ONCOTELIC PROVIDES YE 2021 FINANCIAL RESULTS COMPARED TO YE 2020, PRODUCT DEVELOPMET INITIATIVES AND CORPORATE UPDATE

AGOURA HILLS, Calif., April 18, 2022 (GLOBE NEWSWIRE) -- Oncotelic Therapeutics, Inc. ("*Oncotelic*", "*We*" or the "*Company*") (OTCQB:OTLC) today announced financial results for the full year ended December 31, 2021 ("*FY 2021*") as compared to the full year ended December 31, 2020 ("*FY 2020*"), an update on its product and therapeutic development initiatives and other corporate updates. The financial results were based on the 2021 Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 15, 2022.

FY 2021 compared to FY 2020 Financial Results Overview

ONCOTELIC THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31

	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 FY 2021, compared to a net loss of approximately $10 million for FY 2020. The increased loss from operations was due to reduced revenues of approximately $1.7 million, generated during FY 2020 as against no revenues during the FY 2021, offset by operational expenses of approximately $0.2 million. In addition, part of the operating loss was offset by approximately $0.3 million for the PPP loan forgiveness, approximately $0.3 million of a lower loss on conversion of debt and approximately $0.3 million for change in value of derivatives recorded during FY 2021 as compared FY 2020.

Revenue

We recorded services revenue of $0 for FY 2021 as compared to approximately $1.7 million during FY 2020. The services revenue recorded in 2020 primarily comprised of $1.2 million from services provided to Golden Mountain Partners ("*GMP*") in connection with the development of OT-101 for COVID-19. We also recorded $0.5 million of revenues from Autotelic Bio upon the successful completion of the in-vivo efficacy studies based on the agreement between Oncotelic and Autotelic Bio.

Research and Development Expense

Research and Development ("*R&D*") expense decreased by approximately $0.6 million, from approximately $4.3 million for FY 2020 as compared to approximately $3.7 million for FY 2021. The decrease of approximately $0.6 million in the R&D activities was 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.

General and Administrative Expense

General and administrative ("*G&A*") expense increased by approximately $0.4 million, from approximately $5.4 million for FY 2021 as compared to $5.0 for FY 2020. The increase in G&A expenses was primarily due to approximately $1 million of higher 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.

Change in value of derivatives

During FY 2021, we recorded a gain of $0.3 million due to the change in value of derivatives on certain notes. Correspondingly, during FY 2020, we recorded a nominal loss due to the change in value of derivatives of $45 thousand on certain notes.

Interest Expense

We recorded interest expense, including amortization of debt costs, of $2.0 million for FY 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 FY 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

As the end of FY 2021, the Company had approximately $0.6 million in cash and current liabilities of approximately $15.5 million. Since the Company successfully established the joint venture with Dragon Overseas, the Company is expected to reduce its expenses significantly.

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	$ 95	$ 412

Operating Activities

Net cash used in operating activities was approximately $4.3 million for FY 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.

Financing Activities

For FY 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, approximately $2.8 million raised through issuance of convertible debt, including approximately $1.25 million from five institutional investors, $0.7 million from the CEO, the CFO and 2 bridge investors, $0.5 million of convertible debt provided by GMP, and $0.4 million of other short term loans offset by repayment of $0.4 million of convertible debt due to Geneva and repayment of $0.2 million of other notes.

Highlights for Q4 2021 and thereafter:

In October 2021, the Company entered into an unsecured convertible note purchase agreement with GMP, pursuant to which the Company issued a convertible promissory note in the aggregate principal amount of $0.5 million, which note is convertible into shares of the Company's Common Stock. In January 2022, the Company entered into an unsecured convertible note purchase agreement with GMP, pursuant to which the Company issued a convertible promissory note in the aggregate principal amount of $0.5 million, which note is convertible into shares of the Company's Common Stock. The Company entered into a joint venture ("*JV*") with Dragon Overseas Capital Limited ("*Dragon Overseas*") and GMP Biotechnology Limited ("*GMP Bio*"), both affiliates of GMP, on March 31, 2022. GMP Bio will be owned by Dragon Overseas and the Company in a 55% to 45% ratio, respectively. 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.

In September 2021, the Company entered into an exclusive License Agreement (the "*Agreement*") with Autotelic, Inc. ("*Autotelic*"), pursuant to which Autotelic granted the Company the exclusive right and license to certain Autotelic Patents and Know-How and 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 as defined in the agreement. 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 and royalties equal to 15% of the net sales of any products that incorporate the Autotelic Patents or Autotelic Know-How. With the outlicensing of OT-101 to the JV, AL-101 will be the Company's primary product for development against Parkinson's Disease, erectile dysfunction and female sexual dysfunction.

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 have 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. Further, 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.

"FY 2021 was a challenging, but an exciting year for all of us at Oncotelic," said Amit Shah, CFO of Oncotelic. "We expect FY 2022 to be more exciting, with the completion and the evolution of our JV so that the OT-101 asset can be developed rapidly. At the same time, we shall be leveraging on our previous successes along the 505(b)2 strategy for the development of AL-101 as our lead fast to market drug candidate for the Company. Going forward, with the cash requirement of the Company significantly reduced due to unburdening the development and commercialization cost of OT-101, we anticipate our operational expenses will reduce significantly. We are also contemplating and evaluating uplisting the Company to a national stock exchange to complete the corporate turnaround."

Additional information is included in the Company's Form 10-K for the year ended December 31, 2021, filed on April 15, 2022, a copy of which is available free of charge at https://investor.Oncotelic.com/sec-filings.

Recent Corporate Update

On March 31, 2022, we completed the formation of a JV, with Dragon Overseas, called GMP Bio. Dragon Overseas and GMP Bio are affiliated with GMP. "As previously announced, we are excited to begin this new and exciting partnership with Dragon Overseas, with whom we have formed a JV for

the discovery, development and commercialization of TGF-β therapeutics against all pharmaceutical indications for OT-101," said Dr. Vuong Trieu, CEO and Chairman of Oncotelic. "Now that we have achieved our first objective for out-licensing OT-101, we will be looking to repositioning CA4P and Oxi4503 and maximizing their values to shareholders. Steve King - our BOD- and myself were part of the team under the late Dr. Phil Thorpe who founded Vascular Disruption Agent ("VDA") in 1997 - and we look forward to revitalize the field as originally envisioned by Dr. Thorpe."

Additional information as to corporate strategy and additional information on the JV can be found at:

https://www.youtube.com/watch?v=sr3qbea_mCM&t=35s

https://www.youtube.com/watch?v=Ys4V5qZt4sA&t=19s

Analyst comment on the JV can be found at: https://www.oncotelic.com/wp-content/uploads/2022/03/OTLC-JV-update.pdf

Other highlights of the transaction include:

- Oncotelic to receive up to $50 million on sale of the RPD voucher following marketing approval of OT-101 for diffuse intrinsic pontine glioma, or DIPG.
- Dragon Overseas has agreed to invest cash and other assets with a value of approximately $27.6 million for 55% ownership of the JV.
- Oncotelic has licensed OT-101 to the JV for a 45% ownership in the JV.
- The JV to be headquartered in Hong Kong.
- Initial focus on the further development and commercialization of OT-101, including for DIPG as well as pancreatic cancers and glioblastoma.
- The JV is planned to be taken into an IPO at a future point in time.

Recent Product Development Highlights

AL-101 CNS Program

AL-101 (intranasal apomorphine), is our lead fast-to-market 505(b)2 regulatory pathway drug candidate for Parkinson Disease ("*PD*") and Erectile Dysfunction ("*ED*"), especially phosphodiesterase 5 ("*PDE5*") non-responders. Oncotelic also plans to develop AL-101 as a new class of drug against Female Sexual Dysfunction ("*FSD*"), including Hypoactive Sexual Desire Disorder ("*HSDD*"). Through targeting the dopamine receptors in the brain AL-101 has multiple central nervous system effects that will be leveraged in its development - mirroring the successes we have had previously with Abraxane™ and Cynviloq™ via the 505(b)2 pathway. AL-101 has shown a favorable safety and efficacy profile and is phase 3 ready with six clinical trials completed and over 200 patients (2,200 doses) treated.

With over 60,000 new patients annually being diagnosed with PD in the United States. 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. As reported by Pharmaceutical Technology by GlobalData Healthcare on May 26, 2020, KYNMOBI™ (apomorphine HCI) sublingual film was approved through the 505(b)2 pathway for acute, intermittent treatment of OFF episodes in patients with PD. KYNMOBI™ dissolves under the tongue. Per GlobalData Healthcare, KYNMOBI™ is expected to generate $219 million annually. https://www.pharmaceutical-technology.com/comment/sunovion-pharmaceuticals-kynmobi-parkinsons/. We anticipate AL-101 to be a superior product based on rapid and preferential accumulation in the brain.

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).

FSD is a prevalent problem, afflicting approximately 40% of women and there are few available treatment options. In June 2019, the U.S. Food and Drug Administration approved Vyleesi (bremelanotide) to treat acquired, generalized HSDD in premenopausal women. Currently, 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 an effective therapy against FSD and HSDD.

OT-101/PD-1 Oncology Program

The OT-101/PD-1 program is designed to assess the impact of OT-101 across multiple cancer indications, where local tumoral secretion of transforming growth factor-beta ("*TGF-β*") suppressed the clinical activity of checkpoint inhibitors, CAR-T, and vaccines. Multiple phase 2 trials combination of OT-101, with a PD-1 inhibitor, in collaboration with large pharmaceutical company, and leading KOLs around the world, are being planned and developed. These trials span mesothelioma, glioblastoma, lung, and colorectal cancers where AI driven transcriptome analyses will be used to derive the predictive and prognostic biomarker for TGF-β therapeutics, including OT-101.

TGF- β promotes immune evasion. The different components surrounding a tumor are collectively known as the tumor microenvironment (TME). The TGF-β signaling pathway is activated in the TME and the tumor, leading to alteration in the composition of the TME that favors tumor growth and aggressiveness. A major component of the TME, called Cancer-Associated Fibroblasts. help the tumor grow and escape destruction by the host immune system. As such even if an immune cell is sitting next to the tumor cells, it would not do anything because the tumor is making so much TGF, essentially cloaking the tumors. OT-101 inhibits the making TGF- β protein.

A PD-1 inhibitor, such as pembroluzimab, is not chemotherapy or radiation therapy - it is an immunotherapy and it works with our immune system to help fight cancer. Immunotherapy is spectacularly effective. These agents mobilize the immune system to attack the tumor and achieve cure (not just slowing down of the tumor/remission). However, it will work in only about 10% of patients. The rest have too much TGF- β for PD-1 immunotherapy to be effective. Knocking down TGF with OT-101 should improve the cure rate above the 10%. We are hoping that cure rate can reach 100% in the future.

OT-101/IL-2 Oncology Program

Our OT-101/IL-2 combination trial (the "Trial"), has now successfully completed the safety evaluation of its safety cohort, allowing for further expansion of its clinical program into phase 2 and higher doses.

The Trial - A Multi-center, Open label, Phase Ib clinical study to evaluate the safety, tolerance, and efficacy of TASO-001 (" *OT-101*"), a TGF-β targeting anti-sense oligonucleotide, in combination with recombinant interleukin-2 (Aldesleukin, "*IL-2*"), in patients with advanced or metastatic solid tumor cancer. ClinicalTrials.gov Identifier: NCT04862767. The Trial is being conducted by Autotelic BIO, a partner of Oncotelic on the OT-101/IL-2 combination.

In the safety cohort treated during the Trial, the standard dosage of 140mg/m2 of OT-101was well tolerated in combination with IL-2, which has allowed for ongoing dose escalation to 190 mg/m2. The 140 mg/m2 dose was shown to be the optimal dose for OT-101 in a prior trial targeting pancreatic cancer, melanoma, and colorectal cancer ("*P001*"). In the P001 trial, the maximum tolerated dose was not reached even at 330 mg/m2. Therefore, the Company believes that increasing the dose above 140 mg/m2 should further enhance the clinical activity of OT-101.

OT-101 COVID-19 program

On October 18, the data lock of the Study Data and Analysis Data Models (SDTMs & ADaMS Databases) were generated for the Company's C001 trial for COVID-19. The trial compares OT-101 plus standard of care ("*SOC*") versus Placebo plus SOC, the SOC which includes dexamethasone (N= 32 pts at 2:1 randomization ratio). Dexamethasone is the only known drug to improve outcome for severe COVID-19. The top line data as previously disclosedare:

Safety endpoints met. OT-101 as a TGF-β inhibitor was safe to administer to COVID-19 patients including severe/critical COVID-19 patients.

Efficacy signals were obtained. End of treatment- Day 7-mortality for the entire study population was 4.5% OT-101 versus 20% Placebo.

Incidence of >96% viral load knockdown on End of Treatment- Day 7- was 89% for OT-101 versus 67% for placebo.

Overall survival improved significantly improved from 4 day for placebo to 14 day OT-101 among critically ill COVID-19 patients.

The data form the basis for us to further develop this as a drug to treat severe respiratory viral infections including flu and COVID. Both tumor cells and the SARS-CovCoV-2 viruses induce TGF-β as part of their immune evasion mechanism. Consequently, inhibiting TGF-β by OT-101 is expected to impact both cancer and COVID. By targeting the host protein, OT-101 is expected to work against multiple respiratory viruses agnostic of the emerging variants, unlike traditional antiviral drugs and vaccines.

Artemisinin COVID-19 Program

We deployed Artemisinin as herbal supplement in India under the name PulmoHeal™ together with Chopra Foundation and Heart Care Foundation of India (HCFI) and Parmarth Niketan Ashram to combat COVID during the deadly surge in COVID-19 in summer of 2021 as a humanitarian effort. As we build our patent portfolio around Artemisinin and its analogs for COVID-19 and other respiratory viral infections we are positioning Artemisinin and its analog artesunate as pharmaceutics.

About Oncotelic

Oncotelic (f/k/a Mateon Therapeutics, Inc.), 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 is seeking to leverage its deep expertise in oncology drug development to improve treatment outcomes and survival of cancer patients with a special emphasis on rare pediatric cancers. Oncotelic has rare pediatric designation for DIPG (OT-101), melanoma (CA4P), and AML (OXi 4503). Oncotelic also acquired PointR Data Inc. in November 2019.

Additionally, Oncotelic acquired AL-101, during the 4th quarter of 2021, for the intranasal delivery of apomorphine. We intend to develop AL-101 for the treatment of PD. Over 60,000 new patients are being diagnosed with PD in the United States. 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. Female sexual dysfunction 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 U.S. Food and Drug Administration approved Vyleesi (bremelanotide) to treat acquired, generalized 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.

For more information, please visit www.oncotelic.com

Oncotelic's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, prospects, plans and objectives of management are forward-looking statements. Words such as "may", "expect", "anticipate" "hope", "vision", "optimism", "design", "exciting", "promising", "will", "conviction", "estimate," "intend," "believe", "quest for a cure of cancer", "innovation-driven", "paradigm-shift", "high scientific merit", "impact potential" and similar expressions are intended to identify forward-looking statements. Forward¬ looking statements contained in this press release include, but are not limited to, statements about future plans related to the operations of the JV, taking the JV into an initial public offering or the success thereof, the progress, timing of clinical development, scope and success of future clinical trials of any of our products, the reporting of clinical data for the company's product candidates and the potential use of the company's product candidates to treat various cancer indications as well as obtaining required regulatory approval to conduct clinical trials and upon granting of approval by the regulatory agencies, the successful marketing of the products, the ability to raise any additional funds for the Company to develop our other products, the ability to get uplisted to a national stock exchange. Each of these forward-looking statements involves risks and uncertainties, and actual results may differ materially from these forward-looking statements. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. These risks are not exhaustive, the company faces known and unknown risks, including the risk factors described in the Company's annual report on Form 10-K filed with the SEC on April 15, 2021 and in the company's other periodic filings. Forward-looking statements are based on expectations and assumptions as of the date of this press release. Except as required by law, the company does not assume any obligation to update forward-looking statements contained herein to reflect any change in expectations, whether as a result of new information future events, or otherwise.

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