Executive Summary

Overview

OyaGen has its origins in the science of gene editing enzymes that affect the genetic readout of cells and viruses, through the academic work of Dr. Harold C. Smith, University of Rochester, Rochester, NY (https://haroldsmithlab.com). Founded by Dr. Smith in 2003, OyaGen, Inc. holds exclusive Intellectual Property (IP) licensed from Thomas Jefferson University and numerous self-generated IP on the Company's platform of drug targets and antiviral lead compounds. In 2008 OyaGen began drug discovery work on oral deliverable antiviral compounds for HIV based on a novel viral drug target and methodology that distinguished the Company's approach from all others in the pharmaceutical space. We are the only commercial effort drugging the HIV Vif protein thereby enabling natural (innate) immunity through host cell restriction factors to effectively neutralize all clades and strains of HIV. Lead compounds under development have been tested and acknowledged for their potential as first-in-class drug candidates by the Federal Government (NIAID). In addition, the Company has a platform technology that has enabled advanced lead identification for SARS-CoV2, MERS, Ebola, Lassa virus and Pox viruses whose safety is known in human subjects from prior cancer clinical trials and preclinical animal studies. Furthermore, OyaGen continues to innovate and is actively developing new screening assays for broadly acting antivirals for multiple virus classes and oncology targets.

Coronavirus

OyaGen developed Oya1 (aka sangivamycin) in collaboration with NIH/NIAID as a highly potent compound that prevents the spread of infection of Coronaviruses, Ebola, Lassa virus and Pox virus, at doses that are significantly below those shown to be safe in cancer clinical trials. OyaGen is seeking FDA approval for its patent-protected Oya1 in the treatment of COVID-19 and have completed preIND discussions with the FDA. Oya1 is not a chain terminator for viral replication but it is significantly more effective in stopping live SARS-CoV-2 and Ebola virus infections in the laboratory than chain terminators such as remdesivir. When dosed in combination with remdesivir, Oya1 markedly improved the antiviral efficacy of remdesivir enabling maximal virus stopping power with lower doses for both drugs (Bennett RP, et al., (2022) Sangivamycin is highly effective against SARS-CoV-2 in vitro and has favorable drug properties. **JCI Insight**). Human safety has already been evaluated by the NCI in phase I and phase II clinical trials in the 1960s when Oya1 was evaluated as a candidate for cancer treatment. Oya1 had no serious adverse side effects in these studies when tested in 88 human subjects over a range of doses and

dose intervals but was abandoned due to a lack of efficacy against various cancers. Similarly, the Company determined that there were no serious adverse effects in hamsters that were dosed up to 10-times the antiviral IC_{90} in cell culture. Oya1 is therefore a near term treatment solution addressing the unmet need for a highly effective medical countermeasure for people who become infected with SARS-CoV-2 and for immunocompromised patients who cannot benefit from COVID immunization.

Coronavirus (CoV) infections with higher than expected morbidity and mortality have emerged three-times in the past two decades (SARS1, MERS and SARS2). Global biomedical science is only now racing to identify vaccines for what has now been predicted to be a disease with annual reoccurrence. COVID-19 vaccines have been developed but their global deployment has faced challenges and their efficacy and potential for establishing herd immunity is hotly debated. The international focus on COVID-19 vaccine development for prevention has left an unmet need for highly active, antiviral therapies for treating people who become infected and need highly active antiviral therapies to prevent disease progress, serious side effects or death. Laboratory testing performed in collaboration with NIAID suggested that Oya1 may be the most effective treatment for COVID-19 to date.

The data suggest that Oya1 alone or in combination with other antiviral treatment regimens including small molecule drugs, monoclonal antibodies (Mab), and/or corticosteroids or other immune modulators) holds the potential to halt COVID-19 and future emergent strains of CoV.

OyaGen owns the patent rights to Oya1. Specifically, OyaGen has five patents pending for this highly potent compound that prevents the spread of infection by Coronaviruses, Ebola, Lassa virus and Pox viruses. The compound was taken through late-stage preclinical development by OyaGen. Oya1 has been safely administered to nonhuman primates and humans in the 1960's for cancer but was abandoned as being ineffective in stopping cancer cell growth. Oya1 is a broad-spectrum antiviral and has excellent drug-like ADMET properties and higher potency relative to remdesivir in live virus studies. Oya1 antiviral activity is additive with remdesivir when the drugs are used in combination. Its potential as a preventative for viral infections is suggested by its long half-life in tissues and therefore would be a much needed, life-saving therapeutic approach for those who cannot benefit from a vaccine or will not take a vaccine.

HIV

OyaGen will soon complete IND-enabling studies and engage the FDA in preIND discussions for its patent-protected, first-in-class antagonist of the HIV-1 Vif protein. Vif antagonists prevent Vif-dependent degradation of APOBEC gene editing proteins and thereby enable innate immunity to HIV. Drug targeting of HIV Vif to enable antiviral activity through APOBEC gene editing enzymes is a novel approach (Bennett RP, et al., (2016) An analog of camptothecin inactive against Topoisomerase I is broadly neutralizing of HIV-1 through inhibition of Vif-dependent APOBEC3G degradation. **Antiviral Research**). Formulation for oral dosing is the Company's priority. OyaGen has

developed its lead through grants and contract research with NIAID. OyaGen's Vif antagonist not only has therapeutic potential but holds the potential to reduce viral reservoir formation as part of a strategy for a cure and prevention.

OyaGen has in late-stage preclinical development a unique therapeutic lead for HIV/AIDS that is 14-16 months from a pre-IND meeting with the FDA. Despite several FDA approved treatments, HIV remains a significant health care issue with >60 million people worldwide affected. The emergence of drug resistant HIV strains, enhanced by inconsistent access to a continuum of care continues to promote the spread HIV globally. The incidence of HIV continues to grow at a double-digit rate according to the U.S. Center for Disease Control. Approximately 30% of US citizens infected with HIV are unaware they are HIV positive. While treated patients have longer survival, the failure rate for current frontline therapies is 10% and ultimately the virus's ability to mutate continues to demand new drugs. Consequently, the international drug market is expected to continue to show sustained growth despite advances in controlling the virus for those patients with access to treatment (Cowen & Co.). Our current preclinical efforts have shown our leads to be broadly neutralizing of all strains of HIV and additive in efficacy with all commercial highly active anti-HIV therapeutics. We have developed the chemical path with CROs for producing pure compounds and are developing oral formulations that will enable sustained blood levels for once-a-day dosing.

Each first-in-class HIV drug has achieved blockbuster annual sales (Cowen & Co.). In recent years the Pharma pipeline for new classes of HIV therapeutics has dried up largely due to reduction in R&D expenditure. PimStrategus Professional Valuation Services research suggested that OyaGen's lead compound has great potential in HIV therapeutics and as a stop gap during a scheduled interruption of treatment due to its broad effectiveness against numerous strains of HIV and ART resistant HIV. Vif antagonists may have their highest potential for a blockbuster status in the areas of HIV prevention (PrEP) and HIV cure. In that regard, OyaGen has planned studies in reservoir cells assessing the potency to neutralize viremia associated with reservoir cell reactivation as proof-of-concept that OyaGen's lead compound could be part of a functional cure strategy.

Ebola

Oya1 originally was first discovered as broad microbicide and an Ebola antiviral in collaboration with NIAID. This work was recently published (Bennett RP, et al., (2021) 'A Novel Ebola Virus VP40 Matrix Protein-Based Screening for Identification of Novel Candidate Medical Countermeasures' **Viruses**) and is patent protected. The published data show that Oya1 is markedly more effective than remdesivir but has significant virus stopping capability alone or in combination with remdesivir. Clinical trials showed that Mab therapy had greatest therapeutic value in treating Ebola. Vaccination strategies for Ebola and remdesivir were minimally effective for people infected with Ebola who already have symptoms. The unmet need is that protection through immunization takes 21 days but the virus kills in 14 days. When an Ebola vaccine becomes available, it may prevent the spread of Ebola to those who are immunized but it will not prevent transmission or

death of persons within the disease epicenter who are not immune. Mab production and distribution are costly and require special infrastructure. OyaGen will address the unmet need for highly active antiviral therapies that are low in cost of production and distribution.

OyaGen Key Assets

OyaGen has discovered and patented first-in-class lead that enables our innate immunity against HIV as a treatment with curative potential for HIV/AIDS and patented best-in-class Oya1 as candidate treatment for infections due to Coronavirus, Ebola virus, Lassa virus and Pox virus. In addition, the Company's laboratory, platform technology and broad technical knowhow has enabled the development of multiple virus and cancer drug discovery platforms. There are more than 20 scientists working with the Company through established contract research and co-development relationships with NIH/NIAID, Texas Biomed, ImQuest Biosciences, Cayman Chemical and multiple other companies and institutions. These scientists support viral testing, medicinal chemistry, cGMP compound production. OyaGen works closely with regulatory consultants and clinical CROs. This team is accelerating the preclinical medicinal chemistry, ADME and safety testing needed for filing an IND for our HIV lead and the Coronavirus and Ebola antiviral lead.

Drs. Harold C. Smith, Founder and CEO, Ryan P. Bennett, CSO and Laboratory director and Jason D. Salter, Scientist, lead the Company's drug discovery and drug development efforts. The Company currently occupies a 3,200 sq. ft. state-of-the-art laboratory within the Rochester BioVenture Center in Rochester NY. A broad range of advanced instrumentation, controlled environments, small molecule libraries in a BLS2+ facility enable in-cell and cell-free assay development, infectivity and other functional endpoint analyses and high throughput screening. We maintain a low overhead and sustainable footprint through association with contract laboratories, both federal and private, that perform specialized testing and validation services.

The Company has a management team and external advisors with collectively over 100 years of experience in Biopharma and the Life Sciences. Dr. David Ho, CEO of the Aaron Diamond AIDS Research Center at Rockefeller University (NYC) who was a Time Magazine Man of the Year and one of the world's leading HIV authorities serves on the Scientific Advisory Board (SAB). Dr. Roscoe Moore, former Assistant Surgeon General and OyaGen Board member advises the company on worldwide health priorities, along wiht Dr. Richard Ogden, formerly with Agouron/Pfizer as a scientist and executive. OyaGen's Board member advises the company on pharmaceutical industry trends. Amy Fix, MS. MBA, RAC and VP of regulatory affairs with Arcellx, Inc serves as the company's regulatory consultant, Thomas Fitzgerald, Esq serve as Chief Operations Officer and legal consultant and Kimberly Staffieri provides financial and controller services.

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