of the net sales of any products that incorporate the Autotelic Patents or Autotelic Know-How. The Agreement contains representations, warranties and indemnification provisions of each of the parties thereto that are customary for transactions of this type.

Notes Payable and Short-Term Loan – Related Party

In April 2019, the Company issued a convertible note to Dr. Trieu totaling \$164,444, including OID of \$16,444, receiving net proceeds of \$148,000, which was used by the Company for working capital and general corporate purposes (See Note 6). The Company issued a Fall 2019 Note to Dr. Trieu in the principal amount of \$250,000. Dr. Trieu also offset certain amounts due to him in the amount of \$35,000 and was converted into the Fall 2019 debt. During the year ended December 31, 2020, Dr. Trieu provided additional short-term funding of \$70,000 to the Company, of which the Company repaid \$50,000 prior to December 31, 2020. As such the Company owed \$20,000 for the short term loan as of December 31, 2021. During the year ended December 31, 2020, Dr. Trieu purchased a total of 5 Units under the private placement for a gross total of \$250,000.

During the year ended December 31, 2021, Autotelic Inc, provided a short-term loan of \$120,000 to the Company, which was repaid in April 2021. During the year ended December 31, 2021, Autotelic Inc. provided a short-term loan of \$250,000 to the Company, which was converted into a August 2021 Convertible Note.

Artius Consulting Agreement

On March 9, 2020, the Company and Artius Bioconsulting, LLC (“*Artius*”), for which Mr. Steven King, our Board and Committee member, is the Managing Member, entered into an amendment to that certain Consulting Agreement dated December 1, 2018 (the “*Artius Agreement*”), under which Artius agreed to serve as a consultant to the Company for services related to the Company’s business from time to time, effective December 1, 2019 (the “*Artius Agreement Effective Date*”). In connection with the Artius Agreement, Mr. King also agreed to assist the Company with strategic advisory services with respect to transactional and operational contracts, budgetary input, among other matters in connection with the development EdgePoint AI’s Artificial Intelligence and Blockchain Driven Vision Systems, for which Mr. King serves as Chief Executive Officer.

Under the terms of the Artius Agreement, the Company agreed to grant to Artius, subject to approval by the Company’s Board of Directors and pursuant to the Company’s 2015 Equity Incentive Plan, 148,837 restricted shares of the Company’s Common Stock, in addition to a 30% pre-financing ownership stake in EdgePoint AI. The Artius Agreement contemplates that Mr. King will generally provide his services at a rate of \$237 per hour, not to exceed 44 hours per month and payable monthly, and to reimburse Mr. King for reasonable and necessary expenses incurred by him or Artius in connection with providing services to the Company.

Either the Company or Artius may terminate the Artius Agreement at any time, for any reason following the Artius Agreement Effective Date. The Artius Agreement will automatically renew one year from the Artius Agreement Effective Date, unless the Parties agree to terminate the Artius Agreement at that time.

The Company recorded \$0 and \$106,712 as expense during the year ended December 31, 2021 and 2020, respectively, related to this Agreement.

Maida Consulting Agreement

Effective May 5, 2020, the Company and Dr. Anthony Maida, one of our Board and Committee members, entered into an independent consulting agreement, commencing April 1, 2020 (the “*Maida Agreement*”), under which Dr. Maida will assist the Company in providing medical expertise and advice from time to time in the design, conduct and oversight of the Company’s existing and future clinical trials.

Pursuant to the terms of the Maida Agreement, the Company will grant to Dr. Maida 400,000 restricted shares or stock options of the Company’s Common Stock corresponding to \$80,000 at the stock value of \$0.20 per share, to vest on May 5, 2021. The Company will also pay Dr. Maida \$15,000 per month for a minimum of 20 hours per week, in addition to reimbursement of reasonable and necessary expenses incurred by Dr. Maida in connection with his services to the Company.

Either the Company or Dr. Maida may terminate the Maida Agreement, for any reason, upon 30 days advance written notice.

Dr. Maida was appointed the Chief Clinical Director for the Company effective July 7, 2020. As of the date of this Report, Dr. Maida continues to provide his services under the consulting agreement.

The Company recorded \$215,000 and \$135,000 as expense under the consulting agreement during the year ended December 31, 2021 and 2020 respectively.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table presents fees for professional audit services rendered by our independent public accounting firm, Rose Synder and Jacobs, LLP (RSJ) for the audit for the year ended December 31, 2021 and Baker Tilly LLP (Baker Tilly - formerly Squar Milner LLP which merged into Baker Tilly in November 2020) for the audit of the Company’s annual financial statements for the year ended December 31, 2020, respectively, and fees billed for other services rendered during those periods.

	2021	2020
Audit fees (1)	\$ 116,600	\$ 120,000
Audit-related fees	—	—
Tax fees	—	—
All other fees	—	—
	\$ 116,600	\$ 120,000

- (1) Audit fees consisted of audit work performed on the audit of the annual financial statements, review of quarterly financial statements, as well as work that generally only the independent registered public accounting firm can reasonably be expected to provide, such as the provision of consents in connection with the filing of registration statements and statutory audits.

We have been invoiced \$68,000 by RSJ in connection with the audit for the year ended December 31, 2021.

We paid Baker Tilly \$48,600 in connection with the reviews for the three months ended March 31, 2021, six months ended June 30, 2021 and nine months ended September 30, 2021. We paid Squar Milner \$70,200 for the audit for the Company for 2020 and \$5,400 related to consents, \$45,000 for the reviews for the three months ended March 31, 2020, six months ended June 30, 2020 and nine months ended September 30, 2020; and \$10,000 related to consents.

Policy on Audit Committee Pre-Approval of Audit and Permissible

Non-audit Services of Independent Registered Public Accounting Firm

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation, and overseeing the work of the independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by the independent registered public accounting firm.

Prior to engagement of the independent registered public accounting firm for the next year's audit, management will submit an aggregate of services expected to be rendered during that year for each of four categories of services to the Audit Committee for approval.

1. **Audit** services include audit work performed in the preparation and audit of the annual financial statements, review of quarterly financial statements, as well as work that generally only the independent auditor can reasonably be expected to provide, such as the provision of consents and comfort letters in connection with the filing of registration statements.
2. **Audit-related** services are for assurance and related services that are traditionally performed by the independent auditor, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.
3. **Tax** services consist principally of assistance with tax compliance and reporting, as well as certain tax planning consultations.
4. **Other Fees** are those associated with services not captured in the other categories. The Company generally does not request such services from the independent auditor.

Prior to engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted, and the Audit Committee requires the independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage the independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging the independent registered public accounting firm.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

In the absence of an Audit Committee, the responsibilities of the Audit Committee are fulfilled by the Board of Directors of the Company. As such, for the year ended December 31, 2021 the Board of Directors approved the appointment and services of RSJ.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

- (a) The following documents are filed as part of this Annual Report on Form 10-K.

- (1) *Financial Statements*

See financial statements listed in the accompanying "Index to Financial Statements" covered by the Report of Independent Registered Public Accounting Firm.

(2) *Financial Statement Schedule*

No schedules are submitted because they are not applicable, not required or because the information is included in the Financial Statements as Notes to Financial Statements.

(3) *Exhibits*

Exhibit Number	Description	Incorporated by Reference		
		Form	Filing Date	Exhibit Number
2.1	<u>Agreement and Plan of Merger, dated as of April 17, 2019, by and among the Company, Oncotelic and Oncotelic Acquisition Corporation.</u>	8-K	4/18/2019	2.1
2.2	<u>Agreement and Plan of Merger, dated as of April 17, 2019, by and among the Company, Oncotelic and Oncotelic Acquisition Corporation.</u>	8-K	4/25/2019	2.1
2.3	<u>Agreement and Plan of Merger, dated as of August 17, 2019, by and among the Company, PointR and Paris Acquisition Corporation.</u>	8-K	8/21/2019	2.1
2.4	<u>Agreement and Plan of Merger, dated as of August 17, 2019, by and among the Company, PointR Data, Inc. and Paris Acquisition Corp.</u>	8-K	11/12/2019	2.1
2.5	<u>Amendment No. 1 to Agreement and Plan of Merger, dated as of November 1, 2019, by and among the Company, PointR Data, Inc. and Paris Acquisition Corp.</u>	8-K	11/12/2019	2.2
3.1	<u>Amended and Restated By-Laws of the Registrant.</u>	8-K	6/17/2016	3.2
3.2	<u>Restated Certificate of Incorporation of the Registrant, as amended by Certificates of Amendment dated June 22, 1995, November 15, 1996, July 14, 2005, June 2, 2009, February 8, 2010, August 5, 2010, February 22, 2011, May 29, 2012, December 27, 2012, July 17, 2013, June 16, 2016 and June 20, 2018.</u>	10-Q	8/14/2018	3.1
3.3	<u>Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company.</u>	8-K	4/25/2019	3.1
3.4	<u>Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company.</u>	8-K	11/12/2019	3.1
4.1	<u>Form of Series A/B Common Stock Purchase Warrant.</u>	8-K	4/11/2013	4.1
4.2	<u>Form of Common Stock Purchase Warrant.</u>	8-K	9/20/2013	4.1
4.3	<u>Form of Common Stock Purchase Warrant.</u>	S-1/A	1/31/2014	4.9
4.4	<u>Form of Placement Agent Purchase Warrant.</u>	S-1/A	1/31/2014	4.8
4.5	<u>Form of Common Stock Purchase Warrant.</u>	8-K	2/14/2014	4.1
4.6	<u>Form of Placement Agent Purchase Warrant.</u>	8-K	2/14/2014	4.2
4.7	<u>Form of Common Stock Purchase Warrant.</u>	8-K	5/23/2014	4.1

4.8	<u>Form of Common Stock Purchase Warrant.</u>	8-K	3/20/2015	4.1
4.9	<u>Specimen Common Stock Certificate.*</u>	10-Q	8/2/2016	4.1
4.10	<u>Form of Series A Warrant to purchase Common Stock.</u>	8-K	4/16/2018	4.1
4.11	<u>Form of Series B Warrant to purchase Common Stock</u>	8-K	4/16/2018	4.2
4.12	<u>Form of Placement Agent Purchase Warrant.</u>	S-1	6/13/2018	4.12
4.13	<u>Form of Debenture, issued by the Company to PeakOne.</u>	8-K	4/18/2019	4.1
4.14	<u>Form of Debenture, issued by the Company to the Bridge Investors.</u>	8-K	4/18/2019	4.2
4.15	<u>Form of Debenture, issued by the Company to Peak One Opportunity Fund, L.P. and TFK Investments, LLC Ex. 4.1 Form of Debenture, issued by the Company to the Bridge Investors.</u>	8-K	4/25/2019	4.2
4.16	<u>Form of Debenture, issued by the Company to Peak One Opportunity Fund, L.P. and TFK Investments, LLC.</u>	8-K	6/20/2019	4.1
4.17	<u>Convertible Promissory Note between Mateon Therapeutics, Inc. and PointR Data Inc. dated July 22, 2019.</u>	8-K	7/24/2019	4.1
4.18	<u>Form of Note Purchase Agreement, dated as of November 23, 2019, by and among the Company and the investors identified therein.</u>	8-K	11/25/2019	4.1
10.1	<u>Technology Development Agreement, dated as of May 27, 1997, between the Registrant and the Arizona Board of Regents, acting for and on behalf of Arizona State University.</u>	10-K	4/15/1998	10.9
10.2	<u>Research Collaboration and License Agreement, dated as of December 15, 1999, between OXiGENE Europe AB and Bristol-Myers Squibb Company.*</u>	8-K	12/28/1999	99.1
10.3	<u>Amendment and Confirmation of License Agreement No. 206-01.LIC, dated as of June 10, 2002, between the Registrant and the Arizona Board of Regents, acting for and on behalf of Arizona State University.</u>	10-Q	8/14/2002	10.29
10.4	<u>Termination Agreement by and between OXiGENE Europe AB and Bristol-Myers Squibb Company dated as of February 15, 2002.</u>	10-Q	8/14/2002	10.14
10.5	<u>License Agreement No. 206-01.LIC by and between the Arizona Board of Regents, acting on behalf of and for Arizona State University, and OXiGENE Europe AB, dated August 2, 1999.</u>	10-K/A	8/12/2003	10.27
10.6	<u>Research and License Agreement between the Registrant and Baylor University, dated June 1, 1999.</u>	10-K/A	8/12/2003	10.28
10.7	<u>Agreement to Amend Research and License Agreement between the Registrant and Baylor University, dated April 23, 2002.</u>	10-K/A	8/12/2003	10.29
10.8	<u>Addendum to Research and License Agreement between the Registrant and Baylor University, dated April 14, 2003.</u>	10-K/A	8/12/2003	10.30

10.9	<u>Form of Incentive Stock Option Agreement under Mateon's 2005 Stock Plan.</u>	+	10-K	3/14/2006	10.29
10.10	<u>Form of Non-Qualified Stock Option Agreement under Mateon's 2005 Stock Plan.</u>	+	10-K	3/14/2006	10.30

10.11	<u>Form of Restricted Stock Agreement under Mateon's 2005 Stock Plan.</u> +	10-K	3/14/2006	10.31
10.12	<u>Lease between Broadway 701 Gateway Fee LLC, a Delaware Limited Liability Company, as Landlord, and the Registrant, as Tenant, dated October 10, 2008.</u>	10-K	3/30/2009	10.59
10.13	<u>Form of Indemnification Agreement.</u> +	10-Q	8/13/2012	10.2
10.14	<u>Third Amendment to Lease, dated as of April 1, 2013, by and between the Registrant and DWF III Gateway, LLC, a Delaware limited liability company.</u>	10-Q	5/9/2013	10.1
10.15	<u>Fourth Amendment to Lease, dated April 28, 2014, by and between the Registrant and DWF III Gateway, LLC.</u>	10-Q	5/8/2014	10.1
10.16	<u>Employment Agreement by and between the Registrant and William D. Schwieterman, dated as of May 12, 2015.</u> +	10-Q	8/6/2015	10.1
10.17	<u>Employment Agreement by and between the Registrant and Matthew M. Loar, dated as of July 20, 2015.</u> +	10-Q	8/6/2015	10.2
10.18	<u>Form of Option Agreement under Mateon's 2015 Equity Incentive Plan.</u> +	10-Q	8/6/2015	10.6
10.19	<u>Amendment No. 1 to Employment Agreement by and between William D. Schwieterman, dated as of July 31, 2015.</u> +	10-Q	8/6/2015	10.7
10.20	<u>Second Amended and Restated Employment Agreement by and between the Registrant and David J. Chaplin, effective as of January 1, 2017.</u> +	8-K	10/28/2016	10.1
10.21	<u>Mateon Therapeutics, Inc. Amended and Restated Non-Employee Director Compensation Policy, effective October 25, 2016.</u> +	8-K	10/28/2016	10.2
10.22	<u>Mateon Therapeutics, Inc. 2017 Equity Incentive Plan.</u> +	8-K	1/13/2017	10.1
10.23	<u>Form of Option Agreement under Mateon's 2017 Equity Incentive Plan.</u> +	8-K	1/13/2017	10.2
10.24	<u>Mateon Therapeutics, Inc. 2005 Stock Plan (as amended and restated on January 12, 2017).</u> +	8-K	1/13/2017	10.3
10.25	<u>Amendment No. 2 to Employment Agreement by and between the Registrant and William D. Schwieterman, dated as of October 2, 2017.</u> +	10-Q	11/14/2017	10.1
10.26	<u>Amendment No. 1 to Employment Agreement by and between the Registrant and Matthew M. Loar, dated as of October 2, 2017.</u> +	10-Q	11/14/2017	10.2
10.27	<u>Amendment No. 1 to Second Amended and Restated Employment Agreement by and between the Registrant and David J. Chaplin, dated as of October 2, 2017.</u> +	10-Q	11/14/2017	10.3
10.28	<u>Mateon Therapeutics, Inc. 2015 Equity Incentive Plan (as amended and restated on May 7, 2018).</u> +	Definitive Proxy Statement on Schedule 14A	05/07/2018	Appendix A

10.29	<u>Form of Subscription Agreement for private placement transaction entered into on April 12, 2018.</u>	8-K	4/16/2018	10.1
10.30	<u>Form of Registration Rights Agreement for private placement transaction entered into on April 12, 2018.</u>	8-K	4/16/2018	10.2
10.31	<u>Engagement Letter, dated February 7, 2018, by and between the Registrant and Divine Capital Markets LLC.</u>	8-K	4/16/2018	10.3
10.32	<u>Separation and Release Agreement, dated April 17, 2019 by and between the Company and William D. Schwieterman, M.D.</u>	8-K	4/18/2019	10.1
10.33	<u>Form of Securities Purchase Agreement, dated as of April 17, 2019, by and among the Company and Peak One</u>	8-K	4/18/2019	10.2
10.34	<u>Form of Securities Purchase Agreement, dated as of April 17, 2019, by and among the Company and the Bridge Investors.</u>	8-K	4/18/2019	10.3
10.35	<u>Contingent Value Rights Agreement, dated April 17, 2019, by and among the Company, Oncotelic and American Stock Transfer and Trust Company LLC</u>	8-K	4/25/2019	10.1
10.36	<u>Form of Securities Purchase Agreement, dated as of April 17, 2019, by and among the Company and Peak One Opportunity Fund, L.P. and TFK Investments, LLC.</u>	8-K	4/25/2019	10.2
10.37	<u>Form of Securities Purchase Agreement, dated as of April 17, 2019, by and among the Company and the Bridge Investors</u>	8-K	4/25/2019	10.3
10.38	<u>Form of Securities Purchase Agreement, dated as of April 17, 2019, by and among the Company and Peak One Opportunity Fund, L.P. and TFK Investments, LLC.</u>	8-K	6/20/2019	10.1
10.39	<u>Amendment to Securities Purchase Agreement dated as of June 12, 2019 by and between the Company and Peak One Opportunity Fund, L.P.</u>	8-K	6/20/2019	10.2
10.40	<u>Separation Agreement dated as of July 1, 2019 by and between the Company and Matthew M. Loar Ex.</u>	8-K	7/5/2019	10.1
10.41	<u>Note Purchase Agreement between Mateon Therapeutics, Inc. and PointR Data Inc. dated July 22, 2019.</u>	8-K	7/24/2019	10.1
10.42	<u>Employment Agreement dated August 23, 2019 between the Company and Dr. Vuong Trieu.</u>	8-K	8/29/2019	10.1
10.43	<u>Employment Agreement dated August 23, 2019 between the Company and Dr. Fatih Uckun.</u>	8-K/A	11/25/2019	10.2
10.44	<u>Employment Agreement dated August 23, 2019 between the Company and Dr. Chulho Park.</u>	8-K	8/29/2019	10.3
10.45	<u>Employment Agreement dated August 23, 2019 between the Company and Mr. Amit Shah.</u>	8-K	8/29/2019	10.4
10.46	<u>Investigational Product Supply and Use Authorization Agreement for OT-101 U.S. Expanded Access (IPUSA) dated September 5, 2019, between WideTrial and Oncotelic.</u>	8-K	9/10/2019	10.1

10.47	<u>Agreement for Delivery and Licensed Use of Data Generated from OT-101 U.S. Expanded Access (Data License 1) dated September 5, 2019 between WideTrial and Oncotelic.</u>	8-K	9/10/2019	10.2
10.48	<u>Agreement for Delivery and Licensed Use of WideTrial Bonus Dataset (Data License 2 Agreement) dated September 5, 2019 between WideTrial and Oncotelic.</u>	8-K	9/10/2019	10.3
10.49	<u>Form of Convertible Promissory Note, issued by the Company under the Note Purchase Agreement dated as of November 23, 2019.</u>	8-K	11/25/2019	10.1
10.50	<u>Research and Services Agreement.</u>	8-K	3/23/2020	10.1
10.51	<u>Supplement Research and Services Agreement.</u>	8-K	3/23/2020	10.2
10.52	<u>Paycheck Protection Program Promissory Note dated April 21, 2020 between Mateon Therapeutics, Inc. and Silicon Valley Bank.</u>	8-K	4/27/2020	10.1
10.53	<u>Form of Series A Warrant to purchase Common Stock.</u>	10-Q	06/12/2020	10.1
10.54	<u>Agreement between Oncotelic Inc, Autotelic Inc. and Autotelic BIO.</u>	8-K	6/16/2020	10.1
10.55	<u>Consulting Agreement by Between the Company and Artius, dated March 9, 2020</u>	8-K/A	6/22/2020	10.1
10.56	<u>Consulting Agreement by Between the Company and Dr. Maida, dated May 5, 2020</u>	8-K/A	6/22/2020	10.2
10.57	<u>Loan, Secured Convertible Note Purchase, and Security Agreement between the Company and Golden Mountain Partners, LLC dated June 27, 2020</u>	10-Q	11/16/2020	10.57
10.58	<u>Secured Convertible Promissory Note between the Company and Golden Mountain Partners, LLC dated June 27, 2020</u>	10-Q	11/16/2020	10.58
10.59	<u>License, Development and Commercialization Agreement between Mateon Therapeutics, Inc. and Windlas Biotech Private Limited dated November 10, 2020</u>	10-Q	11/16/2020	10.59

10.60	<u>Amendment to Certificate of Incorporation</u>	8-K	02/02/2021	10.60
10.61	<u>Subscription Agreement by and between the Company and certain accredited investors dated</u>	8-K	03/26/2021	10.1
10.62	<u>Form of Registration Statement to register additional shares of Common Stock under 2015 Equity Incentive Plan</u>	S-8	04/19/2021	10.62
10.63	<u>Equity Purchase Agreement by and between the Company and Peak One Opportunity Fund L.P dated May 3, 2021</u>	8-K	05/07/2021	10.1
10.64	<u>Form for Registration of Securities</u>	S-1	05/24/2021	
10.65	<u>Form of Securities Purchase Agreement by and between the Company and Geneva Roth Remark Holding, Inc dated May 25, 2021</u>	8-K	06/01/2021	10.1
10.66	<u>Form of Securities Purchase Agreement and by and between the Company and Geneva Roth Remark Holding, Inc dated June 28, 2021</u>	8-K	07/02/2021	10.66
10.67	<u>Form of Note Purchase Agreement by and between the Company and Autotelic Inc. dated August 4, 2021</u>	8-K	08/05/2021	10.2
10.68	<u>Licensing Agreement by and between the Company and Autotelic Inc dated August 31, 2021</u>	8-K	09/03/2021	10.1
10.69	<u>Unsecured Convertible Note Purchase Agreement by and between the Company and Golden Mountain Partners LLC dated September 21, 2021</u>	8-K	09/27/2021	10.1
10.70	<u>Licensing Agreement by and between the Company and Autotelic Inc dated September 30, 2021</u>	8-K	10/04/2021	10.1
10.71	<u>Unsecured Convertible Note Purchase Agreement by and between the Company and Golden Mountain Partners LLC dated October 25, 2021</u>	8-K	10/28/2021	10.1
10.72	<u>Form of Securities Purchase Agreement by and between the Company and certain accredited investors</u>	8-K	12/01/2021	10.1
10.73	<u>Form of Convertible Notes by and between the Company and certain accredited investors</u>	8-K	12/01/2021	10.1
10.74	<u>Form of Unsecured Convertible Note Purchase Agreement between the Company and Golden Mountain Partners dated January 31, 2022</u>	8-K	02/02/2022	10.1
10.75	<u>Form of Convertible Promissory Note issued by the Company dated January 31, 2022</u>	8-K	02/02/2022	10.2
10.76	<u>Form of Warrants issued by the Company to certain Investors, under the extension of Notes dated February 9, 2022 of the Note Purchase Agreement dated July 23, 2020</u>	8-K	02/15/2022	10.76
10.77	<u>Form of Securities Purchase Agreement by and between the Company and certain accredited investors dated March 29, 2022</u>	8-K	04/04/2022	10.1
10.78	<u>Form of Joint Venture Agreement between the Company and Dragon Overseas Capital Limited dated March 31,</u>		04/06/2022	10.1

2022

10.78	<u>License Agreement between Oncotelic Therapeutics, Inc. and GMP Biotechnology Limited dated March 31, 2022</u>	04/06/2022	10.2
10.79	<u>License Agreement between Oncotelic Therapeutics, Inc. and Sapu Holdings, LLC dated March 31, 2022</u>	04/06/2022	10.3
23.1	<u>Consent of the Independent Registered Accounting Firm</u>		x
23.2	<u>Consent of the previous Independent Registered Accounting Firm</u>		x
14.1	<u>Corporate Code of Conduct and Ethics.</u>	10-K	3/30/2015
31.1	<u>Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a).</u>		x
31.2	<u>Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a).</u>		x
32.1	<u>Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>		x
32.2	<u>Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>		x
101.1	Interactive Data Files for the fiscal years ended December 31, 2020 and December 31, 2019		x
101.INS	Inline XBRL Instance Document		x
101.SCH	Inline XBRL Taxonomy Extension Schema		x
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase		x
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase		x
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase		x
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase		x
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)		

* Confidential treatment has been granted for portions of this Exhibit. Redacted portions filed separately with the Securities and Exchange Commission.

+ Management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Oncotelic Therapeutics, Inc.
(Formerly Mateon Therapeutics, Inc.)**

/s/ VUONG TRIEU

By: VUONG TRIEU, PH. D.
Chief Executive Officer

Date: April 15, 2022

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ VUONG TRIEU</u> Vuong Trieu, Ph. D.	President, Chief Executive Officer and Chairman of the Board and Director (Principal executive officer)	April 15, 2022
<u>/s/ AMIT SHAH</u> Amit Shah	Chief Financial Officer (Principal financial and accounting officer)	April 15, 2022
<u>/s/ STEVEN KING</u> Steven King	Director	April 15, 2022
<u>/s/ ANTHONY MAIDA</u> Anthony Maida, M.D., Ph. D.	Director	April 15, 2022

Oncotelic Therapeutics, Inc. (Formerly Mateon Theapeutics, Inc.)

Index to Financial Statements

The following financial statements of Oncotelic Therapeutics, Inc.:

	Page
<u>Report of Independent Registered Public Accounting Firm</u> (PCAOB ID No. 468)	F-2
<u>Report of previous Independent Registered Public Accounting Firm</u>	F-4
<u>Consolidated Balance Sheets as of December 31, 2021 and 2020</u>	F-5
<u>Consolidated Statements of Operations for the Years Ended December 31, 2021 and 2020</u>	F-6
<u>Consolidated Statements of Stockholders Equity for the Year Ended December 31, 2021</u>	F-7
<u>Consolidated Statements of Stockholders Equity for the Year Ended December 31, 2020</u>	F-8
<u>Consolidated Statements of Cash Flow for the Years Ended December 31, 2021 and 2020</u>	F-9
<u>Notes to Consolidated Financial Statements</u>	F-10

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Oncotelic Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Oncotelic Therapeutics, Inc. and Subsidiaries (the Company) as of December 31, 2021, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2021, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2021, and the consolidated results of its operations and its cash flows for the year ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit and a working capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Convertible Debt Accounting

Description of the Matter

As described in Notes 6 and 7 to the consolidated financial statements, the Company entered into various capital raising transactions whereby it issued convertible debt with other instruments, including warrants and shares of common stock.

We identified the accounting for the issuance of these convertible notes as a critical audit matter. Accounting for the issuance of convertible debt was complex due to the evaluation of the terms of the agreements as well as the inherent estimation uncertainty in the Company's valuation of the beneficial conversion feature, note agreements and warrants. The Company allocated the proceeds among the freestanding financial instruments that were issued in the respective transactions using the relative fair value method, which affects the determination of each financial instruments' initial carrying amount. The Company utilized the relative fair value method as none of the freestanding financial instruments issued as part of the transactions are measured at fair value. Under the relative fair value method, the Company made separate estimates of the fair value of each freestanding financial instrument and then allocated the proceeds in proportion to those fair value amounts.

How We Addressed the Matter in our Audit

The primary procedures we performed to address this critical audit matter included:

- Obtaining an understanding of the Company's process to account for the issuance of convertible notes, warrants and shares of common stock
- Reviewing the underlying agreements associated with these transactions
- Reviewing the Company's position papers addressing the accounting for these transactions and assessing the appropriateness of the positions
- Testing the completeness and accuracy of the underlying data used in the assessment of relative fair values

Rose, Snyder & Jacobs LLP

We have served as the Company's auditor since 2021.

Encino, CA

April 15, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Oncotelic Therapeutics, Inc. (formerly Mateon Therapeutics, Inc.)

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Oncotelic Therapeutics, Inc. and its subsidiaries (the Company) as of December 31, 2020 the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020, and the results of its operations and its cash flows for year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit and a working capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current year audit of the financial statements that was communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Convertible Debt Accounting

Critical Audit Matter Description

As described in Note 7 to the financial statements, the Company entered into a private placement agreement with investors whereby the Company issued and sold 63 units for total gross proceeds of approximately \$3.15 million. Each unit consisted of a convertible promissory note, shares in a subsidiary, and warrants to purchase the subsidiary's common stock.

We identified the accounting for the issuance of the units and convertible debt as a critical audit matter. Accounting for the issuance of units and convertible debt was complex due to the evaluation of the terms of the unit agreements as well as the inherent estimation uncertainty in the Company's valuation of the beneficial conversion feature, note agreements and warrants. The Company allocated the proceeds among the freestanding financial instruments that were issued in the single transaction using the relative fair value method, which affects the determination of each financial instrument initial carrying amount. The Company

utilized the relative fair value method as none of the freestanding financial instruments issued as part of the single transaction are measured at fair value. Under the relative fair value method, the Company made separate estimates of the fair value of each freestanding financial instrument and then allocated the proceeds in proportion to those fair value amounts.

How the Critical Audit Matter Was Addressed in the Audit

The primary procedures we performed to address this critical audit matter included:

- Obtaining an understanding of the Company's process to account for the issuance of units and convertible notes
- Reviewing unit, convertible debt, and warrant agreements
- Reviewing management's memorandum and assessing the appropriateness of accounting treatment
- Testing the completeness and accuracy of the underlying data used in the calculation to determine the value of the warrants and beneficial conversion feature
- Evaluating the underlying assumptions used in the fair value model

/s/ BAKER TILLY US, LLP

We have served as the Company's auditor from 2019 to 2021.

Los Angeles, California

April 15, 2021

ONCOTELIC THERAPEUTICS, INC. AND SUBSIDIARIES
(Formerly Mateon Therapeutics, Inc.)
CONSOLIDATED BALANCE SHEETS

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash	\$ 568,769	\$ 474,019
Restricted cash	20,000	20,000
Accounts receivable	19,748	19,748
Prepaid & other current assets	<u>18,778</u>	<u>101,869</u>
Total current assets	627,295	615,636
Development equipment, net of accumulated depreciation of \$111,958 and \$101,810	-	10,148
Intangibles, net of accumulated amortization of \$188,339 and \$136,974	821,841	873,206
In process R&D	1,101,760	1,101,760
Goodwill	21,062,455	21,062,455
Total assets	\$ 23,613,351	\$ 23,663,205
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 3,092,723	\$ 2,735,805
Accounts payable to related party	403,423	391,631
Contingent consideration	2,625,000	2,625,000
Derivative liability	340,290	777,024
Convertible debt for clinical trial and JV	4,069,781	2,000,000
Convertible debt, net of costs	1,666,594	1,091,612
Convertible debt, related party, net of costs	717,816	297,989
Convertible debt 2021, net of costs	76,994	-
Private Placement convertible notes, net of costs	2,353,253	943,586
Private Placement convertible notes, related party, net of costs	109,046	67,992
Payroll Protection Plan loan	-	251,733
Total current liabilities	15,454,920	11,182,372
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Convertible Preferred stock, \$0.01 par value, 15,000,000 shares authorized; 0 and 278,188 shares issued and outstanding	-	2,782
Common stock, \$.01 par value; 750,000,000 and 150,000,000 shares authorized; 375,288,146 and 90,601,912 issued and outstanding, respectively	3,752,881	906,019
Additional paid-in capital	35,223,842	32,493,086
Accumulated deficit	(31,021,050)	(21,630,008)
Total Oncotelic Therapeutics, Inc. stockholders' equity	<u>7,955,673</u>	<u>11,771,879</u>
Non-controlling interests	202,758	708,954
Total stockholders' equity	8,158,431	12,480,833
Total liabilities and stockholders' equity	\$ 23,613,351	\$ 23,663,205

The accompanying footnotes are an integral part of these consolidated financial statements.

ONCOTELIC THERAPEUTICS, INC. AND SUBSIDIARIES
(Formerly Mateon Therapeutics, Inc.)
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31,	
	2021	2020
Service Revenue	\$ -	\$ 1,740,855
Total Revenue	- -	1,740,855
Operating expenses:		
Research and development	\$ 3,658,617	\$ 4,302,447
General and administrative	<u>5,467,266</u>	<u>5,023,142</u>
Total operating expenses	9,125,883	9,325,589
Loss from operations	(9,125,883)	(7,584,734)
Other income (expense):		
Interest expense, net	(2,002,813)	(1,998,321)
PPP loan forgiveness	346,761	-
Change in fair value of derivative	292,149	(45,051)
Loss on debt conversion	<u>(27,504)</u>	<u>(343,700)</u>
Total other expense	<u>(1,391,407)</u>	<u>(2,387,072)</u>
Net loss before non-controlling interests	(10,517,290)	(9,971,806)
Net loss attributable to non-controlling interests	<u>(1,126,248)</u>	<u>(469,204)</u>
Net income (loss) attributable to Oncotelic Therapeutics, Inc.	<u>\$ (9,391,042)</u>	<u>\$ (9,502,602)</u>
Basic net loss per share attributable to common stock	\$ (0.03)	\$ (0.11)
Basic weighted average common stock outstanding	<u>303,078,548</u>	<u>88,099,787</u>

The accompanying footnotes are an integral part of these consolidated financial statements.

ONCOTELIC THERAPEUTICS, INC. AND SUBSIDIARIES
(Formerly Mateon Therapeutics, Inc.)
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY FOR THE YEAR ENDED DECEMBER 31, 2021

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Non controlling Interests	Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at January 1, 2021	278,188	\$ 2,782	90,601,912	\$ 906,019	\$32,493,086	\$ (21,630,008)	\$ 708,954	\$ 12,480,833
Common shares issued upon conversion of Preferred Stock	(278,188)	(2,782)	278,187,847	2,781,878	(2,779,096)	-	-	-
Common shares issued upon conversion of debt	-	-	657,200	6,572	203,729	-	-	210,301
Common shares issued in lieu of restricted stock units	-	-	1,257,952	12,580	213,852	-	-	226,432
Common shares issued for services	-	-	1,148,235	11,482	182,159	-	-	193,641
Common shares issued for cash	-	-	3,435,000	34,350	385,952	-	-	420,302
Beneficial Conversion Feature on convertible debt	-	-	-	-	969,754	-	-	969,754
Warrants issued in connection with private placement	-	-	-	-	2,190,127	-	-	2,190,127
Warrants issued in connection with debt issuance	-	-	-	-	600,965	-	-	600,965
Stock compensation expense	-	-	-	-	763,314	-	-	763,314
Increase in non-controlling interest from issuance of additional Edgepoint stock	-	-	-	-	-	620,052	620,052	
Net loss	-	-	-	-	-	(9,391,042)	(1,126,248)	(10,517,290)
Balance as of December 31, 2021	—	\$ —	375,288,146	\$3,752,881	\$35,223,842	\$ (31,021,050)	\$ 202,758	\$ 8,158,431

The accompanying footnotes are an integral part of these consolidated financial statements.

ONCOTELIC THERAPEUTICS, INC. AND SUBSIDIARIES
(Formerly Mateon Therapeutics, Inc.)
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY FOR THE YEAR ENDED DECEMBER 31, 2020

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Non- Controlling Interest	Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at January 1, 2020	278,188	\$ 2,782	84,069,967	\$ 840,700	\$ 28,185,599	\$ (12,127,406)	\$ -	\$ 16,901,675
Stock-based compensation	-	-	-	-	2,147,591	-	-	2,147,591
Common shares issued upon partial conversion of debt	-	-	6,531,945	65,319	1,008,247	-	-	1,073,566
Beneficial Conversion Feature on convertible debt	-	-	-	-	724,278	-	-	724,278
Warrants issued in connection with private placement	-	-	-	-	427,371	-	-	427,371
Non-controlling interest of Edgepoint	-	-	-	-	-	-	1,178,158	1,178,158
Net loss	-	-	-	-	-	(9,502,602)	(469,204)	(9,971,806)
Balance as of December 31, 2020	278,188	\$ 2,782	90,601,912	\$ 906,019	\$ 32,493,086	\$ (21,630,008)	\$ 708,954	\$ 12,480,833

The accompanying footnotes are an integral part of these consolidated financial statements.

ONCOTELIC THERAPEUTICS, INC. AND SUBSIDIARIES
(Formerly Mateon Therapeutics, Inc.)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Twelve Months Ended December 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (10,517,290)	\$ (9,971,806)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Amortization of debt discount and deferred finance costs	1,453,949	1,320,617
Amortization of intangible assets	51,365	326,806
R&D Expenses paid by debt	1,500,000	2,000,000
Loss on debt conversion	-	343,700
Warrants issued in connection with private placement and debt	2,190,127	-
Common shares issued in lieu of restricted stock units	226,432	-
Common shares issued in lieu of services	193,641	-
Stock compensation expense	763,315	2,147,591
PPP loan forgiven	(346,761)	-
Depreciation on development equipment	10,148	37,406
Change in fair value of derivative	(292,149)	45,051
Interest paid in kind	-	54,744
Loss on debt conversion	-	343,700
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	83,091	69,419
Accounts payable and accrued expenses	237,875	680,822
Accounts payable to related party	11,792	(210,051)
Net cash provided by (used in) operating activities	(4,434,465)	(2,812,001)
Cash flows from financing activities:		
Proceeds from private placement	1,545,052	2,929,056
Proceeds from sales of common stock	420,293	-
Proceeds from convertible debt	307,500	-
Repaid to convertible note holder	(307,500)	
Proceeds from convertible notes and short term loans	1,815,825	-
Proceeds from convertible debt for JV	500,000	-
Proceeds from short term loans, others	350,050	75,000
Repaid to note holder	(100,000)	-
Repaid to others	(95,000)	(50,000)
Proceeds from Payroll Protection Plan	92,995	250,000
Proceeds from short term loan net of repayments, related party	-	20,000
Net cash provided by financing activities	4,529,215	3,224,056
Net increase (decrease) in cash	94,750	412,055
Cash and restricted cash - beginning of period	494,019	81,964
Cash and restricted cash - end of period	\$ 588,769	\$ 494,019
Supplemental cash flow information:		
Cash paid for:		
Interest paid	\$ 299,365	\$ 52,066
Income taxes paid	\$ 4,743	\$ 800
Non-cash investing and financing activities:		
Warrants issued in connection with private placement & debt	\$ 2,791,092	\$ -
Beneficial Conversion Feature on convertible debt and restricted common shares	\$ 969,754	\$ 724,278
Common shares issued upon partial conversion of debt	\$ 210,301	\$ 1,073,566
Common shares issued in lieu of services	\$ 193,641	\$ -
Common shares issued in lieu of restricted stock units	\$ 226,432	
Non-cash cost upon sale of common stock	\$ 124,642	

The accompanying footnotes are an integral part of these consolidated financial statements.

ONCOTELIC THERAPEUTICS, INC. AND SUBSIDIARIES
(Formerly Mateon Therapeutics, Inc.)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

Description of Business

Oncotelic Therapeutics, Inc. (f/k/a Mateon Therapeutics, Inc.) (“Oncotelic”), was formed in the State of New York in 1988 as OXiGENE, Inc., was reincorporated in the State of Delaware in 1992, and changed its name to Mateon Therapeutics, Inc. in 2016, and Oncotelic Therapeutics, Inc. in November 2020. Oncotelic conducts business activities through Oncotelic and its wholly-owned subsidiaries, Oncotelic, Inc., a Delaware corporation, PointR Data, Inc. (“PointR”), a Delaware corporation, and EdgePoint AI, Inc. (“Edgepoint”), a Delaware Corporation for which there are non-controlling interests, (Oncotelic, Oncotelic Inc., PointR and Edgepoint are collectively called the “Company” or “We”). The Company is currently developing OT-101 for various cancers and COVID-19, Artemisinin for COVID-19 and AI technologies for clinical development and manufacturing. The Company has acquired apomorphine for Parkinson’s Disease, erectile dysfunction and female sexual dysfunction. In addition, the Company is evaluating the further development of its product candidates OXi4503 as a treatment for acute myeloid leukemia and myelodysplastic syndromes and CA4P in combination with a checkpoint inhibitor for the treatment of advanced metastatic melanoma.

In April 2019, Oncotelic entered into an Agreement and Plan of Merger with Oncotelic Inc. (the “Merger Agreement”), a clinical-stage biopharmaceutical company developing investigational drugs for the treatment of orphan oncology indications and Oncotelic’s wholly owned subsidiary Oncotelic Acquisition Corporation (the “Merger Sub”). Upon the terms of and subject to the satisfaction of the conditions described in the Merger Agreement, the Merger Sub was merged with and into Oncotelic (the “Merger”), with Oncotelic Inc. surviving the Merger as a wholly owned subsidiary of Oncotelic. Also, in April 2019, Oncotelic completed the Merger and Oncotelic Inc. became a wholly owned subsidiary of Oncotelic. The Merger was treated as a recapitalization and reverse acquisition for financial accounting purposes. Oncotelic Inc. is considered the acquirer for accounting purposes, and Oncotelic Inc.’s historical financial statements before the Merger have been replaced with the historical financial statements of Oncotelic Inc. prior to the Merger in the financial statements and filings with the Securities and Exchange Commission (“SEC”).

In August 2019, the Company entered into an Agreement and Plan of Merger (the “PointR Merger Agreement”) with PointR. PointR survived the merger as a wholly-owned subsidiary of the Company (the “PointR Merger”). The PointR Merger was intended to create a publicly-traded artificial intelligence (“AI”) driven immuno-oncology company with a robust pipeline of first in class TGF- β immunotherapies for late stage cancers such as gliomas, pancreatic cancer and melanoma. In November 2019, the Company entered into Amendment No. 1 (the “Amendment”) to the PointR Merger Agreement with PointR. The Amendment revised certain terms of the PointR Merger Agreement to provide that holders of PointR Common Stock would receive shares of the Company’s Series A Preferred Stock in lieu of shares of the Company’s Common Stock in connection with the PointR Merger, as originally contemplated by the PointR Merger Agreement. The Amendment also revised the terms of the milestones for earn-out payment. Also in November 2019, pursuant to the terms of the PointR Merger Agreement, the Company completed the PointR Merger.

In February 2020, the Company formed a subsidiary, Edgepoint. Edgepoint was formed as a start-up company, with plans to develop technologies and IP related to various unmet issues within the pharma and medical device industries. The Company may spin off Edgepoint into a separate public company in the future.

The Company is a cancer immunotherapy company dedicated to the development of first in class self-immunization protocol (“SIP™”) candidates for difficult to treat cancers. The Company’s proprietary SIP™ candidates offer advantages over other immunotherapies because they do not require extraction of the tumor or isolation of the antigens, and they have the potential for broad-spectrum applicability for multiple cancer types. The Company’s proprietary product candidates have shown promising clinical activity in phase 2 trials for the treatment of gliomas and pancreatic cancers. The Company aims to translate its unique insights, which span more than three decades of original work using RNA therapeutics, into the deployment of antisense as a RNA therapeutic for diseases which are caused by TGF- β overexpression, starting with cancer and expanding to Duchenne Muscular Dystrophy (“DMD”) and others. Oncotelic Inc.’s product candidate, OT-101, is being developed as a broad-spectrum anti-cancer drug that can also be used in combination with other standard cancer therapies to establish an effective multi-modality treatment strategy for difficult-to-treat cancers. Together, the Company plans to initiate phase 3 clinical trials for OT-101 in both high-grade glioma and pancreatic cancer, and any other indications that may evolve. The Company is evaluating the further development of its product candidates OXi4503 as a treatment for acute myeloid leukemia and myelodysplastic syndromes and CA4P in combination with a checkpoint inhibitor for the treatment of advanced metastatic melanoma.

The Company is also developing OT-101 for the various epidemics and pandemics, similar to the current corona virus (“COVID-19”) pandemic. In this connection, the Company entered into an agreement and supplemental agreement with Golden Mountain Partners (“GMP”) for a total of \$1.2 million to render services for the development of OT-101. Such amount was recorded as revenue upon completion of all performance obligations under the agreement. Further, In June 2020, the Company secured \$2 million in debt financing from GMP to conduct a clinical trial evaluating OT-101 against COVID-19. The Company discontinued enrollment in its OT-101 clinical trial in patients with COVID-19 in June 2021. The trial completed randomization of 32 out of 36 patients planned, on an intent to treat basis. The discontinuance of the trial was due to the continuing rise of more severe variants in Latin America, leading to exhaustion of medical care infrastructure in Latin America.

In 2020 and 2021, the Company was developing Artemisinin as a potential therapy for COVID-19. Artemisinin, purified from a plant *Artemisia annua*. It can inhibit TGF- β activity and is able to neutralize COVID-19. The Company initially conducted a study and the test results during an in vitro study at Utah State University showed Artemisinin having an EC50 of 0.45 ug/ml, and a Safety Index of 140. Artemisinin can target multiple viral threats, including COVID-19, by suppressing both viral replication and clinical symptoms that arise from viral infection. Viral replication cannot occur without TGF- β . In a clinical study undertaken in India, clinical consequences related to the TGF- β surge, including ARDS and cytokine storm, were suppressed by targeting TGF- β with Artemisinin. The ARTI-19 trials were conducted in India by Windlas Biotech Limited (“Windlas”), the Company’s business partner in India. Windlas had applied for regulatory approval for it’s Artemisinin based product, ArtiShield™, but has not been able to obtain regulatory approval for use of ArtiShield™ as a COVID-19 therapy and as such, no significant revenues have been reported by Windlas nor have we accrued any royalties on Artemisinin due from Windlas. We intend to focus future development on Artemisinin against other respiratory viruses with unmet needs.

On March 31, 2022, the Company formalized a JV with Dragon Overseas Capital Limited and GMP Biotechnology Limited, both affiliates of GMP. For more information on the JV, refer to our Current Report on Form 8-K filed with the SEC on April 6, 2022.

Amendments to Certificate of Incorporation

In November 2020 the Company filed an amendment to its Certificate of Incorporation with the Secretary of State for the State of Delaware changing its name from “Mateon Therapeutics, Inc.” to “Oncotelic Therapeutics, Inc.” A notice of corporate action had been filed with the Financial Industry Regulatory Authority (“FINRA”), requesting confirmation to change its name and approval for a new ticker symbol. On March 29, 2021, the Company received approval from FINRA on its notice of corporate action, and effective March 30, 2021, the Company’s ticker symbol has changed from “MATN” to “OTLC”.

In January 2021, the Company filed an additional amendment to its Certificate of Incorporation with the Secretary of State for the State of Delaware which went effective immediately upon acceptance by the Secretary of State for the State of Delaware. As approved by the Company’s stockholders by written consent on August 10, 2020, the amendment also increased the number of authorized shares of Common Stock from 150,000,000 shares to 750,000,000 shares.

In addition, the Company registered an additional total of 20,000,000 shares of its Common Stock, which may be issued pursuant to the Company’s Amended and Restated 2015 Equity Incentive Plan (the “Plan”). Such additional shares were approved by the shareholders of the Company on August 10, 2020 and as reported to the Securities and Exchange Commission (the “SEC”) on Current Report on Form 8-K on August 14, 2020. As such, the total number of shares of the Company’s Common Stock available for issuance under the 2015 plan is 27,250,000.

Fundraising

J.H. Darbie Financing Notes & Issuance of Oncotelic Warrants

Between July 2020 and March 2021, the Company issued and sold a total of 100 units (“*Units*”), with each Unit consisting of (i) 25,000 shares of Edgepoint common stock, par value \$0.01 per share (“*Edgepoint Common Stock*”), for a price of \$1.00 per share of Edgepoint Common Stock; (ii) one convertible promissory note issued by the Company (the “*Unit Note*”), convertible into up to 25,000 shares of EdgePoint Common Stock at a conversion price of \$1.00 per share, or up to 138,889 shares of the Company’s Common Stock, at a conversion price of \$0.18 per share; and (iii) 100,000 warrants, consisting of (a) 50,000 warrants to purchase an equivalent number of shares of EdgePoint Common Stock at \$1.00 per share (“*Edgepoint Warrant*”), and (b) 50,000 warrants to purchase an equivalent number of shares of Company Common Stock at \$0.20 per share (“*Oncotelic Warrant*”) (collectively, the “*JH Darbie Financing*”).

In June 2021, the Company and the Investors agreed to extend the maturity date of the Notes from June 30, 2021, to March 31, 2022. In addition, the Company and JHDarbie identified an error in the Oncotelic Warrants and JH Darbie Financing documents which intended to have the investors to purchase \$50,000 of shares of Common Stock or Edgepoint Common Stock. However, the Company only issued 50,000 Oncotelic Warrants, with an aggregate exercise price of \$10,000. The error was corrected by the Company and the Company issued to the Investors an aggregate of 20.0 million additional Oncotelic Warrants, and 2.0 million additional Oncotelic Warrants to J.H. Darbie., as placement agent. Each Investor was entitled to receive 200,000 additional Oncotelic Warrants for each Unit purchased. The issuance of the additional warrants resulted in the Company recording an expense of \$2,023,552 in the Company’s statement of operations during the year ended December 31, 2021. No similar expense was recorded in the same period in 2020. Management reviewed the guidance per ASC 470-60 *Troubled debt restructurings* and ASC 470-50 *Debt-Modifications and Extinguishments* and concluded that the terms of the agreements were not substantially different as of June 30, 2021, and, accounted for the transaction as a debt modification.

Equity Purchase Agreement

In May 2021, the Company entered into an Equity Purchase Agreement (the “*EPL*”) and Registration Rights Agreement (the “*Registration Rights Agreement*”) with Peak One Opportunity Fund, L.P. (“*Peak One*”), pursuant to which the Company shall have the right, but not the obligation, to direct Peak One to purchase up to \$10.0 million (the “*Maximum Commitment Amount*”) in shares of the common stock, par value \$0.01 per share (“*Common Stock*”) in multiple tranches. The Company has directed Peak One, on nine occasions, for an aggregate of 3.4 million shares of Common Stock for aggregate net cash proceeds of approximately \$420,000.

Geneva Roth Remark Notes

In May 2021, the Company consummated the closing of a private placement transaction whereby, pursuant to a Securities Purchase Agreement (the “*Geneva Agreement*”) entered into with Geneva Roth Remark (“*Geneva*”), the Company issued a convertible promissory note in the aggregate principal amount of \$203,750 (the “*Note 1*”). Further in June 2021, the Company issued an additional convertible promissory note in the aggregate principal amount of \$103,750 (“*Note 2*”, and collectively with Note 1, the “*Notes*”). The Notes are convertible into shares of the Company’s Common Stock. Additional convertible promissory notes may be issued under the Geneva Agreement for up to \$1.2 million in the aggregate principal amount subject to further agreement by and between the Company and Geneva. The notes were repaid in December 2021 and there is no outstanding balance on these notes.

August 2021 Notes

In August 2021, the Company issued Note Purchase Agreements with Autotelic Inc., the Company's Chief Financial Officer ("CFO"), and certain other accredited investors. Under the terms of the Note Purchase Agreements, the Company issued an aggregate of \$698,500 (the "*Principal Amount*") in debt in the form of unsecured convertible promissory notes (collectively, the "*Notes*"). The Notes are unsecured, and provide for interest at the rate of 5% per annum. Such Notes were issued against some of the short-term debt due as of June 30, 2021. All amounts outstanding under the Notes become due and payable at such time as determined by the holders of a majority of the Principal Amount of the Notes (the "*Majority Holders*"), on or after (a) the one-year anniversary of the Notes, or (b) the occurrence of an Event of Default (as defined in the Note Purchase Agreements) (the "*Maturity Date*"). The Company may prepay the Notes at any time. Events of Default under the Notes include, without limitation, (i) failure to make payments under the Notes within thirty (30) days of the Maturity Date, (ii) breaches of the Note Purchase Agreement or Notes by the Company which is not cured within thirty (30) days of notice of the breach, (iii) bankruptcy, or (iv) a change in control of the Company (as defined in the Note Purchase Agreements). The Majority Holders have the right, at any time not more than five days following the Maturity Date, to elect to convert all, and not less than all, of the outstanding accrued and unpaid interest and principal on the Notes. The Notes may be converted, at the election of the Majority Holders, into shares of the Company's common stock, par value \$0.01 per share ("*Common Stock*"), at a fixed conversion price of \$0.18 per share.

GMP Letter of Intent, Term Sheet, note purchase agreements and unsecured notes

In August 2021 the Company, the Company's Chief Executive Officer (the "CEO"), and GMP executed a letter of intent and a non-binding term sheet (*the "Term Sheet"*), which Term Sheet included certain binding terms relating to a standstill agreement and the issuance of a convertible promissory note (as more fully described below). The Term Sheet sets forth the terms and conditions pursuant to which the Company and GMP will, subject to shareholder approval, form a joint venture (the "*JV*") with the objective to develop the Company's product portfolio. Pursuant to the Term Sheet, the Company will contribute its product portfolio to the JV in consideration for a 35% ownership stake in the JV. As set forth above, the Term Sheet sets forth certain binding terms regarding (i) a 45-day standstill by the Company, and (ii) the issuance by the Company of a convertible note for \$1.5 million to GMP to fund the OT-101 clinical trial study close-out. Although no assurances can be given, the Company and GMP currently intend to conduct an initial public offering of the JV, at a future date, on either the Hong Kong Exchange or other stock exchange. The formation of the JV is not assured as the formation of the JV is subject to approval of the Company's shareholders and the execution of definitive agreements, among other conditions.

In September 2021, the Company entered into an Unsecured Convertible Note Purchase Agreement (the "*Purchase Agreement*") with GMP, pursuant to which the Company issued a convertible promissory note in the aggregate principal amount of \$1.5 million (the "*September 2021 Note*"), which September 2021 Note is convertible into shares of the Company's Common Stock.

The September 2021 Note carries an interest rate of 2% per annum and matures on the earlier of (a) the one year anniversary of the date of the Agreement, (b) early termination of that certain clinical trial known as "A Randomized, Controlled, Multi - Center Study of OT-101 in COVID-19 Patients (Investigational New Drug (IND) Application #149299)" (the "*Clinical Trial*"), or any termination of the Clinical Trial, or (c) the acceleration of the maturity of the September 2021 Note by GMP upon occurrence of an Event of Default (as defined below). The September 2021 Note contains a voluntary conversion mechanism whereby GMP may convert the outstanding principal and accrued interest under the terms of the September 2021 Note into shares of Common Stock (the "*Conversion Shares*"), at the consolidated closing bid price of the Company's Common Stock on the applicable OTC Market as of the date the Company receives a Notice of Conversion (as defined in the September 2021 Note) from GMP. Prepayment of the September 2021 Note may be made at any time by payment of the outstanding principal amount plus accrued and unpaid interest. The September 2021 Note contains customary events of default (each an "*Event of Default*"). If an Event of Default occurs, at GMP's election, the outstanding principal amount of the September 2021 Note, plus accrued but unpaid interest, will become immediately due and payable in cash.

In October 2021, the Company entered into an Unsecured Convertible Note Purchase Agreement (the "*October Purchase Agreement*") with GMP, pursuant to which the Company issued a convertible promissory note in the aggregate principal amount of \$0.5 million (the "*October 2021 Note*"), which October 2021 Note is convertible into shares of the Company's Common Stock.

The October 2021 Note carries an interest rate of 2% per annum and matures on the earlier of (a) the one-year anniversary of the date of the October Purchase Agreement, or (b) the acceleration of the maturity of the October 2021 Note by GMP upon occurrence of an Event of Default (as defined below). The October 2021 Note contains a voluntary conversion mechanism whereby GMP may convert the outstanding principal and accrued interest under the terms of the October 2021 Note into shares of Common Stock (the “*Conversion Shares*”), at the consolidated closing bid price of the Company’s Common Stock on the applicable OTC Market as of the date the Company receives a Notice of Conversion (as defined in the October 2021 Note) from GMP. Prepayment of the October 2021 Note may be made at any time by payment of the outstanding principal amount plus accrued and unpaid interest. The October Note contains customary events of default (each an “*Event of Default*”). If an Event of Default occurs, at GMP’s election, the outstanding principal amount of the October 2021 Note, plus accrued but unpaid interest, will become immediately due and payable in cash. The October Purchase Agreement requires the Company to use of the proceeds received under the October 2021 Note to support the clinical development of OT-101, including payroll and has been made in continuation of the relationship between the Company and GMP.

November/December 2021 Notes

In November and December 2021, the Company entered into various Securities Purchase Agreements with Talos Victory Fund, LLC (the (“Talos”), Mast Hill Fund, LP (“Mast”), FirstFire Global Opportunities Fund, LLC (“FirstFire”), Blue Lake Partners, LLC (“Blue Lake”) and Fourth Man, LLC (“Fourth Man”), pursuant to which the Company issued convertible promissory notes in the aggregate principal amount of \$0.25 million each, aggregating gross \$1.25 million (the “Notes”), which Notes are convertible into shares of the Company’s common stock, par value \$0.01 per share (“Common Stock”).

The Purchase Agreements were entered into as part of a convertible note financing round with aggregate gross proceeds to the Company of up to \$1.25 million (the “Financing”), undertaken by the Company pursuant to that certain Finder’s Fee Agreement between the Company and JH Darbie & Co., Inc. (“JH Darbie”), dated October 26, 2021 (the “Agreement”). All of the Purchase Agreements and the Note contain identical terms except with reference to the name of the holders, the use of proceeds, which include repayment of certain debt, general corporate expenses and payroll, as applicable and the jurisdictions.

The Notes carry an interest rate of 12% per annum and mature on the earlier of (a) the one-year anniversary of the date of the Purchase Agreements or (b) the acceleration of the maturity of the Note by Holder upon occurrence of an Event of Default (as defined below). The Notes contain a voluntary conversion mechanism whereby the applicable holder may convert the outstanding principal and accrued interest under the terms of the Notes into shares of Common Stock (the “*Conversion Shares*”), at a fixed price of \$0.07 per share (the “*Conversion Price*”), subject to adjustments upon the occurrence of certain corporate events. Prepayment of the Notes may be made at any time upon three trading days’ prior written notice to the respective holder, by payment of the then outstanding principal amount plus accrued and unpaid interest and reimbursement of such holder’s administrative fees. The Notes contains customary events of default (each an “*Event of Default*”). If an Event of Default occurs, at the respective holder’s election, the outstanding principal amount of the Notes, plus accrued but unpaid interest, will become immediately due and payable in cash. The Purchase Agreement requires the Company to use the proceeds to the full repayment of that certain convertible promissory note including any accrued interest or prepayment penalty thereon, issued by the Company in May and June 2021 to Geneva.

Licensing Agreement with Autotelic Inc.

In September 2021, the Company entered into an exclusive License Agreement (the “Agreement”) with Autotelic, Inc. (“Autotelic”), pursuant to which Autotelic granted Oncotelic, among other things: (i) the exclusive right and license to certain Autotelic Patents (as defined in the Agreement) and Autotelic Know-How (as defined in the Agreement); and (ii) a right of first refusal to acquire at least a majority of the outstanding capital stock of Autotelic prior to Autotelic entering into any transaction that is a financing collaboration, distribution revenues, earn-outs, sales, out-licensing, purchases, debt, royalties, merger acquisition, change of control, transfer of cash or non-cash assets, disposition of capital stock by way of tender or exchange offer, partnership or any other joint or collaborative venture, research collaboration, material transfer, sponsored research or similar transaction or agreements. In exchange for the rights granted to Oncotelic, Autotelic will be entitled to earn the milestone payments of up to \$50 million upon achievement of certain financial, development and regulatory milestones. In addition to the milestone payments, Autotelic would be entitled to earn royalties equal to 15% of the net sales of any products that incorporate the Autotelic Patents or Autotelic Know-How. The Agreement contains representations, warranties and indemnification provisions of each of the parties thereto that are customary for transactions of this type.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Oncotelic, PointR and Edgepoint for which there are non-controlling interests. Intercompany accounts and transactions have been eliminated in consolidation.

Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred net losses of approximately \$31.0 million since inception of Oncotelic Inc. as the Company's historical financial statements before the Merger have been replaced with the historical financial statements of Oncotelic Inc. prior to the Merger in the financial statements and filings. The Company also has a negative working capital of \$14.8 million at December 31, 2021, of which approximately \$1.3 million is attributable to assumed negative working capital of the Company and \$2.6 million contingent liability of issuance of common shares of the Company to PointR shareholders upon achievement of certain milestones in accordance with the PointR Merger Agreement. The Company has negative cash flows from operations for the year ended December 31, 2021 of \$4.3 million. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of one year from the date of this filing. Management expects to incur additional losses in the foreseeable future and recognizes the need to raise capital to remain viable. The accompanying consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

The Company's long-term plans include continued development of its current pipeline of products to generate sufficient revenues to cover its anticipated expenses, through either technology transfer or product sales, as well as develop AI technologies either directly or through its subsidiaries. Until the Company is able to generate sufficient revenues from its current pipeline, the Company plans on funding its operations through the sale of equity and/or the issuance of debt, combined with or without warrants or other equity instruments.

Between July 2020 and March 2021, the Company raised gross proceeds of \$5 million, through JH Darbie Financing. The Company incurred \$0.7 million of costs associated with the raise, of which \$0.65 million was paid as direct placement fees to JH Darbie. JH Darbie and the Company are parties to a placement agent agreement, dated February 25, 2020 pursuant to which JH Darbie has the right to sell a minimum of 40 Units and a maximum of 100 Units on a best-efforts basis. Concurrently with the sale of the Units, JH Darbie was granted, a warrant, exercisable over a five-year period, to purchase 10% of the number of Units sold in the JH Darbie Financing. As such, the Company granted 10 Units to JH Darbie pursuant to the JH Darbie Placement Agreement.

In addition to the JH Darbie Financing, the Company raised approximately \$0.4 million from the Equity Purchase Agreement with Peak One, \$0.3 million from Geneva, \$2 million from Note Agreements with GMP, which was to be utilized for certain clinical trials, payment of payroll and development of OT-10, approximately \$0.7 million from various bridge financiers, including \$0.3 million from Autotelic Inc., a related party, approximately \$0.1 million from the Paycheck Protection Plan of 2021 for PointR and \$1.25 million from various investors in Notes from November/December 2021 financing.

During the year ended December 31, 2021, the Company had no service revenues. The Company had recorded a total of approximately \$1.7 million in service revenues from GMP and ATB during the year ended December 31, 2020.

Although no assurances can be given as to the Company's ability to deliver on its revenue plans, or that unforeseen expenses may arise, management believes that the potential equity and debt financing or other potential financing will provide the necessary funding for the Company to continue as a going concern. Also, management cannot guarantee any potential debt or equity financing will be available on favorable terms or at all. As such, management does not believe the Company has sufficient cash for 12 months from the date of this report. If adequate funds are not available on acceptable terms, or at all, the Company will need to curtail operations, or cease operations completely.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, equity-based transactions and disclosure of contingent liabilities at the date of the financial statements and revenues and expense during the reporting period. Actual results could materially differ from those estimates.

The Company believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of the financial statements. Significant estimates include the valuation of goodwill and intangible assets for impairment, deferred tax asset and valuation allowance, and fair value of financial instruments.

Cash

As of December 31, 2021 and 2020, respectively, the Company held all its cash in banks in the United States of America. The Company considers investments in highly liquid instruments with a maturity of three months or less to be cash equivalents. The Company did not have any cash equivalents as of December 31, 2021 and 2020, respectively. Restricted cash consists of certificates of deposits held at banks as collateral for various purposes.

Debt issuance Costs and Debt discount

Issuance costs are specific incremental costs that are (1) paid to third parties and (2) directly attributable to the issuance of a debt or equity instrument. The issuance costs attributable to the initial sale of the instrument are offset against the associated proceeds in the determination of the instrument's initial net carrying amount.

Debt issuance costs and debt discounts are being amortized over the lives of the related financings on a basis that approximates the effective interest method. Costs and discounts are presented as a reduction of the related debt in the accompanying balance sheets if related to the issuance of debt or presented as a reduction of additional paid in capital if related to the issuance of an equity instrument. The Company applies the relative fair value to allocate the issuance costs among freestanding instruments that form part of the same transaction.

If the Company amends the terms of its convertible notes, the Company reviews and applies the guidance per ASC 470-60 *Troubled debt restructurings* and ASC 470-50 *Debt-Modifications and Extinguishments*, evaluates and concludes whether the terms of the agreements were or were not substantially different as of a particular reporting date and accounts the transaction as a debt modification or a troubled debt restructuring.

Fair Value of Financial Instruments

The carrying value of cash, accounts payable and accrued expense approximate their fair values based on the short-term maturity of these instruments. As defined in ASC 820, "Fair Value Measurements and Disclosures," fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The Company utilizes market data or assumptions that market participants would use in pricing the asset or liability, including assumptions about risk and the risks inherent in the inputs to the valuation technique. These inputs can be readily observable, market corroborated, or generally unobservable. ASC 820 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurement) and the lowest priority to unobservable inputs (level 3 measurement). This fair value measurement framework applies at both initial and subsequent measurement.

The three levels of the fair value hierarchy defined by ASC 820 are as follows:

- Level 1 – Quoted prices are available in active markets for identical assets or liabilities as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis. Level 1 primarily consists of financial instruments such as exchange-traded derivatives, marketable securities and listed equities.
- Level 2 – Pricing inputs are other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reported date. Level 2 includes those financial instruments that are valued using models or other valuation methodologies. These models are primarily industry-standard models that consider various assumptions, including quoted forward prices for commodities, time value, volatility factors and current market and contractual prices for the underlying instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace throughout the full term of the instrument, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace. Instruments in this category generally include non-exchange-traded derivatives such as commodity swaps, interest rate swaps, options and collars.
- Level 3 – Pricing inputs include significant inputs that are generally less observable from objective sources. These inputs may be used with internally developed methodologies that result in management's best estimate of fair value.

The Company did not have any Level 1 or Level 2 assets and liabilities at December 31, 2021 and 2020.

The derivative liabilities associated with its 2019 convertible note debt /financing (see Note 6), consisted of conversion feature derivatives at December 31, 2021 and 2020, and are classified as Level 3 fair value measurements.

The table below sets forth a summary of the changes in the fair value of the Company's derivative liabilities classified as Level 3 as of December 31, 2021 and 2020:

	December 31, 2021 Conversion Feature	December 31, 2020 Conversion Feature
Balance at beginning of the year ended	\$ 777,024	\$ 540,517
New derivative liability	-	870,268
Reclassification to additional paid in capital from conversion of debt to common stock	(144,585)	(678,812)
Change in fair value	<u>(292,149)</u>	<u>45,051</u>
Balance at the end of the year ended	<u>\$ 340,290</u>	<u>\$ 777,024</u>

At December 31, 2021 and 2020, respectively, the Company estimated the fair value of the conversion feature derivatives embedded in the convertible debentures based on assumptions used in the Black-Scholes valuation model. The key valuation assumptions used consists, in part, of the price of the Company's Common Stock, a risk free interest rate based on the yield of a Treasury note and expected volatility of the Company's Common Stock all as of the measurement dates. The Company used the following assumptions to estimate fair value of the derivatives as of December 31, 2021 and 2020:

	December 31, 2021	December 31, 2020
Risk free interest	0.3%	0.12%
Market price of share	\$ 0.17	\$ 0.22
Life of instrument in years	0.31	1.31 – 1.60
Volatility	140%	147.4- 151.8%
Dividend yield	0%	0%

When the Company changes its valuation inputs for measuring financial liabilities at fair value, either due to changes in current market conditions or other factors, it may need to transfer those liabilities to another level in the hierarchy based on the new inputs used. The Company recognizes these transfers at the end of the reporting period that the transfers occur. For the years ended December 31, 2021 and 2020, there were no transfers of financial assets or financial liabilities between the hierarchy levels.

The \$2,625,000 of contingent consideration, of shares issuable to PointR shareholders which was recorded and associated with the PointR Merger, is also classified as Level 3 fair value measurements. The Company initially recorded the contingency based on a valuation conducted by a third-party valuation expert. The valuation was based on a probability of the completion of certain milestones by PointR for the shareholders to earn additional shares. The Company evaluated the probability of the earning of the milestones and concluded that the probability of achievement of the milestones had not changed, primarily due to the shifting of focus by the Company to develop AI technologies for the COVID-19 pandemic. As such, the Company did not record any change to the valuation during the years ended December 31, 2021 or 2020, respectively; and as of December 31, 2021 and 2020, respectively.

Net Income (Loss) Per Share

Basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted-average number of common shares outstanding during the period. Diluted net income (loss) per share includes the effect of Common Stock equivalents (notes convertible into Common Stock, stock options and warrants) when, under either the treasury or if-converted method, such inclusion in the computation would be dilutive. The following number of shares have been excluded from diluted loss since such inclusion would be anti-dilutive:

	Year ended December 31,	
	2021	2020
Convertible notes	69,544,900	20,237,084
Stock options	16,592,620	3,941,301
Warrants	53,314,424	18,702,500
Potentially dilutive securities	<u>139,451,944</u>	<u>42,880,885</u>

Stock-Based Compensation

The Company applies the provisions of ASC 718, Compensation—Stock Compensation (“ASC 718”), which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and non-employees, including employee stock options, in the statements of operations.

For stock options issued, the Company estimates the grant date fair value of each option using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the Common Stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the Common Stock. For awards subject to service-based vesting conditions, including those with a graded vesting schedule, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are recorded as they are incurred as opposed to being estimated at the time of grant and revised.

For warrants issued in connection with fund raising activities, the Company estimates the grant date fair value of each warrant using the Black-Scholes pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the warrant, the expected volatility of the Common Stock consistent with the expected life of the warrant, risk-free interest rates and expected dividend yields of the Common Stock. If the warrants are issued upon termination or cancellation of prior issued warrants, then the Company estimates the grant date fair value of the new warrants using the Black-Scholes pricing model and evaluates whether the new warrants are deemed as equity instruments or liability instruments. If the warrants are deemed to be equity instruments, the Company records stock compensation expense and an addition to additional paid in capital. If however, the warrants are deemed to be liability instruments, then the fair value is treated as a deemed dividend and credited to additional paid in capital.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including definite-lived intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of these assets is determined by comparing the forecasted undiscounted net cash flows of the operation to which the assets relate to the carrying amount. If the operation is determined to be unable to recover the carrying amount of its assets, then these assets are written down first, followed by other long-lived assets of the operation to fair value. Fair value is determined based on discounted cash flows or appraised values, depending on the nature of the assets. For the years ended December 31, 2021 and 2020, there were no impairment losses recognized for long-lived assets.

Intangible Assets

The Company records its intangible assets at cost in accordance with ASC 350, Intangibles – Goodwill and Other. The Company reviews the intangible assets for impairment on an annual basis or if events or changes in circumstances indicate it is more likely than not that they are impaired. These events could include a significant change in the business climate, legal factors, a decline in operating performance, competition, sale or disposition of a significant portion of the business, or other factors. If the review indicates the impairment, an impairment loss would be recorded for the difference of the value recorded and the new value. For the years ended December 31, 2021 and 2020, there were no impairment losses recognized for intangible assets.

Goodwill

Goodwill represents the excess of the purchase price of acquired business over the estimated fair value of the identifiable net assets acquired. Goodwill is not amortized but is tested for impairment at least once annually, at the reporting unit level or more frequently if events or changes in circumstances indicate that the asset might be impaired. The goodwill impairment test is applied by performing a qualitative assessment before calculating the fair value of the reporting unit. If, on the basis of qualitative factors, it is considered not more likely than not that the fair value of the reporting unit is less than the carrying amount, further testing of goodwill for impairment would not be required. Otherwise, goodwill impairment is tested using a two-step approach.

The first step involves comparing the fair value of the reporting unit to its carrying amount. If the fair value of the reporting unit is determined to be greater than its carrying amount, there is no impairment. If the reporting unit's carrying amount is determined to be greater than the fair value, the second step must be completed to measure the amount of impairment, if any. The second step involves calculating the implied fair value of goodwill by deducting the fair value of all tangible and intangible assets, excluding goodwill, of the reporting unit from the fair value of the reporting unit as determined in step one. The implied fair value of the goodwill in this step is compared to the carrying value of goodwill. If the implied fair value of the goodwill is less than the carrying value of the goodwill, an impairment loss equivalent to the difference is recorded. For the years ended December 31, 2021 and 2020, there were no impairment losses recognized for Goodwill.

Derivative Financial Instruments Indexed to the Company's Common Stock

We have generally issued derivative financial instruments, such as warrants, in connection with our equity offerings. We evaluate the terms of these derivative financial instruments in order to determine their accounting treatment in our financial statements. Key considerations include whether the financial instruments are freestanding and whether they contain conditional obligations. If the warrants are freestanding, do not contain conditional obligations and meet other classification criteria, we account for the warrants as an equity instrument. However, if the warrants contain conditional obligations, then we account for the warrants as a liability until the conditional obligations are met or are no longer relevant. Because no established market prices exist for the warrants that we issue in connection with our equity offerings, we must estimate the fair value of the warrants, which is as inherently subjective as it is for stock options, and for similar reasons as noted in the stock-based compensation section above. For financial instruments which are accounted for as a liability, we report any changes in their estimated fair values as gains or losses in our Consolidated Statement of Income.

Convertible Instruments

The Company evaluates and accounts for conversion options embedded in its convertible instruments in accordance with ASC 815 "Derivatives and Hedging".

ASC 815 generally provides three criteria that, if met, require companies to bifurcate conversion options from their host instruments and account for them as free standing derivative financial instruments. These three criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur, and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument. Professional standards also provide an exception to this rule when the host instrument is deemed to be conventional as defined under professional standards as “The Meaning of Conventional Convertible Debt Instrument.”

The Company accounts for convertible instruments (when it has determined that the embedded conversion options should not be bifurcated from their host instruments) in accordance with ASC 470-20 “Debt – Debt with Conversion and Other Options.” Accordingly, the Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying Common Stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Original issue discounts (“OID”) under these arrangements are amortized over the term of the related debt to their earliest date of redemption. The Company also records when necessary deemed dividends for the intrinsic value of conversion options embedded in preferred shares based upon the differences between the fair value of the underlying Common Stock at the commitment date of the note transaction and the effective conversion price embedded in the note.

ASC 815-40 “Derivatives and Hedging – Contracts in Entity’s Own Equity” provides that, among other things, generally, if an event occurs that is not within the entity’s control could or would require net cash settlement, then the contract shall be classified as an asset or a liability.

Variable Interest Entity (VIE) Accounting

The Company evaluates its ownership, contractual relationships and other interests in entities to determine the nature and extent of the interests, whether such interests are variable interests and whether the entities are VIEs in accordance with ASC 810, Consolidations. These evaluations can be complex and involve Management judgment as well as the use of estimates and assumptions based on available historical information, among other factors. Based on these evaluations, if the Company determines that it is the primary beneficiary of a VIE, the entity is consolidated into the financial statements. At December 31, 2021 and 2020, the Company identified EdgePoint to be the Company’s sole VIE. At December 31, 2021, and 2020, the Company’s ownership percentage of EdgePoint was 29% and 42.7%, respectively. The VIE’s net assets were \$0.1 million and \$0.2 million at December 31, 2021 and December 31, 2020, respectively.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers.

Under ASC 606, the Company recognizes revenue when its customers obtain control of the promised good or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. The Company applies the following five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company identifies the performance obligation(s) in the contract by assessing whether the goods or services promised within each contract are distinct. The Company then recognizes revenue for the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company anticipates generating revenues from rendering services to other third party customers for the development of certain drug products and/or in connection with certain out-licensing agreements. In the case of services rendered for development of the drugs, revenue is recognized upon the achievement of the performance obligations or over time on a straight-line basis over the extended service period. In the case of out-licensing contracts, the Company records revenues either (i) upon achievement of certain pre-defined milestones when there is no obligation of the Company to achieve any performance obligations in connection with the said pre-defined milestones, or (ii) upon achievement of the performance obligations if the milestones require the Company to provide the performance obligations.

The Company occasionally collects advance payments from customers toward commitments to provide services or performance obligations, in which case the advance payment is recorded as a liability until the obligations are fulfilled and revenue is recognized.

Research Service Agreement between GMP and Oncotelic /Oncotelic Inc. (“*Oncotelic Entities*”).

In February 2020, Oncotelic Inc. and GMP entered into a research and services agreement (the “*Agreement*”) memorializing their collaborative efforts to develop and test COVID-19 antisense therapeutics. In March 2020, the Company reported the positive anti-viral activity results of OT-101 (the “*Product*”) in an in vitro antiviral testing performed by an independent laboratory to GMP, at which time, the Oncotelic Entities and GMP entered into a supplement to the Agreement (the “*Supplement*”) to confirm the inclusion of the Product within the scope of the Agreement, pending positive confirmatory testing against COVID-19. In consideration for the financial support provided by GMP for the research, pursuant to the terms of the Agreement (as amended by the Supplement) GMP was entitled to obtain certain exclusive rights to the use of the Product in the COVID field on a global basis, and an economic interest in the use of the Product in the COVID field including 50/50 profit sharing. GMP paid the Company fees of \$0.3 million for the Agreement and \$0.9 million for the Supplement, respectively. The Company also recorded approximately \$40 thousand for reimbursement of actual costs incurred.

Agreement with Autotelic BIO (“*ATB*”)

Oncotelic Inc. had entered into a license agreement in February 2018 (the “*ATB Agreement*”) with ATB. The ATB Agreement licensed the use of OT-101 in combination with Interleukin-2 (the “*Combined Product*”), and granted to ATB an exclusive license under the Oncotelic Inc. technology to develop, make, have made, use, sell, offer for sale, import and export the Combined Product, and the Combination Product only, in the field, throughout the entire world (excluding the United States of America and Canada) as the territory, on the terms and subject to the conditions of the ATB Agreement. The ATB Agreement requires ATB to be responsible for the development of the Combination Product. Oncotelic Inc. was responsible to provide to ATB the technical know-how and other pertinent information on the development of the Combination Product. ATB paid Oncotelic Inc. a non-refundable milestone payment in consideration for the rights and licenses granted to ATB under the ATB Agreement, and ATB was to pay Oncotelic Inc. \$500,000 within sixty days from the successful completion of the in vivo efficacy studies. This payment was made after the successful completion of the in-vivo study and, as such, the Company recorded the revenue. In addition, ATB is to pay Oncotelic Inc.: (i) \$500,000 upon Oncotelic Inc.’s completion of the technology know how and Oncotelic Inc.’s technical assistance and regulatory consultation to ATB, as determined by the preparation of a Current Good Regulation Practices audit or certification by the Food and Drug Administration, with a mutual goal to obtain marketing approval of the Combined Product developed by ATB in the aforementioned territory; (ii) \$1,000,000 upon receiving marketing approval of the Combined Product in Japan, China, Brazil, Mexico, Russia, or Korea; and (iii) \$2,000,000 from receiving marketing approval of the Combined Product in Germany, France, Spain, Italy, or the United Kingdom. The Company recorded \$0 and \$500,000 as revenue under the ATB Agreement for the successful completion of the in-vivo study during the years ended December 31, 2021 and 2020, respectively.

Research & Development Costs

In accordance with ASC 730-10-25 “Research and Development”, research and development costs are charged to expense as and when incurred.

Recent Accounting Pronouncements

In August 2020, the FASB issued “ASU 2020-06, Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40)” (“ASU 2020-06”) which simplifies the accounting for convertible instruments. The guidance removes certain accounting models which separate the embedded conversion features from the host contract for convertible instruments. Either a modified retrospective method of transition or a fully retrospective method of transition was permissible for the adoption of this standard. Update No. 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption was permitted no earlier than the fiscal year beginning after December 15, 2020. The Company has not adopted ASU 2020-06 during the year 2021 and is evaluating the impact of implementation on its financial statements, if any.

All other newly issued but not yet effective accounting pronouncements have been deemed to be not applicable or immaterial to the Company.

NOTE 3 - ACQUISITIONS

2019 Reverse Merger with Oncotelic

The Company completed the merger with Oncotelic Inc. (“Merger”) in 2019. For more details, refer to our annual report on Form 10-K for the fiscal year 2020 filed by the Company on April 15, 2021.

2019 Merger with PointR

The Company completed the merger with PointR Data Inc (“PointR Merger”) in 2019. For more details, refer to our annual report on Form 10-K for the fiscal year 2020 filed by the Company on April 15, 2021.

NOTE 4 – GOODWILL AND INTANGIBLE ASSETS

Goodwill

The Company completed the Merger, which gave rise to Goodwill of \$4,879,999. Further, the Company added goodwill of \$16,182,456 upon the completion of the PointR Merger. In general, goodwill is tested on an annual impairment date of December 31. However, since both assets are currently being developed for various cancer and COVID-19 therapies, the Company does not believe there are any factors or indications that the goodwill is impaired.

Intangible Assets

In April 2018, Oncotelic Inc. entered into an Assignment and Assumption Agreement (the “Assignment Agreement”) with Autotelic Inc., an affiliate company, and Autotelic LLC, an affiliate company, pursuant to which Oncotelic acquired the rights to all intellectual property (“IP”) related to a patented product. As consideration for the Assignment Agreement, Oncotelic Inc. issued 204,798 shares of its Common Stock for a value of \$819,191. The Assignment Agreement also provides that Oncotelic Inc. shall be responsible for all costs related to the IP, including development and maintenance, going forward.

The following table summarizes the balances as of December 31, 2021 and 2020, respectively, of the intangible assets acquired, their useful life, and annual amortization:

	December 31, 2021	Remaining Estimated Useful Life (Years)
Intangible asset – Intellectual Property	\$ 819,191	17.00
Intangible asset – Capitalization of license cost	190,989	17.00
	<u>1,010,180</u>	
Less Accumulated Amortization	(188,339)	
Total	<u>\$ 821,841</u>	

	December 31, 2020	Remaining Estimated Useful Life (Years)
Intangible asset – Intellectual Property	\$ 819,191	18.00
Intangible asset – Capitalization of license cost	190,989	18.00
	<u>1,010,180</u>	
Less Accumulated Amortization	(136,974)	
Total	<u>\$ 873,206</u>	

Amortization of identifiable intangible assets for the year ended December 31, 2021 and 2020 was \$51,365 and \$51,366, respectively.

The future yearly amortization expense over the next five years and thereafter are as follows:

For the years ended December 31,		
2022	51,365	
2023	51,365	
2024	51,365	
2025	51,365	
2026	51,365	
Thereafter	<u>565,016</u>	
	<u><u>\$ 821,841</u></u>	

In-Process Research & Development (“IPR&D”) Summary

The IPR&D assets were acquired in the PointR Merger during the year ended December 31, 2019. Since January 2021, the Company has determined that the IPR&D should be reported as an indefinitely lived asset and therefore will evaluate, on an annual basis, for any impairment on the IPR&D and will record an impairment if identified. The balance of IPR&D as of December 31, 2021 and December 31, 2020 was \$1,101,760.

The following table summarizes the balances as of December 31, 2021 and 2020 of the IPR&D assets acquired in the PointR acquisition during the year ended December 31, 2019. The Company evaluates, on an annual basis, for any impairment and records an impairment if identified. The Company identified no impairment to IPR&D assets during its evaluation.

	December 31, 2021
Intangible asset – Intellectual Property	\$ 1,377,200
	<hr/>
Less Accumulated Amortization	(275,440)
Total	<hr/> \$ 1,101,760

	December 31, 2020
Intangible asset – Intellectual Property	\$ 1,377,200
	<hr/>
Less Accumulated Amortization	(275,440)
Total	<hr/> \$ 1,101,760

NOTE 5 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expense consists of the following amounts:

	December 31, 2021	December 31, 2020
Accounts payable	\$ 1,927,749	\$ 1,937,419
Accrued expenses	1,164,974	798,386
	<hr/>	<hr/>
	\$ 3,092,723	\$ 2,735,805
	December 31, 2021	December 31, 2020
Accounts payable – related party	<hr/> \$ 403,423	<hr/> \$ 391,631

NOTE 6 – CONVERTIBLE DEBENTURES, NOTES AND OTHER DEBT

As of December 31, 2021, special purchase agreements (SPAs) with convertible debentures and notes, net of debt discount and including accrued interest, if any, consist of the following amounts:

	December 31, 2021
Convertible debentures	
10% Convertible note payable, due April 23, 2022 – Bridge Investor	31,167
10% Convertible note payable, due April 23, 2022 – Related Party	144,951
10% Convertible note payable, due August 6, 2022 – Bridge Investor	188,319
	<hr/>
	364,437
Fall 2019 Notes	
5% Convertible note payable – Stephen Boesch	118,958
5% Convertible note payable – Related Party	276,233
5% Convertible note payable – Dr. Sanjay Jha (Through his family trust)	275,753
5% Convertible note payable – CEO, CTO* & CFO– Related Parties	90,357
5% Convertible note payable – Bridge Investors	185,122
	<hr/>
	946,423
August 2021 Convertible Notes	
5% Convertible note – Autotelic Inc– Related Party	256,634
5% Convertible note – Bridge investors	381,123
5% Convertible note – CFO – Related Party	76,531
	<hr/>
	714,288
Other Debt	
Short term debt from CEO	20,000
Short term debt – Bridge investors	265,000

Short term debt from CFO – Related Party	45,050
Short term debt – Autotelic Inc– Related Party	20,000
Accrued Interest on Loans	9,212
	<hr/>
	359,262
Total of debentures, notes and other debt	<hr/> <hr/> <hr/> \$ 2,384,410

* The CTO was a related party till July 2021, when he resigned as the CTO due to health reasons.

As of December 31, 2020, convertible debentures and notes, net of debt discount, consist of the following amounts:

	December 31, 2020
Convertible debentures	
10% Convertible note payable, due June 12, 2022 – Peak One	\$ -
10% Convertible note payable, due April 23, 2022 - TFK	39,065
10% Convertible note payable, due April 23, 2022 – Related Party	14,256
10% Convertible note payable, due April 23, 2022 – Bridge Investor	69,848
10% Convertible note payable, due August 6, 2022 – Bridge Investor	168,421
	291,590
Fall 2019 Notes	
5% Convertible note payable – Stephen Boesch	213,046
5% Convertible note payable – Related Party	263,733
5% Convertible note payable – Dr. Sanjay Jha (Through his family trust)	263,253
5% Convertible note payable – CEO, CTO & CFO – Related Parties	86,257
5% Convertible note payable – Bridge Investors	176,722
	1,003,011
Other Debt	
Short term debt from CFO – Related Party	25,000
Short term debt from CEO – Related Party	20,000
Other short term debt – Bridge Investor	50,000
	95,000
Total of debentures, notes and other debt	\$ 1,389,601

The gross principal balances on the convertible debentures listed above totaled \$1,000,000 and included an initial debt discount totaling \$800,140, resulting from the recording of the original issue discount, the related financing costs, the beneficial conversion feature (“BCF”) for the intrinsic value of the non-bifurcated conversion option and the restricted shares issued contemporaneously with the convertible notes.

Total amortization expense related to these debt discounts was \$139,417 and \$732,767 for the years ended December 31, 2021 and 2020, respectively. In addition, during the year ended December 31, 2021 and 2020, we recorded additional and accelerated amortization of debt discounts, which was created from the bifurcation of the conversion option related to the host hybrid instruments of \$24,491 and \$332,351 upon the partial and/or full conversion of debt by Peak One and TFK to shares of the Company’s common stock. The total unamortized debt discount at December 31, 2021 and 2020, was approximately \$35,564 and \$200,205.

All the above notes issued to Peak One, TFK, our CEO and the bridge investors reached the 180 days during the year ended December 31, 2020. As such, all the note holders had the ability to convert that debt into equity at the variable conversion price of 65% of the Company’s lowest traded price after the first 180 days or at the lower of the Fixed Price or 55% of the Company’s traded stock price under certain circumstances. This gave rise to a derivative liability for the debt instrument. As of December 31, 2020, we had a derivative liability of approximately \$777,000. The Company decreased the fair value of the derivative liability by approximately \$292,000 during the year ended December 31, 2021. The Company also extinguished approximately \$145,000 of derivative liability following the conversion of certain notes to the Company’s common stock during the year ended December 31, 2021.

The Company recorded additional derivative liability of approximately \$870,000 during the year ended December 31, 2020 since the conversion option attached to certain notes became convertible into a variable number of shares of our common stock. The Company also extinguished approximately \$679,000 of derivative liability following the conversion of certain notes to the Company's common stock during the year ended December 31, 2020. Following the recognition as derivative liability of the embedded conversion options, the Company fully amortized the remaining unamortized beneficial conversion feature for approximately \$232,000, recorded an initial \$258,070 from the initial recognition of the debt discount following the bifurcation of the embedded conversion option. As of December 31, 2021 and 2020, the Company had a derivative liability of approximately \$338,000 and \$777,000, respectively and a change in fair value of approximately \$295,000 and \$45,100, respectively.

Bridge Financing

Peak One Financing

On April 17, 2019, the Company entered into a Securities Purchase Agreement (the “*Purchase Agreement*”) with Peak One Opportunity Fund, L.P. (the “*Buyer*”, “*Peak One*”), for a commitment to purchase convertible notes in the aggregate amount of \$400,000, pursuant to which, for an aggregate purchase price of \$400,000, the Buyer purchased (a) Tranche #1 in the form of a Convertible Promissory Note in the principal amount of \$200,000 (the “*Convertible Note*”) and (b) 350,000 restricted shares of the Company’s Common Stock (the “*Shares*”) (the “*Purchase and Sale Transaction*”). The Company used the net proceeds from the Purchase and Sale Transaction for working capital and general corporate purposes.

The Convertible Note has a principal balance of \$200,000, including a 10% OID of \$20,000 and \$5,000 in debt issuance costs, receiving net proceeds of \$175,000, with a maturity date of April 23, 2022. Upon the occurrence of certain events of default, the Buyer, amongst other remedies, has the right to charge a penalty in a range of 18% to 40% dependent on the specific default event. Amounts due under the Convertible Note may also be converted into shares (the “*Tranche #1 Conversion Shares*”) of the Company’s Common Stock at any time, at the option of the holder, at (i) a conversion price, during the first 180 days, of \$0.10 per share (the “*Fixed Price*”), and then (2) at the lower of the Fixed Price or 65% of the Company’s lowest traded price after the first 180 days or at the lower of the Fixed Price or 55% of the Company’s traded stock price under certain circumstances. The Company has agreed to at all times, reserve and keep available out of its authorized Common Stock a number of shares equal to at least two times the full number of the Tranche #1 Conversion Shares. The Company may redeem the Convertible Note at rates of 110% to 140% over the principal balance dependent on certain events and redeem the value with accrued interest thereon, if any.

The issuance of the Convertible Note resulted in a discount from the beneficial conversion feature totaling \$84,570, including \$52,285 related to the beneficial conversion feature and a discount from the issuance of restricted stock of 350,000 shares for \$32,285. Total amortization of these OID and debt issuance cost discounts totaled \$84,376 for the year ended December 31, 2020. Total unamortized discount on this note was \$0 as of December 31, 2020.

In June, 2019, the Company entered into an amendment of the Purchase Agreement (“*Amendment #1*”) in connection with the draw-down of the second tranche, and to provide for additional borrowing capacity under that agreement. Amendment #1 increased the borrowing amount up to \$600,000, adding the ability to borrow an additional \$200,000 in a third tranche.

In June, 2019, the Buyer purchased Convertible Note Tranche #2 (“*Tranche #2*”) totaling \$200,000, including a 10% OID of \$20,000 and a \$1,000 debt issuance cost, receiving net proceeds of \$179,000 against the April 17, 2019, Purchase Agreement with Peak One, with a maturity date of June 12, 2022. Amounts due under Tranche #2 are convertible at the same terms as Tranche #1 above.

In November, 2019, the Company and Peak One amended the Convertible Note under Tranche #1 to extend the date of conversion of the Convertible Note into Common Stock of the Company at 65% of the traded price of the Company's Common Stock until January 8, 2020. This amendment put a temporary hold on Peak One to convert the debt under Tranche 1. This restriction did not apply if Peak One opted to convert the Convertible Note at \$0.10. The Company compensated Peak One 300,000 shares of the Company's Common Stock for delaying the conversion until January 18, 2020. Such shares were issued to Peak One on November 14, 2019. Non-cash compensation expense of \$60,000 was recorded for such issuance.

Peak One converted \$200,000 of Tranche #1 out of their total debt into 2,581,945 shares of the Company during the year ended December 31, 2020. Further, Peak One converted \$200,000 of Tranche #2 of their total debt into 2,000,000 shares of the Company during the year ended December 31, 2020. As such, the total outstanding debt for Peak One was \$0 as of December 31, 2020.

The issuance of Tranche #2 resulted in a discount from the beneficial conversion feature totaling \$180,000, including \$132,091 related to the conversion feature and a discount from the issuance of restricted stock of 350,000 shares for \$47,909. Total amortization of these OID and debt issuance cost discounts totaled \$37,046 for the year ended December 31, 2019. Total unamortized discount on this note was \$163,954 as of December 31, 2019. Total amortization of these OID and debt issuance cost discounts totaled \$55,208 for the twelve months ended December 31, 2020. Total unamortized discount on this note was \$108,746 as of December 31, 2020.

TFK Financing

On April 23, 2019, the Company, entered into a Convertible Note (the "TFK Note") with TFK Investments, LLC ("TFK"). The TFK Note has a principal balance of \$200,000, including a 10% OID of \$20,000 and \$5,000 in debt issuance costs, receiving net proceeds of \$175,000, with a maturity date of April 23, 2022. Upon the occurrence of certain events of default, the Buyer, amongst other remedies, has the right to charge a penalty in a range of 18% to 40% dependent on the specific default event. Amounts due under the Convertible Note may also be converted into shares (the "TFK Conversion Shares") of the Company's Common Stock at any time, at (i) a conversion price, during the first 180 days, of \$0.10 per share (the "Fixed Price"), and then (2) at the lower of the Fixed Price or 65% of the Company's lowest traded price after the first 180 days or at the lower of the Fixed Price or 55% of the Company's traded stock price under certain circumstances. The Company has agreed to at all times reserve and keep available out of its authorized Common Stock a number of shares equal to at least two times the full number of the TFK Conversion Shares. The Company may redeem the Convertible Note at rates of 110% to 140% rates over the principal balance dependent on certain events and redeem the value with accrued interest thereon, if any.

The issuance of the TFK Note resulted in a discount from the beneficial conversion feature totaling \$84,570, including \$52,285 related to the beneficial conversion feature and a discount from the issuance of restricted, stock of 350,000 shares for \$32,285. Total amortization of these OID and debt issuance cost discounts totaled \$3,015 and \$81,362 for the year ended December 31, 2021 and 2020. Total unamortized discount on this note was \$0 and \$3,015 as of December 31, 2021 and 2020.

In November 2019, the Company and TFK amended the TFK Convertible Note to extend the date of conversion of the Convertible Note into Common Stock of the Company at 65% of the traded price of the Company's Common Stock until January 8, 2020. This restriction did not apply if TFK wished to convert the Convertible Note at \$0.10 per share. The Company compensated TFK 300,000 shares of the Company's Common Stock for delaying the conversion until January 8, 2020. Such shares were issued to TFK on November 14, 2019. Non-cash compensation expense of \$60,000 was recorded for such issuance.

TFK converted \$133,430 of their total debt into 1,950,000 shares of common stock of the Company during the year ended December 31, 2020. As such, the total gross outstanding debt for TFK was approximately \$67,000 as of December 31, 2020. TFK had a balance of approximately \$109,000 related to the derivative liability as of December 31, 2020. During the year ended December 31, 2021, the Company recorded approximately \$38,000 as an increase in fair value for the derivative liability, leaving a balance associated with TFK of approximately \$145,000 of derivative liability. During the year ended December 31, 2021, TFK converted their remaining debt balance of approximately \$65,000 into 657,200 shares of common stock. In connection with the conversion, the Company reclassified \$145,000 of derivative liability to equity. The balance outstanding on the TFK debt amounted to \$0 at December 31, 2021.

Notes with a Related Party and Bridge Investor

In April 2019, the Company entered into a Securities Purchase Agreement (the “*Bridge SPA*”) with our CEO, a related party, and the Bridge Investor with a commitment to purchase convertible notes in the aggregate of \$400,000.

In April 2019, the Company entered into a convertible note with our Chief Executive Officer, Vuong Trieu, Ph. D. (the “*Trieu Note*”). The Trieu Note has a principal balance of \$164,444, including a 10% OID of \$16,444, resulting in net proceeds of \$148,000, with a maturity date of April 23, 2022. Upon the occurrence of certain events of default, the Buyer, amongst other remedies, has the right to charge a penalty in a range of 18% to 40% dependent on the specific default event. Amounts due under the Convertible Note may also be converted into shares (the “*Trieu Conversion Shares*”) of the Company’s Common Stock at any time, at the option of the holder, at a conversion price of \$0.10 per share (the “*Fixed Price*”), at the lower of the Fixed Price or 65% of the Company’s lowest traded price after the 180th day or at the lower of the Fixed Price or 55% of the Company’s traded stock price under certain circumstances. The Company has agreed to at all times reserve and keep available out of its authorized Common Stock a number of shares equal to at least two times the full number of Conversion Shares. The Company may redeem the Convertible Note at rates of 110% to 140% rates over the principal balance dependent on certain events and redeem the value with accrued interest thereon, if any.

The issuance of the Trieu Note resulted in a discount from the beneficial conversion feature totaling \$131,555 related to the conversion feature. Total amortization of the 10% OID discount and beneficial conversion feature totaled \$75,103 and \$5,464 for the year ended December 31, 2021 and 2020. Total unamortized discount on this note was \$19,493 and \$7,199 as of December 31, 2021 and 2020.

On April 23, 2019, pursuant to the Bridge SPA the Company entered into Convertible Note Tranche #1 (“*Tranche #1*”) with the Bridge Investor. Tranche #1 has a principal balance of \$35,556, an OID of \$3,556, resulting in net proceeds of \$32,000, with a maturity date of April 23, 2022. Upon the occurrence of certain events of default, the Buyer, among other remedies, has the right to charge a penalty in a range of 18% to 40% dependent on the specific default event. Amounts due under Tranche #1 may also be converted into shares (the “*Bridge SPA Conversion Shares*”) of the Company’s Common Stock at any time, at (i) a conversion price, during the first 180 days, of \$0.10 per share (the “*Fixed Price*”), and then (2) at the lower of the Fixed Price or 65% of the Company’s lowest traded price after the first 180 days or at the lower of the Fixed Price or 55% of the Company’s traded stock price under certain circumstances. The Company may redeem the Convertible Note at rates of 110% to 140% rates over the principal balance dependent on certain events and redeem the value with accrued interest thereon, if any.

The issuance of the note resulted in a discount from the beneficial conversion feature totaling \$28,445. Total amortization of the OID and discount totaled \$16,911 and \$1,344 for the year ended December 31, 2021 and 2020. Total unamortized discount on this note was \$4,389 and \$1,393 as of December 31, 2021 and 2020.

On August 6, 2019, pursuant to the Bridge SPA the Company entered into Convertible Note Tranche #2 (“*Tranche #2*”) with the Bridge Investor. Tranche #2 has a principal balance of \$200,000, an OID of \$20,000 and debt issuance costs of \$5,000, resulting in net proceeds of \$175,000, with a maturity date of August 6, 2022. Upon the occurrence of certain events of default, the Buyer, among other remedies, has the right to charge a penalty in a range of 18% to 40% dependent on the specific default event. Amounts due under Tranche #1 may also be converted into Bridge Conversion Shares of the Company’s Common Stock at any time, at the option of the holder, at a conversion price equal to the Fixed Price, at the lower of the Fixed Price or 65% of the Company’s lowest traded price after the 180th day or at the lower of the Fixed Price or 55% of the Company’s traded stock price under certain circumstances. The Company may redeem the Convertible Note at rates of 110% to 140% rates over the principal balance dependent on certain events and redeem the value with accrued interest thereon, if any.

The issuance of the note resulted in a discount from the beneficial conversion feature totaling \$175,000. Total amortization of the OID and discount totaled \$19,898 and \$159,860 for the year ended December 31, 2021 and 2020. Total unamortized discount on this note was \$11,681 and \$13,315 as of December 31, 2021 and 2020.

All the above notes issued to Peak One, TFK, our CEO and the bridge investors reached the 180 days prior to the end of the year ended December 31, 2020. As such, all the note holders had the ability to convert that debt into equity at the variable conversion price of 65% of the Company's lowest traded price after the first 180 days or at the lower of the Fixed Price or 55% of the Company's traded stock price under certain circumstances. As of December 31, 2021, Peak One and TFK had fully converted their notes.

Fall 2019 Debt Financing

In December 2019, the Company closed its Fall 2019 Debt Financing, raising an additional \$500,000 bringing the gross proceeds of all debt financings under the Fall 2019 Debt Financing to \$1,000,000. The Company entered into those certain Note Purchase Agreements (the "*Fall 2019 Note Purchase Agreements*") with certain accredited investors and the officers of the Company for the sale of convertible promissory notes (the "*Fall 2019 Notes*"). The Company completed the initial closing under the Fall 2019 Note Purchase Agreements in November 2019. The Company issued Fall 2019 Notes in the principal amount of \$250,000 to each of Dr. Vuong Trieu, the Company's Chief Executive Officer, and Stephen Boesch, in exchange for gross proceeds of \$500,000. In connection with the second and final closing of the Fall 2019 Debt Financing, the Company issued Fall 2019 Notes to additional investors including \$250,000 to Dr. Sanjay Jha, through his family trust, the former CEO of Motorola and COO/President of Qualcomm. The Company also offset certain amounts due to Dr. Vuong Trieu, the Company's Chief Executive Officer, Chulho Park, the Company's Chief Technology Officer, and Amit Shah, the Company's Chief Financial Officer, all related parties as Officers of the Company, and converted such amounts due into the Fall 2019 Notes. \$35,000 due to Dr. Vuong Trieu, \$27,000 due to Chulho Park and \$20,000 due to Amit Shah were converted into debt. The Company also issued the Fall 2019 Notes of \$168,000 to two accredited investors. The Company repaid \$0 and \$100,000 of principal in the three and twelve ended December 31, 2021. The total unamortized principal amount of the Fall 2019 Notes was \$850,000 and \$950,000 as of December 31, 2021 and 2020, respectively.

All the Fall 2019 Notes provided for interest at the rate of 5% per annum and are unsecured. All amounts outstanding under the Fall 2019 Notes became due and payable upon the approval of the holders of a majority of the principal amount of outstanding Fall 2019 Notes (the "*Majority Holders*") on or after (a) November 23, 2020 or (b) the occurrence of an event of default (either, the "*Maturity Date*"). The Majority Holders have waived the default in the maturity of the Fall 2019 Notes and as such there is no event of default. The Company had the option to prepay the Fall 2019 Notes at any time. Events of default under the Fall 2019 Notes included failure to make payments under the Fall 2019 Notes within thirty (30) days of the date due, failure to observe of the Fall 2019 Note Purchase Agreement or Fall 2019 Notes which is not cured within thirty (30) days of notice of the breach, bankruptcy, or a change in control of the Company (as defined in the Fall 2019 Note Purchase Agreement).

The Majority Holders had the right, at any time not more than five (5) days following the Maturity Date, to elect to convert all, and not less than all, of the outstanding accrued and unpaid interest and principal on the Fall 2019 Notes. The Fall 2019 Notes may be converted, at the election of the Majority Holders, either (a) into shares of the Company's Common Stock at a conversion price of \$0.18 per share, or (b) into shares of common stock of the Edgepoint, at a conversion price of \$5.00 (based on a \$5.0 million pre-money valuation) of Edgepoint and 1,000,000 shares outstanding. The issuance of the Fall 2019 notes resulted in a discount from the BCF totaling \$222,222 related to the conversion feature. Total amortization of the discount totaled \$0 and \$200,000 for the year ended December 31, 2021 and 2020. Total unamortized discount on this note was \$0 as of December 31, 2021 and 2020.

Further, the Company recorded interest expense of \$43,412 and \$49,142 on these Fall 2019 Notes for the year ended December 31, 2021 and 2020. The total amount outstanding under the Fall 2019 Notes, net of discounts and including accrued interest thereon, as of December 31, 2021 and 2020 was \$946,424 and \$1,003,011, respectively.

Geneva Roth Remark Notes

In May and June 2021, the Company entered into Securities Purchase Agreement with Geneva Roth Remark Holdings Inc. (“Geneva”), whereby the Company issued two convertible notes in the aggregate principal amount of \$307,500 convertible into shares of common stock of the Company with additional tranches of financing of up to \$1,200,000 in the aggregate term of the note. The convertible notes carry a six (6%) percent coupon and a default coupon of 22%, and both mature one year from issuance. Geneva has the right from time to time, and at any time during the period beginning on the date which is one hundred eighty (180) days following issuance date and ending on the maturity date to convert all or any part of the outstanding and unpaid amount of the note into the Company’s common stock at a conversion price established at sixty five (65%) percent multiplied by the lowest two (2) daily volume weighted average price over the fifteen (15) consecutive trading days. The convertible notes carry a put feature, at the option of Geneva, whereby upon the occurrence of certain events of default, the convertible notes repayment should be accelerated, in the amount of principal plus accrued but unpaid interest plus default interest, in cash with premium.

The notes were prepaid in December 2021 and the Company recorded interest expense, including prepayment penalty of \$75,195. There was no similar expense recorded in 2020. The total amount outstanding under the Geneva Notes as of December 31, 2021 was \$0.

Paycheck Protection Program

In April 2020, the Company received loan proceeds in the amount of \$250,000 under the Paycheck Protection Program (“1st PPP”) which was established under the Coronavirus Aid, Relief and Economic Security (“CARES”) Act and is administered by the Small Business Administration (“SBA”). The 1st PPP provides loans to qualifying businesses in amounts up to 2.5 times the average monthly payroll expenses and was designed to provide direct financial incentive to qualifying businesses to keep their workforce employed during the Coronavirus crisis. The Payment Protection Plan loans (“PPP Loans”) are uncollateralized and guaranteed by the SBA and forgivable after a “covered period” (8 weeks or 24 weeks) as long as the borrower maintained its payroll levels and uses the loan proceeds for eligible expenses, including payroll, benefits, mortgage interest, rent and utilities. The forgiveness amount would be reduced if the borrower terminated employees or reduced salaries and wages more than 25% during the covered period. Any unforgiven portion was payable over 2 years if issued before, or 5 years if issued after, June 5, 2020 at an interest rate of 1% with payments deferred until the SBA remits the borrowers loan forgiveness amount to the lender, or if the borrower did not apply for forgiveness, 10 months after the covered period. PPP loans provide for customary events of default, including payment defaults, breach of representations and warranties, and insolvency events and may be accelerated upon occurrence of one or more of these events of default. Additionally, the PPP Loans do not include prepayment penalties.

The Company met the 1st PPP loan forgiveness requirements and on August 7, 2021 applied for forgiveness. On Aug 17, 2021, the Company received the 1st PPP loan forgiveness approval from the lender and wrote off the loan outstanding amount inclusive of interest accrued, in the amount of \$253,347. The Company recorded the amount forgiven as forgiveness income within the other income (expense) section of its statement of operations. The balance outstanding on 1st PPP loan, inclusive of accrued interest, was \$0 and \$251,733 on December 31, 2021 and December 31, 2020, respectively.

In July 2021, the Company’s wholly owned subsidiary, PointR, received loan proceeds in the amount of \$92,995 under the PPP (“2nd PPP”). The 2nd PPP was at terms similar to the 1st PPP. The Company met the 2nd PPP loan forgiveness requirements and received the 2nd PPP loan forgiveness approval from the lender on December 8, 2021 and wrote off the loan outstanding amount inclusive of interest accrued, in the amount of \$93,413. The Company recorded the amount forgiven as forgiveness income within the other income (expense) section of its statement of operations. The balance outstanding on the 2nd PPP loan was \$0 and \$0 on December 31, 2021 and 2020, respectively.

The SBA reserves the right to audit any PPP loan, regardless of size. These audits may occur after the forgiveness has been granted. In accordance with the CARES Act, all borrowers are required to maintain their PPP loan documentation for six years after the loan was forgiven or repaid in full and to provide that documentation to the SBA upon request.

GMP Notes

In June 2020, the Company secured \$2 million in debt financing, evidenced by a one-year convertible note (the “*GMP Note*”) from GMP, to conduct a clinical trial evaluating OT-101 against COVID-19 bearing 2% annual interest, and is personally guaranteed by Dr. Vuong Trieu, the Chief Executive Officer of the Company. The GMP Note is convertible into the Company’s Common Stock upon the GMP Note’s maturity of the GMP Note, at the Company’s Common Stock price on the date of conversion with no discount. GMP has waived the default in the maturity of the GMP Note and as such there is no event of default and also agreed to extend the date of maturity of the GMP Note to June 30, 2022. GMP does not have the option to convert prior to the GMP Note’s maturity. Such financing will be utilized solely to fund the clinical trial. The Company’s liability under GMP Note commenced to accrue when GMP first began to pay for services related to the clinical trial to our third-party clinical research organization, up to a maximum of \$2 million. GMP has been invoiced by the clinical research organization for the full \$2 million as of December 31, 2021 and as such the Company has recognized the liability as a convertible debt.

In September 2021, the Company secured a further \$1.5 million in debt financing, evidenced by a one-year convertible note (the “*GMP Note 2*”) from GMP, to fund the same clinical trial evaluating OT-101 against COVID-19 bearing 2% annual interest. The GMP Note is convertible into the Company’s Common Stock upon the GMP Note 2’s maturity one year from the date of the GMP Note 2, at the Company’s Common Stock price on the date of conversion with no discount. GMP does not have the option to convert prior to the GMP Note 2’s maturity at the end of one year. Such financing will be utilized solely to fund the clinical trial. As of September 30, 2021, GMP was invoiced by the clinical research organization for \$0.5 million. GMP paid the clinical trial organization the first tranche of \$0.5 million in October 2021.

In October 2021, the Company entered into an Unsecured Convertible Note Purchase Agreement (the “*October Purchase Agreement*”) with GMP, pursuant to which the Company issued a convertible promissory note in the aggregate principal amount of \$0.5 million (the “*October 2021 Note*”), which October 2021 Note is convertible into shares of the Company’s Common Stock.

The GMP Note 2 and the October 2021 Note carries an interest rate of 2% per annum and matures on the earlier of (a) the one-year anniversary of the date of the Purchase Agreement, or (b) the acceleration of the maturity by GMP upon occurrence of an Event of Default (as defined below). The GMP Note 2 and October 2021 Note contains a voluntary conversion mechanism whereby GMP may convert the outstanding principal and accrued interest under the terms of the GMP Note 2 and October 2021 Note into shares of Common Stock (the “*Conversion Shares*”), at the consolidated closing bid price of the Company’s Common Stock on the applicable OTC Market as of the date the Company receives a Notice of Conversion from GMP. Prepayment of the GMP Note 2 and October 2021 Note may be made at any time by payment of the outstanding principal amount plus accrued and unpaid interest. The October Note contains customary events of default (each an “*Event of Default*”). If an Event of Default occurs, at GMP’s election, the outstanding principal amount of the GMP Note 2 and October 2021 Note, plus accrued but unpaid interest, will become immediately due and payable in cash. The October Purchase Agreement requires the Company to use of the proceeds received under the October 2021 Note to support the clinical development of OT-101, including payroll and has been made in continuation of the relationship between the Company and GMP.

The total principal outstanding on all the GMP notes, inclusive of accrued interest, was \$4,069,781 and \$2,060,493 as of December 31, 2021 and 2020, respectively.

August 2021 Convertible Notes

In August 2021, the Company entered into Note Purchase Agreements with Autotelic - a related party, our CFO – a related party, and certain accredited investors (the “*August 2021 investors*”), whereby the Company issued four convertible notes in the aggregate principal amount of \$698,500 convertible into shares of common stock of the Company for net proceeds of \$690,825. The convertible notes carry a five (5%) percent coupon and mature one year from issuance. The majority of the August 2021 investors have the right, but not the obligation, not more than five days following the maturity date, to convert all, but not less than all, the outstanding and unpaid principal plus accrued interest into the Company’s common stock, at a conversion price of \$0.18. The Company determined that the economic characteristics and risks of the embedded conversion option are not clearly and closely related to the economic characteristics and risks of the debt host instrument. Further, the Company determined that the embedded conversion feature meets the definition of a derivative but met the scope exception to the derivative accounting required under ASC 815 for certain contracts involving a reporting entity’s own equity.

As of December 31, 2021 and 2020, convertible notes, net of debt discount, consist of the following amounts:

	December 31, 2021	December 31, 2020
Autotelic - related party convertible note, 5% coupon August 2022	\$ 256,634	\$ -
CFO convertible note – Related Party, 5% coupon August 2022	76,531	
2 accredited investors convertible note, 5% coupon August 2022	381,123	-
	\$ 714,288	\$ -

During the year ended December 31, 2021, the Company recognized approximately \$16,000 of interest expense on the August 2021 Investors notes of which approximately \$6,600 are attributable to related parties. No similar expense was recorded on such notes during the same periods of 2020.

November – December 2021 Financing

In November and December 2021, the Company entered into securities purchase agreement with five institutional investors, whereby the Company issued five convertible notes in the aggregate principal amount of \$1,250,000 convertible into shares of common stock of the Company. The convertible notes carry a twelve (12%) percent coupon and a default coupon of 16% and mature at the earliest of one year from issuance or upon event of default. Investors has the right at any time following issuance date to convert all or any part of the outstanding and unpaid amount of the note into the Company's common stock at a conversion price established at a fixed rate of \$0.07. The Company granted a total number of 9,615,385 warrants convertible into an equivalent number of the Company common shares at a strike price of \$0.13 up to five years after issuance. The Placement agent was also granted a total amount of 961,540 as part of a finder's fee agreement.

As of December 31, 2021, and December 31, 2020, convertible notes under the November-December 2021 Financing, net of debt discount, consist of the following amounts:

	December 31, 2021	December 31, 2020
Mast Hill Convertible note, 12% coupon November 21	\$ 250,000	\$ -
Talos Victory Convertible note, 12% coupon November 2021	250,000	-
First Fire Global Opportunities LLC Convertible note, 12% coupon, December 2021	250,000	-
Blue Lake Partners LLC Convertible note, 12% coupon, December 2021	250,000	-
Fourth Man LLC Convertible note, 12% coupon December 2021	250,000	-
Convertible notes, gross	\$ 1,250,000	\$ -
Less: Debt discounts recorded	(1,250,000)	-
Amortization of debt discounts	76,994	
Convertible notes, net of discounts	\$ 76,994	-

The Company recognized approximately \$10,300 and \$0 of accrued interest during the year ended December 31, 2021, and 2020, respectively. The Company recognized approximately \$77,000 and \$0 of interest expense attributable to the amortization of the debt discount from the original debt discount, deferred financing costs, fair value allocated to the warrants and the beneficial conversion feature during the year ended December 31, 2021, and 2020, respectively.

The Company recorded an initial debt discount of approximately \$0.3 million representing the intrinsic value of the conversion option embedded in the convertible debt instrument based upon the difference between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. The Company recognized amortization expense related to the debt discount and debt issuance costs of approximately \$0.1 million for the year ended December 31, 2021, which is included in interest expense in the consolidated statements of operations.

Other short-term advances

As of December 31, 2021, other short-term advances consist of the following amounts obtained from various employees and related parties:

Other Advances	December 31, 2021
Short term advance from CEO – Related Party	\$ 20,000
Short term advances – bridge investors	265,000
Short term advances from CFO – Related Party	45,050
Short term advance – Autotelic Inc. – Related Party	20,000
Accrued Interest on advances	9,212
	\$ 359,262

During the year ended December 31, 2020, the Company's CEO provided additional funding of \$70,000 to the Company, of which \$50,000 was repaid before December 31, 2020. As such, \$20,000 and \$70,000 was outstanding at December 31, 2021 and December 31, 2020, respectively.

During the year ended December 31, 2021, Autotelic Inc. provided a short-term funding of \$120,000 to the Company, which was repaid in 2021. In May 2021, Autotelic provided an additional short-term funding of \$250,000 to the Company, which was converted into the August 2021 Notes. Autotelic provided an additional \$20,000 short-term loan to the Company, and as such, \$20,000 was outstanding and payable to Autotelic at December 31, 2021.

During the year ended December 31, 2021, the Company's CFO, a related Party, provided short term advances of approximately \$45,000. During the year ended December 31, 2020, the Company's CFO had provided a short term advance of \$25,000, which was repaid during the year ended December 31, 2021. As such approximately \$45,000 and \$25,000 was outstanding at December 31, 2021 and December 31, 2020, respectively.

NOTE 7 - PRIVATE PLACEMENT AND JH DARBIE FINANCING

Since July 2020 to March 2021, the Company entered into subscription agreements with certain accredited investors pursuant to the JH Darbie Financing, whereby the Company issued and sold a total of 100 Units, for total gross proceeds of approximately \$5 million, pursuant to the JH Darbie Placement Agreement, with each Unit consisting of:

- 25,000 shares of Edgepoint Common Stock for a price of \$1.00 per share of Edgepoint Common Stock.
- One convertible promissory note, convertible into up to 25,000 shares of Edgepoint Common Stock, at a conversion price of \$1.00 per share or up to 138,889 shares of the Company's Common Stock, at a conversion price of \$0.18 per share.
- 50,000 warrants to purchase an equivalent number of shares of Edgepoint Common Stock at \$1.00 per share or an equivalent number of shares of the Company's Common Stock at \$0.20 per share with a three-year expiration date.

As of December 31, 2021 and 2020, debt recorded under the JH Darbie Financing, net of debt discounts, consist of the following amounts:

	December 31, 2021	December 31, 2020
Convertible promissory notes		
Subscription agreements - accredited investors	\$ 2,353,253	\$ 943,586
Subscription agreements – related party	109,046	67,992
Total convertible promissory notes	\$ 2,462,299	\$ 1,011,578

The Company incurred approximately \$0.64 million of issuance costs, including legal costs of approximately \$39,000, that are incremental costs directly related to the issuance of the various instruments bundled in the offering.

Concurrently with the sale of the Units, JH Darbie was granted, for nominal consideration, a warrant, exercisable over a five-year period, to purchase 10% of the number of Units sold in the JH Darbie Financing. As such, the Company granted 10 Units to JH Darbie pursuant to the JH Darbie Placement Agreement.

The terms of convertible notes are summarized as follows:

- Term: Through March 31, 2022.
- Coupon: 16%.
- Convertible at the option of the holder at any time in the Company's Common Stock or Edgepoint Common Stock.
- The conversion price is initially set at \$0.18 per share for the Company's Common Stock or \$1.00 for Edgepoint Common Stock, subject to adjustment.

The Company allocated the proceeds among the freestanding financial instruments that were issued in the single transaction using the relative fair value method, which affects the determination of each financial instrument initial carrying amount. The Company utilized the relative fair value method as none of the freestanding financial instruments issued as part of the single transaction are measured at fair value. Under the relative fair value method, the Company made separate estimates of the fair value of each freestanding financial instrument and then allocated the proceeds in proportion to those fair value amounts. The Company recorded aggregate non-controlling interests of approximately \$1.8 million in Edgepoint between 2021 and 2020. Non-controlling interests represent the portion of net assets in consolidated entities that are not owned by the Company and are reported as a component of equity in the consolidated balance sheets.

As of the multiple closings of the Company, during the year ended December 31, 2021, under the private placement memorandum with JH Darbie, the estimated volume weighted grant date fair value of approximately \$0.23 per share associated with the warrants to purchase up to 2,035,000 shares of common stock issued in this offering, or a total of approximately \$0.5 million, was recorded to additional paid-in capital on a relative fair value basis. All warrants sold in this offering had an exercise price of \$0.20 per share of the Company stock or \$1.00 per share of Edge Point, subject to adjustment, are exercisable immediately and expire three years from the date of issuance. The fair value of the warrants was estimated using a Black Scholes valuation models using the following input values

Expected Term	1.5 years
Expected volatility	152.3%-164.8%
Risk-free interest rates	0.09%-0.11%
Dividend yields	0.00%

As of the multiple closings of the Company, during the year ended December 31, 2020, under the private placement memorandum with JH Darbie, the estimated grant date fair value of approximately \$0.18 per share associated with the warrants to purchase up to 3,465,000 shares of common stock issued in this offering, or a total of approximately \$0.4 million, was recorded to additional paid-in capital on a relative fair value basis. All warrants sold in this offering had an exercise price of \$0.20 per share of the Company stock or \$1.00 per share of Edge Point, subject to adjustment, are exercisable immediately and expire three years from the date of issuance. The fair value of the warrants was estimated using a Black Scholes valuation models using the following input values.

Expected Term	1.5 years
Expected volatility	168.5%-191.9%
Risk-free interest rates	0.12%-0.15%
Dividend yields	0.00%

The Company recorded an initial debt discount of approximately \$0.6 and \$0.7 million during the years ended December 31, 2021 and 2020, respectively, representing the intrinsic value of the conversion option embedded in the convertible debt instrument based upon the difference between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note.

The Company recognized amortization expense related to the debt discount and debt issuance costs of \$1,229,865 and \$412,318 for the years ended December 31, 2021, and 2020, respectively, which is included in interest expense in the statements of operations.

In June 2021, the Company executed amendment #4 to the private placement memorandum. Originally, the investor was granted 50,000 of the Company's warrants to purchase an equivalent number of shares of the Company's common stock at a strike price of \$0.20 or 50,000 warrants to purchase an equivalent number of Edgepoint's common share at strike price of \$1.00. However, the PPM was written in a way that the investor could only invest in \$10,000 of common stock of the Company (50,000 shares of common stock at \$0.20 per share) or \$50,000 (50,000 shares of common stock in Edgepoint AI, Inc. at \$1.00 per share). In conjunction with amendment #4, the Company approved the issuance of an additional 20,000,000 warrants to purchase shares of common stock of the Company to the investors in the 100 Units and 2,000,000 warrants to purchase shares of common stock of the Company to the Placement Agent at the same terms and conditions of the PPM. To clarify further, each unit will receive additional 200,000 warrants to purchase an equivalent number of shares of the Company's common stock at \$0.20 per share, so as to make it overall 250,000 warrants to buy an equivalent number of shares of the Company's common stock, for which the investor would pay a total of \$50,000 per unit invested upon exercise.

In connection with the additional 22 million warrants issued by the Company pursuant to amendment #4, the Company recorded a charge to earnings of approximately \$2.0 million during the year ended December 31, 2021. No similar expense was recorded during the same period of 2020. The fair value of the warrants was estimated using a Black Scholes valuation model using the following input values.

Expected Term	1-2 years
Expected volatility	94.4%-130.0%
Risk-free interest rates	0.08%-0.25%
Dividend yields	0.00%

In February 2022, the Company and all except one of the Investors agreed to extend the maturity date of the Notes from March 31, 2022, to March 31, 2023. In consideration for the extension of the Notes, the Company issued to the Investors an aggregate of 33,000,066 Oncotelic Warrants at a price of \$0.15 per share of Company's Common Stock. Each Investor will be entitled to receive 333,334 Oncotelic Warrants for each Unit purchased.

NOTE 8 - RELATED PARTY TRANSACTIONS

Master Service Agreement with Autotelic Inc.

In October 2015, Oncotelic Inc. entered into a Master Service Agreement (the "MSA") with Autotelic Inc. ("Autotelic"), a related party that is partly owned by Dr. Trieu. Dr. Trieu, a related party, is a control person in Autotelic. Autotelic currently owns less than 10% of the Company. The MSA stated that Autotelic will provide business functions and services to the Company and allowed Autotelic to charge the Company for these expenses paid on its behalf. The MSA includes personnel costs allocated based on amount of time incurred and other services such as consultant fees, clinical studies, conferences and other operating expenses incurred on behalf of the Company. The MSA requires a 90-day written termination notice in the event either party requires to terminate such services.

Expenses related to the MSA were \$276,763 and \$629,617 for the years ended December 31, 2021 and 2020, respectively. Amounts outstanding at the end of the year 2021 and 2020 were \$269,872 and \$0, respectively.

In September 2021, the Company entered into an exclusive License Agreement (the “Agreement”) with Autotelic, pursuant to which Autotelic granted Oncotelic, among other things: (i) the exclusive right and license to certain Autotelic Patents (as defined in the Agreement) and Autotelic Know-How (as defined in the Agreement); and (ii) a right of first refusal to acquire at least a majority of the outstanding capital stock of Autotelic prior to Autotelic entering into any transaction that is a financing collaboration, distribution revenues, earn-outs, sales, out-licensing, purchases, debt, royalties, merger acquisition, change of control, transfer of cash or non-cash assets, disposition of capital stock by way of tender or exchange offer, partnership or any other joint or collaborative venture, research collaboration, material transfer, sponsored research or similar transaction or agreements. In exchange for the rights granted to Oncotelic, Autotelic would be entitled to earn the following milestone payments (collectively, the “Milestone Payments”).

Milestones	Transaction Value	Actions
Tranche 1	\$ 1,000,000	Upon the earlier to occur of: (i) the Company receiving an investment of at least \$20 million, and (ii) the uplisting of the Company’s common stock to any NASDAQ market or the New York Stock Exchange.
Tranche 2	\$ 2,000,000	Upon approval by the United States Food and Drug Administration of the Company’s 505(b)2 application for purposes of treating PD.
Tranche 3	\$ 2,000,000	Upon first patient in (“FPI”) for any clinical trial supporting the use of AL-101 for the treatment of PD or ED.
Tranche 4	\$ 2,500,000	Upon FPI for phase 2 clinical trials supporting the use of AL-101 to treat FSD.
Tranche 5	\$ 2,500,000	Upon FPI for phase 3 clinical trials supporting the use of AL-101 to treat FSD
Tranche 6	\$ 10,000,000	Upon Marketing approval for the use of AL-101 to treat PD.
Tranche 7	\$ 10,000,000	Upon Marketing approval for the use of AL-101 to treat ED.
Tranche 8	\$ 10,000,000	Upon Marketing approval for the use of AL-101 to treat FSD
Tranche 9	\$ 10,000,000	Upon the earlier of: (i) the Company entering into a licensing agreement with a third party for the use of AL-101 for the treatment of PD, ED or FSD with an aggregate licensing value of at least \$50 million; and (ii) the Company’s gross revenue derived from sales of AL-101 for the treatment of PD, ED or FSD reaches at least \$50.0 million.

In addition to the Milestone Payments, Autotelic will be entitled to royalties equal to 15% of the net sales of any products that incorporate the Autotelic Patents or Autotelic Know-How. The Agreement contains representations, warranties and indemnification provisions of each of the parties thereto that are customary for transactions of this type.

Notes Payable and Short-Term Loan – Related Party

In April 2019, the Company issued a convertible note to Dr. Trieu totaling \$164,444, including OID of \$16,444, receiving net proceeds of \$148,000, which was used by the Company for working capital and general corporate purposes (See Note 6). The Company issued a Fall 2019 Note to Dr. Trieu in the principal amount of \$250,000. Dr. Trieu also offset certain amounts due to him in the amount of \$35,000 and was converted into the Fall 2019 debt. During the year ended December 31, 2020, Dr. Trieu provided additional short-term funding of \$70,000 to the Company, of which the Company repaid \$50,000 prior to December 31, 2020. As such the Company owed \$20,000 for the short term loan as of December 31, 2021. During the year ended December 31, 2020, Dr. Trieu purchased a total of 5 Units under the private placement for a gross total of \$250,000.

During the year ended December 31, 2021, Autotelic Inc, provided a short-term loan of \$120,000 to the Company, which was repaid in April 2021. During the year ended December 31, 2021, Autotelic Inc. provided a short-term loan of \$250,000 to the Company, which was converted into the August 2021 Convertible Note. Further, Autotelic Inc. provided a short term advance of \$20,000 which was outstanding at December 31, 2021.

During the year ended December 31, 2021, the CFO provided approximately \$120,000 of short term advances to the Company, of which \$75,000 was converted into the August 2021 Note. During the year ended December 31, 2020, the CFO provided \$25,000 of advances to the Company, which were repaid during the year ended December 31, 2021. As such, the Company owed \$20,000 under the Fall 2019 Notes, \$75,000 under the August 2021 Notes and approximately \$45,000 as short term advances as of December 31, 2021.

Artius Consulting Agreement

On March 9, 2020, the Company and Artius Bioconsulting, LLC (“Artius”), for which Mr. Steven King, our Board and Committee member, is the Managing Member, entered into an amendment to that certain Consulting Agreement dated December 1, 2018 (the “*Artius Agreement*”), under which Artius agreed to serve as a consultant to the Company for services related to the Company’s business from time to time, effective December 1, 2019 (the “*Artius Agreement Effective Date*”). In connection with the Artius Agreement, Mr. King also agreed to assist the Company with strategic advisory services with respect to transactional and operational contracts, budgetary input, among other matters in connection with the development EdgePoint AI’s Artificial Intelligence and Blockchain Driven Vision Systems, for which Mr. King serves as Chief Executive Officer.

Under the terms of the Artius Agreement, the Company agreed to grant to Artius, subject to approval by the Company’s Board of Directors and pursuant to the Company’s 2015 Equity Incentive Plan, 148,837 restricted shares of the Company’s Common Stock, in addition to a 30% pre-financing ownership stake in EdgePoint AI. The Artius Agreement contemplates that Mr. King will generally provide his services at a rate of \$237 per hour, not to exceed 44 hours per month and payable monthly, and to reimburse Mr. King for reasonable and necessary expenses incurred by him or Artius in connection with providing services to the Company.

Either the Company or Artius may terminate the Artius Agreement at any time, for any reason following the Artius Agreement Effective Date. The Artius Agreement will automatically renew one year from the Artius Agreement Effective Date, unless the Parties agree to terminate the Artius Agreement at that time.

The Company recorded \$0 and \$106,712 as expense during the year ended December 31, 2021 and 2020, respectively, related to this Agreement.

Maida Consulting Agreement

Effective May 5, 2020, the Company and Dr. Anthony Maida, one of our Board and Committee members, entered into an independent consulting agreement, commencing April 1, 2020 (the “*Maida Agreement*”), under which Dr. Maida will assist the Company in providing medical expertise and advice from time to time in the design, conduct and oversight of the Company’s existing and future clinical trials.

Pursuant to the terms of the Maida Agreement, the Company will grant to Dr. Maida 400,000 restricted shares or stock options of the Company’s Common Stock corresponding to \$80,000 at the stock value of \$0.20 per share, to vest on May 5, 2021. The Company will also pay Dr. Maida \$15,000 per month for a minimum of 20 hours per week, in addition to reimbursement of reasonable and necessary expenses incurred by Dr. Maida in connection with his services to the Company.

Either the Company or Dr. Maida may terminate the Maida Agreement, for any reason, upon 30 days advance written notice.

Dr. Maida was appointed the Chief Clinical Director for the Company effective July 7, 2020. As of the date of this Report, Dr. Maida continues to provide his services under the consulting agreement.

The Company recorded \$215,000 and \$135,000 as expense under the consulting agreement during the year ended December 31, 2021 and 2020 respectively.

NOTE 9 - EQUITY PURCHASE AGREEMENT AND REGISTRATION RIGHTS AGREEMENT

On May 3, 2021, the Company entered into an Equity Purchase Agreement (“EPL”) and Registration Rights Agreement with Peak One Opportunity Fund LP (“Peak One” or the “Investor”). Under the terms of the EPL, the Company issued 250,000 shares of Common Stock to Peak One. Further, under the terms of the EPL, Peak One agreed to purchase from the Company up to \$10,000,000 of the Company’s Common Stock upon effectiveness of a registration statement on Form S-1 filed with the U.S. Securities and Exchange Commission and subject to certain limitations and conditions set forth in the Equity Purchase Agreement. The Registration Rights Agreement provided that the Company would (i) file the Registration Statement with the SEC by July 2, 2021; and (ii) use its best efforts to have the Registration Statement declared effective by the Commission at the earliest possible date (in any event, within 90 days after the execution date of the definitive agreements). The Company filed a Registration Statement on Form S-1 with the Commission on May 24, 2021, and the Form S-1 was declared effective on June 2, 2021.

Following effectiveness of the Registration Statement, and subject to certain limitations and conditions set forth in the Equity Purchase Agreement, the Company shall have the discretion to deliver put notices to the Investor and the Investor will be obligated to purchase shares of the Company's Common Stock based on the investment amount specified in each put notice. The minimum amount that the Company shall be entitled to put to the Investor in each put notice is \$20,000 and the maximum amount is up to the lesser of \$1.0 million or two hundred fifty percent (250%) of the average daily trading volume of the Company's Common Stock defined as the average trading volume of the Company's Common Stock in the ten (10) days preceding the date on the put notice multiplied by the lowest closing bid price in the ten (10) immediately preceding the date of the put notice. Pursuant to the Equity Purchase Agreement, the Investor will not be permitted to purchase, and the Company may not put shares of the Company's Common Stock to the Investor that would result in the Investor's beneficial ownership of the Company's outstanding Common Stock exceeding 4.99%. The price of each put share shall be equal to ninety one percent (91%) of the market price, which is defined as the lesser of (i) closing bid price of the Common stock on the trading date immediately preceding the respective put date, or (ii) the lowest closing bid price of the Common Stock during the seven (7) trading days immediately following the clearing date associated with the applicable put notice.

In connection with the EPL, the Company issued 250,000 shares of Common Stock to Peak One and recorded a fair value in lieu of service of approximately \$70,000.

During the year ended December 31, 2021, the Company sold a total of 3,435,000 shares of Common Stock at prices ranging from \$0.09 and \$0.23 for total net proceeds of approximately \$420,000.

NOTE 10 – STOCKHOLDERS' EQUITY

The following transactions affected the Company's Stockholders' Equity:

Equity Transactions During the Period Since the Merger

Issuance and conversion of Preferred Stock

In April 2019, pursuant to the Oncotelic merger the Company issued 193,713 shares of Series A Preferred in exchange for 77,154 shares of Oncotelic Common Stock. Further, in November 2019 the Company issued 84,475 shares of Series A Preferred to PointR in exchange of 11,135,935 shares of PointR Common Stock upon the consummation of the PointR merger. In March 2021, 278,188 shares of the Company's preferred stock converted to 278,187,847 shares of its Common Stock, effective March 31, 2021.

Issuance of Common Stock during the year ended December 31, 2021

During the year ended December 31, 2021, the Company issued 657,200 shares of its Common Stock to TFK in connection with the partial but final conversion of their convertible notes payable. As such, the debt outstanding to TFK at December 31, 2021 was \$0.

During the year ended December 31, 2021, the Company issued a total of 1,148,235 shares of its Common Stock to various service providers for services rendered. A total cost of approximately \$194,000 was recorded for such services.

During the year ended December 31, 2021, the Company sold 3,435,000 shares of its Common Stock in connection with the EPL for cash at prices ranging from \$0.09 to \$0.23 per share of Common Stock. The Company received a total of approximately \$420,000 against such sale of its Common Stock.

During the third quarter of 2021, the Company issued 1,257,952 shares of Common Stock to its employees in lieu of fully vested restricted stock units ("RSUs") under the 2015 Equity Incentive Plan. The Company recorded a stock-based compensation cost of \$226,431 related to such issuance.

In connection with the fully vested RSUs, the Company estimated the fair value using the stock price as of the date of issuance as the RSUs were fully vested and issued as Common Stock of the Company. As such, there were no unvested RSUs as of December 31, 2021.

Issuance of Common Stock during the year ended December 31, 2020

During the year ended December 31, 2020, the Company issued 6,531,945 shares of its Common Stock to Peak One in connection with the full conversion of its Tranche 1 Note and partial conversion of its Tranche 2 Note; and TFK in connection with the partial conversions of its Note (See Note 6 for more information)

NOTE 11 – STOCK-BASED COMPENSATION

Options

Pursuant to the Merger, the Company's Common Stock and corresponding outstanding options survived. The below information details the Company's associated option activity pre and post-merger.

As of December 31, 2021, options to purchase the Company's Common Stock were outstanding under three stock option plans – the 2017 Equity Incentive Plan (the “2017 Plan”), the 2015 Equity Incentive Plan (the “2015 Plan”) and the 2005 Stock Plan (the “2005 Plan”). Under the 2017 Plan, up to 2,000,000 shares of the Company's Common Stock may be issued pursuant to awards granted in the form of nonqualified stock options, restricted and unrestricted stock awards, and other stock-based awards. Under the 2015 and 2005 Plans, taken together, up to 7,250,000 shares of the Company's Common Stock may be issued pursuant to awards granted in the form of incentive stock options, nonqualified stock options, restricted and unrestricted stock awards, and other stock-based awards.

Employees, consultants, and directors are eligible for awards granted under the 2017 and 2015 Plans. Since the adoption of the 2015 Plan, no further awards may be granted under the 2005 Plan, although options previously granted remain outstanding in accordance with their terms. Further, the shareholders of the Company have approved the expansion of the pool available under the 2015 Plan up to 20,000,000 shares of the Company's Common Stock that may be issued pursuant to awards granted in the form of nonqualified stock options, restricted and unrestricted stock awards, and other stock-based awards.

A summary of stock option activity for the years ended December 31, 2021 and 2020 are summarized as follows:

For the year ended December 31, 2021	Weighted Average	
	Shares	Exercise Price
Outstanding at January 1, 2021	3,941,301	\$ 0.78
Granted	12,652,761	0.15
Expired or cancelled	(1,442)	19.80
Outstanding at December 31, 2021	<u>16,592,620</u>	<u>\$ 0.30</u>

For the year ended December 31, 2020

	Shares	Weighted Average Exercise Price
Outstanding at January 2020	6,145,044	\$ 0.75
Expired or canceled	(2,203,743)	0.70
Outstanding at December 31, 2020	3,941,301	\$ 0.78

The following table summarizes information about options to purchase shares of the Company's Common Stock outstanding and exercisable at December 31, 2021:

Exercise prices	Outstanding Options	Weighted-Average Remaining Life In Years	Weighted-Average Exercise Price	Number Exercisable
\$ 0.14	7,150,000	9.67	\$ 0.14	530,000
0.16	5,502,761	9.51	0.16	5,502,761
0.22	1,750,000	4.33	0.22	1,750,000
0.38	900,000	3.65	0.38	900,000
0.73	762,500	3.28	0.73	762,500
1.37	150,000	1.49	1.37	150,000
1.43	300,000	3.40	1.43	300,000
11.88	2,359	0.005	11.88	2,359
15.00	75,000	3.40	15.00	75,000
	16,592,620	8.22	\$ 0.30	9,972,620

The compensation expense attributed to the issuance of the options is recognized as they are vested.

The employee stock option plan stock options are generally exercisable for ten years from the grant date and vest over various terms from the grant date to three years.

The aggregate intrinsic value totaled approximately \$0.2 million and was based on the Company's closing stock price of \$0.17 as of December 31, 2021, which would have been received by the option holders had all option holders exercised their options as of that date. Correspondingly, the aggregate intrinsic value totaled approximately \$0.1 million and was based on the Company's closing stock price of \$0.22 as of December 31, 2020, which would have been received by the option holders had all option holders exercised their options as of that date.

As of December 31, 2021, there was approximately \$0.4 million of unamortized stock compensation cost related to the stock options granted during the year.

In August 2019, the Company entered into Employment Agreements and incentive compensation arrangements with each of its executive officers, including Dr. Vuong Trieu, the Chief Executive Officer; Dr. Fatih Uckun, the Chief Medical Officer; Dr. Chulho Park, its Chief Technology Officer; and Mr. Amit Shah, the Chief Financial Officer. The incentive stock options and the restricted stock awards approved for the Company's executive officers were granted and issued in July 2021. The Company issued an aggregate of 1,257,952 of its common shares in lieu of fully vested restricted stock units and 4,244,809 incentive and non-qualified stock options to purchase its Common Stock to all its employees, including the awards due to the CEO, CFO, the prior CTO and Saran Saund, the Chief Business Officer of the Company. Further, the Company issued all its employees, including the CEO and CBO and consultants 4,325,000 performance-based stock options that would vest over two tranches subject to certain corporate goals being achieved, of which none have vested as of December 31, 2021. In addition, the Company granted its Board of Directors 2,825,000 stock options, which for the Board of Directors vest over 5 quarters commencing the quarter ended September 30, 2021. Of the options granted to the Board members, 353,333 have vested as of December 31, 2021.

The Company recorded stock-based compensation of \$763,314 for stock options vested during the year ended December 31, 2021 and for those expected to vest. No similar expense was recorded during the same periods in 2020. The grant date fair value of stock options granted during 2021 was assessed using a Black Scholes valuation model using the following input values.

Expected Term	2.25 year
Expected volatility	129.9 – 131.4%
Risk-free interest rates	0.22%
Dividend yields	0.00%

In addition, the Company recorded stock-based compensation of \$226,432 for the fully vested restricted stock units issued during the year ended December 31, 2021. No similar expense was recorded during the same periods in 2020. The fair value of the restricted units was calculated using the stock price of the restricted stock units on the date of the grant. All restricted stock units granted during 2021 vested immediately upon issuance.

Warrants

During the year ended December 31, 2020, the Company offered to cancel to all the prior warrants of the warrant holders from the 2018 debt financing and offered to reissue new warrants to such warrant holders. Out of all the warrant holders, holders of 13,750,000 warrants opted to participate in the reissuance. In addition, the Company issued 3,465,000 new warrants to certain accredited investors in connection with the financing through JH Darbie (See note 7).

During the year ended December 31, 2021, 2,035,000 warrants were issued in connection with the financing through JH Darbie (See note 7). The fair value of these warrants on issue date amounted to \$467,637 as calculated using a Black Scholes valuation model. The Company also issued 22,000,000 warrants in connection with the financing through JH Darbie (See note 7). The fair value of these warrants on the issue date amounted to \$2,190,127 as calculated using a Black Scholes valuation model. Further, the Company issued 10,576,924 warrants related to the November/December 2021 Notes (See Note 6). The fair value of these warrants on issue date amounted to \$1,172,753 as calculated using a Black Scholes valuation model.

The issuance of warrants to purchase shares of the Company's Common Stock, including those attributed to debt issuances, for the years ended December 31, 2021 and 2020, respectively are summarized as follows:

For the year ended December 31, 2021	Weighted-Average	
	Shares	Exercise Price
Outstanding at January 1, 2021	18,702,500	\$ 0.20
Issued during the year ended December 31, 2021	34,611,924	0.13-0.20
Outstanding at December 31, 2021	53,314,424	\$ 0.20

For the year ended December 31, 2020	Shares	Weighted-Average Exercise Price
Outstanding at January 1, 2020	19,515,787	\$ 0.60
Issued during the year ended December 31, 2020	17,215,000	0.20
Expired or cancelled	<u>(18,028,287)</u>	0.63
Outstanding at December 31, 2020	<u>18,702,500</u>	<u>\$ 0.20</u>

The following table summarizes information about warrants outstanding and exercisable at December 31, 2021:

Exercise Price	Outstanding and exercisable				Number Exercisable
	Number Outstanding	Weighted-Average Remaining Life in Years	Weighted-Average Exercise Price		
\$ 0.20	1,487,500	1.33	\$ 0.20	1,487,500	
0.20	27,500,000	1.25	0.20	27,500,000	
0.20	13,750,000	1.23	0.20	13,750,000	
0.13	10,576,924	5.0	0.13	10,576,924	
	<u>53,314,424</u>	<u>1.97</u>	<u>\$ 0.19</u>	<u>53,314,424</u>	

For more information on the grant fair values and Black Scholes valuation method input values related to the JH Darbie Financing, refer to Note 7 of the Consolidated Notes to the Financial Statements.

13,750,000 warrants were issued during the year ended December 31, 2020 and the Company recorded stock-based compensation of approximately \$2.1 million as the fair value of the warrants using a Black Scholes valuation model using the following input values. The expense attributed to the issuances of the warrants was recognized as they vested/earned. These warrants were exercisable for three to five years from the grant date. All the warrants are currently exercisable

Expected Term	3 years
Expected volatility	140.5%
Risk-free interest rates	1.40%
Dividend yields	0.00%

10,576,924 warrants were issued in November and December 2021. The fair value of these warrants on issue dates amounted to \$1,172,753 with an expected life of 5 years, as calculated using a Black Scholes valuation model, using the following input values

Expected Term	5 years
Expected volatility	132.4-132.8%
Risk-free interest rates	0.67-0.81%
Dividend yields	0.00%

NOTE 12 – INCOME TAXES

Significant components of the Company's deferred tax assets and liabilities for federal and state income taxes as of December 31, 2021 and 2020 are as follows in thousands:

	December 31, 2021	December 31, 2020
Deferred tax assets:		
Stock-based compensation	\$ 1,164	\$ 1,164
Assets	5,736	6,227
Liability accruals	361	173
R&D Credit	4,792	4,760
Capital Loss	528	528
Deferred state tax	(2,246)	(2,086)
Net operating loss carry forward	57,343	56,090
Total gross deferred tax assets	67,678	66,856
Less - valuation allowance	(67,678)	(66,856)
Net deferred tax assets	<u>\$ -</u>	<u>\$ -</u>

The Company had gross deferred tax assets of approximately \$67.7 million and \$66.9 million as of December 31, 2021 and 2020, respectively, which primarily relate to net operating loss carryforwards.

As of December 31, 2021 and 2020, the Company had gross federal net operating loss carryforwards of approximately \$236.1 million and \$237.7 million, respectively, which are available to offset future taxable income, if any. The Company recorded a valuation allowance in the full amount of its net deferred tax assets since realization of such tax benefits has been determined by our management to be unlikely.

At December 31, 2021 and 2020, the Company had California state gross operating loss carry-forwards of approximately \$76.3 and \$69.8 million, which will expire in various amounts from 2028 through 2040. At December 31, 2020, the Company had federal research and development tax credits of approximately \$3.3 million which will expire in 2021 and California state research and development tax credits of approximately \$1.4 million which have no expiration date.

The Company identified its federal and California state tax returns as “major” tax jurisdictions. The periods our income tax returns are subject to examination for these jurisdictions are 2016 through 2019. We believe our income tax filing positions and deductions will be sustained on audit, and we do not anticipate any adjustments that would result in a material change to our financial position. Therefore, no liabilities for uncertain income tax positions have been recorded. The Company filed its 2020 federal and state corporate tax returns in October 2021.

Portions of these carryforwards will expire through 2038, if not otherwise utilized. The Company's utilization of net operating loss carryforwards could be subject to an annual limitation because of certain past or future events, such as stock sales or other equity events constituting a “change in ownership” under the provisions of Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitations could result in the expiration of net operating loss carryforwards and tax credits before they can be utilized. We have not performed a formal analysis, but we believe our ability to use such net operating losses and tax credit carryforwards will be subject to annual limitations, due to change of ownership control provisions under Section 382 and 383 of the Internal Revenue Code, which would significantly impact our ability to realize these deferred tax assets.

NOTE 13 – COMMITMENTS AND CONTINGENCIES

Leases

Currently, the Company is leasing the office located at 29397 Agoura Road, Suite 107, Agoura Hills, CA 91301 on a month-to-month basis until such time a new office is identified. The Company believes the office is sufficient for its current operations.

Legal Claims

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. The Company is not presently a party to any legal proceedings that it currently believes, if determined adversely to the Company, would individually or taken together have a material adverse effect on the Company's business, operating results, financial condition or cash flows.

PointR Merger Consideration

The total purchase price of \$17,831,427 represented the consideration transferred from the Company in the PointR Merger and was calculated based on the number of shares of Common Stock plus the preferred shares outstanding but convertible into Common Stock outstanding at the date of the PointR Merger and includes \$2,625,000 of contingent consideration of shares issuable to PointR shareholders, which can increase to \$15 million of contingent consideration, upon achievement of certain milestones. The \$2,625,000 of contingent consideration of shares issuable to PointR shareholders was recorded and associated with the PointR Merger is also classified as Level 3 fair value measurements. The Company initially recorded the contingency based on a valuation conducted by a third-party valuation expert. The valuation was based on a probability of the completion of certain milestones by PointR for the shareholders to earn additional shares. The Company evaluated the probability of the earning of the milestones and concluded that the probability of achievement of the milestones had not changed, primarily due to the shifting of focus by the Company to develop AI technologies for the COVID-19 pandemic. As such, the Company did not record any change to the valuation during the years ended and as of December 31, 2021 or 2020, respectively.

NOTE 14 – SUBSEQUENT EVENTS

GMP Notes

In January 2022, the Company entered into an Unsecured Convertible Note Purchase Agreement with GMP (the "Purchase Agreement"), pursuant to which the Company issued a convertible promissory note in the aggregate principal amount of \$0.5 million (the "Note"), which Note is convertible into shares of the Company's common stock, par value \$0.01 per share ("Common Stock"). The Note and Purchase Agreement are both part of a series of a cumulative funding of up to \$1.5 million in three equal monthly instalments. The Note was entered into as continuation of the relationship between the Company and GMP moving to formation of a joint venture.

The Purchase Agreements and the Notes contain identical terms to the securities purchase agreements (and promissory notes issued thereunder), to Golden Mountain Partners, LLC on October 25, 2021. (See Note 6). The Purchase Agreement requires the Company to use of the proceeds received under the Note to support payroll and development of OT-101.

JH Darbie Financing

Commencing July 2020 to March 2021, the Company entered into subscription agreements with certain accredited investors pursuant to the JH Darbie Financing, whereby the Company issued and sold a total of 100 Units, for total gross proceeds of approximately \$5 million, pursuant to the JH Darbie Placement Agreement. (See Note 7)

In February 2022, the Company and all except one of the Investors agreed to extend the maturity date of the Notes from March 31, 2022, to March 31, 2023. In consideration for the extension of the Notes, the Company issued to the Investors an aggregate of 33,000,066 Oncotelic Warrants at a price of \$0.15 per share of Company's Common Stock. Each Investor will be entitled to receive 333,334 Oncotelic Warrants for each Unit purchased.

November/December 2021 Notes

In January 2022, three of the five note holders under the November and December 2021 Notes exercised their warrants to purchase shares of Common Stock of the Company on a cashless basis. As such, the Company issued the note holders 3,041,958 shares of Common Stock.

On March 29, 2022, the Company entered into a securities purchase agreement, note and issued warrants to purchase 1,250,000 shares of the Common Stock with one of the 5 institutional investors for an additional \$250,000 of gross proceeds. The terms of the securities purchases agreements and notes are the same as those contained in the November/December 2021

agreements and notes, except with references to the conversion price of the notes increasing to \$0.10 from \$0.07 and the warrant exercise price to \$0.20 from \$0.13. For more information on the notes, refer to Note 6: November – December 2021 Financing of the Notes to the Consolidated Financial Statements.

JV with GMP Bio

The Company entered into a JV with Dragon Overseas Capital Limited (“*Dragon Overseas*”) and GMP Biotechnology Limited (“*GMP Bio*”), affiliates of GMP on March 31, 2022. GMP Bio will be owned by Dragon Overseas and the Company in a 55% to 45% ratio. Dragon Overseas will contribute about \$28 million in cash and assets into GMP Bio and the Company will input the licenses for OT-101 for US and Ex-US rights into GMP Bio. GMP Bio will develop OT-101 for multiple oncology pharmaceutical indications. The Company is currently evaluating the accounting and reporting requirements for this transaction.

For more information on the JV, refer to our Current Report on form 8-K filed with the SEC on April 6, 2022.