

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

FORM 10-K

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

For the fiscal year ended **June 30, 2022**

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

For the transition period from

Commission file number **000-54478**

ENOCHIAN BIOSCIENCES INC.

(Name of registrant in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

1927 Paseo Rancho Castillo
Los Angeles, CA

(Address of principal executive offices)

45-2559340

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

90032

(Zip Code)

+1(305) 918-1980

(Registrant's telephone number, including area code)

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

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, par value \$0.0001 per share	ENOB	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$0.0001 par value

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 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 Exchange Act during the last 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, if any, 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 and post such files). Yes No

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.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" 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 Act). Yes No

On December 31, 2021, the aggregate market value of the voting and non-voting common equity held by non-affiliates was \$242,848,672.

As of February 27, 2023, the number of shares outstanding of the registrant’s common stock, par value \$0.0001 per share (the “Common Stock”) was 55,705,521.

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Cautionary Language Regarding Forward-Looking Statements and Industry Data

This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 regarding the plans and objectives of management for future operations and market trends and expectations. Forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts. Forward-looking statements are based upon our current assumptions, expectations and beliefs concerning future developments and their potential effect on our business. In some cases, you can identify forward-looking statements by the following words: “may,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “approximately,” “estimate,” “predict,” “project,” “potential” or the negative of these terms or other comparable terminology, although the absence of these words does not necessarily mean that a statement is not forward-looking.

Forward-looking statements include, but are not limited to, statements concerning:

- Our ability to continue as a going concern and ability to raise additional capital if needed;
- Our potentially continuous incurrence of losses as a pre-clinical-stage biotechnology company with no products that have achieved regulatory approval;
- Our ability to generate revenue if we fail to develop marketable product;
- Our dependence on substantial additional financing to support the research, development, licensing, manufacture, and marketing of product candidates and products, and the possibility that unforeseen operational costs will arise;
- The dilutive effect on stockholders’ ownership interests of the Company raising capital through an equity issuance in connection with future equity financing or equity debt agreements;
- Our dependence on the services of experts, including third parties to research and develop product candidates in cooperation with our employees and officers;
- The difficulty or impossibility of predicting future clinical trial results and regulatory outcomes of our products based upon our pre-clinical or earlier clinical trial performance;
- The application of heightened regulatory and commercial scrutiny to our gene, cell, and immunotherapy products given their novel nature and concomitant potential for actual or perceived safety issues;
- Our ability to compete in a rapidly developing field, and the potential impact to our financial condition, product marketability, and operational capacities of a competitor receiving regulatory approval before us, or a competitor developing a more advanced or efficacious therapy than our product;
- Potential delays or total failures of third parties, such as universities, non-profits, and clinical research centers, to perform obligations on which our product research and development rely;
- Potential interruption or delay of our and our third-party contractors’ business operations due to COVID-19, which may prevent the timely initiation and conclusion of pre-clinical studies;
- The impact on our competitive position, business operations, and financial condition of implementation of amended healthcare laws and regulations related to healthcare pricing and reimbursement;
- The dependence of certain of our pipelines on intellectual property licensed from licensors, and the severe adverse impact to our business operations of a disruption of one of our licensing relationships;
- The potential monetary costs of defending our intellectual property rights in a dispute, and the possibility that an intellectual property dispute will not be settled in our favor;
- The possibility that our patents and patent applications, even if unchallenged, will not sufficiently protect or provide exclusive use of our intellectual property, which could jeopardize our ability to commercialize our products and dissuade companies from subsequently collaborating with us;

- The negative impact to our competitive position and the value of our technology of our failure to protect trade secrets through the use of non-disclosure and confidentiality agreements, or the unavailability of adequate recourse for breach of such agreements;
- The fluctuation and volatility of the market price of our Common Stock due to its limited public market, and the possibility that these issues will compound and strain our stockholders' ability to resell their Common Stock;
- Our significant dependence on sophisticated management with highly technical expertise to oversee business operations, and our ability to attract and retain qualified personnel to sustain growth;
- Our ability to adapt to future growth by training an expanding employee base and shifting away from reliance on third-party contractors;
- The risk of liability arising from claims of environmental damage, personal injury, and property damages in connection with our research and development activities, including those that involve the use of hazardous materials;
- The possibility that enforcement actions to suspend or severely restrict our business operations will be brought against the Company for our failure to comply with laws or regulations and the potential costs of defending against such actions;
- Our reliance on adequate maintenance of the security and integrity of our information technology systems to effectively operate our business; and
- Such other factors as discussed throughout Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and in Part I, Item 1A. Risk Factors herein.

A forward-looking statement is neither a prediction nor a guarantee of future events or circumstances, and those future events or circumstances may not occur. You should not place undue reliance on forward-looking statements, which speak only as of the date of this Annual Report. Forward-looking statements involve known and unknown risks, uncertainties, and other factors, including without limitation the risks and uncertainties described below the heading "Item 1.A. Risk Factors" in this report, that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. The forward-looking statements included herein are based on current expectations and assumptions that involve numerous risks and uncertainties. Our plans and objectives are based, in part, on assumptions involving the continued expansion of our business. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond our control. This is especially emphasized by the anticipated impacts from the COVID-19 pandemic on the Company, including the related effects to our business operations, results of operations, cash flows, and financial position. Although we believe that our assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate and, therefore, there can be no assurance that the forward-looking statements included in this Annual Report will prove to be accurate. Given these risks and uncertainties, you should not rely on forward-looking statements as a prediction of actual results. Any or all of the forward-looking statements contained in this Annual Report and any other public statement made by us, including by our management, may turn out to be incorrect. We are including this cautionary note to make applicable and take advantage of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We expressly disclaim any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Information regarding market and industry statistics contained in this report is included based on information available to us that we believe is accurate. It is generally based on academic and other publications that are not produced for purposes of securities offerings or economic analysis. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and the additional uncertainties accompanying any estimates of future market size, revenue and market acceptance of products and services. Except as required by U.S. federal securities laws, we have no obligation to update forward-looking information to reflect actual results or changes in assumptions or other factors that could affect those statements.

PART I

Unless otherwise indicated or the context otherwise requires, all references in this prospectus to “we,” “us,” “our,” “Enochian BioSciences” or the “Company” are to Enochian BioSciences Inc., a Delaware corporation (“Registrant”), together with its wholly owned subsidiaries, Enochian Biopharma, Inc., a Delaware corporation (“Enochian Biopharma”) Enochian Biosciences Denmark ApS, a Danish limited company, organized under the Danish Act on Limited Companies of the Kingdom of Denmark (“DanDrit Denmark”), and Enochian Technologies, Inc., a Nevada corporation (“Enochian Technologies”).

Our Business

We are a biotechnology company committed to developing advanced allogeneic cell and gene therapies to promote stronger immune system responses potentially for long-term or life-long cancer remission in some of the deadliest cancers, and potentially to treat or cure serious infectious diseases such as Human Immunodeficiency Virus (HIV) and Hepatitis B virus (HBV) infection.

Our Product Development strategy is anchored in the use of “non-self” or allogeneic cells that enhance the immune response that we seek to elicit.

Over the past several years, Enochian BioSciences has evolved from a company with a single product candidate as a potential cure for HIV, adding two additional pipeline candidates for HIV, a pipeline for Hepatitis B Virus (HBV), and with a significant expansion into cancer immune therapies to address high unmet needs from difficult-to- treat solid tumors.

The oncology platform is now at the forefront of our development activities, beginning with pancreatic cancer.

Many operational aspects of our platforms can be quickly adapted to multiple disease states from a single therapeutic approach, potentially streamlining and accelerating development, and regulatory process, as well as manufacturing operations. Moreover, because our products candidates do not require specialized delivery devices and surgical procedures, our potentially groundbreaking interventions could have worldwide applicability.

The Company responds quickly to new data and perceived development opportunities and risks assessments. Based on the maturation of our pipelines, the Company makes business decisions to prioritize the programs that could move more rapidly through development and commercial processes.

Therapeutic Areas of focus

Solid Tumors

Cancer is caused by an uncontrolled proliferation of abnormal cells. The immune system plays a key role in identifying and destroying those abnormal cells. In the past 10 years, there has been significant investment in research and development to retrain the immune system in people with cancer to restore the effectiveness of that immune response – so called “immune-therapy”. Immune-therapies have made substantial advances to treat various types of blood cell-derived cancers. However, solid tumors still represent a key challenge for long-term remission or cure. Certain solid tumors have evolved mechanisms that can either hide from normal immune control and immune-therapies or release certain signaling factors that can block attempts by the immune system to recognize and destroy cancer cells.

Enochian Biosciences is developing innovative, proprietary approaches that involve gene- and/or cell-therapy to promote cancer fighting cells that are designed to potentially overcome those mechanisms and enhance the ability of a person living with a solid tumor to more easily recognize cancer cells and mount a much more robust and effective immune reaction to destroy them.

Pancreatic cancer remains a very deadly disease with only 5-10 percent of patients surviving 5 years. Initial preclinical *in vitro* and proof of concept *in vivo* studies of our immune-therapeutic approach for pancreatic cancer have demonstrated promising results.

Because of the flexibility provided by the platform technology for quick adaptations during research and development and manufacturing processes, it could accelerate the development of potential products for other solid tumors beyond pancreatic cancer. For example, triple-negative breast cancer, glioblastoma, and renal cell carcinoma are all solid tumors with poor survival rates and limited treatment options. The platform might also allow for non-specific immune enhancement that could have impact against a broad array of solid tumors. As currently conceived, our approach could potentially allow for outpatient therapy without significant impairment of the patient's immune system, as many current approaches require.

Because many types of solid tumors do not have adequate therapies, are difficult to treat and have relatively low survival rates, there is a large market potential.

Infectious Diseases

Infectious diseases such as HIV and HBV cause disease and death in hundreds of millions of people every year. In a similar way to solid tumors, those viruses escape from natural immune response by hiding inside of human cells, creating sanctuaries or reservoirs of infection that can evade the immune system. Advances in anti-viral drugs have made a huge impact on the ability to extend and improve the quality of life for many, but are often associated with side effects, and can be very expensive. In the USA, therapy for HIV is estimated to cost \$35,000 to \$50,000 *per year*.

Through its advanced cell- and gene- therapy platforms, Enochian BioSciences is developing unique tools potentially to enhance a person's ability to both recognize and fight infections. Because those mechanisms aim to eliminate the cells that serve as a reservoir for viral replication, our therapy could potentially either cure or at least provide long term remission to people living with chronic infections.

HIV

HIV attacks the human immune system, specifically killing off CD4+ T-cells, a central part of a person's ability to control other infections and certain cancers. Left untreated, over time, the number of CD4+ T-cells drops to such low levels that people die from those infections and cancers.

Thanks to scientific advances, there are over 30 antiretroviral drugs, or ARVs, approved by the U.S. Food and Drug Administration ("FDA") to treat HIV that can allow many people to live almost as long as people without HIV. But, as mentioned, the drugs are expensive, require taking pills every day, and can have significant side effects over time.

More than 30 million people are living with HIV. In addition, as many as 1 million people, including people in high-income countries, continue to die each year from HIV due to the ability of the virus to evolve to evade the effects of the drugs, in particular in people who have been taking various drugs for many years. To date, there are no treatments that can eliminate the reservoir of immune cells that are infected with HIV from the body. Consequently, treatment for HIV is life-long.

HBV

Despite the availability of an effective vaccine and treatment that can control infection if it is taken daily for life, HBV is the world's most common serious liver infection. Two billion people have been infected with HBV, approximately 300 million have chronic HBV infection, and nearly one million people die every year around the world. HBV remains the leading cause of liver cancer and the second leading cause of cancer deaths in the world.

While vaccines are increasingly required for children, many adults have not been vaccinated. Life-long treatment access can be limited and also can be difficult for certain people to follow due to its side effects.

Current efforts to develop novel treatments or cure largely focus on approaches to deplete the pool of the covalently closed circular DNA (cccDNA), a type of HBV DNA that is the root cause of HBV chronicity. Enochian Biosciences is exploring the development of an innovative gene therapy approach to co-opt HBV polymerase, a key factor that the virus needs to reproduce itself and to induce the death of liver cells infected with the virus.

Therapeutic Platforms

The Company's general approach with gene- and/or cell-therapy is to enhance the immune system to allow a person to better fight diseases. The Company is leveraging general principals and advances in the knowledge of the immune response to engineer cells with enhanced attributes to promote the recognition and elimination of diseased cells.

Advanced Allogeneic Cell Therapy

The strategic benefit of cell therapy platforms is to potentially allow for manufacture of large, "off-the-shelf" banks of therapeutic cells that could be accessed on demand by health care professionals to potentially decrease the time between diagnosis and treatment.

In addition, because we focus on cells from donors the strategy could potentially enhance the ability of the therapeutic candidates to induce a more robust response once injected into patients. The human immune system is designed to recognize and distinguish "self" from "non-self" and destroy "otherness" such as bacteria, viruses, and damaged or diseased cells such as cancer cells. Alloreactivity (reacting against another person's cells) is the most powerful response the immune system generates. Several of our technologies take advantage of the alloreactivity to hyper stimulate a person's immune response to better attack a chronic infection (e.g., HIV) or solid tumor.

In certain treatments (e.g., HIV and cancer), cells taken from healthy donors are sometimes genetically modified to introduce signaling molecules that are designed to enhance the ability of specific immune cells to recognize diseased cells, and to help recruit other cells that will destroy cancer or virus infected cells.

The Company believes that the combination of off-the-shelf allogeneic cells, combined with genetic modifications designed to enhanced immune signaling, could potentially generate therapeutic candidates that have unique attributes that will increase the likelihood of success.

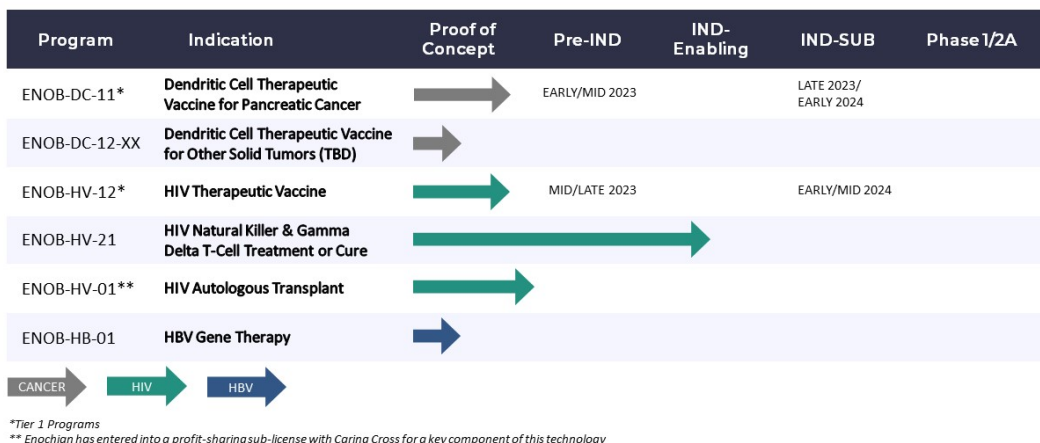
Cell Therapy enabling technology

In addition to the platform described above, Enochian BioSciences has an innovative gene therapy approach to enhance the selection and engraftment (uptake) of cells carrying therapeutic attributes. Enhanced uptake or engraftment could play a critical role in some cases to increase the likelihood of therapeutic benefit. This technology was initially developed for autologous cell therapy from a person living with HIV, and genetically modifying those cells so they cannot be infected with most variants of HIV plus a gene modification to enhance uptake. We have sublicensed under a profit-sharing agreement our technology to potentially increase engraftment for potential use in CAR-T therapy as a potential cure for HIV.

HBV Gene Therapy

Enochian BioSciences is exploring various approaches for gene therapy design elements to potentially eliminate virus-infected cells with an innovative molecular mechanism that co-opts the virus' machinery to induce the death of infected cells rather than reproducing and causing more infection and exacerbate diseases.

OUR DEVELOPMENT PIPELINE



Oncology:

ENOB-DC-11: Genetically modified Allogeneic Dendritic Cell Therapeutic Vaccine as Potential Product for Long-term Remission of Solid Tumors – Starting with Pancreatic Cancer

Allogeneic Cell Therapy Platform –moderately Advanced Pre-Clinical

Based on learning from peer-reviewed publications of Phase I/IIa trials, we have designed an innovative therapeutic vaccination platform that could potentially be used to induce life-long remission from some of the deadliest solid tumors. The survival rate in pancreatic cancer is currently only 5 to 10 percent at 5 years.

Initial preclinical *in vitro* and proof of concept *in vivo* studies have been encouraging. The platform might also allow for non-specific immune enhancement that could have impact against a broad array of solid tumors. We initially plan to target pancreatic cancer. Other potential targets for later development could include triple-negative breast cancer, glioblastoma, or renal cell carcinoma. As with HIV, our approach would potentially allow for outpatient therapy without wiping out or significantly impairing the patient’s immune system, as many current approaches require.

Enochian BioSciences has initiated a collaboration with Dr. Anahid Jewett from UCLA to study further the *in vitro* and *in vivo* effectiveness of the approach in pancreatic cancer. Dr. Jewett created an innovative pancreatic cancer mouse model that mimics the human immune system in combination with implanted human cancer cells. Early results show promising substantial tumor size reduction. We are now fully committed to process development/improvements and hope to have confirmatory *in vivo* data by early 2023 with potential Pre-IND submission early/mid 2023. If successful, clinical trials in humans could be possible by the end of 2023 or the first half of 2024.

ENOB-DC-12--XX: Genetically modified Allogeneic Dendritic Cell Therapeutic Vaccine as Potential Product for Long-term Remission of Additional Indications

The technology is a platform that could potentially be adapted to other solid tumors first line and/or salvage therapy, by itself or, potentially, in combination with other cancer treatments. Additional indications are being evaluated strategically to balance risk and opportunity to advance therapeutic development quickly in cancer indications with few treatment options.

Infectious Diseases:

HIV:

ENOB-HV 12: HIV Therapeutic Vaccines for Potential Long-term Remission/Cure

Allogeneic Cell Therapy Platform - Advanced Pre-Clinical Stage; Non-Human Primate Studies Ongoing.

In persons living with HIV who are controlling the spread of virus with anti-retroviral (ARV) treatment, boosting the immune system in a different way than the virus already has through infection, could allow for control of HIV after stopping ARVs.

Enochian BioSciences is developing ENOB-HV-12 that utilizes a novel cellular and immunotherapy approach that could potentially provide therapeutic vaccines for HIV (ENOB-HV-12). A non-human primate study of the therapeutic vaccine in primates at the Fred Hutchinson Cancer Research Center is ongoing. Animals began receiving the first injections of the potential therapeutic vaccine in August, 2022. Preliminary results could potentially be available in early 2023. A Pre-IND request could be submitted by mid-2023, with IND submission and the beginning of Phase I clinical trials by mid- to end-2024.

ENOB-HV-01: Autologous Transplant with Genetically Modified Cells:

FDA INTERACT Meeting Held February 2020 - Advanced Pre-Clinical Stage

There have been several efforts to cure HIV by re-engineering a person's own T cells so that these cells no longer express a special protein (C-C chemokine co-receptor type 5 or CCR5), which HIV uses to gain entry to them. A naturally occurring mutation that blocks expression of CCR5 on T cells occurs in ~1% of people living in or from Northern Europe with no known adverse effects. The "Berlin patient", and more recently the "London patient" were HIV-positive people who developed cancer and were treated with a bone marrow transplant with cells donated from people with this naturally occurring mutation of CCR5. The Berlin and London patients seem to have been effectively cured from HIV providing proof-of-concept that HIV can be cured. However, because the transplanted cells come from another person, such transplants carry high risk and can result in death in a significant proportion of patients. Given the success with these two patients, several researchers and companies have attempted to replicate this experience by genetically modifying T cells of HIV-positive patients to render them unable to be infected by HIV and then returning them to the patient. Because the transplanted cells are from the same person, the risks to the patient are much lower. The uptake, or engraftment of the modified T cells, however, has not been optimal, leading to failure to achieve a cure. In addition, the transplant pre-treatment that has been used is bone marrow-destroying chemotherapy, which wipes out the patient's immune system and can have long-term side effects including the risk of developing cancer.

We have pioneered a novel enabling technology (ALDH gene modification) that we believe will allow sufficient engraftment of the CCR5 gene-modified Hematopoietic Stem Cell (HSC) to eliminate the need for Antiretroviral Treatment (ART.)

Management conducted a successful FDA INTERACT Meeting in alignment with the Company's experimental plan. Although *in vitro* and *in vivo* studies have demonstrated promising results, further development of ENOB-HV-01 at this time was deemed costly and a long-term undertaking. While the Company plans to return to full development of the approach when resources are available, it has become less attractive and been deprioritized for business reasons, while pipelines that could move more quickly have been prioritized (e.g., DC-11). Therefore, a business decision was made to sub-license the ALDH gene modification.

ENOB-HV-01 was sub-licensed to Caring Cross with a profit share arrangement. Caring Cross is developing a CAR-T approach that they believe, when combined with Enochian Biosciences ALDH gene modification, could enhance engraftment of their CAR-T cell therapy and enhance their likelihood of success.

ENOB-HV-21: Immunotherapy with Allogeneic NK/GDT Cells

Allogeneic Cell Therapy Platform -Pre-IND conducted - Advanced Pre-Clinical with Human Data through a Collaboration

We are also exploring ENOB-HV-21, an innovative treatment for HIV with allogeneic Natural Killer (NK) and Gamma Delta T-Cells (GDT). It is believed that the GDT cells, a small subset of immune cells that can be infected with HIV, could both be infected by, and be a key factor in controlling the virus. The initial scientific findings were presented during the American Society of Gene & Cell Therapy (ASCGT) Annual Meeting in 2021. Enochian BioSciences has an exclusive license to use the underlying patent to develop ENOB-HV-21 for potential treatment or cure of HIV. A successful investigator-initiated Pre-IND was completed in October 2021. However, due to a shift in priorities to the Oncology pipeline, Enochian BioSciences does not plan to pursue the IND and potential clinical trial in the near to medium-term.

HBV:

ENOB-HB-01: Potential Cure for HBV

HBV Gene Therapy -Pre-Clinical

ENOB-HB-01 is in an early pre-clinical phase as we explore various approaches for gene therapy design elements. If those explorations are successful, it is possible we could begin the regulatory process at the earliest in the first half of 2024. However, our highest priority is currently the oncology platform, beginning with pancreatic cancer.

Collaborations

We have established strategic partnerships with leading scientists and research centers, such as the University of California, Los Angeles, Fred Hutchinson Cancer Research Center, and Caring Cross for some of our programs. We will continue to pursue partnerships and collaborations when appropriate with selected philanthropic, pharmaceutical, and biotechnology companies to fund internal research and development activities, and to assist in product development and commercialization. We are applying our technology platform to several commercial applications in which our products provide us and our strategic partners and collaborators with potential technical, competitive, and economic advantages.

Our Intellectual Property

Patents and licenses are key to our business. Our strategy is to file for patent applications to protect technology, inventions, and improvements to inventions that we consider important for the development of our business. We rely on a combination of patent, copyright, trademark, and trade secret laws, as well as continuing technological innovations, proprietary knowledge, and various third-party agreements, including, without limitation, confidentiality agreements, materials transfer agreements, research agreements, and licensing agreements, to establish and protect our proprietary rights. We aim to take advantage of all of the intellectual property rights that are available to us and seek the protection of those rights so that we can fully exploit our innovations.

We also protect our proprietary information by requiring our employees, consultants, contractors, and other advisors to execute nondisclosure and assignment of invention agreements upon commencement of their respective employment or engagement. Our patent filings are discussed briefly below.

Internally Developed Intellectual Property

Protocol for generating dendritic cells (2005 DK, 2008 PCT)

This patent family is directed to the generation of dendritic cells based on a blood sample by culturing monocytes at reduced temperatures. Dendritic cells exposed to tumor antigens followed by treatment with T(h) 1-polarizing differentiation signals have paved the way for the development of dendritic cell-based cancer vaccines. Issued claims are directed to a method of generating immature dendritic cells under certain temperature settings, which by further activation has been shown to give a high yield of homogeneous and fully matured dendritic cells. The patent expiration date is December 2026 subject to any applicable patent term extension, patent term adjustment, or supplementary protection certificates that may be available in a country or jurisdiction. This patent has been issued in the USA, Canada, China, Eurasia, Russia, Europe, Israel, Mexico, Malaysia, and New Zealand. This patent is owned by the Company and was not licensed from third parties.

Assigned Intellectual Property

On August 16, 2022, the USPTO issued U.S. Patent No. 11,413,338 B2, “Methods and Compositions Using Recombinant Dendritic Cells for Cancer Therapy”, pertaining to methods and compositions for treating cancer by eliciting an immune response by administering dendritic cells expressing heterologous proteins. This patent protects **ENOB-DC-11: Genetically modified Allogeneic Dendritic Cells as Potential Product for Long-term Remission of Solid Tumors – Starting with Pancreatic Cancer** and potential future products **ENOB-DC-12-XX: Genetically modified Allogeneic Dendritic Cells as Potential Product for Long-term Remission of Additional Indications** for twenty years. This patent is owned by the Company, through assignment as of July 15, 2019.

On June 17, 2020, a patent application was filed entitled:-, “Allogeneic T-Cell-Based HIV Vaccine to Induce Cellular and Humoral Immunity”, US 2021/0030795 A1 for the composition and method of use concepts for HV-12. This patent application is owned by the Company, through assignment as of September 28, 2021.

In-Licensed Technology

On February 16, 2018, Enochian Biopharma, the Registrant’s wholly owned subsidiary, entered into a License Agreement (the “HIV License Agreement”) with Weird Science, LLC (“Weird Science”). The License Agreement contains, among other things, the following terms: (a) a perpetual, fully paid-up, royalty-free, sublicensable, and exclusive (including to the exclusion of Weird Science) worldwide license from Weird Science to Enochian Biopharma to use Weird Science’s intellectual property and technology for the prevention, treatment, and/or amelioration of and/or therapy for HIV in humans, and research and development exclusively relating to HIV in humans (the “Field”) worldwide; (b) a nonexclusive, royalty-free, sublicensable license from Enochian Biopharma to Weird Science to use the Enochian technology to commercialize products outside of the Field worldwide; (c) a nonexclusive, royalty-free license from Enochian Biopharma to Weird Science to use the results of a study with syngeneic and humanized mice models outside the Field and, at Weird Science’s own expense, to prosecute patents relating to the results of the study, which Weird Science will own, and (d) a perpetual, fully paid-up, royalty-free, sublicensable, and sole and exclusive (including to the exclusion of Weird Science) worldwide license from Weird Science to Enochian Biopharma (which will be part of the license described in (a) above) to use patent applications and patents related to the study results disclosed in (d) above solely in the Field, and to make, have made, use, sell, offer to sell and import inventions claimed in such patent applications and patents solely in the Field. Our current product candidates covered by this license include ENOB-HV-01: Autologous Transplant with Genetically Modified Cells (See Note 9 in the Financial Statements).

On January 31, 2020, the Company entered into a Statement of Work and License Agreement (the “HBV License Agreement”) by and among the Company, G Tech Bio, LLC “(G-Tech”), and G Health Research Foundation, a not for profit entity organized under the laws of California doing business as Seraph Research Institute (“SRI”), whereby the Company acquired a perpetual, sublicensable, exclusive license (the “HBV License”) for a treatment under development (aimed to treat HBV infections in accordance with its agreement in principle with G-Tech and SRI announced by the Company on November 25, 2019). The HBV License Agreement states that in consideration for the HBV License, the Company shall provide cash funding for research costs and equipment and certain other in-kind funding related to the Treatment over a 24-month period. The Company paid an upfront payment of \$1.2 million on February 6, 2020. Our current product candidate under this license is ENOB-HB-01 HBV Gene Therapy. (See Note 9 in the Financial Statements)

On August 25, 2021, the Company entered into an ALC Patent License and Research Funding Agreement in the HIV Field (the “ALC License Agreement”) with SRI whereby the Company was granted an exclusive, worldwide, perpetual, fully paid-up, royalty-free license (the “ALC License”), with the right to sublicense, the proprietary technology subject to a U.S. patent application, to make, use, offer to sell, sell or import products for use solely for the prevention, treatment, amelioration of or therapy exclusively for HIV in humans, and research and development exclusively relating to HIV in humans; provided the licensor retained the right to conduct HIV research in the HIV Field. Pursuant to the ALC License Agreement, the Company granted a non-exclusive license back to licensor, under any patents or other intellectual property owned or controlled by the Company, to the extent arising from the ALC License, to make, use, offer to sell, sell or import products for use in the diagnosis, prevention, treatment, amelioration or therapy of any (i) HIV comorbidities and (ii) any other diseases or conditions outside the HIV Field. The Company made an initial payment to SRI of \$600,000 and agreed to fund future HIV research, as mutually agreed to by the parties. Our current product candidate under this license is ENOB-HV-21: HIV Natural Killer and Gamma Delta T Cell Treatment or Cure.

Trade Secrets and Proprietary Know-How

In addition to intellectual property protected by patents and copyrights, we have trade secrets and proprietary know-how relating to our products, production processes, and future strategies.

Competition

The biotechnology and pharmaceutical industries, including in the field of gene therapy, are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on intellectual property. While we believe that our technology platforms, strong intellectual property portfolio, and scientific expertise in the gene therapy field provide us with competitive advantages, we face potential competition from many different sources, including larger and better-funded pharmaceutical and biotechnology companies, new market entrants, and new technologies.

We are aware of several companies focused on other methods for editing genes and regulating their expression, and a limited number of commercial and academic groups pursuing the development of gene regulation and genome editing technology. The field of applied gene regulation and genome editing is highly competitive, and we expect competition to persist and intensify in the future from several different sources, including pharmaceutical and biotechnology companies; academic and research institutions, and government agencies.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval, or commercializing competitive products before us. If we commence commercial product sales, we may be competing against companies with greater marketing and manufacturing capabilities, areas in which we have limited or no experience. In addition, any product candidate that we successfully develop may compete with existing products that have long histories of safe and effective use.

The competitive landscape that we are facing is as follows:

Gene therapy companies developing gene-based products in clinical trials. uniQure N.V.’s product for lipoprotein lipase deficiency and GlaxoSmithKline plc, or GSK’s, product for severe combined immunodeficiency due to adenosine deaminase deficiency are approved in Europe. No other gene therapy products have yet been approved. Our competitors in this category may include, but not be limited to, Sangamo Therapeutics, Inc., uniQure N.V., bluebird bio, Inc., Regenxbio Inc., Shire, Pfizer Pharmaceutical, and GSK.

Cell therapy companies developing cell-based products. Our competitors in this category may include Novartis AG, Adaptimmune Therapeutics PLC, Atara Biotherapeutics, Inc., bluebird bio, Inc., Cellectis S.A., Juno Therapeutics, Inc., Kite Pharma, and Iovance Biotechnologies, Inc.

For ENOB-DC-11, the competitive landscape is more complex.

Immunotherapy is an active area of research and a number of immune-related products have been identified in recent years that are alleged to modulate the immune system. Many of these products utilize dendritic cells, a form of immune cell that presents cancer target peptides to T cells and that can in turn result in T cell activation. More recently, bi-specific antibodies and checkpoint inhibitors (for instance PD-1/PD-L1 antibodies) have been identified as having utility in the treatment of cancer. Bi-specific antibodies commonly target both the cancer peptide and the T cell receptors (“TCR”), thus bringing both cancer cells and T cells into close proximity to maximize the chance of TCR binding and hence an immune response to the cancer cells. Checkpoint inhibitors on the other hand work by targeting receptors that inhibit T cell effectiveness and proliferation and essentially activate T cells. Other immunotherapies that are being actively investigated include antibody-drug complexes, TCR-mimic antibodies, oncolytic viruses, and cancer vaccines. A variety of cell-based autologous and allogeneic approaches are also being researched and developed.

CAR-T in solid tumors

In addition to hematological malignancies, there are a growing number of pharmaceutical, biotechnology, and academic institutions researching and developing autologous and allogeneic chimeric antigen receptor T cell (“CAR-T”) therapies in the solid tumor setting. These CAR-T cell therapies are at a variety of stages of preclinical and clinical development, as well as directed towards a broad target spectrum. Two CAR-T therapies have been approved for treatment of leukemia.

TCR T cells

Competitors are developing TCR T cells (including affinity engineered T cells) that are directed towards a multitude of targets. Juno Therapeutics has developed an engineered TCR therapeutic candidate where the end TCR is purported to have enhanced affinity through stem-cell selection.

Other cell-based approaches

In addition to all the adoptive cell therapy approaches above, our competitors are also investigating the potential of Gamma Delta T cell, CAR-NK cell, NK cell, NKT cell and CTLs either in a preclinical or clinical setting (both hematologic malignancies and solid tumors). In addition, Bristol Myers Squibb’s Abraxane is used for pancreatic cancer.

For ENOB-HV-12, we are aware of a few biotech companies developing an HIV vaccine such as Geovax, Biosantech SA, and FIT Biotech, among a few others.

For ENOB-HV-01, we are aware of two companies developing a gene therapy for HIV/AIDS: Sangamo and American Gene Technology.

For ENOB-HB-01, there is an approved vaccine to prevent HBV infection. In addition, several approved combination antivirals can suppress replication, but do not cure HBV. Several companies are pursuing cures, mostly targeting the depletion of ccc-DNA.

Manufacturing

Our intent is to rely on contract manufacturing organizations (CMOs) and contract development and manufacturing organizations (CDMOs), to help develop processes and manufacture our product candidates in accordance with FDA and European Medicine Agency (EMA) mandated regulations, also known as current good manufacturing practices, (“cGMPs”). We employ a technical operations staff in the areas of process development, analytical development, quality control, quality assurance, project management, and manufacturing, which will facilitate appropriate oversight of our CMOs, support of our regulatory filings, and execution of clinical trials.

Government Regulation

FDA Review and Approval

Government authorities in the United States, at the federal, state, and local levels, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. Any products we develop will require regulatory review and allowance to proceed prior to conducting clinical trials and additional regulatory approvals prior to commercialization. In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (FDCA) and the Public Health Service Act (PHSA) and their implementing regulations govern, among other things, biopharmaceutical testing, manufacturing, safety, efficacy, labeling, storage, recordkeeping, advertising, and other promotional practices.

Obtaining FDA approval is a costly and time-consuming process. Generally, FDA approval requires that preclinical studies be conducted in the laboratory and in animal model systems to gain preliminary information on efficacy and to identify any major safety concerns. The results of these studies are then submitted as a part of an IND, which the FDA must review and allow before human clinical trials can start. The IND includes a detailed description of the proposed clinical investigations. An independent Institutional Review Board (“IRB”) must also review and approve the clinical protocol and each clinical site.

A company must submit an IND for each investigational medical product and specific indication(s) and must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA approval. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension, or termination of clinical trials if an unwarranted risk is presented to patients.

Obtaining FDA approval prior to marketing a biopharmaceutical product in the United States typically requires several phases of clinical trials to demonstrate the safety and efficacy of the product candidate. Clinical trials are the means by which experimental treatments are tested in humans and are conducted following preclinical testing. Clinical trials may be conducted within the United States or in foreign countries. If clinical trials are conducted in foreign countries, the products under development as well as the trials are subject to regulations of the FDA and/or its regulatory counterparts in the other countries. Upon successful completion of clinical trials, approval to market the treatment for a particular patient population may be requested from the FDA in the United States and/or its counterparts in other countries.

Clinical trials for therapeutic products are normally conducted in three phases. Phase 1 clinical trials are typically conducted with a small number of subjects/patients to evaluate the safety, determine a safe dosage range, identify side effects, and, if possible, gain early evidence of effectiveness. Phase 2 clinical trials are conducted with a larger group of patients to evaluate the effectiveness of an investigational product for a defined patient population, and to determine common short-term side effects and risks associated with the drug. Phase 3 clinical trials involve large scale, multi-center, comparative trials that are conducted to evaluate the overall benefit-risk relationship of the investigational product and to provide an adequate basis for product labeling. In some special cases where the efficacy testing of a product may present a special challenge to testing in humans, such as in the case of a vaccine to protect healthy humans from a life-threatening disease that is not a naturally occurring threat, effectiveness testing may be required in animals. For certain advanced therapies that meet eligibility criteria for expedited program designations, clinical development may be accelerated.

Clinical trials involve the administration of the treatment/drug product candidate to healthy volunteers or patients under the supervision of qualified investigators who generally are physicians not employed by, or under, the control of the trial sponsor. Clinical trials are conducted under written study protocols detailing, 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, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the Good Clinical Practice ("GCP") requirements, and any additional requirements for the protection of human research subjects and their health information including the requirement that all research subjects provide informed consent.

Further, each clinical trial must be reviewed and approved by an IRB at or servicing, each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers items such as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject, or their legal representative, reviews and approves the study protocol, and must monitor the clinical trial until completed. Clinical trials involving recombinant DNA also must be reviewed by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research that utilizes recombinant DNA at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

After completion of clinical trials of a new product, FDA marketing approval must be obtained. If the product is regulated as a biologic, a Biologics License Application, or BLA, is required. If the product is classified as a new drug, a New Drug Application, or NDA is required. The NDA or BLA must include results of product development activities, preclinical studies, and clinical trials in addition to detailed chemistry, manufacturing and control information.

Applications submitted to the FDA are subject to an unpredictable and potentially prolonged approval process. Despite good-faith communication and collaboration between the applicant and the FDA during the development process, the FDA may ultimately decide, upon final review of the data, that the application does not satisfy its criteria for approval or requires additional product development or further preclinical or clinical studies. Even if FDA regulatory approval(s) are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Before marketing approval can be secured for a product, the facility in which the product is manufactured must be inspected by the FDA and must comply with the FDA's current Good Manufacturing Practices, ("cGMP") regulations. In addition, after marketing approval is secured, the manufacturing facility must be inspected periodically for cGMP compliance by FDA inspectors, and, if the facility is located in California, by inspectors from the Food and Drug Branch of the California Department of Health Services.

Sponsors of clinical trials are required to register, and report results for, all controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation. Trial registration may require public disclosure of certain confidential commercial development data.

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 U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The FDA offers several programs to expedite the development of products that treat serious or life-threatening illnesses and that provide meaningful therapeutic benefits to patients over existing treatments.

RMAT designation:

A drug is eligible for designation as an RMAT if: the drug is a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product or any combination product using such therapies or products, except for those regulated solely under certain other sections; the drug is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition; and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. Some of our current and future products may be eligible for RMAT designation.

Orphan designation:

Under the Orphan Drug Act, the FDA may grant orphan designation to a product 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, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a product available for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA or BLA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan designation subsequently receives the first FDA approval for such product for the disease or condition 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 a product containing the same active moiety for the same use or indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. A product is clinically superior if it is safer, more effective or makes a major contribution to patient care. Any claims of clinical superiority could require a head-to-head clinical trial between such drugs. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. If a product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

Other Healthcare Laws and Compliance Regulations

Although we currently do not have any products on the market, we may also be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. In the United States, among other things, the research, manufacturing, distribution, sale and promotion of pharmaceutical and biological products are potentially subject to regulation and enforcement by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (“CMS”), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety and Health Administration, the Environmental Protection Agency, state Attorneys General and other state and local government agencies. Our current and future business activities, including for example, sales, marketing, and scientific/educational grant programs, must comply with health care regulatory laws, as applicable, including, without limitation:

- the federal anti-kickback statute, which is a criminal statute that makes it a felony for individuals or entities to knowingly and willfully offer or pay, or to solicit or receive, direct or indirect remuneration, in order to induce the purchase, order, lease, or recommending of items or services, or the referral of patients for services, that are reimbursed under a federal health care program, including Medicare and Medicaid;
- the federal False Claims Act, which prohibits, among other things, individuals and entities from knowingly submitting, or causing to be submitted, false or fraudulent claims for payment of government funds, with penalties that include three times the government’s damages plus civil penalties for each false claim; in addition, the False Claims Act permits a person with knowledge of fraud, referred to as a qui tam plaintiff, to file a lawsuit on behalf of the government against the person or business that committed the fraud, and, if the action is successful, the qui tam plaintiff is rewarded with a percentage of the recovery;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical suppliers to report annually to CMS information related to payments and other transfers of value to physicians, other healthcare professionals and teaching hospitals, and ownership and investment interests held by physicians and other healthcare professionals and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws, such as state anti-kickback and false claims laws which may impose stricter requirements than federal law and may apply to items or services reimbursed by any payor (including commercial insurers and cash-paying patients); state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare professionals and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of such laws or any other governmental laws or regulations that apply, they may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, exclusion from participation in federal and state healthcare programs, additional program integrity obligations, individual imprisonment, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, refusal to permit us to enter into supply contracts, including government contracts, contractual damages, reputational harm, administrative burdens, diminished profits, and future earnings, any of which could have a material adverse effect on our business, financial condition, result of operations, and cash flows. These additional healthcare regulations could affect our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors.

Moreover, the introduction of legislation, implementation of new regulations, or enforcement of existing regulations that have a negative impact on the commercial prospects for the types of products we are developing could negatively impact our share price and our ability to raise capital.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate that receives regulatory approval. In the United States and markets in other countries, sales of our product candidates, if approved, will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels.

In the United States, third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all the FDA-approved drugs for a particular indication. Third-party payor coverage may be more limited than the purposes for which the product is approved by the FDA or foreign regulatory authorities. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product.

Moreover, the process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved or that the product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. There may be significant delays in obtaining reimbursement for approved products, and reimbursement rates may fluctuate over time or vary according to the use of the product or clinical setting in which a product is used. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States.

Further, third-party payers are increasingly challenging the price of medical products and services, and there is increasing pressure on biotechnology companies to reduce healthcare costs. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and whether adequate third-party coverage will be available. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for future products we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize potential products, and our overall financial condition.

Healthcare Reform

In March 2010, former President Obama signed into law The Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "Affordable Care Act"), which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The Affordable Care Act contains a number of provisions, including those governing enrollments in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the Affordable Care Act increases the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; requires collection of rebates for drugs paid by Medicaid managed care organizations; requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted, including aggregate reductions of Medicare payments to providers and reduced payments to several types of Medicare providers. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, proposing to encourage importation from other countries and bulk purchasing. We cannot predict what healthcare reform initiatives may be adopted in the future.

We also are subject to various federal, state, and local laws, regulations, and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. The extent of government regulation that might result from any future legislation or administrative action cannot be accurately predicted.

Foreign Corrupt Practices Act

Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations, or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Employees

As of June 30, 2022, we had 22 full-time employees. In July 2022, the Company began to streamline the organization to focus around two of its therapies (oncology and HIV therapeutic vaccine). The Company has tailored its workforce to focus on these therapies. As of February 2023, we have 11 full-time employees. We believe that we have good relations with our employees.

Corporate Information

On February 16, 2018, we completed our acquisition of Enochian Biopharma pursuant to an acquisition agreement, dated January 12, 2018, by and among the Registrant, its wholly owned subsidiary DanDrit Acquisition Sub, Inc., Enochian Biopharma and Weird Science (the “Acquisition Agreement”), with Enochian Biopharma surviving as a wholly owned subsidiary of the Registrant. As consideration for the acquisition, the stockholders of Enochian Biopharma received (i) 18,081,962 shares of Common Stock and (ii) the right to receive Contingent Shares pro rata upon the exercise or conversion of warrants, which were outstanding at closing (See Note 1 to the Financial Statements).

We trade on the NASDAQ Capital Market under the ticker “ENOB.”

Our website is <http://www.enochianbio.com>. We make available free of charge, on or through our internet site, our annual, quarterly, and current reports and any amendments to those reports filed or furnished pursuant to Section 13(a) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information contained in our website is not part of, nor incorporated by reference into, this report.

Item 1A. Risk Factors

RISK FACTORS

Investing in our common stock involves a high degree of risk. Investors should carefully consider all of the risk factors and uncertainties described below, in addition to the other information contained in this Annual Report on Form 10-K, including the section of this report titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes, before investing in our common stock.

The risks described below may not be the only ones relating to our Company and additional risks that we currently believe are immaterial may also affect us. If any of these risks, including those described below, materialize, our business, competitive position, reputation, financial condition, results of operations, cash flows and future prospects could be seriously harmed. In these circumstances, the market price of our common stock could decline, and investors may lose all or a part of their investment.

Risks Related to Our Financial Results and Capital Needs

We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.

We are a pre-clinical-stage biotechnology company. Investment in biotechnology related to genetically modified cells is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities and have not generated any revenues from product sales or otherwise to date, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. For the years ended June 30, 2022 and 2021, respectively, we reported a net loss of \$113.4 million and \$26.7 million. We had an accumulated deficit of \$204.3 million and \$90.9 million as of June 30, 2022 and 2021, respectively.

We do not expect to generate revenues for the foreseeable future. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue to research, develop, and seek regulatory approvals for our product candidates and any additional product candidates we may acquire, in-license or develop, and potentially begin to commercialize product candidates that may achieve regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If any of our product candidates fails in clinical studies or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We anticipate that our expenses will increase in the future as we continue to invest in research and development of our existing product candidates, investigate and potentially acquire new product candidates and expand our manufacturing and commercialization activities.

There is substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Our consolidated financial statements as of June 30, 2022 have been prepared under the assumption that we will continue as a going concern for the next twelve months. As of June 30, 2022, we had cash and cash equivalents of \$9.2 million and an accumulated deficit of \$204.3 million. We do not believe that our cash and cash equivalents are sufficient for the next twelve months. As a result of our financial condition and other factors described herein, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. We continue to analyze various alternatives, including potentially obtaining debt or equity financings or other arrangements. Our future success depends on our ability to raise capital. We cannot be certain that raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current shareholders may experience dilution. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current development programs, cut operating costs, forego future development and other opportunities, or even terminate our operations.

We are a pre-clinical biotechnology company and may never be able to successfully develop marketable products or generate any revenue. We have a very limited relevant operating history upon which an evaluation of our performance and prospects can be made. There is no assurance that our future operations will result in profits. If we cannot generate sufficient revenues, we may suspend or cease operations.

We are an early-stage biotechnology company and have not generated any revenues to date. All of our product candidates are in the discovery stage or pre-clinical development stage. Moreover, we cannot be certain that our research and development efforts will be successful or, if successful, that our potential treatments will ever be approved for sale to generate commercial revenues. Our pipeline includes cell, gene and immunotherapy involving genetically modified cells targeted to treat cancer, HIV, and Hepatitis B, and we rely on third parties under contract in the development of product candidates in our pipeline. There is no guarantee that we will be able to manage and fund the development of a pipeline with multiple target conditions, nor that third parties will meet their obligations to us in connection with our research and development. We and certain third parties, on which we rely, have no relevant operating history upon which an evaluation of our performance and prospects can be made. We are subject to all of the business risks associated with a new enterprise, including, but not limited to, risks of unforeseen capital requirements, failure of treatments either in non-clinical testing or in clinical trials, failure to establish business relationships, failure of our third parties to meet their obligations to us and competitive disadvantages against larger and more established companies. If we fail to become profitable, we may suspend or cease operations.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

We expect to expend substantial resources for the foreseeable future to continue the pre-clinical development of our cell, gene and immunotherapy product candidates, and the advancement and potential expansion of our pre-clinical research pipeline. We also expect to continue to expend resources for the development and manufacturing of product candidates and the technology we have licensed or have a right to license from our licensors. These expenditures will include costs associated with research and development, potentially acquiring or licensing new product candidates or technologies, conducting pre-clinical and clinical studies and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any. Under the terms of certain of our license agreements, we are obligated to make payments upon the achievement of certain development, regulatory and commercial milestones. We will also need to make significant expenditures to develop a commercial organization capable of sales, marketing, and distribution for any products, if any, that we intend to sell ourselves in the markets in which we choose to commercialize on our own. In addition, other unanticipated costs may arise. Because the design and outcome of our ongoing, planned and anticipated pre-clinical and clinical studies is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the costs and payments associated with license agreements for our potential products and technologies;
- the costs of conducting pre-clinical and clinical studies and the costs of manufacturing our product candidates
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates, if clinical studies are successful, including any costs from post-market requirements;

- the cost of commercialization activities for our product candidates, if any of these product candidates is approved for sale, including marketing, sales and distribution costs;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical studies, or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales, marketing and distribution capabilities or other activities that may be necessary to commercialize our product candidates.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies.

Until such time as we can generate substantial product revenues, we may attempt to finance our cash needs through equity offerings, debt financings, government and/or other third-party grants or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances, and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our investors' ownership interest will be diluted. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more clinical research or development programs, which would adversely impact our potential revenues, future results of operations and financial condition.

From time to time, we may be subject to legal proceedings, regulatory investigations or disputes, and governmental inquiries that could cause us to incur significant expenses, divert our management's attention, and materially harm our business, financial condition, and operating results.

From time to time, we may be subject to claims, lawsuits, government investigations, and other proceedings involving intellectual property, privacy, securities, tax, labor and employment, and other matters that could adversely affect our business operations and financial condition. Recently, we have seen a rise in the number and significance of these disputes and inquiries. The arrest and indictment of Serhat Gümrükcü, has, and could in the future, subject us to regulatory proceedings and litigation by governance agencies and private litigants brought against us, that regardless of their merits, could harm our reputation, divert management's attention from our operations and result in substantial legal fees and other costs. Additionally, we have in the past been subject to intense media scrutiny, which exposes us to increasing regulation, government investigations, legal actions, and penalties.

We have also been named in several lawsuits related to Mr. Gümrükcü. For example, the Company and certain of its current and former officers have been named in securities class actions by purported stockholders of ours, alleging defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder, by making false and misleading statements and omissions of material fact in connection with the Company's relationship with Mr. Gümrükcü and its commercial prospects. In addition, two shareholders filed shareholder derivative action lawsuits purportedly on behalf of the Company against certain of our executive officers and the members of our Board of Directors alleging violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934 and also setting out claims for breach of fiduciary duty, contribution and indemnification, aiding and abetting, and gross mismanagement. Additionally, from time to time, we may be, and currently are, subject to inquiries from regulators in which they seek information about us. Such further inquiries could result in more formal investigations or allegations, which could adversely impact our business, financial condition, and operating results.

Litigation, regulatory proceedings, such as the investigations described above, as well as the related class action claims and lawsuits, and securities matters that we are currently facing or could face, can be protracted and expensive, and have results that are difficult to predict. Certain of these matters include speculative claims for substantial or indeterminate amounts of damages and include claims for injunctive relief. Additionally, our legal costs for any of these matters, either alone or in the aggregate could be significant. Adverse outcomes with respect to any of these legal or regulatory proceedings may result in significant settlement costs or judgments, penalties, and fines. Even if these proceedings are resolved in our favor, the time and resources necessary to resolve them could divert the resources of our management and require significant expenditures. See *Note 9 - Commitments and Contingencies* in the Notes to our Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K and the section titled “Legal Proceedings” in Part I, Item 3 of this Annual Report on Form 10-K.

The results of litigation, investigations, claims, and regulatory proceedings cannot be predicted with certainty, and determining reserves for pending litigation and other legal and regulatory matters requires significant judgment. There can be no assurance that our expectations will prove correct, and even if these matters are resolved in our favor or without significant cash settlements, these matters, and the time and resources necessary to litigate or resolve them, could harm our business, financial condition, and operating results.

The recent negative publicity has had and may continue to have a negative impact on our business and may have a long-term effect on our relationships with our customers, partners and collaborators.

Our business and reputation have been negatively affected by the recent negative publicity resulting from the arrest and indictment of Serhat Gümürkücü, a co-founder of the Company and an inventor of some of the Company’s intellectual property. If we are unable to rebuild the trust of our collaborators, research institutions and investors, and if further negative publicity continues, we could experience a substantial negative impact on our business. We have experienced claims and litigation as a consequence of these matters, including shareholder class actions in connection with a decline in our stock price and litigation with Mr. Gümürkücü. Related legal expenses of defending these claims have negatively impacted our operating results. Continuing higher legal fees, potential new claims, liabilities from existing cases and continuing negative publicity could continue to have a negative impact on our operating results.

Risks Related to the Development of Our Product Candidates

We are highly dependent on the services of third parties to conduct research and development of our pipeline, and our failure to maintain the services of such third parties could harm our business.

We are highly dependent on third parties working in conjunction with our officers, employees, scientific advisory board and research institutions in the research and development of product candidates in our pipeline. The loss of the services of any of the foregoing, or of any of our key employees or scientific advisory board members could impede the achievement of our research, development, regulatory approvals, and commercialization objectives.

The results of pre-clinical studies or earlier clinical studies are not necessarily predictive of future results, and if we fail to demonstrate efficacy in our pre-clinical studies and/or clinical trials in the future our future business prospects, financial condition and operating results will be materially adversely affected.

The success of our research and development efforts will depend upon our ability to demonstrate the efficacy of the treatments in our pipeline in pre-clinical studies, as well as in clinical trials following IND approval by the FDA. Pre-clinical studies involve testing potential product candidates in appropriate non-human disease models to demonstrate efficacy and safety.

Success in pre-clinical studies does not ensure that later clinical studies will generate adequate data to demonstrate the efficacy and safety of an investigational drug. Currently, several of our product candidates, including DC-11, our genetically-modified allogeneic dendritic therapeutic vaccination platform for solid tumors, ENOB-HV-12, our therapeutic HIV vaccine, and ENOB-HV-01, our autologous HIV curative treatment are all currently in various stages of pre-clinical development with ongoing and planned pre-clinical studies in conjunction with research institutions and third parties. Despite preliminary data we believe is positive, this does not guarantee that any of these products will proceed to the clinical stage or to approval for commercial use. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical studies, even after seeing promising results in earlier preclinical studies or clinical studies.

Regulatory agencies evaluate these data carefully before they will approve clinical testing in humans. If certain non-clinical data reveals potential safety issues or the results are inconsistent with an expectation of the potential product candidates' efficacy in humans, the regulatory agencies may require additional more rigorous testing before allowing human clinical trials. This additional testing will increase program expenses and extend timelines. We may decide to suspend further testing on our potential products or abandon the product lines altogether if, in the judgment of our management and advisors, the pre-clinical test results do not support further development, as we did with our pan-coronavirus and influenza product lines.

Our novel gene, cell and immunotherapy product candidates and new therapeutic approaches could result in heightened regulatory scrutiny, delays in clinical development or delays in our inability to achieve regulatory approval or commercialization of our product candidates.

Our future success is dependent on the successful development of novel gene, cell and immunotherapy product candidates. Because these programs, particularly our pipeline of allogeneic T-cell product candidates that are bioengineered from healthy donor cells, represent a new approach to immunotherapy for the treatment of cancer and other diseases, developing and commercializing our product candidates subject us to a number of challenges.

Moreover, actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical studies, or if approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics. The FDA or other applicable regulatory authorities may ask for specific post-market requirements, and additional information informing benefits or risks of our products may emerge at any time prior to or after regulatory approval.

We face significant competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our product candidates.

The development of treatments in the fields of cancer, HIV, and Hepatitis B is highly competitive and many pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and other public and private research organizations may pursue the research and development of technologies, drugs or other therapeutic products for the treatment of some or all of the diseases we are targeting. Nearly all of our competitors have greater capital resources, larger overall research and development staffs and facilities, and a longer history in drug discovery and development, obtaining regulatory approval and pharmaceutical product manufacturing and marketing than we do. Techniques in gene, cell and immunotherapy are subject to rapid technological change and development and are significantly affected by existing rival products and medical procedures, new product introductions and the market activities of other participants. With additional resources, our competitors may be able to respond to the rapid and significant technological changes faster than we can. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies. We may also face competition from products, which have already been approved and accepted by the medical community for the treatment of these same indications. If we are unable to compete effectively with any existing products, new treatment methods and new technologies, we may be unable to commercialize therapeutic products that we may develop in the future, which could adversely impact our potential revenues, results of operations and financial condition or lead to abandonment of product candidates in our pipeline.

Our reliance on third parties, such as university laboratories, contract manufacturing organizations and contract or clinical research organizations, may result in delays in completing, or a failure to complete, non-clinical testing or clinical trials if they fail to perform under our agreements with them.

In the course of the development of our pipeline, we have and expect to continue to engage university laboratories, non-profit organizations, independent contractors, other biotechnology companies or contract or clinical manufacturing organizations to conduct and manage research and development, pre-clinical and clinical studies and to manufacture materials for us to be used in pre-clinical and clinical testing. Due to engagements with these organizations, many important aspects of our research have been and will be out of our direct control. If any of these organizations we may engage in the future, fail to perform their obligations under our agreements with them or fail to perform non-clinical testing and/or clinical trials in a satisfactory manner, we may face delays in completing our clinical trials, as well as commercialization of any of our product candidates. Furthermore, any loss or delay in obtaining contracts with such entities may also delay the completion of our clinical trials, regulatory filings and the potential market approval of our product candidates.

Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy, may negatively impact our ability to generate revenues.

In the United States and some foreign jurisdictions, there have been a number of proposed legislative and regulatory changes related to the healthcare system that could affect our ability to profitably sell or commercialize our product candidates for which we obtain marketing approval in the future. The potential pricing and reimbursement environment for our product candidates may change in the future and become more challenging due to, among other reasons, policies advanced by the current or any new presidential administration, federal agencies, healthcare legislation passed by Congress, or fiscal challenges faced by all levels of government health administration authorities, or by similar changes in foreign countries. The implementation of any such changes could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects, including our share price and ability to raise capital.

We have limited experience in drug development and may not be able to successfully develop any drugs, which would cause us to cease operations.

We have never successfully developed a new drug and brought it to market. Our management and clinical teams have experience in drug development, but they may not be able to successfully develop any drugs. Our ability to achieve revenues and profitability in our business will depend on, among other things, our ability to develop products internally or to obtain rights to them from others on favorable terms; complete laboratory testing and human studies; obtain and maintain necessary intellectual property rights to our products; successfully complete regulatory review to obtain requisite governmental agency approvals; enter into arrangements with third parties to manufacture our products on our behalf; and enter into arrangements with third parties to provide sales and marketing functions. If we are unable to achieve these objectives, we will be forced to cease operations.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would harm our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could harm our business.

The COVID-19 pandemic has also resulted in the FDA imposing preventive measures, including postponements of non-U.S. manufacturing and product inspections. If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our gene therapy product candidates are still in development and will require extensive clinical testing before we are prepared to submit an application for marketing approval to regulatory authorities. We cannot predict with any certainty if or when we might submit any such application for regulatory approval for our product candidates or whether any such application will be approved by the applicable regulatory authority in our target markets. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, regulatory authorities may not agree with our proposed endpoints for any clinical trials of our gene therapy product candidates, which may delay the commencement of our clinical trials.

Clinical trials are expensive, time-consuming, difficult to design and implement, and involve an uncertain outcome.

Our product candidates are still in development and will require extensive clinical testing before we are prepared to submit an application for marketing approval to regulatory authorities. We cannot predict with any certainty if or when we might submit any such application for regulatory approval for our product candidates or whether any such application will be approved by the applicable regulatory authority in our target markets. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, regulatory authorities may not agree with our proposed endpoints for any clinical trials of our product candidates, which may delay the commencement of our clinical trials. The clinical trial process is also time-consuming. We estimate that clinical trials of our product candidates will take at least several years to complete.

A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and in the regulatory approval process. In addition, the design of a clinical trial, such as endpoints, inclusion and exclusion criteria, statistical analysis plans, data access protocols and trial sizing, can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues may be delayed. In addition, any delays in our clinical trials could increase our costs, cause a drop in our stock price, slow down the approval process and jeopardize our ability to commence product sales and generate revenues. Further, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in commencing or completing clinical trials. Any of these occurrences may harm our business, financial condition, and results of operations.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the effectiveness of our patient recruitment efforts, delays in enrollment due to travel or quarantine policies, or other factors, related to COVID-19, the existing body of safety and efficacy data with respect to the study candidate, the perceived risks and benefits of gene therapy approaches for the treatment of certain diseases, the number and nature of competing existing treatments for our target indications, the number and nature of ongoing trials for other product candidates in development for our target indications, perceived risk of the delivery procedure, patients with pre-existing conditions that preclude their participation in any trial, the proximity of patients to clinical sites and the eligibility criteria for the study. Furthermore, the results we have reported in clinical trials to date and any other results we may report in clinical trials of any of our gene therapy product candidates in the future may make it difficult or impossible to recruit and retain patients in other clinical trials of those gene therapy product candidates. Similarly, negative results reported by our competitors about their product candidates may negatively affect patient recruitment in our clinical trials. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our gene therapy product candidates or could render further development impossible. In addition, we expect to rely on clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to control their actual performance.

Risks Related to Our Intellectual Property

We have licensed a significant portion of our intellectual property from our licensors. If we breach any of our license agreements with these licensors, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We hold rights under license agreements with our licensors that are important to our business. Our research and development platform is built, in part, around patent rights licensed from such licensors. Under our existing license agreements, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, provision of support with respect to development of licensed intellectual property, prosecution of intellectual property protection, payment obligations upon achievement of certain milestones and royalties on product sales. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If any of these licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of product candidates covered by any such licenses. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under license agreements and other interpretation-related issues;
- payment obligations due to licensors under license agreements and other disputes related to the obligations for payment related to intellectual property protection;
- the extent to which our product candidates, technology and processes infringe on intellectual property of a licensor that is not subject to a licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under license agreements and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we do not obtain required intellectual property licenses or rights, we could encounter delays in our product development efforts while we attempt to design around other patents or even be prohibited from developing, manufacturing or selling products requiring these rights or licenses. There is also a risk that legal disputes may arise as to the rights to technology developed in collaboration with other parties, all with attendant risk, distraction, expense, and lack of predictability.

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.

We rely upon a combination of patents, trademarks, trade secrets and confidentiality agreements – either that we own or possess or that are owned or possessed by our licensors that are licensed to us – to protect the intellectual property related to our technology and product candidates. When we refer to “our” technologies, inventions, patents, provisional patents, patent applications or other intellectual property rights, we are referring to both the rights that we own or possess as well as those that we license, many of which are critical to our intellectual property protection and our business. For example, the product candidates and platform technology we have licensed from our licensors are protected primarily by patent or patent applications of our licensors that we have licensed and as confidential know-how and trade secrets. If the intellectual property that we rely on is not adequately protected, competitors may be able to use our technologies and erode or negate any competitive advantage we may have.

The patentability of inventions and the validity, enforceability and scope of patents in the biotechnology field is uncertain because it involves complex legal, scientific and factual considerations, and it has in recent years been the subject of significant litigation. Moreover, the standards applied by the U.S. Patent and Trademark Office, or USPTO, and non-U.S. patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents.

There is no assurance that all potentially relevant prior art relating to our patents and patent applications is known to us or has been found in the instances where searching was done. We may be unaware of prior art that could be used to invalidate an issued patent or prevent a pending patent application from issuing as a patent. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of such claim. We also may not be able to obtain full patent protection from provisional patents for which we have sought or will seek further patent protection. As a consequence of these and other factors, our patent applications may fail to result in issued patents with claims that cover our product candidates in the U.S. or in other countries.

Even if patents have issued or do successfully issue from patent applications, and even if these patents cover our product candidates, third parties may challenge the validity, enforceability or scope thereof, which may result in these patents being narrowed, invalidated or held to be unenforceable. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable.

Even if unchallenged, our patents and patent applications or other intellectual property rights may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. The possibility exists that others will develop products on an independent basis which have the same effect as our product candidates and which do not infringe our patents or other intellectual property rights, or that others will design around the claims of patents that we have had issued that cover our product candidates. If the breadth or strength of protection provided by our patents and patent applications with respect to our product candidates is threatened, it could jeopardize our ability to commercialize our product candidates and dissuade companies from collaborating with us.

We may also desire to seek a license from a third party who owns intellectual property that may be useful for providing exclusivity for our product candidates, or for providing the ability to develop and commercialize a product candidate in an unrestricted manner. There is no guarantee that we will be able to obtain a license from such a third party on commercially reasonable terms, or at all.

In addition, the United States Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

We and our licensors have filed a number of patent applications covering our product candidates or methods of using or making those product candidates. We cannot offer any assurances about which, if any, patents will be issued with respect to these pending patent applications, the breadth of any such patents that are ultimately issued or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Because patent applications in the U.S. and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to a product candidate. We or our licensors may also become involved in proceedings regarding our patents, including patent infringement lawsuits, interference or derivation proceedings, oppositions, and *inter partes* and post-grant review proceedings before the USPTO, the European Patent Office and other non-U.S. patent offices.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be negatively impacted and our business would be harmed.

In addition to the protection afforded by patents we hold rights to, we also rely on trade secret protection for certain aspects of our intellectual property. However, trade secrets are difficult to protect. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we might not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, it could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our success will depend in part on our ability to commercialize our product candidates without infringing the proprietary rights of others. While some of the intellectual property utilized in our product candidates is owned, some is licensed from our licensors, who hold patents and provisional patents in their names. We have not conducted extensive freedom of use patent searches and no assurance can be given that patents do not exist or could be issued which would have an adverse effect on our ability to market our technology or maintain our competitive position with respect to our technology. We also cannot be sure that patents or provisional patents filed by others are valid or will be upheld if challenged. It is possible that there are additional patents that may cover certain other aspects of technology used in our product candidates that is not covered by our licensed intellectual property. If our licensed technology or other subject matter are claimed under other United States patents or other international patents or are otherwise protected by third party proprietary rights, we or our licensors may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our technology. There can be no assurances that we would be successful in a challenge or be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to succeed in a challenge, develop a commercially viable alternative or obtain needed licenses could have significant adverse consequences to the development of our pipeline. Adverse consequences include delays in marketing some or all of our product candidates based on our technology or the inability to proceed with the development, manufacture or sale of products requiring such licenses. If we defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease the research and development of our technology.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Additionally, parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Risks Related to our Common Stock

Our stock price has been and will likely continue to be volatile and may decline regardless of our operating performance.

Our stock price has fluctuated in the past and can be expected to be volatile in the future. From July 1, 2021 through June 30, 2022, the reported sale price of our Common Stock has fluctuated between \$12.55 and \$1.93 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our Common Stock. The market price of our Common Stock may be influenced by many factors, including the following:

- negative publicity;
- our compliance with Nasdaq rules and regulations;
- the success of competitive products or technologies;
- regulatory actions with respect to our product candidates or products or our competitors' product candidates or products;

- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- results of clinical studies of our product candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our Common Stock by us, our insiders or our other stockholders;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other risks described in this “Risk Factors” section.

In addition, the stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies.

Sales of a substantial number of shares of our Common Stock in the public market could cause our stock price to fall.

A significant portion of our Common Stock is held in restricted form, and consequentially a minority of our outstanding Common Stock actively trades in the public markets. Sales of a substantial number of such shares of our Common Stock in the public market could occur at any time. While a large majority of such shares are unregistered and subject to volume restrictions on sale pursuant to Rule 144 under the Securities Act, these restrictions could be lifted if any of our stockholders ceased to be bound by such restrictions. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Common Stock.

We previously received notices of failure to satisfy a continued listing rule from Nasdaq, and we may in the future fail to comply with applicable Nasdaq rules.

On each of October 17, 2022, November 23, 2022, and February 16, 2023, we received a notice, or the Notices, from the Listing Qualifications Department of Nasdaq stating that we were not in compliance with Nasdaq Listing Rule 5250(c)(1), or the “Rule”, because we did not timely file our Form 10-K for the period ended June 30, 2022 and our Form 10-Q for the period ended September 30, 2022 and December 31, 2022 with the SEC. The Rule requires listed companies to timely file all required periodic financial reports with the SEC. Today we filed our Form 10-K for the period ended June 30, 2022, but have not yet filed our Form 10-Q for the periods ended September 30, 2022 and December 31, 2022, and therefore we have not regained compliance with the Rule. We were unable to file the Annual Report on Form 10-K for the period ended June 30, 2022 and the Quarterly Report on Form 10-Q for the periods ended September 30, 2022 and December 31, 2022 by their initial deadlines, due to the reasons described in the Notifications of Late Filing on Form 12b-25, filed with the SEC on September 29, 2022 and November 15, 2022. While we were able to file the Annual Report on Form 10-K for the period ended June 30, 2022 within the extension period provided pursuant to SEC rules, we have not yet filed the Form 10-Q for the periods ended September 30, 2022 and December 31, 2022, and there can be no assurance that we will be able to remain compliant with the Rule or with other Nasdaq listing requirements in the future. If we are unable to regain compliance with the Rule or with any of the other continued listing requirements, Nasdaq may take steps to delist our securities, which could have adverse consequences, including a limited availability of market quotations for our securities, reduced liquidity for our securities, a limited amount of news and analyst coverage and a decreased ability to issue additional securities or obtain additional financing in the future.

Trading of our Common Stock may be volatile and sporadic, which could depress the market price of our Common Stock and make it difficult for our stockholders to resell their shares.

There is currently a limited market for our Common Stock and the volume of our Common Stock traded on any day may vary significantly from one period to another. Trading in our stock is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with our operations or business prospects. The availability of buyers and sellers represented by this volatility could lead to a market price for our Common Stock that is unrelated to operating performance. There is no assurance that a sufficient market will develop in the stock, in which case it could be difficult for our stockholders to resell their stock.

We have incurred and will continue to incur increased costs as a result of being a public company and our management expects to devote substantial time to public company compliance programs.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Stock Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. As a Smaller Reporting Company and Non-accelerated Filer, we are able to take advantage of certain accommodations afforded to such companies, including being exempt from the requirement to conduct an audit of our internal controls. In the event we no longer qualify as a Smaller Reporting Company and Non-accelerated Filer, we will lose such accommodations, which could involve significant costs that could affect our operations. Changes in reporting requirements, the current political environment and the potential for future regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and make some activities more time-consuming and costly. To the extent these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of potential gain for our stockholders.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our Common Stock will be the sole source of gain for our stockholders for the foreseeable future.

Future sales and issuances of our Common Stock or rights to purchase Common Stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of Common Stock or securities convertible into or exchangeable for Common Stock in one or more transactions at prices and in a manner, we determine from time to time. These future issuances of Common Stock or Common Stock-related securities, together with the exercise of outstanding options or warrants, and any additional shares that may be issued in connection with acquisitions or licenses, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to those of holders of our Common Stock. Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our employees, non-employee directors and consultants. Future grants of RSUs, options and other equity awards and issuances of Common Stock under our equity incentive plans will result in dilution and may have an adverse effect on the market price of our Common Stock.

Some terms of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Our Certificate of Incorporation, and our Bylaws, as well as Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include terms that:

- permit our Board of Directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences, and privileges as they may designate;
- provide that all vacancies on our Board of Directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice; and
- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of Common Stock entitled to vote in any election of directors to elect all of the directors standing for election.

Any of the factors listed above may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors, who are responsible for appointing the members of our management.

In addition, because we are incorporated in Delaware, we are governed by Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the Board of Directors has approved the transaction. Any term of our Certificate of Incorporation or Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our Common Stock and could also affect the price that some investors are willing to pay for our Common Stock.

Risks Related To Our Business Operations and Managing Growth

If our operations require a full time Chief Medical Officer (“CMO”), and we are not able to hire a full time CMO to manage our clinical operations or if our current Chief Executive Officer (“CEO”), Chief Financial Officer (“CFO”), Chief Operating Officer (“COO”) or key scientific personnel cease to serve, our business will be harmed.

Currently, our management team is led by Dr. Mark Dybul, the Chief Executive Officer, Luisa Puche, our Chief Financial Officer, and Francois Binette, our Chief Operating Officer. If Dr. Dybul, Ms. Puche or Mr. Binette should cease to serve, our business operations may suffer. Additionally, we may in the future require a Chief Medical Officer, and if we are unable to hire a CMO, our business operations and the continued development of our product candidates may suffer.

In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified additional management and scientific personnel. If we are not able to retain our management and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we might not be able to sustain our operations or grow.

We have limited corporate infrastructure and may experience difficulties in managing growth.

As of June 30, 2022, we had 22 full time employees. In July 2022, the Company began to streamline the organization to focus around two of its therapies (oncology and HIV therapeutic vaccine). The Company has tailored its workforce to focus on these therapies. As of February 2023, we have 11 full-time employees, and we rely on third-party contractors for the provision of professional, scientific, regulatory, and other services. As our development and commercialization plans and strategies develop, we may need additional managerial, scientific, operational, financial, and other resources. Our management may need to divert a disproportionate amount of its attention away from our day-to-day operations and devote a substantial amount of time to managing these growth activities. We might not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected and our ability to generate and grow revenue could be reduced and we might not be able to implement our business strategy. Our future financial performance, our ability to commercialize product candidates, develop a scalable infrastructure and compete effectively will depend, in part, on our ability to effectively manage any future growth.

If we, our service providers, or third parties fail to comply with environmental and health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

If we, our service providers, or any third parties engaged in the development of our product candidates fail to comply with laws regulating the protection of the environment, health and animal and human safety, we could be subject to enforcement actions and our business prospects could be adversely affected.

Our research and development activities, and the research and development activities of our service providers and any third parties engaged in development of our product candidates, may involve the use of hazardous materials and chemicals or other regulated activities. In conjunction with our service providers and other third parties, we are also engaged in pre-clinical studies using live animals and samples of infectious diseases. Failure to adequately handle and dispose of hazardous materials or to meet various standards imposed by federal, state, local or foreign regulators could lead to liabilities for resulting damages, which could be substantial. We also may be subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of bio-hazardous materials.

If we, our service providers, or any third parties engaged in development of our product candidates fail to comply with applicable federal, state, local or foreign laws or regulations, we could be subject to enforcement actions, which could adversely affect our ability to develop, market and sell our product candidates successfully and could harm our reputation and lead to reduced acceptance of our product candidates. These enforcement actions may include:

- restrictions on, or prohibitions against, marketing our product candidates;
- restrictions on importation of our product candidates;
- suspension of review or refusal to approve new or pending applications;
- suspension or withdrawal of product approvals;
- product seizures;
- injunctions; and
- civil and criminal penalties and fines.

We rely upon information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.

Our business operations could suffer in the event of system failure. Despite the implementation of security measures, our internal computer systems and those of our contract research organizations, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of formulas or data from completed or ongoing or planned pre-clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and further development of our product candidates could be delayed.

Our business plan may lead to the initiation of one or more product development programs, the discontinuation of one or more development programs, or the execution of one or more transactions that you do not agree with or that you do not perceive as favorable to your investment in our Common Stock.

We are pursuing a strategy to leverage our clinical experience and expertise for the clinical development and regulatory approval of our gene therapy product candidates. As part of our ongoing business strategy, we continue to explore potential opportunities to acquire or license new product candidates and to collaborate on our existing products in development. We cannot be certain that our product candidates will be successfully developed, or that the early clinical trial results of these product candidates will be predictive of future clinical trial results. During 2022, we decided to abandon our pan-coronavirus and influenza pipelines as the results did not support further development. We again may determine at any time that one or more of our in-licensed product candidates is not suitable for continued development due to cost, feasibility of obtaining regulatory approvals or any other reason, and may terminate the related license.

Our business plan requires us to be successful in a number of challenging, uncertain and risky activities, including pursuing development of our gene therapy product candidates in indications for which we have limited or no human clinical data, designing and executing a nonclinical and/or clinical development program for our product candidates, building internal or outsourced gene therapy capabilities, converting early stage gene therapy research efforts into clinical development opportunities, identifying additional promising new assets for development that are available for acquisition or in-license and that fit our strategic focus and identifying potential partners to collaborate on our products. We may not be successful at one or more of the activities required for us to execute this business plan. In addition, we may consider other strategic alternatives, such as mergers, acquisitions, divestitures, joint ventures, partnerships and collaborations. We cannot be sure when or if any type of transaction will result. Even if we pursue a transaction, such transaction may not be consistent with our stockholders' expectations or may not ultimately be favorable for our stockholders, either in the shorter or longer term.

Our growth prospects and the future value of our Company are primarily dependent on the progress of our ongoing and planned development programs for our product candidates as well as the outcome of our ongoing business development efforts and pipeline progression, together with the amount of our remaining available cash. The development of our product candidates and the outcome of our ongoing business development efforts and pipeline are highly uncertain. We expect to continue to reassess and make changes to our existing development programs and pipeline strategy. Our plans for our development programs may be affected by the results of competitors' clinical trials of product candidates addressing our current target indications, and our business development efforts and pipeline progression may also be affected by the results of competitors' ongoing research and development efforts. We may modify, expand or terminate some or all of our development programs, clinical trials or collaborative research programs at any time as a result of new competitive information or as the result of changes to our product pipeline or business development strategy.

If serious adverse events or other undesirable side effects or safety concerns attributable to our product candidates occur, they may adversely affect or delay our clinical development and commercialization of some or all of our product candidates.

Undesirable side effects or safety concerns caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval. Although no treatment-related serious adverse events ("SAEs") have been observed in any clinical trials of any of our product candidates to date, if treatment-related SAEs or other undesirable side effects or safety concerns, or unexpected characteristics attributable to our product candidates are observed in any future clinical trials, they may adversely affect or delay our clinical development and commercialization of the effected product candidate, and the occurrence of these events could have a material adverse effect on our business and financial prospects. Results of our future clinical trials could reveal a high and unacceptable severity and prevalence of adverse side effects. In such an event, our trials could be suspended or terminated and the FDA or other regulatory agency could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects or safety concerns caused by these product candidates, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend, or limit approvals of such product and require us to take them off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a REMS or REMS-like plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials, or change the labeling of a product;
- we may be required to conduct additional post-marketing studies or surveillance;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to regulatory investigations,
- government enforcement actions, litigation, or product liability claims; and
- our products may become less competitive, or our reputation may suffer.

Any of these events could prevent us or any collaborators from achieving or maintaining market acceptance of our product candidates or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenue from the sale of our product candidates.

We have no manufacturing experience, and the failure to comply with all applicable manufacturing regulations and requirements could have a materially adverse effect on our business.

We have never manufactured products in the highly regulated environment of pharmaceutical manufacturing, and our team has limited experience in the manufacture of drug therapies. There are numerous regulations and requirements that must be maintained to obtain licensure and permitting required prior to the commencement of manufacturing, as well as additional requirements to continue manufacturing pharmaceutical products. In addition, we do not have the resources at this time to acquire or lease suitable facilities. If we or our CMO fail to comply with regulations, to obtain the necessary licenses and knowhow or to obtain the requisite financing in order to comply with all applicable regulations and to contract with, own or lease the required facilities in order to manufacture our products, we could be forced to cease operations, which would cause you to lose all of your investment in our Common Stock.

In addition, the FDA and other regulatory authorities require that product candidates and drug products be manufactured according to cGMP. Any failure by our third-party manufacturers to comply with cGMP could lead to a shortage of our product candidates. In addition, such failure could be the basis for action by the FDA to withdraw approval, if granted to us, and for other regulatory enforcement action, including Warning Letters, product seizure, injunction or other civil or criminal penalties.

Product candidates that we develop may have to compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If we need to find another source of drug substance or drug product manufacturing for our product candidates, we may not be able to identify, or reach agreement with, commercial-scale manufacturers on commercially reasonable terms, or at all. If third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience significant delays in obtaining sufficient quantities of product for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of any product candidate that we develop, or the drug substances used to manufacture it, it will be more difficult for us to compete effectively, generate revenue, and further develop our products. In addition, if we are unable to assure a sufficient quantity of the drug for patients with rare diseases or conditions, we may lose any FDA Orphan Drug designation to which the product otherwise would be entitled.

We may, in the future, choose to seek FDA Orphan Drug designation for one or more of our current or future CNS product candidates. Even if we obtain Orphan Drug designation from the FDA for a product candidate, there are limitations to the exclusivity afforded by such designation.

In the U.S., the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application, including a full NDA to market the same drug for the same orphan indication, except in very limited circumstances, including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines “same drug” as a drug that contains the same active moiety and is intended for the same use as the drug in question. To obtain Orphan Drug status for a drug that shares the same active moiety as an already approved drug, it must be demonstrated to the FDA that the drug is safer or more effective than the approved orphan designated drug, or that it makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition or if another drug with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care.

1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

The Company currently leases the following properties:

Location	Use	Terms
5901 W. Olympic Blvd, Suite 419 Los Angeles, CA 90036	Physical office space	On November 13, 2017, the Company entered into a Lease Agreement for a term of five years and two months from November 1, 2017. The Leased Premises consist of approximately 2,325 rentable square feet. The base rent for such leased premises increases by 3% each year over the term, and ranges from approximately \$8,719 per month for the first year to \$10,107 per month for the two months of the sixth year. The Company was entitled to \$70,800 in tenant improvement allowance in the form of free rent applied over 10 months in equal installments from January 2018. The lease was terminated early without penalties or additional costs as of September 30, 2022.
1927 Paseo Rancho Castilla, Los Angeles, CA 90032	Headquarters	As of August 26, 2022, the Company entered into a short-term lease with option to extend at the new premier incubator, LA BioSpace on the California State University, Los Angeles campus located at 1927 Paseo Rancho Castilla, Los Angeles, CA 90032.
2080 Century Park East, Suite 906 Los Angeles, CA 90067		<p>The Company entered into a Lease Agreement on June 19, 2018 for our corporate headquarters located at Century City Medical Plaza. We have a ten-year lease that was for approximately 2,453 square feet at this location. In February 2019, we extended our corporate headquarters to encompass the adjoining suite for approximately 1,101 square feet, bringing the total workspace to 3,554 square feet. The new base rent for this leased premises increases by 3% each year over the term, and ranges from \$17,770 per month as of the date of the amendment until the end of the first year to \$23,186 per month for the tenth year. The additional suite was in the form of an amendment to the original lease and will expire on the same date as the original lease. The Company was entitled to a total of \$148,168 in contributions toward tenant improvements for both spaces.</p> <p>On June 25, 2022, the Company subleased the 3,554 square feet for a period of 3.5 years with an option to renew for the remaining term of the lease that ends as of June 19, 2028. The base rent is \$17,770 per month and will increase by 3% each year over the term of the sub-lease.</p>

Item 3. Legal Proceedings

Securities Class Action Litigation. On July 26, 2022 and July 28, 2022, securities class action complaints were filed by purported stockholders of ours in the United States District Court for the Central District of California against us and certain of our current and former officers and directors. The complaints allege, among other things, that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder, by making false and misleading statements and omissions of material fact in connection with the Company's relationship with Serhat Gümrükcü and its commercial prospects. The complaints seek unspecified damages, interest, fees, and costs. The defendants have not yet responded to the complaints.

Federal Derivative Litigation. On September 22, 2022, Samuel E. Koenig filed a shareholder derivative action in the United States District Court for the Central District of California. On January 19, 2023, John Solak filed a substantially similar shareholder derivative action in the United States District Court for the District of Delaware. Both derivative actions recite similar underlying facts as those alleged in the Securities Class Action Litigation. The actions, filed on behalf of the Company, name Serhat Gümrükcü and certain of the Company’s current and former directors as defendants. The actions also name the Company as a nominal defendant. The actions allege violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934 and also set out claims for breach of fiduciary duty, contribution and indemnification, aiding and abetting, and gross mismanagement. Plaintiffs do not quantify any alleged injury, but seek damages, disgorgement, restitution, and other costs and expenses. On January 24, 2023, the United States District Court for the Central District of California stayed the Koenig matter pending resolution of the defendants’ anticipated motion to dismiss in the Securities Class Action Litigation. The defendants have not yet responded to either complaint.

State Derivative Litigation. On October 20, 2022, Susan Midler filed a shareholder derivative action in the Superior Court of California, Los Angeles County, reciting similar underlying facts as those alleged in the Securities Class Action Litigation. The action, filed on behalf of the Company, names Serhat Gümrükcü and certain of the Company’s current and former directors as defendants. The action also names the Company as a nominal defendant. The action sets out claims for breaches of fiduciary duty, contribution and indemnification, aiding and abetting, and gross mismanagement. Plaintiff does not quantify any alleged injury, but seeks damages, disgorgement, restitution, and other costs and expenses. The defendants have not yet responded to the complaint.

On October 21, 2022, the Company filed a Complaint in the Superior Court of the State of California for the County of Los Angeles against Serhat Gümrükcü, William Anderson Wittekind, G Tech Bio LLC, SG & AW Holdings LLC, and Seraph Research Institute. The Complaint alleges that the defendants engaged in a “concerted, deliberate scheme to alter, falsify, and misrepresent to the Company the results of multiple studies supporting its [Hepatitis B] and SARS-CoV-2/influenza pipelines.” Specifically, “Defendants manipulated negative results to reflect positive outcomes from various studies, and even fabricated studies out of whole cloth.” As a result of the defendants’ conduct, the Company claims that it “paid approximately \$25 million to Defendants and third-parties that it would not otherwise have paid.” The defendants have not yet answered the allegations set forth in the Company’s Complaint.

On December 28, 2022, the Company received a demand letter on behalf of Weird Science LLC (“Weird Science”), William Anderson Wittekind, the William Anderson Wittekind 2020 Annuity Trust, the William Anderson Wittekind 2021 Annuity Trust, the Dybul 2020 Angel Annuity Trust, and the Ty Mabry 2021 Annuity Trust alleging that the Company breached the February 16, 2018 Investor Rights Agreement between the Company, Weird Science, and RS Group ApS. Specifically, the demand letter alleges that the Company “breached its obligations under the Investor Rights Agreement to provide the requisite thirty days’ notice” to Holders of Registrable Securities in connection with SEC Form S-3 filings on July 13, 2020 and February 11, 2022 and demands over \$64 million in damages. The Company denies these allegations and intends to vigorously defend against this claim.

On March 1, 2021, former Enochian BioSciences Chief Financial Officer, Robert Wolfe and his company, Crossfield, Inc., filed a Complaint in the U.S. District Court for the District of Vermont against the Company, Enochian BioSciences Denmark ApS, and certain directors and officers. In the Complaint, Mr. Wolfe and Crossfield, Inc. asserted claims for abuse of process and malicious prosecution, alleging, inter alia, that the Company lacked probable cause to file and prosecute an earlier action, and sought millions of dollars of compensatory damages, as well as punitive damages. The allegations in the Complaint relate to an earlier action filed by the Company and Enochian BioSciences Denmark ApS in the Vermont Superior Court, Orange Civil Division.

On March 3, 2022, the court partially granted the Company’s motion to dismiss, dismissing the abuse of process claim against all defendants and all claims against Mark Dybul and Henrik Grønfeldt-Sørensen. On November 29, 2022, the Company filed a motion for summary judgment with respect to the sole remaining claim of malicious prosecution. The Company denies the allegations set forth in the Complaint and will continue to vigorously defend against the remaining claim.

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

Market Information and Holders of our Common Stock

Our Common Stock trades on the Nasdaq Capital Market under the symbol “ENOB”.

As of February 27, 2023, the Company had 55,705,521 shares of Common Stock issued and outstanding and approximately 190 stockholders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Recent Sales of Unregistered Securities

None.

Company Purchases of Equity Securities

None.

Dividends

The Company has not declared or paid any cash dividends on its Common Stock and does not intend to declare or pay any cash dividend in the foreseeable future. The payment of dividends, if any, is within the discretion of the Board and will depend on the Company’s earnings, if any, its capital requirements and financial condition and such other factors as the Board may consider.

Item 6. [Reserved]

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements, and the related notes to those statements included elsewhere in this report. In addition to the historical financial information, the following discussion and analysis contains forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements.

Our Business

Enochian BioSciences Inc. is a biotechnology company committed to developing advanced allogeneic cell and gene therapies to promote stronger immune system responses potentially for long-term or life-long cancer remission in some of the deadliest cancers, and potentially to treat or cure serious infectious diseases such as HIV and Hepatitis B virus (HBV) infection.

To date, our operations have been funded by sales of our securities and debt financing. We have never generated any sales revenue and we expect this to continue until our therapies or products are approved for marketing in the United States and/or Europe. Even if we are successful in having our therapies or products approved for sale in the United States and/or Europe, we cannot guarantee that a market for the therapies or products will develop. We may never be profitable.

Recent Developments

On July 15, 2022, certain of our warrant holders exercised warrants to purchase 1,250,000 shares of Common Stock for total proceeds to the Company of \$1,625,000, with corresponding earn-out distribution in the same amount in connection with the acquisition of Enochian BioPharma, Inc., which was distributed on October 12, 2022, based on the share price on that date of \$2.21. This non-cash transaction impacted stockholders' equity in the amount of \$2,762,500 (see Note 11 of the Financial Statements.)

Subsequent to June 30, 2022, the Company became involved in a number of legal proceedings. Please see above Item 3 - Legal Proceedings for details of such matters.

Regaining Compliance with Nasdaq Listing Requirements

On each of October 17, 2022, November 23, 2022, and February 16, 2022, we received a notice, or the Notices, from the Listing Qualifications Department of Nasdaq stating that we were not in compliance with Nasdaq Listing Rule 5250(c)(1), or the "Rule", because we did not timely file our Form 10-K for the period ended June 30, 2022 and our Form 10-Q for the periods ended September 30, 2022 and December 31, 2022 with the SEC. The Rule requires listed companies to timely file all required periodic financial reports with the SEC. Today we filed our Form 10-K for the period ended June 30, 2022 but have not yet filed our Form 10-Q for the periods ended September 30, 2022 nor December 31, 2022, and therefore we have not regained compliance with the Rule. We were unable to file the Annual Report on Form 10-K for the period ended June 30, 2022 and the Quarterly Report on Form 10-Q for the periods ended September 30, 2022 and December 31, 2022 by their initial deadlines, due to the reasons described in the Notifications of Late Filing on Form 12b-25, filed with the SEC on September 29, 2022 and November 15, 2022. While we were able to file the Annual Report on Form 10-K for the period ended June 30, 2022 within the extension period provided pursuant to Nasdaq rules, we have not yet filed the Form 10-Q for the periods ended September 30, 2022 and December 31, 2022, and there can be no assurance that we will be able to remain in compliance with the Rule or with other Nasdaq listing requirements in the future.

If we are unable to regain compliance with the Rule or with any of the other continued listing requirements, Nasdaq may take steps to delist our securities, which could have adverse consequences, including a limited availability of market quotations for our securities, reduced liquidity for our securities, a limited amount of news and analyst coverage and a decreased ability to issue additional securities or obtain additional financing in the future.

Going Concern and Management's Plans

The financial statements included elsewhere herein for the year ended June 30, 2022, were prepared under the assumption that we would continue our operations as a going concern, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. As of June 30, 2022, we had cash and cash equivalents of \$9,172,142, an accumulated deficit of \$204,345,197, and total liabilities of \$12,013,815. We have incurred losses from continuing operations, have used cash in our continuing operations, and are dependent on additional financing to fund operations. These conditions raise substantial doubt about our ability to continue as a going concern for one year after the date the financial statements are issued. The financial statements included elsewhere herein do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Management has reduced overhead and administrative costs by streamlining the organization to focus around two of its therapies (oncology and HIV therapeutic vaccine). The Company has tailored its workforce to focus on these therapies. In addition, management has extended its \$1.2 million convertible notes 12 months out to be payable on February 28, 2024, and the Company intends to attempt to secure additional required funding through equity or debt financing. However, there can be no assurance that the Company will be able to obtain any sources of funding. Such additional funding may not be available or may not be available on reasonable terms, and, in the case of equity financing transactions, could result in significant additional dilution to our stockholders. If we do not obtain required additional equity or debt funding, our cash resources will be depleted and we could be required to materially reduce or suspend operations, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that could result in our stockholders losing some or all of their investment in us.

Funding that we may receive during fiscal 2023 is expected to be used to satisfy existing and future obligations and liabilities and working capital needs, to support commercialization of our products and conduct the clinical and regulatory work to develop our product candidates, and to begin building working capital reserves.

COVID-19

The COVID-19 pandemic continues to evolve. COVID-19 may cause delays in our research activities. To date, the COVID-19 pandemic has not materially affected our operations. However, it has caused delays in the conduct of experiments due to limitations in resources and supply chain issues, in particular for those conducting experiments. There have also been increases in the cost to conduct animal studies due to staffing and other limitations.

The full extent to which the COVID-19 pandemic may impact our business and operations is subject to future developments, which are uncertain and difficult to predict.

We continue to monitor the impact of the COVID-19 pandemic on our business and operations and will seek to adjust our activities as appropriate.

RESULTS OF OPERATIONS

Year ended June 30, 2022 compared to the year ended June 30, 2021.

The following table sets forth our revenues, expenses and net income for the years ended June 30, 2022 and 2021. The financial information below is derived from our audited consolidated financial statements included elsewhere in this Annual Report.

	For the Years Ended June 30,		Increase/(Decrease)	
	2022	2021	\$	%
Operating Expenses				
General and administrative	\$ 14,329,801	\$ 7,557,990	6,771,811	90%
Research and development	8,372,800	15,720,262	(7,347,461)	(47)%
Indefinite life intangible assets impairment charge	93,253,000		93,253,000	100%
Depreciation and amortization	123,590	123,535	55	0%
Total Operating Expenses	<u>116,079,191</u>	<u>23,401,787</u>	<u>92,677,404</u>	<u>396%</u>
LOSS FROM OPERATIONS	<u>(116,079,191)</u>	<u>(23,401,787)</u>	<u>(92,677,404)</u>	<u>(396)%</u>
Other Income (Expenses)				
Change in fair value of contingent consideration	2,896,627	(3,048,033)	5,944,660	(195)%
Interest expense	(372,844)	(379,608)	6,764	(2)%
Gain (loss) on currency transactions	9	(32,634)	32,643	(100)%
Interest and other income	122,041	13,179	108,862	826%
Total Other Income (Expenses)	<u>2,645,833</u>	<u>(3,447,096)</u>	<u>6,092,929</u>	<u>(177)%</u>
Loss Before Income Taxes	<u>(113,433,358)</u>	<u>(26,848,883)</u>	<u>(86,584,475)</u>	<u>322%</u>
Income Tax (Expense) Benefit	<u>(34)</u>	<u>125,276</u>	<u>(125,310)</u>	<u>(100)%</u>
NET LOSS	<u>\$ (113,433,392)</u>	<u>\$ (26,723,607)</u>	<u>(86,709,785)</u>	<u>324%</u>

	For the Years Ended June 30,		Increase/(Decrease)	
	2022	2021	\$	%
Net Loss	\$ (113,433,392)	\$ (26,723,607)	\$ (86,709,785)	(324)%
Other Comprehensive Income (Loss)				
Foreign Currency Translation, net of taxes	(19,602)	30,582	(50,184)	(164)%
Other Comprehensive Loss	<u>\$ (113,452,994)</u>	<u>\$ (26,693,025)</u>	<u>\$ (86,759,969)</u>	<u>(325)%</u>

Revenues

We are a pre-clinical stage pre-revenue biotechnology company. We have never generated revenues and have incurred losses since inception. We do not anticipate earning any revenues until our therapies or products are approved for marketing and sale.

Operating Expenses

Our operating expenses for the years ended June 30, 2022 and 2021 were \$116,079,191 and \$23,401,787, respectively, representing an increase of \$92,677,404 or 396%. The largest contributors to the increase in operating expenses for the year ended June 30, 2022, were the non-cash intangible asset impairment of \$93,253,000 (see Note 4 to the Financial Statements) and the increase in general and administrative expenses of \$6,771,811 partially offset by the decrease in research and development expenses of \$7,347,462 compared to the year ended June 30, 2021.

General and administrative expenses for the years ended June 30, 2022 and 2021, were \$14,329,801 and \$7,557,990, respectively, representing an increase of \$6,771,811, or 90%. The increase in general and administrative expenses is primarily related to increases of \$4,045,804 in stock-based compensation, \$1,485,613 in salaries and related costs, \$353,853 related to recruiting expenses, and \$351,928 in legal fees.

Research and development expenses for the years ended June 30, 2022, and 2021, were \$8,372,800 and \$15,720,262, respectively, representing a decrease of \$7,347,461 or 47%. The decrease in research and development expenses is primarily related to \$10,760,000 in fees related to the Coronavirus and Influenza License Agreement that was incurred in the prior period. The decrease was partially offset by increases in costs with CDMO and CRO partners totaling \$3,093,160.

Other Income (Expenses)

Net other income (expenses) for the years ended June 30, 2022 and 2021 was \$2,645,833 and \$(3,447,096), respectively, representing an increase of \$6,092,929 or 177%. The increase in other income was due primarily to the change in the fair value of the contingent consideration in the amount of \$5,944,660, which resulted from the mark to market adjustment on the remaining contingent consideration liability and the contingent shares issued during the period.

Net Loss

Net loss for the years ended June 30, 2022 and June 30, 2021 was \$113,433,392 and \$26,723,607, respectively, representing an increase in net loss of \$86,709,785 or 324%. The increase in net loss was primarily due to the non-cash intangible asset impairment of \$93,253,000, and \$6,771,811 increase in general and administrative expenses, offset by a decrease in research and development costs of \$7,347,462 and an approximate increase in the change in fair value of contingent consideration of \$5,944,660.

Liquidity and Capital Resources

We have historically satisfied our capital and liquidity requirements through funding from stockholders, the sale of our Common Stock and warrants, and debt financing. We have never generated any sales revenue to support our operations and we expect this to continue until our therapies or products are approved for marketing in the United States and/or Europe. Even if we are successful in having our therapies or products approved for sale in the United States and/or Europe, we cannot guarantee that a market for the therapies or products will develop. We may never be profitable.

As noted above under the heading “Going Concern and Management’s Plans,” through June 30, 2022, we have incurred substantial losses. We may need additional funds for (a) research and development, (b) increases in personnel, and (c) the purchase of equipment, specifically to advance towards an Investigational New Drug Application (IND) following Pre-IND readouts from the FDA for ENOB-DC11, ENOB-HV-12, ENOB-HV-01, ENOB-HV-21 and ENOB-HB-01. The availability of any required additional funding cannot be assured. In addition, an adverse outcome in legal or regulatory proceedings in which we are currently involved or in the future may be involved could adversely affect our liquidity and financial position. If additional funds are required, we may raise such funds from time to time through public or private sales of our equity or debt securities. Such financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely affect our growth plans and our financial condition and results of operations.

As of June 30, 2022, the Company had \$9,172,142 in cash and working capital of \$3,114,170 as compared to \$20,664,410 in cash and working capital of \$19,013,100 as of June 30, 2021. The decrease in cash of \$11,492,268 is primarily due to the cost of operations primarily related to general and administrative expenses of \$8,715,609, net of non-cash items, in addition to research and development costs of \$8,372,800, partially offset by funding totaling \$4,811,312 related to drawdowns from the LPC equity line, and the exercise of warrants and options during the period.

Equity

On July 8, 2020, we entered into a purchase agreement (the “LPC Purchase Agreement”) with Lincoln Park Capital Fund, LLC, (“LPC”), pursuant to which LPC is committed to buy, and we had the right, but not the obligation, to sell to LPC up to an aggregate of \$20,000,000 of our Common Stock, subject to certain limitations and conditions set forth in the LPC Purchase Agreement, including a limitation on the number of shares of Common Stock we can put to LPC and the pricing parameters for the sales. For the year ended June 30, 2022, the Company issued 497,340 shares of Common Stock for proceeds of \$4,676,399 (see Note 8 of the Financial Statements.) As of October 17, 2022, we no longer have access to this Purchase Agreement.

Pursuant to a private placement offering, the Company issued 1,275,719 shares of Common Stock resulting in proceeds of \$5,000,800. The Company effected the issuances of the shares of Common Stock from March 15, 2021 to June 9, 2021. The private placement was made directly by the Company in reliance upon Regulation S of the Securities Act of 1933. No underwriter or placement agent was engaged by the Company for this private placement (see Note 8 of the Financial Statements.)

On June 14, 2021, the Company and certain institutional investors entered into a securities purchase agreement (the “Purchase Agreement”), pursuant to which the Company agreed to sell to such investors an aggregate of 3,866,668 shares of Common Stock, in a registered direct offering, for gross proceeds of approximately \$29 million (the “Financing”). The purchase price for each share of Common Stock was \$7.50. The Company agreed not to issue or enter into any agreement to issue Common Stock from June 14, 2021 until ninety (90) days after the closing of the Financing. The Company entered into a letter agreement dated June 14, 2021 (the “Letter Agreement”) with H.C. Wainwright & Co., LLC, as exclusive placement agent (the “Placement Agent”), pursuant to which the Placement Agent agreed to act as the exclusive placement agent for the Financing. The Company agreed to pay the Placement Agent an aggregate fee equal to 7.0% of the gross proceeds raised in the Financing. The Company also agreed to pay the Placement Agent certain expenses. The Company paid \$2,090,000 in commissions and incurred offering expenses, and issuance costs of \$66,011, resulting in net proceeds of \$26,843,999 in connection with the Financing. The Financing closed on June 16, 2021 (see Note 8 of the Financial Statements.)

Warrant Exercises

For the year ended June 30, 2021, the Company issued 63,122 shares of Common Stock for total proceeds of \$82,056 upon the exercise of warrants. On December 24, 2021, certain of our warrant holders exercised warrants to purchase 100,000 shares of Common Stock for total proceeds to the Company of \$130,000.

Debt

On February 6, 2020, the Company issued two Convertible Notes (the “Convertible Notes”) to Paseco APS (the “Holder”), a Danish limited company and an existing stockholder of the Company each with a face value amount of \$600,000, convertible into shares of Common Stock. The Holder did not exercise the conversion feature that expired on February 6, 2021. The outstanding principal amount of the Convertible Notes was due and payable on February 6, 2023. Interest on the Convertible Notes commenced accruing on the date of issuance at six percent (6%) per annum, computed on the basis of twelve 30-day months, and is compounded monthly on the final day of each calendar month based upon the principal and all accrued and unpaid interest outstanding as of such compound date. The interest was payable in cash on a semi-annual basis. For the years ended June 30, 2022 and 2021, the interest expense amounted to \$72,875 and \$72,967, respectively. Effective December 30, 2022, Company amended and restated the Convertible Notes (the “Amended and Restated Secured Notes”). Pursuant to the Amended and Restated Secured Notes, the due date was extended to February 28, 2024, and the interest was increased to twelve percent (12%) per annum, which was prepaid by the Company in full on the date of amendment through the issuance of 198,439 shares of the Company’s Common Stock based on the closing market price on that date, of \$1.03, which included 29,419 shares for interest accrued through December 30, 2022, and the obligations of the Company under the Amended and Restated Secured Notes were secured by a security Agreement (the “Security Agreement”). (see Note 6 to the Financial Statements.)

On March 30, 2020 (the “Issuance Date”), the Company issued a Promissory Note in the principal amount of \$5,000,000 (the “Promissory Note”) to the “Holder”. The principal amount of the Promissory Note was payable on November 30, 2021, and bore interest at a fixed rate of 6% per annum, which was prepaid by the Company in full on the date of issuance through the issuance of 188,485 shares of the Company’s Common Stock based on the closing market price on that date, valued at \$501,370. On February 11, 2021, the Company and the Holder amended the original Promissory Note to extend the maturity date to November 30, 2022. The Company prepaid in full all accrued interest from November 30, 2021 to the new maturity date November 30, 2022, through the issuance of 74,054 shares of Common Stock based on the closing market price on that date, valued at \$299,178. On May 17, 2022, the Company entered into a second amendment to the Promissory Note that extended the maturity date out to November 30, 2023 and increased the interest rate from 6% to 12% per annum. The Company prepaid six months of interest through May 31, 2023, through issuance of 47,115 shares of Common Stock based on the closing market price on that date, valued at \$299,178. All other terms of the Promissory Note remained the same. Effective December 30, 2022, the Company entered into a third amendment to the Promissory Note. Pursuant to the third amendment, the Company’s obligations under the Promissory Note were secured by the Security Agreement. (see Note 6 to the Financial Statements.)

To secure the Company’s obligations under each of the Amended and Restated Secured Notes and the Promissory Note, the Company entered into a Security Agreement with the Holder, pursuant to which the Company granted a lien on all assets of the Company (the “Collateral”) for the benefit of the Holder. Upon an Event of Default (as defined in the Amended and Restated Secured Notes and Promissory Note, respectively) the Holder may, among other things, collect or take possession of the Collateral, proceed with the foreclosure of the security interest in the Collateral or sell, lease or dispose of the Collateral.

Cash Flows

Year ended June 30, 2022 compared to the year ended June 30, 2021

Following is a summary of the Company's cash flows provided by (used in) operating, investing, and financing activities:

	For the Years Ended	
	June 30,	
	2022	2021
Net Cash Used in Operating Activities	\$ (15,732,336)	\$ (20,610,723)
Net Cash Used in Investing Activities	(5,156)	(48,892)
Net Cash Provided by Financing Activities	4,250,464	32,601,553
Effect of exchange rates on cash	(5,240)	26,111
Net Increase (Decrease) in Cash	\$ (11,492,268)	\$ 11,968,049

At June 30, 2022, we had cash and cash equivalents of \$9,172,142, a decrease of \$11,492,268, when compared to the June 30, 2021 balance of \$20,664,410. This decrease was primarily due to cash used in operating activities, partially offset by cash provided by financing activities.

We plan to use our cash and cash equivalents to fund research and development, specifically to open an Investigational New Drug Application (IND) following Pre-IND readouts from the FDA (the first step in the drug review process by the FDA) for ENOB-DC11, ENOB-HV-12, ENOB-HV-01, ENOB-HV-21 and ENOB-HB-01. These activities will require an increase in selling, general and administrative costs, and research and development costs to support the expected growth. As additional funds are required, we may raise such funds from time to time through public or private sales of our equity or debt securities.

Cash used in operating activities represents the cash receipts and disbursements related to all of our activities other than investing and financing activities. Operating cash flow is derived by adjusting our net income for non-cash items and changes in operating assets and liabilities. Net cash used in operating activities for the years ended June 30, 2022 and 2021 was \$15,732,336 and \$20,610,723, respectively, representing a decrease of \$4,878,387. The decrease is primarily related to the increase in our net loss as adjusted for non-cash items, and by changes in our operating assets and liabilities of \$1,415,111.

Net cash used in investing activities for the years ended June 30, 2022 and 2021 was \$(5,156) and \$(48,892), respectively, representing a decrease of \$43,736. The decrease is primarily due to less purchases of equipment in the current year.

Net cash provided by financing activities for the years ended June 30, 2022 and 2021 was \$4,250,464 and \$32,601,553, respectively, representing a decrease of \$28,351,089. The net cash provided by financing activities in the current year consists primarily of \$4,676,399 in proceeds from issuance of Common Stock related to equity line draws. The prior year net cash from financing activities primarily consisted of \$26,843,998 of net proceeds from the issuance of Common Stock as part of a direct offering, \$5,000,800 of proceeds from the issuance of Common Stock through a private placement, and \$1,221,350 of proceeds from issuance of Common Stock related to equity line draws.

Off-Balance Sheet Arrangements

As of June 30, 2022, and 2021, we had no off-balance sheet arrangements. We are not aware of any material transactions which are not disclosed in our consolidated financial statements.

Significant Accounting Policies and Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our most critical accounting estimates are detailed below, and our significant accounting policies are more fully described in Note 1 of the accompanying consolidated financial statements.

Intangible Assets - The Company has both definite and indefinite life intangible assets.

Definite life intangible assets relate to patents. The Company accounts for definite life intangible assets in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 350, *Goodwill and Other Intangible Assets*. Intangible assets are recorded at cost. Patent costs capitalized consist of costs incurred to acquire the underlying patent. If it is determined that a patent will not be issued, the related remaining capitalized patent costs are charged to expense. Definite life intangible assets are amortized on a straight-line basis over their estimated useful life. The estimated useful life of patents is twenty years from the date of application.

Indefinite life intangible assets include license agreements and goodwill acquired in a business combination. The Company accounts for indefinite life intangible assets in accordance with ASC 350. License agreement costs represent the fair value of the license agreement on the date acquired and are tested annually for impairment.

Goodwill - Goodwill is not amortized but is evaluated for impairment annually as of June 30 or whenever events or changes in circumstances indicate the carrying value may not be recoverable.

Impairment of Goodwill and Indefinite Lived Intangible Assets – We test for goodwill impairment at the reporting unit level, which is one level below the operating segment level. Our detailed impairment testing involves comparing the fair value of each reporting unit to its carrying value, including goodwill. Fair value reflects the price a market participant would be willing to pay in a potential sale of the reporting unit and is based on discounted cash flows or relative market-based approaches. If the carrying value of the reporting unit exceeds its fair value, we record an impairment loss for such excess. The annual fair value analysis performed on goodwill supported that goodwill is not impaired as of June 30, 2022 (see Note 4 to the financial statements.)

For indefinite-lived intangible assets, such as licenses acquired as an In-Process Research and Development (“IPR&D”) asset, on an annual basis we determine the fair value of the asset and record an impairment loss, if any, for the excess of the carrying value of the asset over its fair value. For the year ended June 30, 2022, the carrying value of the licenses acquired as an IPR&D asset exceeded its fair value, due to changes in the projected economic benefits to be realized from these assets. Therefore, the Company recorded an impairment loss of \$93,253,000 during the year ended June 30, 2022 (see Note 4 to the financial statements.)

The carrying value of IPR&D and goodwill at June 30, 2022, were \$61,571,000 and \$11,640,000, respectively.

Fair Value of Financial Instruments - The Company accounts for fair value measurements for financial assets and financial liabilities in accordance with FASB ASC Topic 820, Fair Value Measurement. Under the authoritative guidance, fair value is defined as the exit price, representing the amount that would either be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the guidance established a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1. Observable inputs such as quoted prices in active markets for identical assets or liabilities;
- Level 2. Inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3. Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

There were no assets that use Level 1, 2 or 3 inputs, nor any liabilities that use Level 1 or 2 inputs as of June 30, 2022.

Liabilities that use Level 3 inputs held as of June 30, 2022 consisted of a contingent consideration liability related to the February 16, 2018 acquisition of Enochian BioPharma Inc. (the “Acquisition”). As consideration for the Acquisition, the stockholders of Enochian Biopharma received (i) 18,081,962 shares of common stock, and (ii) the right to receive contingent shares pro rata upon the exercise of warrants, which were outstanding at closing. The contingent consideration liability was recorded at fair value of \$21,516,000 at the time of the Acquisition and is subsequently remeasured to fair value at each reporting date. At June 30, 2022, 1,250,000 contingent shares are issuable in connection with the Acquisition.

The fair value of the contingent consideration liability is estimated using an option-pricing model. The key inputs to the model are all contractual or observable with the exception being volatility, which is computed based on the value of the Company's underlying stock. The key inputs to valuing the contingent consideration liability on the date of acquisition and as of June 30, 2022 include the Company's stock price, the exercise price of the warrants of \$1.30 per share, the risk-free rate, the expected volatility of the Company's common stock and the digital call rate. The fair value measurements are highly sensitive to changes in these inputs and significant changes in these inputs could result in a significantly higher or lower fair value (see Note 1 to the Financial Statements.)

Stock-Based Compensation - The Company has granted stock options, restricted share units ("RSUs") and warrants to certain employees, officers, directors, and consultants. The Company accounts for options in accordance with the provisions of *FASB ASC Topic 718, Compensation – Stock Compensation*. Stock based compensation costs for the vesting of options and RSUs granted to certain employees, officers, directors, and consultants for the years ended June 30, 2022 and 2021 were \$5,490,602 and \$1,444,798, respectively (see Note 8 to the Financial Statements).

The Company recognizes compensation costs for stock option awards to employees, officers and directors based on their grant-date fair value. The value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model. The weighted-average assumptions used to estimate the fair value of the stock options granted using the Black-Scholes option-pricing model are the expected term of the award, the underlying stock price volatility, the risk-free interest rate, and the expected dividend yield.

The Company records stock-based compensation for services received from non-employees in accordance with *ASC 718, Compensation—Stock Compensation Non-Employees*. All transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. Equity instruments issued to consultants and the cost of the services received as consideration are measured and recognized based on the fair value of the equity instruments issued and are recognized over the consultants' required service period, which is generally the vesting period (see Note 8 to the Financial Statements.)

Recently Enacted Accounting Standards

For a description of recent accounting standards, including the expected dates of adoption and estimated effects, if any, on our consolidated financial statements, see "Note 1: Recent Accounting Pronouncements" in the financial statements included elsewhere in this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

The Registrant is a smaller reporting company and is not required to provide this information.

Item 8. Financial Statements and Supplementary Data

ENOCHIAN BIOSCIENCES INC. AND SUBSIDIARIES

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Enochian Biosciences, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Enochian Biosciences, Inc. (“the Company”) as of June 30, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholders’ equity, and cash flows for each of the years in the two-year period ended June 30, 2022 and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of June 30, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended June 30, 2022, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has a net 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 2. 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 audits 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 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 audits, 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 audits included performing procedures to assess the risks of material misstatement of the 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 financial statements. Our audits 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 audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) related to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgements. 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Indefinite-Lived Intangible Asset Impairment Assessment

Critical Audit Matter Description

The Company has an indefinite-lived intangible asset related to an acquired license treated as an in-process research and development asset (“IPR&D”). As of June 30, 2022, the carrying value of the asset is \$61,571,000, post an impairment charge of \$93,253,000 taken during the year. To assess the carrying value of the IPR&D asset for impairment, management estimated the fair value of IPR&D on its elected assessment date of June 30, 2022, using a multi-period excess earnings method, which is a specific discounted cash flow method. The determination of the fair value requires management to make significant estimates including, but not limited to, the discount rate used in the model, the total addressable market for each potential drug, market penetration assumptions, and for the estimated timing of commercialization of the drugs. Changes in these assumptions could have a significant impact on the fair value of the IPR&D.

How the Critical Audit Matter was Addressed in the Audit

We identified the impairment testing of the IPR&D asset as a critical audit matter because of the significant estimates and assumptions management makes related to determining the fair value of the IPR&D asset. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate such significant estimates and assumptions. In addition, the audit effort involved the use of professionals with specialized skill and knowledge.

Our audit procedures related to the following:

- Tested and evaluated the methods, data and significant assumptions used in developing the IPR&D fair value.
- Evaluating the reasonableness and consistency of the selected valuation methodology and assumptions utilized by the Company including the Company's intent and ability to carry out a particular course of action.
- Identified significant assumptions used by the Company and evaluated each assumption used to develop the estimate, both individually and in combination with other significant assumptions.
- Testing the completeness and accuracy of underlying data used in the fair value estimate.
- Evaluated the changes to the valuation model from the prior year including changes related to data inputs and significant assumptions used.
- Developed an independent expectation for comparison to the Company's estimate of fair value of the IPR&D asset.
- Evaluated evidence from events or transactions occurring after the measurement date of June 30, 2022, related to the accounting estimate.

In addition, professionals with specialized skill and knowledge were utilized by the Firm to assist in the performance of these procedures.

Goodwill Impairment Assessment

Critical Audit Matter Description

As of June 30, 2022, the carrying value of goodwill was \$11,640,000. As described in note 1 to the consolidated financial statements, the Company tests goodwill for impairment annually at the reporting unit level, or more frequently if events or circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying amount. To assess the carrying value of the goodwill for impairment, management estimated the fair value of goodwill on its elected assessment date of June 30, 2022, using a discounted cash flow model. The determination of the fair value requires management to make significant estimates and assumptions.

How the Critical Audit Matter was Addressed in the Audit

We identified the evaluation of the impairment analysis for goodwill as a critical audit matter because of the significant estimates and assumptions management makes in determining the fair value of the goodwill. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the reasonableness of such estimates and assumptions. In addition, the audit effort involved the use of professionals with specialized skill and knowledge.

Our audit procedures related to the following:

- Tested and evaluated the methods, data and significant assumptions used in developing the fair value of goodwill.
- Evaluating the reasonableness and consistency of the selected valuation methodology and assumptions utilized by the Company including the Company's intent and ability to carry out a particular course of action.
- Identified significant assumptions used by the Company and evaluated each assumption used to develop the estimate, both individually and in combination with other significant assumptions.
- Testing the completeness and accuracy of underlying data used in the fair value estimate.
- Evaluated the changes to the valuation model from the prior year including changes related to data inputs and significant assumptions used.
- Developed an independent expectation for comparison to the Company's estimate of fair value of goodwill.
- Evaluated evidence from events or transactions occurring after the measurement date of June 30, 2022, related to the accounting estimate.

In addition, professionals with specialized skill and knowledge were utilized by the Firm to assist in the performance of these procedures.

/s/ Sadler, Gibb & Associates, LLC

We have served as the Company's auditor since 2018.

Draper, UT
February 27, 2023

ENOCHIAN BIOSCIENCES INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	June 30,	
	<u>2022</u>	<u>2021</u>
ASSETS		
CURRENT ASSETS:		
Cash	\$ 9,172,142	\$ 20,664,410
Prepays and other assets	392,996	234,583
Total Current Assets	<u>9,565,138</u>	<u>20,898,993</u>
Property and equipment, net	<u>586,536</u>	<u>719,364</u>
OTHER ASSETS		
Definite life intangible assets, net	44,268	65,906
Indefinite life intangible assets, net	61,571,000	154,824,000
Goodwill	11,640,000	11,640,000
Deposits and other assets	68,635	20,984
Operating lease rights-of-use assets	1,157,086	1,435,978
Total Other Assets	<u>74,480,989</u>	<u>167,986,868</u>
TOTAL ASSETS	<u>\$ 84,632,663</u>	<u>\$ 189,605,225</u>

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

ENOCHIAN BIOSCIENCES INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS (CONTINUED)

	June 30,	
	2022	2021
LIABILITIES		
CURRENT LIABILITIES:		
Accounts payable – trade	\$ 1,401,867	\$ 320,559
Accrued expenses	1,031,462	1,182,323
Other current liabilities	220,685	90,602
Contingent consideration liability	2,343,318	—
Convertible notes payable	1,200,000	—
Current portion of operating lease liabilities	253,636	292,409
Total Current Liabilities	6,450,968	1,885,893
NON-CURRENT LIABILITIES:		
Contingent consideration liability	—	6,037,945
Convertible notes payable	—	1,200,000
Notes payable, net	4,577,148	4,579,114
Operating lease liabilities, net of current portion	985,699	1,239,334
Total Non-Current Liabilities	5,562,847	13,056,393
Total Liabilities	12,013,815	14,942,286
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, par value \$0.0001, 100,000,000 shares authorized, 53,007,082 shares issued and outstanding at June 30, 2022; 52,219,661 shares issued and outstanding at June 30, 2021	5,302	5,222
Additional paid-in capital	276,989,179	265,580,356
Accumulated deficit	(204,345,197)	(90,911,805)
Accumulated other comprehensive (loss)	(30,436)	(10,834)
Total Stockholders' Equity	72,618,848	174,662,939
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 84,632,663	\$ 189,605,225

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

ENOCHIAN BIOSCIENCES INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended June 30,	
	2022	2021
Operating Expenses		
General and administrative	\$ 14,329,801	\$ 7,557,990
Research and development	8,372,800	15,720,262
Indefinite life intangible assets impairment charge	93,253,000	—
Depreciation and amortization	123,590	123,535
Total Operating Expenses	116,079,191	23,401,787
LOSS FROM OPERATIONS	(116,079,191)	(23,401,787)
Other Income (Expenses)		
Change in fair value of contingent consideration	2,896,627	(3,048,033)
Interest expense	(372,844)	(379,608)
Gain (loss) on currency transactions	9	(32,634)
Interest and other income	122,041	13,179
Total Other Income (Expenses)	2,645,833	(3,447,096)
Loss Before Income Taxes	(113,433,358)	(26,848,883)
Income Tax (Expense) Benefit	(34)	125,276
NET LOSS	\$ (113,433,392)	\$ (26,723,607)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$ (2.16)	\$ (0.57)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK OUTSTANDING - BASIC AND DILUTED	52,528,024	47,167,262

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

ENOCHIAN BIOSCIENCES INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	For the Years Ended June 30,	
	<u>2022</u>	<u>2021</u>
Net Loss	\$ (113,433,392)	\$ (26,723,607)
Other Comprehensive Income (Loss)		
Foreign currency translation, net of taxes	<u>(19,602)</u>	<u>30,582</u>
Other Comprehensive Loss	<u>\$ (113,452,994)</u>	<u>\$ (26,693,025)</u>

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

ENOCHIAN BIOSCIENCES INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
For the Years Ended June 30, 2022 and June 30, 2021

	# of Shares	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance June 30, 2020	46,497,409	\$ 4,650	\$ 230,497,225	\$ (64,188,198)	\$ (41,416)	\$ 166,272,261
Issuance of commitment shares related to LPC purchase agreement	139,567	14	(14)	—	—	—
Stock issued pursuant to warrants exercised	63,122	6	82,050	—	—	82,056
Contingent shares issued pursuant to acquisition agreement	63,122	6	192,516	—	—	192,522
Shares issued pursuant to 2021 private placement	1,275,719	128	5,000,672	—	—	5,000,800
Shares issued in lieu of interest on \$5 million notes payable extension	74,054	7	298,171	—	—	298,178
Shares issued pursuant to LPC purchase agreement	200,000	20	1,221,330	—	—	1,221,350
Shares issued pursuant to direct offering, net of issuance costs	3,866,668	387	26,843,612	—	—	26,843,999
Shares issued for fully vested RSUs	5,000	—	—	—	—	—
Restricted shares converted to shares for services rendered	35,000	4	146,996	—	—	147,000
Stock-based compensation	—	—	1,297,798	—	—	1,297,798
Net loss	—	—	—	(26,723,607)	—	(26,723,607)
Foreign currency translation gain	—	—	—	—	30,582	30,582
Balance June 30, 2021	52,219,661	5,222	265,580,356	(90,911,805)	(10,834)	174,662,939
Stock issued pursuant to warrants exercised	100,000	10	129,990	—	—	130,000
Contingent shares issued pursuant to acquisition agreement	100,000	10	797,990	—	—	798,000
Shares issued in lieu of interest on \$5 million notes payable extension	47,115	5	299,173	—	—	299,178
Shares issued pursuant to LPC purchase agreement	497,340	50	4,676,349	—	—	4,676,399
Shares issued for fully vested RSUs	6,266	1	9,810	—	—	9,811
Shares issued pursuant to options exercised	1,700	—	4,913	—	—	4,913
Restricted shares converted to shares for services rendered	35,000	4	252,346	—	—	252,350
Stock-based compensation	—	—	5,238,252	—	—	5,238,252
Net loss	—	—	—	(113,433,392)	—	(113,433,392)
Foreign currency translation loss	—	—	—	—	(19,602)	(19,602)
Balance June 30, 2022	<u>53,007,082</u>	<u>\$ 5,302</u>	<u>\$ 276,989,179</u>	<u>\$ (204,345,197)</u>	<u>\$ (30,436)</u>	<u>\$ 72,618,848</u>

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

ENOCHIAN BIOSCIENCES INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended June 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (113,433,392)	\$ (26,723,607)
ADJUSTMENTS TO RECONCILE NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES :		
Depreciation and amortization	123,590	123,534
Change in fair value of contingent consideration	(2,896,627)	3,048,033
Non-cash stock-based compensation expense	5,490,602	1,444,798
Indefinite life intangible assets impairment charge	93,253,000	—
Amortization of discount on note payable	297,212	296,505
Loss on disposal of fixed assets	18,168	—
Changes in assets and liabilities:		
Other receivables	1,594	342
Prepaid expenses/deposits	461,310	733,739
Accounts payable	1,081,308	(272,318)
Other current liabilities	24,056	30,004
Operating leases, net	(13,516)	(3,440)
Accrued expenses	(139,641)	711,687
NET CASH USED IN OPERATING ACTIVITIES	(15,732,336)	(20,610,723)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(5,156)	(48,892)
NET CASH USED IN INVESTING ACTIVITIES	(5,156)	(48,892)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repayments of finance agreement	(560,848)	(546,651)
Proceeds from exercise of warrants	130,000	82,056
Proceeds from exercise of options	4,913	—
Proceeds from 2021 private placement	—	5,000,800
Proceeds from direct offering, net of issuance costs	—	26,843,998
Proceeds from LPC equity agreement	4,676,399	1,221,350
NET CASH PROVIDED BY FINANCING ACTIVITIES	4,250,464	32,601,553
Effect of exchange rates on cash	(5,240)	26,111
NET INCREASE (DECREASE) IN CASH	(11,492,268)	11,968,049
CASH, BEGINNING OF PERIOD	20,664,410	8,696,361
CASH, END OF PERIOD	\$ 9,172,142	\$ 20,664,410

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

ENOCHIAN BIOSCIENCES INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

Cash Paid during the year for:

Interest	\$	79,716	\$	89,224
Income Taxes	\$	34	\$	37

**SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING
ACTIVITIES**

Contingent Shares issued pursuant to Acquisition Agreement	\$	798,000	\$	192,522
Shares issued in lieu of interest expense on note payable	\$	(299,178)	\$	(298,178)
Finance agreement entered into in exchange for prepaid assets	\$	666,875	\$	607,250

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

ENOCHIAN BIOSCIENCES INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Business— Enochian BioSciences Inc., (“Enochian”, or “Registrant”, and together with its subsidiaries, the “Company”, “we” or “us”) engages in the research and development of pharmaceutical and biological products for the treatment of HIV, HBV, and cancer with the intent to manufacture said products.

Going Concern - These financial statements have been prepared on a going concern basis, which assumes that the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The Company has not generated any revenue, has incurred substantial recurring losses from continuing operations and has an accumulated deficit of \$204,345,197 as of June 30, 2022. The continuation of the Company as a going concern is dependent upon (i) its ability to successfully obtain FDA approval of its product candidates, (ii) its ability to obtain any necessary debt and/or equity financing, and (iii) its ability to generate profits from the Company’s future operations. These factors raise substantial doubt regarding the Company’s ability to continue as a going concern. These financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Basis of Presentation- The Company prepares consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and follows the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”).

Consolidation - For the years ended June 30, 2022 and 2021, the consolidated financial statements include the accounts and operations of the Registrant, and its wholly owned subsidiaries. All material inter-company transactions and accounts have been eliminated in the consolidation.

Reclassification – Certain amounts in the prior period financial statements have been reclassified to conform to the current presentation. For the year ended June 30, 2021, we reclassified lab expenses of \$182,140 from general and administrative expenses to research and development expenses.

Accounting Estimates - The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosures of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. Actual results could differ from those estimated. Significant estimates include the fair value and potential impairment of intangible assets, the fair value of the contingent consideration liability, and the fair value of equity instruments issued.

Subsidiaries- Enochian Biopharma Inc. (“Enochian Biopharma”) was incorporated on May 19, 2017 in Delaware and is a 100% owned subsidiary of the Registrant. Enochian Biopharma owns a perpetual, fully paid-up, royalty-free, sublicensable, and sole and exclusive worldwide license to research, develop, use, sell, have sold, make, have made, offer for sale, import and otherwise commercialize certain intellectual property in cellular therapies for the prevention, treatment, amelioration of and/or therapy exclusively for HIV in humans, and research and development exclusively relating to HIV in humans. As of June 30, 2022 and June 30, 2021, 1,250,000 and 1,350,000 shares of Common Stock, respectively, remain contingently issuable in connection with the acquisition of Enochian BioPharma in February 2018 (the “Contingent Shares”).

Enochian Biosciences Denmark ApS, a Danish corporation was incorporated on April 1, 2001 (“Enochian Denmark”). On February 12, 2014, in accordance with the terms and conditions of a Share Exchange Agreement, the Company acquired Enochian Denmark and it became a 100% owned subsidiary of the Registrant subject to 185,053 shares of common stock of the Registrant held in escrow according to Danish law (the “Escrow Shares”). As of June 30, 2022, there are 17,414 Escrow Shares remaining (see Note 8).

COVID-19 Update

The COVID-19 pandemic continues to evolve. COVID-19 may cause delays in our research activities. To date, the COVID-19 pandemic has not materially affected our operations. However, it has caused delays in the conduct of experiments due to limitations in resources and supply chain issues, in particular for those third-parties conducting experiments. There have also been increases in the cost to conduct animal studies due to staffing and other limitations.

The full extent to which the COVID-19 pandemic may impact our business and operations is subject to future developments, which are uncertain and difficult to predict. We continue to monitor the impact of the COVID-19 pandemic on our business and operations and will seek to adjust our activities as appropriate.

In addition, the pandemic could result in significant and prolonged disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect the financial resources available to us.

Functional Currency and Foreign Currency Translation - The functional currency of Enochian Denmark is the Danish Kroner (“DKK”). Enochian Denmark’s reporting currency is the U.S. Dollar for the purpose of these financial statements. Enochian Denmark’s consolidated balance sheet accounts are translated into U.S. dollars at the period-end exchange rates and all revenue and expenses are translated into U.S. dollars at the average exchange rates prevailing during the years ended June 30, 2022 and 2021. Translation gains and losses are deferred and accumulated as a component of other comprehensive income in stockholders’ equity. Transaction gains and losses that arise from exchange rate fluctuations from transactions denominated in a currency other than the functional currency are included in the statement of operations as incurred.

Cash and Cash Equivalents - The Company considers all highly liquid debt instruments purchased with a maturity of three months or less to be cash equivalents. The Company’s cash balances at June 30, 2022, and 2021, are \$9,172,142 and \$20,664,410, respectively. The Company had balances held in financial institutions in Denmark and in the United States in excess of federally insured amounts at June 30, 2022 and 2021 of \$8,805,495, and \$20,287,212, respectively.

Property and Equipment - Property and equipment are stated at cost. Expenditures for major renewals and betterments that extend the useful lives of property and equipment are capitalized and depreciated upon being placed in service. Expenditures for maintenance and repairs are charged to expense as incurred. Depreciation is computed for financial statement purposes on a straight-line basis over the estimated useful lives of the assets, which range from four to ten years (see Note 3).

Intangible Assets - The Company has both definite and indefinite life intangible assets.

Definite life intangible assets relate to patents. The Company accounts for definite life intangible assets in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 350, *Goodwill and Other Intangible Assets*. Intangible assets are recorded at cost. Patent costs capitalized consist of costs incurred to acquire the underlying patent. If it is determined that a patent will not be issued, the related remaining capitalized patent costs are charged to expense. Definite life intangible assets are amortized on a straight-line basis over their estimated useful life. The estimated useful life of patents is twenty years from the date of application.

Indefinite life intangible assets include license agreements and goodwill acquired in a business combination. The Company accounts for indefinite life intangible assets in accordance with ASC 350. License agreement costs represent the fair value of the license agreement on the date acquired and are tested annually for impairment or whenever events or changes in circumstances indicate the fair value of the license is less than the carrying amount.

ENOCHIAN BIOSCIENCES INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Goodwill - Goodwill is not amortized but is evaluated for impairment annually as of June 30 or whenever events or changes in circumstances indicate the carrying value of the reporting unit may be less than the fair value of the reporting unit.

Impairment of Goodwill and Indefinite Lived Intangible Assets – We test for goodwill impairment at the reporting unit level, which is one level below the operating segment level. Our detailed impairment testing involves comparing the fair value of each reporting unit to its carrying value, including goodwill. Fair value reflects the price a market participant would be willing to pay in a potential sale of the reporting unit and is based on discounted cash flows or relative market-based approaches. If the carrying value of the reporting unit exceeds its fair value, we record an impairment loss for such excess. The annual fair value analysis performed on goodwill supported that goodwill is not impaired as of June 30, 2022 (see Note 4.)

For indefinite-lived intangible assets, such as licenses acquired as an IPR&D asset, on an annual basis we determine the fair value of the asset and record an impairment loss, if any, for the excess of the carrying value of the asset over its fair value. For the year ended June 30, 2022, the carrying value of the licenses acquired as an IPR&D asset exceeded its fair value. Therefore, the Company recorded an impairment loss of \$93,253,000 during the year ended June 30, 2022 (see Note 4.)

The carrying value of IPR&D and goodwill at June 30, 2022, were \$61,571,000 and \$11,640,000, respectively.

Impairment of Long-Lived Assets - Long-lived assets, such as property and equipment and definite life intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Circumstances which could trigger a review include, but are not limited to: significant decreases in the market price of the asset; significant adverse changes in the business climate or legal factors; current period cash flow or operating losses combined with a history of losses or a forecast of continuing losses associated with the use of the asset; and current expectations that the asset will more likely than not be sold or disposed of significantly before the end of its estimated useful life.

Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of would be separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell and would no longer be depreciated. The depreciable basis of assets that are impaired and continue in use are their respective fair values.

Leases - In accordance with ASC Topic 842, the Company determined the initial classification and measurement of its right-of-use assets and lease liabilities at the lease commencement date and thereafter. The lease terms include any renewal options and termination options that the Company is reasonably assured to exercise, if applicable. The present value of lease payments is determined by using the implicit interest rate in the lease, if that rate is readily determinable; otherwise, the Company develops an incremental borrowing rate based on the information available at the commencement date in determining the present value of the future payments.

Effective June 25, 2022, the Company entered into a sub-lease agreement (see Note 5.) Pursuant to ASC 842, the Company treats the sublease as a separate lease, as the Company was not relieved of the primary obligation under the original lease. The Company continues to account for the Century City Medical Plaza lease as a lessee and in the same manner as prior to the commencement date of the sublease. The Company accounts for the sublease as a lessor of the lease. The sublease is classified as an operating lease, as it does not meet the criteria of a sales-type or direct financing lease.

Rent expense for operating leases is recognized on a straight-line basis, unless the operating lease right-of-use assets have been impaired, over the reasonably assured lease term based on the total lease payments and is included in general and administrative expenses in the consolidated statements of operations. For operating leases that reflect impairment, the Company will recognize the amortization of the operating lease right-of-use assets on a straight-line basis over the remaining lease term with rent expense still included in general and administrative expenses in the consolidated statements of operations.

The Company has elected the practical expedient to not separate lease and non-lease components. The Company's non-lease components are primarily related to property maintenance, insurance and taxes, which vary based on future outcomes, and thus are recognized in general and administrative expenses when incurred (see Note 5.)

Research and Development Expenses - The Company expenses research and development costs incurred in formulating, improving, validating, and creating alternative or modified processes related to and expanding the use of the HIV, HBV, and Oncology therapies and technologies for use in the prevention, treatment, amelioration of and/or therapy for HIV, HBV, and Oncology. Research and development expenses for the year ended June 30, 2022 and 2021 amounted to \$8,372,800 and \$15,720,262, respectively.

Income Taxes - The Company accounts for income taxes in accordance with FASB ASC Topic 740 Accounting for Income Taxes, which requires an asset and liability approach for accounting for income taxes (see Note 7.)

Loss Per Share - The Company calculates earnings (loss) per share in accordance with FASB ASC 260 Earnings Per Share. Basic earnings per common share (EPS) are based on the weighted average number of shares of Common Stock outstanding during each period. Diluted earnings per common share are based on shares outstanding (computed as for basic EPS) and potentially dilutive common shares. Potential shares of Common Stock included in the diluted earnings per share calculation include in-the-money stock options that have been granted but have not been exercised. The shares of Common Stock outstanding at June 30, 2022 and 2021 were 53,007,082 and 52,219,661, respectively. Because of the net loss for each of years ended June 30, 2022 and June 30, 2021, dilutive shares for both periods were excluded from the diluted EPS calculation, as the effect of these potential shares of Common Stock is anti-dilutive. The Company had 6,807,820 and 4,011,653 potential shares of Common Stock excluded from the diluted EPS calculation for the years ended June 30, 2022 and 2021, respectively.

Fair Value of Financial Instruments - The Company accounts for fair value measurements for financial assets and financial liabilities in accordance with FASB ASC Topic 820, *Fair Value Measurements*. Under the authoritative guidance, fair value is defined as the exit price, representing the amount that would either be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the guidance established a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1. Observable inputs such as quoted prices in active markets for identical assets or liabilities;
- Level 2. Inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3. Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

There were no assets that use Level 1, 2 or 3 inputs, nor any liabilities that use Level 1 or 2 inputs as of June 30, 2022.

Liabilities that use Level 3 inputs held as of June 30, 2022 consisted of a contingent consideration liability related to the February 16, 2018 acquisition of Enochian BioPharma (the "Acquisition"). As consideration for the Acquisition, the stockholders of Enochian Biopharma received (i) 18,081,962 shares of Common Stock, and (ii) the right to receive contingent shares pro rata upon the exercise of warrants, which were outstanding at closing. The contingent consideration liability was recorded at fair value of \$21,516,000 at the time of the Acquisition and is subsequently remeasured to fair value at each reporting date. At June 30, 2022, 1,250,000 contingent shares are issuable in connection with the Acquisition.

The fair value of the contingent consideration liability is estimated using an option-pricing model. The key inputs to the model are all contractual or observable with the exception being volatility, which is computed, based on the Company's underlying stock. The key inputs to valuing the contingent consideration liability on the date of acquisition and as of June 30, 2022, include the Company's stock price on the valuation date of \$1.93; the exercise price of the warrants of \$1.30, the risk-free rate of 0.00%, the expected volatility of the Company's Common Stock of 109.0%, and the digital call rate of 97%. Fair Value measurements are highly sensitive to changes in these inputs and significant changes in these inputs could result in a significantly higher or lower fair value.

Unless otherwise disclosed, the fair value of the Company's financial instruments including cash, accounts receivable, prepaid expenses, accounts payable, accrued expenses, and notes payable approximate their recorded values due to their short-term nature.

The following table sets forth the liabilities at June 30, 2022 and 2021, which are recorded on the balance sheet at fair value on a recurring basis by level of input within the fair value hierarchy. As required, these are classified based on the lowest level of input that is significant to the fair value measurement:

	Fair Value Measurements at Reporting Date Using		
	Quoted Prices in Active Markets for Identical Assets Inputs (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Contingent Consideration Liability at June 30, 2022	\$ —	\$ —	\$ 2,343,318
The roll forward of the contingent consideration liability is as follows:			
Balance June 30, 2021			6,037,945
Contingent Shares issued pursuant to the Acquisition Agreement			(798,000)
Fair value adjustment	—	—	(2,896,627)
Balance June 30, 2022	\$ —	\$ —	\$ 2,343,318

Stock Options and Warrants - During the years presented in the accompanying consolidated financial statements, the Company has granted stock options and warrants. The Company accounts for options and warrants in accordance with the provisions of FASB ASC Topic 718, Compensation – Stock Compensation. Stock-based compensation costs related to employee compensation and consulting fees for the years ended June 30, 2022 and 2021 were \$5,490,602 and \$1,444,798, respectively (see Note 8).

Stock-Based Compensation —The Company records stock-based compensation for services received from non-employees in accordance with ASC 718. All transactions in which goods or services are the consideration received for the issuance of equity instruments are measured based on the grant-date fair value. Equity instruments issued for goods or services and the cost of the services received as consideration are measured and recognized based on the fair value of the equity instruments issued and are recognized over the consultants' required service period, which is generally the vesting period.

New Accounting Pronouncements Not Yet Adopted - Recent accounting pronouncements issued by the FASB that have not yet been adopted by the Company are not expected to have a material impact on the Company's present or future consolidated financial statements.

ENOCHIAN BIOSCIENCES INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 2 – GOING CONCERN

The Company's consolidated financial statements are prepared using the generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. However, the Company has incurred substantial recurring losses from continuing operations, has used cash in the Company's continuing operations, and is dependent on additional financing to fund operations. We incurred a net loss of approximately \$113,433,392 and \$26,723,607 for the years ended June 30, 2022 and 2021. As of June 30, 2022, the Company had cash and cash equivalents of \$9,172,142 and an accumulated deficit of \$204,345,198. These conditions raise substantial doubt about the Company's ability to continue as a going concern for one year after the date the financial statements are issued. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence. Management intends to raise additional funds for (a) research and development, (b) increases in personnel, and (c) the purchase of equipment, specifically to advance the Company's potential products through the regulatory process. We may raise such funds from time to time through public or private sales of our equity or debt securities. Such financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely affect our growth plans and our financial condition and results of operations.

NOTE 3 - PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at June 30, 2022 and 2021:

	Useful Life	June 30, 2022	June 30, 2021
Lab equipment and instruments	4-7	\$ 546,524	\$ 583,421
Leasehold improvements	10	224,629	224,629
Furniture, fixtures, and equipment	4-7	172,861	171,975
Total		944,014	980,025
Less accumulated depreciation		(357,478)	(260,661)
Net Property and Equipment		<u>\$ 586,536</u>	<u>\$ 719,364</u>

Depreciation expense amounted to \$108,595 and \$107,647 for the years ended June 30, 2022 and 2021, respectively. The Company disposed of property and equipment with a net book value totaling \$18,168 resulting in a loss on disposal of \$18,168.

ENOCHIAN BIOSCIENCES INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 4 — INTANGIBLE ASSETS AND GOODWILL

At June 30, 2022 and 2021, definite-life intangible assets, net of accumulated amortization, consisted of patents on the Company’s products and processes of \$44,268 and \$65,906, respectively. The patents are recorded at cost and amortized over twenty years from the date of application. Amortization expense for the year ended June 30, 2022 and 2021 was \$14,995 and \$15,888, respectively.

At June 30, 2022 and 2021, indefinite life intangible assets consisted of a license agreement classified as In-Process Research and Development (“IPR&D”) intangible assets, which are not amortizable until the intangible assets provide economic benefit, and goodwill.

At June 30, 2022 and 2021, definite-life and indefinite-life intangible assets consisted of the following:

	Useful Life	June 30, 2021	Period Change	Effect of Currency Translation	June 30, 2022
Definite Life Intangible Assets					
Patents	20 Years	\$ 316,115	\$ —	(36,858)	\$ 279,257
Less Accumulated Amortization		(250,209)	(14,995)	30,215	(234,989)
Net Definite-Life Intangible Assets		<u>\$ 65,906</u>	<u>\$ (14,995)</u>	<u>\$ (6,643)</u>	<u>\$ 44,268</u>
Indefinite Life Intangible Assets					
License Agreement		\$ 154,824,000	\$ (93,253,000)	\$ —	\$ 61,571,000
Goodwill		11,640,000	—	—	11,640,000
Total Indefinite Life Intangible Assets		<u>\$ 166,464,000</u>	<u>\$ (93,253,000)</u>	<u>\$ —</u>	<u>\$ 73,211,000</u>

Expected future amortization expense is as follows:

Years ended June 30,		
2023	\$	11,067
2024		11,067
2025		11,067
2026		11,067
	<u>\$</u>	<u>44,268</u>

During February 2018, the Company acquired a License Agreement (as licensee) to the HIV therapy being developed as ENOB-HV-01 which consists of a perpetual, fully paid-up, royalty-free, sub-licensable, and sole and exclusive worldwide license to research, develop, use, sell, have sold, make, have made, offer for sale, import and otherwise commercialize certain intellectual property in cellular therapies for the prevention, treatment, amelioration of and/or therapy exclusively for HIV in humans, and research and development exclusively relating to HIV in humans. Because the HIV License Agreement is considered an IPR&D intangible asset, it is classified as an indefinite life asset that is tested annually for impairment.

Impairment – Following the fourth quarter of each year, management performs its annual test of impairment of intangible assets by performing a quantitative assessment and determines if it is more likely than not that the fair value of the asset is greater than or equal to the carrying value of the asset. The results of the quantitative assessment indicated that the carrying value of the licenses acquired as an IPR&D asset exceeded its fair value, due to the sublicensing of ENOB HV-01, which required a different valuation approach and the significant decrease in our market capitalization value. Therefore, an impairment adjustment of \$93,253,000 was recorded as of June 30, 2022.

NOTE 5 — LEASES

Operating Leases — On November 13, 2017, the Registrant entered into a lease agreement for a term of five years and two months from November 1, 2017 with Plaza Medical Office Building, LLC, pursuant to which the Registrant agreed to lease approximately 2,325 rentable square feet (the “Plaza Lease”). The base rent for the Plaza Lease increased by 3% each year, and ranged from approximately \$8,719 per month, for the first year to \$10,107 per month for the two months of the sixth year. The lease was terminated early without penalties or additional costs as of September 30, 2022.

On June 19, 2018, the Registrant entered into a lease agreement for a term of ten years from September 1, 2018 with Century City Medical Plaza Land Co., Inc., pursuant to which the Company agreed to lease approximately 2,453 rentable square feet. On February 20, 2019, the Registrant entered into an Addendum to the original lease agreement with an effective date of December 1, 2019, where it expanded the leased area to include another 1,101 square feet for a total rentable 3,554 square feet. The base rent increases by 3% each year, and ranges from \$17,770 per month as of the date of the amendment to \$23,186 per month for the tenth year. The equalized monthly lease payment for the term of the lease is \$20,050. The Company subleased the space as of June 25, 2022 (see subsection below “*Sublease Agreement*” for details.)

The Company identified and assessed the following significant assumptions in recognizing the right-of-use assets and corresponding liabilities:

Expected lease term — The expected lease term includes both contractual lease periods and, when applicable, cancelable option periods when it is reasonably certain that the Company would exercise such options. The Company’s leases have remaining lease terms between 6 months and 62 months. As of June 30, 2022, the weighted-average remaining term is 4.95 years.

Incremental borrowing rate — The Company’s lease agreements do not provide an implicit rate. As the Company does not have any external borrowings for comparable terms of its leases, the Company estimated the incremental borrowing rate based on the U.S. Treasury Yield Curve rate that corresponds to the length of each lease. This rate is an estimate of what the Company would have to pay if borrowing on a collateralized basis over a similar term in an amount equal to the lease payments in a similar economic environment. As of June 30, 2022, the weighted-average discount rate is 4%.

Lease and non-lease components — In certain cases the Company is required to pay for certain additional charges for operating costs, including insurance, maintenance, taxes, and other costs incurred, which are billed based on both usage and as a percentage of the Company’s share of total square footage. The Company determined that these costs are non-lease components and they are not included in the calculation of the lease liabilities because they are variable. Payments for these variable, non-lease components are considered variable lease costs and are recognized in the period in which the costs are incurred.

Below are the lease commitments for the next 5 years:

Years Ending June 30	Lease Expense
2023	\$ 298,305
2024	246,004
2025	253,384
2026	260,985
2027	313,836
Thereafter	—
Less imputed interest	(133,178)
Total	\$ 1,239,336

Sublease Agreement

On June 20, 2022, the Company entered into a sublease Agreement with One Health Labs (the “Subtenant”), whereby the Subtenant agreed to lease 3,554 square feet of space currently rented by the Company in Century City Medical Plaza as of June 25, 2022 for a period of 3.5 years with an option to renew for the remaining term of the lease that ends as of June 19, 2028. The base rent is \$17,770 per month plus \$750 towards utility fees that are part of the original lease agreement and will increase by 3% each year over the term of the sub-lease. The Company received a total of \$57,021.67 on July 1, 2022 after execution of the sublease to cover the first month rent, utility fee and deposit. The first sublease payment began on August 1, 2022.

In accordance with ASC Topic 842, the Company treats the sublease as a separate lease, as the Company was not relieved of the primary obligation under the original lease. The Company continues to account for the Century City Medical Plaza lease as a lessee and in the same manner as prior to the commencement date of the sublease. The Company accounts for the sublease as a lessor of the lease. The sublease is classified as an operating lease, as it does not meet the criteria of a sales-type or direct financing lease.

The Company will recognize operating income from the sublease on a straight-line basis in its statements of operations over the lease term.

During the year ended June 30, 2022 and 2021, the net operating lease expenses were as follows :

	Years ended June 30,	
	2022	2021
Operating Lease Expense	\$ 356,073	\$ 339,094
Sublease income	(2,962)	—
Total Net Lease Expense	\$ 353,111	\$ 339,094

NOTE 6 — NOTES PAYABLE

Convertible Notes Payable- On February 6, 2020, the Company issued two Convertible Notes (the “Convertible Notes”) to Paseco APS (the “Holder”), a Danish limited company and an existing stockholder of the Company each with a face value amount of \$600,000, convertible into shares of Common Stock, \$0.0001 par value per share. The outstanding principal amount of the Convertible Notes was due and payable on February 6, 2023. Interest on the Convertible Notes commenced accruing on the date of issuance at six percent (6%) per annum, computed on the basis of twelve 30-day months, and is compounded monthly on the final day of each calendar month based upon the principal and all accrued and unpaid interest outstanding as of such compound date. The interest was payable in cash on a semi-annual basis.

The holder of the Convertible Notes had the right at any time prior to the date that is twelve months from issuance to convert all or any part of the outstanding and unpaid principal and all unpaid interest into shares of the Company’s Common Stock. The conversion price was equal to \$12.00 per share of Common Stock. The Holder did not exercise the conversion feature that expired on February 6, 2021. The Company evaluated the Convertible Notes in accordance with ASC 470-20 and identified that they each contain an embedded conversion feature that shall not be bifurcated from the host document (i.e., the Convertible Notes) as they are not deemed to be readily convertible into cash. All proceeds received from the issuance have been recognized as a liability on the balance sheet. The Convertible Notes balance as of June 30, 2022 and June 30, 2021, was \$1,200,000. As of June 30, 2022 and 2021, the Company recorded accrued interest in the amount of \$24,181, which is included in accrued expenses. For the years ended June 30, 2022 and 2021, the interest expense related to the Convertible Notes amounted to \$72,875 and \$72,967 respectively. Effective December 30, 2022, the Company amended and restated the Convertible Notes (the “Amended and Restated Secured Notes”). Pursuant to the Amended and Restated Secured Notes, the due date was extended to February 28, 2024, and the interest was increased to twelve percent (12%) per annum, which was prepaid by the Company in full on the date of amendment through the issuance of 198,439 shares of the Company’s Common Stock based on the closing market price on that date, of \$1.03, which included 29,419 shares for interest accrued through December 30, 2022, and the obligations of the Company under the Amended and Restated Secured Notes were secured by a security Agreement (the “Security Agreement”).

Note Payable- On March 30, 2020 (the “Issuance Date”), the Company issued a Promissory Note in the principal amount of \$5,000,000 (the “Promissory Note”) to the Holder. The principal amount of the Promissory Note was originally payable on November 30, 2021 (the “Maturity Date”). The Promissory Note bore interest at a fixed rate of 6% per annum, computed based on the number of days between the Issuance Date and the Maturity Date, which was prepaid by the Company in full on the Issuance Date through the issuance of 188,485 shares of the Company’s Common Stock based on the closing market price on that date for a total value of \$501,370. The Company evaluated the Promissory Note and PIK interest in accordance with ASC 470-Debt and ASC 835-Interest, respectively. Pursuant to ASC 470-20, proceeds received from the issuance are to be recognized at their relative fair value, thus the liability is shown net of the corresponding discount of \$493,192, which is the relative fair value of the shares issued for the PIK interest on the closing date using the effective interest method. The discount of \$493,192 will be accreted over the life of the Promissory Note.

On February 11, 2021, the Company entered into an amendment to the Promissory Note in the principal amount of \$5,000,000 that extended the Maturity Date to November 30, 2022. All other terms of the Promissory Note remained the same. The change in Maturity Date required an additional year of interest at the fixed rate of 6% per annum, which was prepaid by the Company in full on the date of the amendment through the issuance of 74,054 shares of the Company’s Common Stock based on the closing market price on that date for a total value of \$298,178.

On May 17, 2022, the Company entered into a second amendment to the Promissory Note that extended the Maturity Date out to November 30, 2023 and increased the interest rate from 6% to 12% per annum. All other terms of the Promissory Note remained the same. The change in Maturity Date required an additional year of interest at the fixed rate of 12% per annum. Pursuant to the amendment, the Company prepaid interest for the period November 30, 2022 until May 30, 2023 on the date of the amendment through the issuance of 47,115 shares of the Company’s Common Stock based on the closing market price on that date for a total value of \$299,178. All other accrued interest payable from May 30, 2023 to the Maturity Date shall be payable by the Company on May 30, 2023, at the option of the Holder either (i) in cash or (ii) in non-assessable shares of the Company’s Common Stock, valued at the closing sale price of the Common Stock of the Nasdaq Capital Market on May 30, 2023. For the year ended June 30, 2022 and 2021, discount amortization of \$297,212 and \$296,506 was charged to interest expense. The Promissory Note balance, net of discount at June 30, 2022 is \$4,577,148. Effective December 30, 2022, the Company entered into a third amendment to the Promissory Note. Pursuant to the third amendment, the Company’s obligations under the Promissory Note were secured by the Security Agreement.

To secure the Company's obligations under each of the Amended and Restated Secured Notes and the Promissory Note, the Company entered into a Security Agreement with the Holder, pursuant to which the Company granted a lien on all assets of the Company (the "Collateral") for the benefit of the Holder. Upon an Event of Default (as defined in the Amended and Restated Secured Notes and Promissory Note, respectively) the Holder may, among other things, collect or take possession of the Collateral, proceed with the foreclosure of the security interest in the Collateral or sell, lease, or dispose of the Collateral.

Finance Agreement — On November 30, 2021, the Company entered into a premium finance agreement (the "Agreement") with a principal amount of \$666,875 at 3.99% interest per annum. The repayment of the Agreement will be made in nine equal monthly installments of \$56,469. The remaining balance at June 30, 2022 is \$166,625; the amount is reflected in other current liabilities. For the year ended June 30, 2022, the Company recorded total interest expense in the amount of \$5,565 related to the Agreement. This amount is reflected in other income and expenses.

Total interest expense recorded for the years ended June 30, 2022 and 2021, was \$372,844 and \$379,608, respectively.

NOTE 7 — INCOME TAXES

The Company accounts for income taxes in accordance with FASB ASC Topic 740, Accounting for Income Taxes; which requires the Company to provide a net deferred tax asset or liability equal to the expected future tax benefit or expense of temporary reporting differences between book and tax accounting and any available operating loss or tax credit carryforwards. The amount of and ultimate realization of the benefits from the deferred tax assets for income tax purposes is dependent, in part, upon the tax laws in effect, the Company's future earnings, and other future events, the effects of which cannot be determined.

As of June 30, 2022 and 2021, the Company had net operating loss carryforwards of approximately \$244,899,881 and \$51,327,066, respectively, giving rise to deferred tax assets of \$71,299,011 and \$13,536,884 respectively. The net operating loss carryforwards generated prior to January 1, 2018 expire over various dates from 2031 to 2036. All subsequent net operating loss carryforwards are indefinite.

The Company files Danish and U.S. income tax returns and these returns are generally no longer subject to tax examinations for years prior to 2018 for the Danish tax returns and 2017 for the U.S. tax returns.

The temporary differences, tax credits and carry forwards gave rise to the following deferred tax assets (liabilities) at June 30, 2022 and 2021:

	June 30	
	2022	2021
Excess of tax over book depreciation of fixed assets	\$ 6,406	\$ (6,100)
Excess of tax over book depreciation of patents	5,716	5,449
Stock/options compensation	2,831,137	1,192,741
Depreciation and amortization	118,020	81,140
Net operating loss carryforwards	71,299,011	13,536,884
Change in tax rate	—	—
Valuation allowance	(74,260,290)	(14,810,114)
Total Deferred Tax Assets (Liabilities)	<u>\$ —</u>	<u>\$ —</u>

In accordance with prevailing accounting guidance, the Company is required to recognize and disclose any income tax uncertainties. The guidance provides a two-step approach to recognizing and measuring tax benefits and liabilities when realization of the tax position is uncertain. The first step is to determine whether the tax position meets the more-likely-than-not condition for recognition, and the second step is to determine the amount to be recognized based on the cumulative probability that exceeds 50%. The amount of and ultimate realization of the benefits from the deferred tax assets for income tax purposes is dependent, in part, upon the tax laws in effect, the Company's future earnings, and other future events, the effects of which can be difficult to determine and can only be estimated. Management estimates that it is more likely than not that the Company will not generate adequate net profits to use the deferred tax assets; and consequently, a valuation allowance was recorded for all deferred tax assets.

A reconciliation of income tax expense at the federal statutory rate to income tax expense at the Company's effective rate is as follows for the year ended June 30, 2022 and 2021:

	Years ended June 30,	
	2022	2021
Computed tax at expected statutory rate	\$ (59,450,176)	\$ (7,070,732)
Non-US income taxed at different rates	—	(125,276)
Non-deductible expenses / other items	34	—
Valuation allowance	59,450,176	7,070,732
Income Tax Expense (Benefit)	\$ 34	\$ (125,276)

The components of income tax expense (benefit) from continuing operations for the years ended June 30, 2022 and 2021 consisted of the following:

	Years ended June 30,	
	2022	2021
Current Income Tax Expense		
Danish income tax (benefit)	\$ —	\$ (125,276)
Total Current Tax Expense (Benefit)	\$ —	\$ (125,276)
Deferred Income Tax Expense (Benefit)		
Excess of tax over book depreciation of fixed assets	\$ 6,406	\$ (6,100)
Excess of tax over book depreciation of patents	5,716	5,449
Stock/options compensation	2,831,137	1,192,741
Depreciation and amortization	118,020	81,140
Net operating loss carryforwards	13,536,884	13,536,884
Change in tax rate	—	—
Change in the valuation allowance	(74,260,290)	(14,810,114)
Total Deferred Tax Expense	\$ —	\$ —

Deferred income tax expense (benefit) results primarily from the reversal of temporary timing differences between tax and financial statement income.

NOTE 8 — STOCKHOLDERS' EQUITY

Preferred Stock — The Company has 10,000,000 authorized shares of Preferred Stock, par value \$0.0001 per share. At June 30, 2022 and 2021, there were zero shares issued and outstanding.

Common Stock — The Company has 100,000,000 authorized shares of Common Stock, par value \$0.0001 per share. At June 30, 2022 and 2021, there were 53,007,082 and 52,219,661 shares issued and outstanding, respectively.

Voting — Holders of Common Stock are entitled to one vote for each share held of record on each matter submitted to a vote of stockholders, including the election of directors, and do not have any right to cumulate votes in the election of directors.

Dividends — Holders of Common Stock are entitled to receive ratably such dividends as the Company's Board of Directors from time to time may declare out of funds legally available.

Liquidation Rights — In the event of any liquidation, dissolution or winding-up of the affairs of the Company, after payment of all of our debts and liabilities, the holders of Common Stock will be entitled to share ratably in the distribution of any of our remaining assets.

Purchase Agreement with Lincoln Park Capital

On July 8, 2020, we entered into a purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which the Company may sell and issue to Lincoln Park, and Lincoln Park is obligated to purchase, up to \$20,000,000 of shares of our Common Stock from time to time through August 1, 2023.

In consideration for entering into the Purchase Agreement, we issued 139,567 shares of Common Stock to Lincoln Park as a commitment fee on July 21, 2020.

During the years ended June 30, 2022 and June 30, 2021 we issued 497,340 and 200,000 shares of Common Stock to Lincoln Park under the Purchase Agreement for a purchase price of \$4,676,399 and \$1,221,350, respectively. At June 30, 2022, an amount of \$14,102,251 remained available under the Purchase Agreement. As of October 17, 2022, we no longer have access to this Purchase Agreement as we are no longer able to use the registration statement on Form S-3.

Common Stock Issuances

On June 17, 2022, the Company issued 47,115 shares of Common Stock valued at \$299,178 based on the closing price on that date, issued in lieu of prepaid interest related to an amendment that extended the maturity date of the Unsecured Note to November 30, 2023 (see Note 6).

During the period ending June 30, 2022, the Company issued 497,340 shares of Common Stock at an average price of \$9.25 per share pursuant to the Purchase Agreement with Lincoln Park for total proceeds to the Company of \$4,676,399.

On April 4, 2022, the Company issued 1,700 shares of Common Stock valued at the price of \$2.89 per share pursuant to the exercise of vested stock options for total proceeds of \$4,913.

On January 11, 2022, the Company issued 6,266 shares of Common Stock related to restricted share units that vested on January 07, 2022, at a value of \$40,561.

On December 28, 2021, there were 35,000 restricted share units issued that immediately vested and were converted into shares of Common Stock in exchange for consulting services valued at \$252,350.

On December 24, 2021, the Company issued 100,000 shares of Common Stock valued at the price of \$1.30 per share pursuant to the exercise of vested warrants for total proceeds of \$130,000, with corresponding earn-out distribution in the same amount in connection with the acquisition of Enochian BioPharma, Inc., which was distributed on March 31, 2022, based on the share price on December 23, 2021 of \$7.98. This non-cash transaction impacted stockholders' equity in the amount of \$798,000.

On June 30, 2021, the Company issued 5,000 shares of Common Stock related to restricted share units that vested on January 7, 2021. These shares were expensed during the period.

On June 16, 2021, the Company issued 3,866,668 shares of Common Stock at a price of \$7.50 per share pursuant to a Registered Direct Purchase Agreement for total proceeds to the Company of \$26,843,998 net of \$2,156,012 of issuance costs.

In June 2021, the Company issued 200,000 shares of Common Stock at an average price of \$5.42 per share pursuant to the Purchase Agreement with Lincoln Park for total proceeds to the Company of \$1,221,350.

From March 18, 2021 through June 9, 2021, the Company issued 1,275,719 shares of Common Stock at a price of \$3.92 per share pursuant to a private placement for total proceeds to the Company of \$5,000,800.

On February 18, 2021, there were 35,000 restricted share units issued that immediately vested and were converted into shares of Common Stock in exchange for consulting services valued at \$147,000.

On February 11, 2021, the Company issued 74,054 shares of Common Stock valued at \$298,178 based on the closing price on that date, issued in lieu of prepaid interest related to an amendment that extended the maturity date of an Unsecured Note to November 30, 2022 (see Note 6).

On December 14, 2020, the Company issued 63,122 shares of Common Stock valued at the price of \$1.30 per share pursuant to the exercise of vested warrants for total proceeds of \$82,056.

On December 14, 2020, the Company issued 63,122 shares of Common Stock valued at the price of \$3.05 per share in connection with the acquisition of Enochian Biopharma Inc. This non-cash transaction impacted stockholders' equity in the amount of \$192,522.

Acquisition of Enochian Biopharma / Contingently issuable shares

On February 16, 2018, the acquisition of Enochian Biopharma was completed. As part of the acquisition, the stockholders of Enochian Biopharma received (i) 18,081,962 shares of Common Stock, and (ii) the right to receive Contingent Shares of Common Stock pro rata upon the exercise or conversion of warrants, which were outstanding at closing. As of June 30, 2022, 1,250,000 Contingent Shares are potentially issuable (see Note 1).

Acquisition of Enochian Denmark

At June 30, 2022 and 2021, the Company maintained a reserve of 17,414 Escrow Shares, all of which are reflected as issued and outstanding in the accompanying financial statements. The Escrow Shares are reserved to acquire the shares of Enochian Denmark held by non-consenting shareholders of Enochian Denmark on both June 30, 2022 and 2021, in accordance with Section 70 of the Danish Companies Act and the Articles of Association of DanDrit Denmark. There have been 167,639 shares of Common Stock issued to non-consenting shareholders of Enochian Denmark as of June 30, 2022. During the years ended June 30, 2022 and 2021, the Company issued zero and 59,835 shares of Common Stock, respectively, to such non-consenting shareholders of Enochian Denmark.

Stock-based Compensation

The Company recognizes compensation costs for stock option awards to employees based on their grant-date fair value. The value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model. In the year ended June 30, 2022, the weighted-average assumptions used to estimate the grant date fair values of the stock options granted using the Black-Scholes option-pricing model are as follows:

	Enochian Biosciences Inc.
Expected term (in years)	5.0 – 6.50
Volatility	82.29% – 90.39%
Risk free interest rate	0.77%- 3.02%
Dividend yield	0%

The Company recognized stock-based compensation expense related to all equity instruments of \$5,490,602 and \$1,444,798 for the years ended June 30, 2022 and 2021, respectively. At June 30, 2022, the Company had approximately \$6,235,329 of unrecognized compensation cost related to non-vested options.

Plan Options

On February 6, 2014, the Board adopted the Company’s 2014 Equity Incentive Plan (the “2014 Plan”), and the Company reserved 1,206,000 shares of Common Stock for issuance in accordance with the terms of the 2014 Plan.

On October 30, 2019, the Board approved and on October 31, 2019, the Company’s stockholders adopted Enochian’s 2019 Equity Incentive Plan (the “2019 Plan”), which replaced the 2014 Plan. The 2019 Plan authorized options to be awarded to not exceed the sum of (1) 6,000,000 new shares, and (2) the number of shares available for the grant of awards as of the effective date under the 2014 Plan plus any options related to awards that expire, are terminated, surrendered, or forfeited for any reason without issuance of shares under the 2014 Plan after the effective date of the 2019 Plan.

Pursuant to the 2019 Plan, the Company granted options to purchase 3,219,200 shares to employees with a three-year vesting period during the year ended June 30, 2022. One million of those shares are subject to performance based vesting criteria, and as of June 30, 2022, no expense has been recognized on this option based on the assessment that these shares are not probable of vesting. As performance criteria for Year 1 was not probable, one-third of this amount was forfeited. During previous quarters, this option was assessed as probable of vesting, such that approximately \$1.9 million of expense was reversed in the quarter ended June 30, 2022. For the year ended June 30, 2021, the Company granted options to purchase 31,700 shares with a three-year vesting period under the 2019 Plan.

During the year ended June 30, 2022 and 2021, the Company granted options to purchase 65,000 and zero shares of Common stock, respectively, to employees with a one-year vesting period.

During the years ended June 30, 2022 and 2021, the Company granted options to purchase 103,668 and 184,509 shares, respectively, to the Board of Directors and Scientific Advisory Board Members with a one-year vesting period.

During the years ended June 30, 2022, and 2021, the Company granted options to purchase 60,000 and zero shares, respectively, for consulting services with a three-year vesting period.

During the years ended June 30, 2022, and 2021, the Company granted options to purchase 29,642 and zero shares, respectively, for consulting services with a one-year vesting period.

During the years ended June 30, 2022 and 2021, the Company granted options to purchase 21,979 and 15,000 shares, respectively, for consulting services with immediate vesting.

All of the above options are exercisable at the market price of the Company’s Common Stock on the date of the grant.

To date the Company has granted options under the Plan (“Plan Options”) to purchase 4,828,642 shares of Common Stock.

A summary of the Plan Options outstanding at June 30, 2022 is presented below:

	Options Outstanding				Options Exercisable		
	Exercise Price Ranges	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price
	2.00– \$ 4.50	264,057	7.62	\$ 3.27	233,431	7.41	\$ 3.19
	4.51– \$ 6.50	3,193,369	8.70	\$ 4.83	488,372	6.72	\$ 6.18
	6.51– \$ 12.00	850,393	8.27	\$ 8.04	543,067	7.56	\$ 7.92
Total		<u>4,307,820</u>	<u>8.55</u>	<u>\$ 5.37</u>	<u>1,264,869</u>	<u>7.21</u>	<u>\$ 6.38</u>

A summary of changes since July 1, 2021 are presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Life	Weighted Average Intrinsic Value
Outstanding at July 1, 2021	1,329,153	\$ 6.24	8.42	\$ 511,239
Granted	3,499,489	5.00		
Exercised	(1,700)	2.89		
Forfeited	(519,122)	5.16		
Expired/Canceled	—			
Outstanding at June 30, 2022	<u>4,307,820</u>	<u>\$ 5.37</u>	<u>8.55</u>	<u>\$ —</u>
Exercisable at June 30, 2022	<u>1,264,869</u>	<u>\$ 6.38</u>	<u>7.21</u>	<u>\$ —</u>

At June 30, 2022, the Company has 1,264,869 exercisable Plan Options. The total intrinsic value of options exercisable at June 30, 2022 was zero. Intrinsic value is measured using the fair market value at the date of exercise (for shares exercised) and at June 30, 2022 (for outstanding options), less the applicable exercise price.

Common Stock Purchase Warrants

A summary of the warrants outstanding at June 30, 2022, and changes in the warrants in the year ended June 30, 2022 are presented below:

	Underlying Shares	Weighted Average Exercise Price	Weighted Average Remaining Life
Outstanding at July 1, 2021	1,350,000	\$ 1.30	1.02
Granted	—	—	—
Exercised	(100,000)	1.30	—
Cancelled/Expired	—	—	—
Outstanding at June 30, 2022	<u>1,250,000</u>	<u>\$ 1.30</u>	<u>0.03</u>
Exercisable at June 30, 2022	<u>1,250,000</u>	<u>\$ 1.30</u>	<u>0.03</u>

Exercise Prices	Underlying Shares	Weighted Average Remaining Contractual Life (years)	Outstanding	Equivalent Shares Exercisable	
			Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 1.30	1,250,000	0.03	\$ 1.30	1,250,000	\$ 1.30

Restricted Stock Units (RSUs)

The Company recognized stock-based compensation expense related to RSUs of \$258,559 and \$147,000 for the years ended June 30, 2022 and 2021, respectively. At June 30, 2022, the Company had approximately zero unrecognized compensation cost related to restricted stock units.

A summary of Restricted Stock Units outstanding at June 30, 2021 and changes in the RSUs in the year ended June 30, 2022 are presented below

	Shares	Weighted Average Issuance Price	Weighted Average Remaining Life	Weighted Average Intrinsic Value
Outstanding at July 1, 2021	5,000	\$ 6.15	.52	\$ —
Granted	36,266	7.23	—	—
Exercised	(41,266)	7.10	—	—
Cancelled/Expired	—	—	—	—
Outstanding at June 30, 2022	—	\$ —	—	\$ —

NOTE 9 — COMMITMENTS AND CONTINGENCIES

Commitments

Consulting Agreements - On July 9, 2018, the Company entered into a consulting agreement with G-Tech Bio, LLC, a California limited liability company (“G-Tech”) to assist the Company with the development of the gene therapy and cell therapy modalities for the prevention, treatment, and amelioration of HIV in humans, and with the development of a genetically enhanced Dendritic Cell for use as a wide spectrum platform for various diseases (including but not limited to cancers and infectious diseases) (the “G-Tech Agreement”). G-Tech was entitled to consulting fees for 20 months with a monthly consulting fee of not greater than \$130,000 per month. Upon the completion of the 20 months, a monthly consulting fee of \$25,000 continued for scientific consulting and knowledge transfer on existing HIV experiments until the services were no longer being rendered or the G-Tech Agreement is terminated. G Tech is controlled by certain members of Weird Science. For the years ended June 30, 2022 and 2021, \$275,000 was charged to research and development expenses in the accompanying consolidated statements of operations related to this consulting agreement. As of May 25, 2022, the consultant was no longer able to render services.

On January 31, 2020, the Company entered into a Statement of Work and License Agreement (the “HBV License Agreement”) by and among the Company, and G-Tech, and G Health Research Foundation, a not for profit entity organized under the laws of California doing business as Seraph Research Institute (“SRI”) (collectively the “Licensors”), whereby the Company acquired a perpetual, sublicensable, exclusive license (the “HBV License”) for a treatment under development (the “Treatment”) aimed to treat Hepatitis B Virus (HBV) infections.

The HBV License Agreement states that in consideration for the HBV License, the Company shall provide cash funding for research costs and equipment and certain other in-kind funding related to the Treatment over a 24 month period, and provides for an up-front payment of \$1.2 million within 7 days of January 31, 2020, along with additional payments upon the occurrence of certain benchmarks in the development of the technology set forth in the HBV License Agreement, in each case subject to the terms of the HBV License Agreement. Additionally, the HBV License Agreement provides for cooperation related to the development of intellectual property related to the Treatment and for a 2% royalty to G-Tech on any net sales that may occur under the HBV License. On February 6, 2020, the Company paid the \$1.2 million up-front payment. The HBV License Agreement contains customary representations, warranties, and covenants of the parties with respect to the development of the Treatment and the HBV License.

The cash funding for research costs pursuant to the HBV License Agreement consisted of monthly payments amounting to \$144,500 that covered scientific staffing resources to complete the project as well as periodic payments for materials and equipment needed to complete the project. There were no payments made after January 31, 2022. During the years ended June 30, 2022 and 2021, the Company paid a total of \$1,011,500 and \$2,409,000, respectively, for scientific staffing resources, R&D and IND Enabling studies. During the year ended June 30, 2022, the Company paid \$1,500,000 in August 2021 for the milestone completion of a Pre-Investigational New Drug (IND) process following receipt of written comments in accordance the HBV License Agreement. The Company has filed a claim against the Licensors, which includes certain payments it made related to this license (see Contingencies sub-section below).

On April 18, 2021, the Company entered into a Statement of Work and License Agreement (the “License Agreement”), by and among the Company, and G Tech and SRI (collectively, the “Licensors”), whereby the Company acquired a perpetual sublicensable, exclusive license (the “Development License”) to research, develop, and commercialize certain formulations which are aimed at preventing and treating pan-coronavirus or the potential combination of the pan-coronavirus and pan-influenza, including the SARS-coronavirus that causes COVID-19 and pan-influenza (the “Prevention and Treatment”).

The License Agreement was entered into pursuant to the existing Framework Agreement between the parties dated November 15, 2019. The License Agreement states that in consideration for the Development License, the Company shall provide cash funding for research costs and equipment and certain other in-kind funding related to the Prevention and Treatment over a 24-month period. Additionally, the License Agreement provides for an up-front payment of \$10,000,000 and a \$760,000 payment for expenditures to date prior to the effective date related to research towards the Prevention and Treatment within 60 days of April 18, 2021. The License Agreement provides for additional payments upon the occurrence of certain benchmarks in the development of the technology set forth in the License Agreement, in each case subject to the terms of the License Agreement.

The License Agreement provides for cooperation related to the development of intellectual property related to the Prevention and Treatment and for a 3% royalty to G Tech on any net sales that may occur under the License Agreement. For the year ended June 30, 2022 and June 30, 2021, the Company paid \$150,000 and \$10,760,000 related to the Prevention and Treatment research. The Company is no longer pursuing any product candidates that relate to this license. The Company has filed a claim against the Licensors to recover all monies it paid related to this license (see Contingencies sub-section below).

On August 25, 2021, the Company entered into an ALC Patent License and Research Funding Agreement in the HIV Field (the "ALC License Agreement") with Gümürkcü and SRI and its principals (collectively, the "Licensors") whereby the Licensors granted the Company an exclusive, worldwide, perpetual, fully paid-up, royalty-free license, with the right to sublicense, his proprietary technology subject to a U.S. patent application, to make, use, offer to sell, sell or import products for use solely for the prevention, treatment, amelioration of or therapy exclusively for HIV in humans, and research and development exclusively relating to HIV in humans; provided the Licensors retained the right to conduct HIV research in the field. Pursuant to the ALC License Agreement, the Company granted a non-exclusive license back to the Licensors, under any patents or other intellectual property owned or controlled by the Company, to the extent arising from the ALC License, to make, use, offer to sell, sell or import products for use in the diagnosis, prevention, treatment, amelioration or therapy of any (i) HIV Comorbidities and (ii) any other diseases or conditions outside the HIV Field. The Company made an initial payment to SRI of \$600,000 and agreed to fund future HIV research conducted by the Licensors, as mutually agreed to by the parties. On September 10, 2021, pursuant to the ALC License Agreement, the Company paid the initial payment of \$600,000.

G-Tech and SRI are controlled by Serhat Gümürkcü and Anderson Wittekind, shareholders of the Company.

Shares held for non-consenting stockholders – The 17,414 remaining shares of Common Stock related to the Acquisition of Enochian Denmark have been reflected as issued and outstanding in the accompanying financial statements. There were zero shares of Common Stock issued to such non-consenting stockholders during the year ended June 30, 2022 (see Note 8.)

Service Agreements - The Company has a consulting agreement for services of a Senior Medical Advisor for up to \$210,000 per year on a part-time basis. This consulting agreement was terminated as of October 31, 2022. The Company maintains employment agreements with other staff in the ordinary course of business.

Contingencies

Securities Class Action Litigation. On July 26, 2022 and July 28, 2022, securities class action complaints were filed by purported stockholders of ours in the United States District Court for the Central District of California against us and certain of our current and former officers and directors. The complaints allege, among other things, that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder, by making false and misleading statements and omissions of material fact in connection with the Company's relationship with Serhat Gümürkcü and its commercial prospects. The complaints seek unspecified damages, interest, fees, and costs. The defendants have not yet responded to the complaints.

Federal Derivative Litigation. On September 22, 2022, Samuel E. Koenig filed a shareholder derivative action in the United States District Court for the Central District of California. On January 19, 2023, John Solak filed a substantially similar shareholder derivative action in the United States District Court for the District of Delaware. Both derivative actions recite similar underlying facts as those alleged in the Securities Class Action Litigation. The actions, filed on behalf of the Company, name Serhat Gümürkcü and certain of the Company's current and former directors as defendants. The actions also name the Company as a nominal defendant. The actions allege violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934 and also set out claims for breach of fiduciary duty, contribution and indemnification, aiding and abetting, and gross mismanagement. Plaintiffs do not quantify any alleged injury, but seek damages, disgorgement, restitution, and other costs and expenses. On January 24, 2023, the United States District Court for the Central District of California stayed the Koenig matter pending resolution of the defendants' anticipated motion to dismiss in the Securities Class Action Litigation. The defendants have not yet responded to either complaint.

State Derivative Litigation. On October 20, 2022, Susan Midler filed a shareholder derivative action in the Superior Court of California, Los Angeles County, reciting similar underlying facts as those alleged in the Securities Class Action Litigation. The action, filed on behalf of the Company, names Serhat Gümürkcü and certain of the Company's current and former directors as defendants. The action also names the Company as a nominal defendant. The action sets out claims for breaches of fiduciary duty, contribution, and indemnification, aiding and abetting, and gross mismanagement. Plaintiff does not quantify any alleged injury, but seeks damages, disgorgement, restitution, and other costs and expenses. The defendants have not yet responded to the complaint.

On October 21, 2022, the Company filed a Complaint in the Superior Court of the State of California for the County of Los Angeles against Serhat Gümürükcü, William Anderson Wittekind, G Tech Bio LLC, SG & AW Holdings LLC, and Seraph Research Institute. The Complaint alleges that the defendants engaged in a “concerted, deliberate scheme to alter, falsify, and misrepresent to the Company the results of multiple studies supporting its [Hepatitis B] and SARS-CoV-2/influenza pipelines.” Specifically, “Defendants manipulated negative results to reflect positive outcomes from various studies, and even fabricated studies out of whole cloth.” As a result of the defendants’ conduct, the Company claims that it “paid approximately \$25 million to Defendants and third-parties that it would not otherwise have paid.” The defendants have not yet answered the allegations set forth in the Company’s Complaint.

On December 28, 2022, the Company received a demand letter on behalf of Weird Science LLC (“Weird Science”), William Anderson Wittekind, the William Anderson Wittekind 2020 Annuity Trust, the William Anderson Wittekind 2021 Annuity Trust, the Dybul 2020 Angel Annuity Trust, and the Ty Mabry 2021 Annuity Trust alleging that the Company breached the February 16, 2018 Investor Rights Agreement between the Company, Weird Science, and RS Group ApS. Specifically, the demand letter alleges that the Company “breached its obligations under the Investor Rights Agreement to provide the requisite thirty days’ notice” to Holders of Registrable Securities in connection with SEC Form S-3 filings on July 13, 2020 and February 11, 2022 and demands over \$64 million in damages. The Company denies these allegations and intends to vigorously defend against this claim.

On March 1, 2021, former Enochian BioSciences Chief Financial Officer, Robert Wolfe and his company, Crossfield, Inc., filed a Complaint in the U.S. District Court for the District of Vermont against the Company, Enochian BioSciences Denmark ApS, and certain directors and officers. In the Complaint, Mr. Wolfe and Crossfield, Inc. asserted claims for abuse of process and malicious prosecution, alleging, inter alia, that the Company lacked probable cause to file and prosecute an earlier action, and sought millions of dollars of compensatory damages, as well as punitive damages. The allegations in the Complaint relate to an earlier action filed by Company and Enochian BioSciences Denmark ApS in the Vermont Superior Court, Orange Civil Division. On March 3, 2022, the court partially granted the Company’s motion to dismiss, dismissing the abuse of process claim against all defendants and all claims against Mark Dybul and Henrik Grønfeldt-Sørensen. On November 29, 2022, the Company filed a motion for summary judgment with respect to the sole remaining claim of malicious prosecution. The Company denies the allegations set forth in the Complaint and will continue to vigorously defend against the remaining claim.

ENOCHIAN BIOSCIENCES INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 10 — RELATED PARTY TRANSACTIONS

The Company paid G-Tech \$4,031,500 and \$13,804,000, which included payments for consulting agreements related to HIV, and contractual costs related to the HBV License, the Development License and the ALC License (see Note 9), and security expenses, for the years ended June 30, 2022 and 2021, respectively.

The Company leased office space from landlord affiliated with G-Tech from May 15, 2022 to August 31, 2022, on a month-to-month basis for a total of \$43,750, of which \$18,750 relates to the current period. The amount has been recorded in accrued expenses. The Company paid amount in full in August 2022.

NOTE 11 — SUBSEQUENT EVENTS

On July 15, 2022, certain of our warrant holders exercised warrants to purchase 1,250,000 shares of Common Stock for total proceeds to the Company of \$1,625,000, with corresponding earn-out distribution in the same amount in connection with the acquisition of Enochian BioPharma, Inc., which was distributed on October 12, 2022, based on the share price on that date of \$2.21. This non-cash transaction impacted stockholders' equity in the amount of \$2,762,500.

Subsequent to June 30, 2022, the Company became involved in a number of legal proceedings. Please see Note 9 above and Item 3 - Legal Proceedings for details of such matters.

As of December 30, 2022, the Company entered into amended and restated secured convertible promissory notes (see Note 6.)

On December 30, 2022, the Company entered into a security agreement with the Holder (see Note 6.)

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures**Evaluation of Disclosure Controls and Procedures**

Our Principal Executive Officer and Principal Financial Officer (the “Certifying Officers”) are responsible for establishing and maintaining disclosure controls and procedures for the Company. The Certifying Officers have designed such disclosure controls and procedures to ensure that material information is made known to the Certifying Officers, particularly during the period in which this Report was prepared.

The Certifying Officers conducted a review of the Company’s “disclosure controls and procedures” (as defined in the Exchange Act, Rules 13a-15(e) and 15-d-15(e)) as of the end of the period covered by this Annual Report (the “Evaluation Date”). Based upon that evaluation, the Certifying Officers concluded that, as of June 30, 2022, our disclosure controls and procedures were not effective in ensuring that the information we were required to disclose in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms.

Management Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Management used the “Internal Control over Financial Reporting Integrated Framework” issued by the Committee of Sponsoring Organizations (“COSO”) to conduct a review of the Company’s internal controls over financial reporting. As of June 30, 2022, Management concluded that internal controls over financial reporting was not effective, based on COSO’s framework. The deficiency is attributed to the Company not having adequate resources to address complex accounting matters. This control deficiency will be monitored, and attention will be given to this matter as we grow.

This Annual Report does not include an attestation report from the Company’s registered public accounting firm regarding internal controls over financial reporting. Management’s report was not subject to attestation by the Company’s registered public accounting firm pursuant to the rules of the SEC that permit the Company to provide only management’s report in this Annual Report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Identification of Directors

The following is a description of the business experience, qualifications, skills and educational background of each of our directors, including each director’s relevant business experience:

Mr. Renè Sindlev. Mr. Sindlev, age 61, has served as the Chairman of the Board of Directors since June 2017. Mr. Sindlev has been successfully self-employed since 1985 from the age of 23. He has been an investor and entrepreneur since 1997 through his holding companies including RS Group ApS, RS Arving ApS, RS Family ApS, RS Aviation ApS and RS Bio ApS. In January of 2014, Mr. Sindlev established Dr. Smood Group of companies in both Denmark and the United States—a retail-chain of USDA Certified Organic health restaurants, an on-line e-commerce platform and several beverage companies. Since 2014 he has served as its chairman. Mr. Sindlev has previously founded, owned, developed, and sold more than 28 companies in the jewelry, aviation charter, real estate and biosciences businesses, such as World of Watches, Pandora A/S, RS Aviation ApS, MyFamily Office ApS, Enochian Biosciences Inc among many others. In 2002, Mr. Sindlev co-founded Pandora A/S and served as its President & Board Member, and as an advisor to the board before and after its IPO on Nasdaq Copenhagen in 2010. Mr. Sindlev co-founded Enochian Biosciences Inc. in February 2018 as an early biotech investor in DanDrit Biotech, Inc. We believe Mr. Sindlev’s experience as an entrepreneur in successfully building start-up companies from the ground up qualifies him to serve as a director and Chairman of the Board.

Dr. Mark Dybul. Dr. Dybul, age 59, was appointed our Chief Executive Officer (CEO) and principal executive officer, effective July 1, 2021. Prior to the appointment, he served as Executive Vice Chair of the Board since January of 2019 and as a director since February of 2018. Dr. Dybul served as a Professor in the Department of Medicine at Georgetown University Medical Center as of July 2017 and was the Faculty Co-Director of the Center for Global Health and Quality until he became Enochian BioSciences' CEO. Dr. Dybul has worked on HIV and public health for nearly 30 years as a clinician, scientist, teacher, and administrator, most recently as the Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria from 2013 through May of 2017. Prior to joining the Global Fund, he was a principal architect and ultimately the head of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the largest international health initiative in history dedicated to a single disease, which achieved historic prevention, care, and treatment goals on time and on budget. During his tenure, the program's funding grew from approximately \$500 million to \$6.5 billion annually. After serving as Chief Medical Officer, Assistant, Deputy and Acting Director, he was appointed as its leader in 2006, becoming U.S. Global AIDS Coordinator, with the rank of Ambassador at the level of an Assistant Secretary of State. He served until early 2009. Earlier in his career, after graduating from Georgetown Medical School in Washington D.C., Dr. Dybul joined the National Institute of Allergy and Infectious Diseases, as a research fellow under director Dr. Anthony Fauci, where he conducted basic and clinical studies on HIV virology, immunology, and treatment optimization, including the first randomized, controlled trial with combination antiretroviral therapy in Africa. Dr. Dybul has written extensively in scientific and policy literature, and has received several honorary degrees and awards, including a Doctor of Science, Honoris Causa, from Georgetown University. Dr. Dybul is a member of the National Academy of Medicine. We believe Dr. Dybul's extensive experience in HIV and public health, as well as from being an educator and administrator qualifies him to serve as director and Chief Executive Officer.

Carol L. Brosgart, MD. Dr. Brosgart, age 71, has served as a Director since December of 2019. Dr. Brosgart serves on the boards of public and privately held biotech companies and public, not-for-profit, domestic and global health organizations. She is also a member of the Board of Directors of Galmed Pharmaceuticals, Ltd. (headquartered in Tel Aviv, Israel); Abivax, (headquartered in Paris, France), Merlin (headquartered in Doylestown, PA) and Eradivir (headquartered in West Lafayette, Indiana). She also is the Chair of Enochian's Scientific Advisory Board on HBV Cure and is the Chair of the Scientific Advisory Committee for Hepion (formerly ContraVir), a biotechnology company working in the area of HBV Cure, NASH and Hepatocellular Carcinoma. Previously, she served as a member of Tobira Therapeutics' Board of Directors from September 2009 until Allergan acquired Tobira in November 2016; and, she was formerly on the following biotechnology Boards: Juvaris, a vaccine company, until Bayer Company acquired its assets; and on the Boards of Intrivo Diagnostics and Mirum Pharmaceuticals. She is a scientific advisor and consultant to a number of biotechnology companies in the areas of liver disease and infectious diseases (Dynavax, Hepion, immgenuity, Mirum Pharmaceuticals, Moderna, and Pardes Biosciences). Dr. Brosgart serves as a Board member for the non-profit organization, Berkeley Community Scholars (headquartered in California). She serves on the Steering Committee of the HBV Cure Group and is also member of the Liver Forum, both at the Forum for Collaborative Research at UC Berkeley School of Public Health. She is a member of the Board of the Hepatitis B Foundation (HBF); serves on the Medical and Scientific Advisory Committee of the Hepatitis B Foundation; and, she is the Research Integrity Officer for the Hepatitis B Foundation and the Baruch S. Blumberg Institute. Dr. Brosgart also serves on the National Advisory Committee of Hepatitis B United. She served for many years on the Boards of the SF AIDS Foundation and the Pangaea Global AIDS Foundation. She is active in the public policy arena for the following professional organizations: AASLD and IDSA/HIVMA. Dr. Brosgart served as Senior Advisor on Science and Policy to the Division of Viral Hepatitis at the CDC and the Viral Hepatitis Action Coalition at the CDC Foundation from 2011 to 2014. Dr. Brosgart has also served as a member on the faculty of the School of Medicine at the University of California, San Francisco for the past four decades, where she is a Clinical Professor of Medicine, Biostatistics and Epidemiology in the Division of Global Health and Infectious Diseases. Previous positions include, serving as Chief Medical Officer at biotechnology company Alios BioPharma, Inc. Prior to Alios, Dr. Brosgart served as Senior Vice President and Chief Medical Officer of Children's Hospital & Research Center in Oakland, California, from 2009 until February 2011. Previously, she served for eleven years, from 1998 until 2009, at the biopharmaceutical company Gilead Sciences, Inc., where she held a number of senior management roles, most recently as Vice President, Public Health and Policy and earlier as Vice President, Clinical Research and Vice President, Medical Affairs and Global Medical Director, Hepatitis. She led the clinical development and FDA approval of a number of agents at Gilead, including Viread™ and Hepsera™. Prior to Gilead, Dr. Brosgart worked for more than 20 years in clinical care, research, and teaching at several Bay Area medical centers. She was the founder and Medical Director of the East Bay AIDS Center at Alta Bates Medical Center in Berkeley, California, from 1987 until 1998 and served as the Medical Director of Central Health Center, Oakland, California, of the Alameda County Health Care Services Agency from 1978 until 1987. Dr. Brosgart received a B.S. in Community Medicine from the University of California, Berkeley and received an M.D. from the University of California, San Francisco. Her residency training was in pediatrics, public health, and preventive medicine at UCSF and UC Berkeley School of Public Health. She has published extensively in the areas of HIV, HBV, CMV, and liver disease. We believe Dr. Brosgart's extensive clinical experience in HIV and HBV, her significant clinical research and regulatory experience, and her service in senior management and on numerous public and private boards in the biotechnology industry qualify her to serve as a director.

Mr. Gregg Alton. Mr. Alton, age 56, has served as a director since December 2019. Mr. Alton joined the Board after serving for 20 years at the biopharmaceutical company Gilead Sciences, Inc. At Gilead, Mr. Alton served as interim Chief Executive Officer, responsible for the company's strategy, growth and operations. As Chief Patient Officer, he led Gilead's patient outreach and engagement initiatives and the company's efforts to facilitate access to its medicines around the world. He oversaw the corporate and medical affairs functions and developing world access programs, as well as its digital patient solutions and patient-centered outcomes groups and commercial operations in certain countries. Mr. Alton joined Gilead in 1999 and held a number of positions at the company with experience in legal, medical affairs, policy and commercial. He previously served as general counsel. Prior to joining Gilead, he was an attorney at the law firm of Cooley Godward, LLP, where he specialized in mergers and acquisitions, corporate partnerships and corporate finance transactions for healthcare and information technology companies. Mr. Alton is a member of the Board of Directors of Corcept Therapeutics, Bii Biosciences, Novavax, Inc., the Hepatitis Fund and the Boys and Girls Clubs of Oakland. Mr. Alton serves as a board observer for GARDP. He also serves on the U.S. government's President's Advisory Council on HIV/AIDS, and the advisory board for the UC Berkeley College of Letters & Science. Mr. Alton received a bachelor's degree in legal studies from the University of California at Berkeley and a law degree from Stanford University. We believe Mr. Alton's decades of experience in senior management at a large pharmaceutical company, along with his legal and governance experience qualifies him to serve as a director.

Mr. James Sapirstein. Mr. Sapirstein, age 61, has served as a director since March of 2018. Mr. Sapirstein joined the Board after having served over thirty-seven years in the pharmaceutical industry. He is currently the Chairman, President and CEO of First Wave BioPharma (formerly AzurRx BioPharma) and has served as the CEO of ContraVir Pharmaceuticals, Inc. (now Hepion), which is a company specializing in the Hepatitis B space. After beginning his career in 1984 with Eli Lilly, he accepted a position at Hoffmann-LaRoche in 1987, where he served for almost a decade as part of its commercial teams in the US and abroad. He held a number of positions at Hoffmann-LaRoche, before moving to Bristol Myers Squibb (BMS) in 1996 as the Director of International Marketing in the Infectious Disease group. While at BMS, he worked on several important HIV/AIDS projects including Secure the Future. Later, Mr. Sapirstein started his career in smaller biotech companies when he joined Gilead Sciences, Inc. (GILD) in order to lead the Global Marketing team in its launch of Viread (tenofovir). In 2002, he accepted the position of Executive Vice President Metabolic and Endocrinology for Serono Laboratories before becoming the founding CEO of Tobira Therapeutics in 2006. In 2012, after several years in the infectious diseases space, Mr. Sapirstein became the CEO of Alliqua Therapeutics at Alliqua, Inc. He is also a Board Director for the Emerging Companies Section Governing group of the Biotechnology Innovation Organization (BIO) and the Chairman Emeritus of BIO's New Jersey Chapter (BioNJ). Mr. Sapirstein received his MBA from Fairleigh Dickinson University and his B.Pharm. from Rutgers University. We believe Mr. Sapirstein's extensive experience as a biotechnology executive and as a board member in the biopharma industry and industry associations qualifies him to serve as a director.

Mr. Henrik Grønfeldt-Sørensen. Mr. Grønfeldt-Sørensen, age 50, has served as a director since October of 2017, has been the Chief Executive Officer of RS Group ApS, RS Arving ApS and RS Family ApS since October of 2012, and he has served as a director of Dr. Smood Group, Inc. since January of 2014. RS Group of Companies is a family office in Denmark with global investments within the real estate, charter business, food & beverage, and biosciences industries. Mr. Grønfeldt-Sørensen has over 10 years' experience in different CEO & management positions; Danske Bank in Denmark, and the Danish Bank Nykredit in France. Mr. Grønfeldt-Sørensen holds an eMBA from University of Monaco (2011). We believe Mr. Grønfeldt-Sørensen's significant experience in corporate management and in investor relations qualifies him to serve as a director.

Ms. Jayne McNicol. Ms. McNicol, age 57, has served as a director and chair of our audit committee since May of 2021. Since May 2017, Ms. McNicol has been the Chief Financial Officer of the California Life Sciences Association, a nonprofit, membership-based trade association that empowers the life sciences community to deliver innovative solutions for healthier lives. Previously, from July 2001 to April 2017, Ms. McNicol was a Partner of Assurance Services at Ernst & Young LLP serving public and private life sciences companies primarily in the San Francisco Bay Area. Prior to this, Ms. McNicol served in positions of increasing responsibility at Ernst & Young and its predecessor, Arthur Young, initially in Bristol, England and later in the San Francisco Bay Area. Ms. McNicol is a Certified Public Accountant with the California Board of Accountancy and a Chartered Accountant with the Institute of Chartered Accountants in England and Wales. She holds a Bachelor of Arts degree in English from the University of Leeds, England. We believe Ms. McNicol's significant experience in financial management within the life sciences industry qualifies her to serve as a director and chair of our audit committee.

There are no family relationships, as defined in subparagraph (d) of Item 401 of Regulation S-K, among any of our executive officers and directors. To the best of our knowledge, none of our directors or executive officers has, during the past ten years, been involved in any legal proceedings described in subparagraph (f) of Item 401 of Regulation S-K.

The Board and Board Committees

The Board. The Board met 5 times for meetings during fiscal 2022, and also acts by written consent. Four of such meetings were regularly scheduled meetings and other special Board meetings and telephonic calls were held as needed. During fiscal year 2022, each incumbent director attended 75% or more of the Board meetings for the periods during which each such director served. Directors are not required to attend annual meetings of our stockholders.

Audit Committee and Audit Committee Financial Experts

The Audit Committee has been structured to comply with the requirements of Rule 10A-3(b)(1) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the listing standards of NASDAQ, and each member and former member of the Audit Committee complied with such requirements and standards. The members of the Audit Committee are currently Jayne McNicol (Chair), James Sapirstein and Gregg Alton.

The Audit Committee oversees and reports to our Board on various auditing and accounting-related matters, including, among other things, the maintenance of the integrity of our financial statements, reporting process and internal controls; the selection, evaluation, compensation, and retention of our independent registered public accounting firm; legal and regulatory compliance, including our disclosure controls and procedures; and oversight over our risk management policies and procedures. The Audit Committee appoints and sets the compensation for the independent registered public accounting firm annually and reviews and evaluates such auditor. This external auditor reports directly to the Audit Committee. The Audit Committee establishes our hiring policies regarding current and former partners and employees of the external auditor. In addition, the Audit Committee pre-approves all audit and non-audit services undertaken by the external auditor and any outside consultants engaged in work related to the Company’s financial reporting. The Audit Committee has direct responsibility for overseeing the work of the external auditor engaged for the purpose of preparing or issuing an auditor’s report or performing other audits, review or attest services, including the resolution of disagreements between the external auditor and management. The Audit Committee meets at least once per fiscal quarter to fulfill its responsibilities under its charter and in connection with the review of the Company’s quarterly and annual financial statements.

The Board has determined that each member of the Audit Committee has the appropriate level of financial understanding and industry specific knowledge to be able to perform the duties of the position; and they are financially literate and have the requisite financial sophistication as required by the applicable listing standards of NASDAQ. The Board has determined that both Ms. McNicol and Mr. Alton are “audit committee financial experts” as defined by applicable SEC and Nasdaq rules.

The Audit Committee met 4 times during fiscal 2022, which meetings were all attended by each member during his or her period of service, and the Committee also acts by written consent. The Audit Committee operates under a charter that was adopted by our Board and is posted on our website at www.enochianbio.com.

The Audit Committee reviewed and discussed the audited financial statements for the 2022 fiscal year with management, and with Sadler, Gibb & Associates, LLC (“Sadler”), the Company’s independent registered public accounting firm. Further, the Audit Committee also discussed with Sadler the matters required to be discussed by the applicable requirements of the Public Company Accounting Oversight Board (the “PCAOB”) and the SEC. The Audit Committee reviewed permitted services under rules of the SEC as currently in effect and discussed with Sadler its independence from management and the Company, including the matters in the written disclosures and the letter from Sadler required by the applicable requirements of the PCAOB regarding the independent accountant’s communications with the Audit Committee concerning independence.

Based on its review of the financial statements and the aforementioned discussions, the Audit Committee recommended to the Board of Directors that the audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2022 for filing with the SEC.

THE AUDIT COMMITTEE

Jayne McNicol (Chair)
James Sapirstein
Gregg Alton

Nominating and Corporate Governance Committee

The members of our Nominating and Corporate Governance Committee are currently Carol L. Brosgart, M.D. and Gregg Alton (Chair).

The Nominating and Corporate Governance Committee, as permitted by, and in accordance with, its charter, is responsible for matters related to the selection of directors for appointment and/or election to the Board. This includes establishing criteria for, identifying and recommending potential candidates for nomination to serve on the Board, and establishing criteria to consider recommendations from the stockholders of the Company. The Nominating and Corporate Governance Committee considers and makes recommendations with respect to the independence of all directors.

The Nominating and Corporate Governance Committee is also responsible for maintaining compliance with applicable corporate governance requirements under the Exchange Act and the listing standards of NASDAQ. The Nominating and Corporate Governance Committee oversees the evaluation of the Board, including with respect to corporate governance, and develops and recommends to the Board corporate governance guidelines.

The Nominating and Corporate Governance Committee acted 1 time during fiscal 2022 by written consent. The Nominating and Corporate Governance Committee operates under a charter that was adopted by our Board and is posted on our website at www.enochianbio.com.

Compensation Committee

The members of our Compensation Committee are currently James Sapirstein (Chair) and Carol L. Brosgart, M.D.

The Compensation Committee, as permitted by, and in accordance with, its charter, is responsible for assisting the Board in fulfilling its responsibilities relating to matters of human resources and compensation, including equity compensation, and to establish a plan of continuity and development for our senior management. The Compensation Committee periodically assesses compensation of our executive officers in relation to companies of comparable size, industry, and complexity, taking the performance of the Company and such other companies into consideration. All decisions with respect to the compensation of our principal executive officer are determined and approved solely by the Compensation Committee. All decisions with respect to other executive compensation, including incentive-compensation and equity-based plans are first approved by the Compensation Committee and then submitted, together with the Compensation Committee's recommendation, to the members of the Board for final approval. In addition, the Compensation Committee will, as appropriate, review and approve public or regulatory disclosure relating to compensation, including the Compensation Disclosure and Analysis, and any metrics for performance measurements. The Compensation Committee has the authority to retain and compensate any outside adviser as it determines necessary to permit it to carry out its duties and engaged such a consultant in connection with the Company's compensation for the 2022 fiscal year.

The Board has determined that each member of the Compensation Committee is a “nonemployee director” as that term is defined under Rule 16b-3 of the Exchange Act and an “outside director” as that term is defined in Treasury Regulation Section 1.162-27(e)(3). The Compensation Committee meets periodically and at least annually in connection with determining the compensation of management for each fiscal year.

The Compensation Committee met 2 times during fiscal year 2022 and acted by written consent 4 times. The Compensation Committee operates under a charter that was adopted by our Board and is posted on our website at www.enochianbio.com.

The Compensation Committee has considered the potential risks arising from the Company’s compensation for all employees and does not believe the risks from those compensation practices are reasonably likely to have a material adverse effect on the Company.

Executive Officers Who Are Not Directors

Luisa Puche. Ms. Puche, age 60, is our Chief Financial Officer and principal financial officer. Prior to becoming our Chief Financial Officer in January of 2019, Ms. Puche served as a senior accounting and financial advisor and president of Puche Group, LLC, since 2015 where she served in a variety of advisory capacities for both public and private organizations, such as technical accounting consultations, complex technical implementations, M&A transactions, IT Risk assessments and SOX 404 implementations. Previously, Ms. Puche served in various senior executive roles at Brightstar Corp., a global distributor and service provider in the wireless industry, with public reporting requirements, including as Vice President and Global Controller and Interim Chief Accounting Officer. During her tenure at Brightstar, she was responsible for financial reporting from 55 countries, and was instrumental in various key transactions including the \$1.6 billion sale of Brightstar to SoftBank. Ms. Puche also worked at Ernst & Young for 10 years. Ms. Puche holds a Bachelor’s of Accounting from Florida International University.

François Binette. On October 18, 2022, the Company appointed Francois Binette PhD, age 59, as Chief Operating Officer of the Company, effective November 1, 2022. Dr. Binette has served as the Company’s Executive VP for Research & Development since April 2022. Dr. Binette has over 25 years of product development expertise in advanced therapies and regenerative medicine. From 2016 to just prior to joining the Company, Dr. Binette was at Lineage Cell Therapeutics, Inc (NYSE:LCTX), a leading company in the field of pluripotent stem cell therapy development with a global footprint focused on ophthalmology, cancer vaccines, and spinal cord injuries, where he served as the Senior Vice President R&D, Global Head of Product Development and led the CNS franchise as well as general pipeline development, contributing to one of the largest non-cancer cell therapy corporate partnership deals with Genentech worth over \$650 million in upfront and milestone payments. During his first industry appointment at Genzyme Tissue Repair in Cambridge, he helped pioneer Carticel™ for cartilage repair, the first FDA BLA-approved cell therapy product for human use. He then led R&D for Biosyntech, a startup biomaterials company in Montreal applying its proprietary platform for various tissue engineering and drug delivery applications. Dr. Binette then joined the DePuy Franchise of Johnson and Johnson (NYSE:JNJ), the second largest orthopedic business worldwide where he led several innovative regenerative medicine combination product development initiatives from discovery to approved clinical trials in US and Europe. Dr. Binette received his PhD from Laval University in Québec City, followed with post-doctoral training at the Sanford-Burnham institute, and Harvard Medical School.

Delinquent Section 16(a) Reports

Section 16(a) of the Securities Exchange Act of 1934 requires executive officers, directors and persons who own more than 10% of a registered class of our equity securities to file reports of ownership with the Securities and Exchange Commission. Based solely on our review of the copies of such forms received by us, we believe that during the fiscal year ended June 30, 2022, all filing requirements were timely satisfied, except (i) late Form 4’s were filed for Rene Sindlev on December 22, 2021 and January 4, 2022, (ii) late Form 4’s were filed for Henrik Gronfeldt-Sorensen on December 22, 2021 and January 4, 2022, (iii) late Form 4’s were filed for Carl Sandler on December 22, 2021, January 7, 2022 and February 23, 2022, (iv) a late Form 4 was filed for Jayne McNicol on June 13, 2022, (v) late Form 4’s were filed for Carol Brosgart on December 21, 2021 and January 3, 2022, (vi) a late Form 4 was filed for Gregg Alton on December 22, 2021, (vii) late Form 4’s were filed for Mark Dybul on July 22, 2021, and (viii) late Form 4’s were filed for Luisa Puche on November 23, 2021 and January 11, 2022.

Code of Ethics

Our Board has adopted a Code of Ethics and Conduct (our “Code of Ethics”). Our Code of Ethics sets forth standards of conduct applicable to our employees, officers and directors to promote honest and ethical conduct, proper disclosure in our periodic filings, and compliance with applicable laws, rules and regulations. Our Code of Ethics is available to view at our website, www.enochianbio.com by clicking on Investors/Media-Corporate Governance. We intend to provide disclosure of any amendments or waivers of our Code of Ethics on our website within four business days following the date of the amendment or waiver.

Item 11. Executive Compensation

Name and Principal Position	Year	Salary (\$)	Bonus	Stock Awards (\$)	Option Awards (\$)(1)	Non-equity incentive plan compensation (\$)	Other Compensation (\$)	Total (\$)
Mark Dybul, M.D. (2)	2022	\$850,000	\$100,000	\$ —	\$9,801,000	\$ —	\$ —	\$10,751,000
Chief Executive Officer	2021	\$430,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 430,000
Luisa Puche	2022	\$293,750	\$110,000	\$ 9,812	\$ 375,780	\$ —	\$ —	\$ 795,592
Chief Financial Officer	2021	\$275,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 275,000

(1) Amounts shown do not reflect compensation actually received by the executive officer. Instead, the amounts shown are the total grant date valuations of stock option grants awarded during the year as determined pursuant to ASC Topic 718. The valuations are expensed for financial reporting purposes over the vesting period of the grant.

(2) Effective July 1, 2021, Dr. Dybul was appointed our Chief Executive Officer. He previously served as our Executive Vice Chair.

Arrangements with Named Executive Officers

During the fiscal year ended June 30, 2022, we had agreements in place with Dr. Dybul and Ms. Puche. A description of each agreement is set forth below.

Mark R. Dybul, M.D. Since January 7, 2019, when Dr. Dybul became our principal executive officer by virtue of his appointment as Executive Vice-Chair of the Board, Dr. Dybul received compensation as Executive Vice Chair of the Board under his Amended and Restated Director’s Agreement, as amended on May 1, 2019 (the “Director Agreement”), which called for cash compensation of \$430,000 per annum, and the grant of options to purchase 300,000 shares of common stock, which was granted on November 21, 2018. The Director Agreement did not provide for any payments or other benefits upon a change in control. Dr. Dybul was given a one-time grant of options to purchase 450,000 shares of common stock at a strike price of \$8.00 per share on June 11, 2020.

On October 30, 2019, the Compensation Committee approved and presented to the Board an employment agreement whereby Dr. Dybul would serve as the Company’s Chief Executive Officer (the “Employment Agreement”) which was recommended by the Board for approval by our stockholders. On October 31, 2019, our stockholders approved the Employment Agreement via written consent. Effective July 1, 2021, Dr. Dybul and the Company entered into the Executive Employment Agreement in connection with his appointment to Chief Executive Officer. The Employment Agreement was subsequently amended on December 12, 2022, effective January 1, 2023. The following is a summary of the Employment Terms and other material terms of the Employment Agreement, as amended.

Term. Dr. Dybul will serve as Chief Executive Officer for a term of three (3) years with automatic yearly renewal terms thereafter unless terminated at least 90 days before the expiry of a term.

Duties. Dr. Dybul will perform duties consistent with the position of Chief Executive Officer, as directed by and reporting to the Board, where he shall remain a director but without further compensation for Board service. Dr. Dybul will devote a substantial majority of his business time and attention to the performance of his duties with the Company, but he will be able to hold positions with charitable organizations approved by the Board, and serve on boards of up to five non-competitive entities, with prior approval by the Board required for publicly traded companies.

Place of Employment and Expenses. Dr. Dybul shall work out of the Company's headquarters in Los Angeles, commuting as needed. Dr. Dybul shall be reimbursed for reasonable expenses for accommodations in Los Angeles and a company car.

Cash Compensation. Dr. Dybul shall be entitled to a base salary of Five Hundred Fifty Thousand Dollars (\$550,000) per year. Dr. Dybul shall be eligible for a bonus of up to \$800,000 per year in the sole discretion of the Compensation Committee and in accordance with any short-term incentive plan adopted by the Company.

Benefits. Dr. Dybul shall receive benefits provided to similarly situated employees of the Company and five (5) weeks vacation per year.

Termination. The Employment Agreement may be terminated by the Company for "Cause" or by Dr. Dybul without "Good Reason" (each as defined therein), in which case Dr. Dybul will only receive accrued compensation and benefits. In the event the Company terminates the Employment Agreement without Cause or Dr. Dybul terminates the Agreement with Good Reason, Dr. Dybul will receive his base salary for one (1) year and vesting of one (1) year's worth of unvested options.

Change in Control. Upon a change in control, the option grant described below shall immediately vest, and Dr. Dybul shall have the right to terminate the Employment Agreement for Good Reason.

Restrictive Covenants. Dr. Dybul shall be subject to restrictive covenants set forth in that certain Confidential and Proprietary Information Agreement attached to the Employment Agreement, which are independent of the obligations set forth in the Employment Agreement. The restrictive covenants include non-compete, non-solicitation and non-disparagement obligations for one (1) year, provided that the Company shall continue to pay his base salary for such one (1) year period.

Description of the Option Grant. Upon appointment to Chief Executive Officer, Dr. Dybul was awarded an option to purchase 3,000,000 shares of the Company's common stock at an exercise price equivalent to the closing price per share quoted on the NASDAQ Stock Market on the trading day prior to the grant date. The option has a ten-year term, subject to continued employment, and 2,000,000 of the shares will vest ratably on July 1, 2022, July 1, 2023 and July 1, 2024. One-third of the remaining 1,000,000 shares are subject to vesting at the end of each of the three years beginning with the year ending June 30, 2022, based upon the achievement by the Company of certain benchmarks.

Luisa Puche. Pursuant to her offer letter from the Company, dated December 28, 2018 (the "Offer Letter"), Ms. Puche received an annual base salary of \$200,000, and is eligible for a discretionary cash bonus, with a target of 40% of her base salary. Ms. Puche also received a grant of options to purchase 60,000 shares of Common Stock and 15,000 restricted stock units, each vesting in equal increments over three years. The Offer Letter provides for at will employment; provided however, that upon termination of Ms. Puche's employment by the Company without cause, or for a termination of employment by Ms. Puche for good reason, she will receive six months' salary and COBRA eligibility. Additionally, if the termination without cause or for good reason occurs within 12 months of a change in control, Ms. Puche will also be entitled to a pro-rata bonus and immediate vesting of any unvested options or restricted stock units. Ms. Puche had a base salary of \$300,000 for the fiscal year 2022. Effective October 18, 2022, Ms. Puche received an increase in base salary to \$350,000 following the completion of the 2022 fiscal year and 80,000 options, vesting in equal increments over three years.

Francois Binette. Pursuant to his offer letter from the Company, dated February 22, 2022, Mr. Binette was hired as the Company's Executive VP for Research & Development starting April 2022 with an annual base salary of \$375,000, and is eligible for a discretionary cash bonus, with a target of 40% of his base salary. Mr. Binette also received a grant of options to purchase 65,000 shares of Common Stock, vesting on the first anniversary of the date of hire. On October 18, 2022, Mr. Binette was appointed as Chief Operating Officer of the Company, effective November 1, 2022, and pursuant to an amendment to his offer letter, received an increase in base salary to \$420,000 and 40,000 options, vesting in equal increments over three years.

Outstanding Equity Awards as of June 30, 2022

The following table provides information concerning outstanding equity awards held by our named executive officers as of June 30, 2022.

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Shares of Stock That Have Not Vested (#)	Market Value of Shares or Shares of Stock That Have Not Vested (\$)
Mark R. Dybul, M.D. Chief Executive Officer	7,563	—	\$ 8.00	02/27/2028	—	—
	5,226	—	\$ 5.74	09/18/2028	—	—
	300,000	—	\$ 6.50	11/21/2028	—	—
	450,000	—	\$ 8.00	06/11/2030	—	—
	—	3,000,000	\$ 4.57	07/19/2031	—	—
Luisa Puche Chief Financial Officer	60,000	—	\$ 6.15	06/06/2029	—	—
	—	60,000	\$ 8.58	10/26/2031	—	—

Board Compensation

The table below sets forth the compensation earned by directors, all of whom are non-employees for services during the fiscal year ended June 30, 2022:

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)(1)	All Other Compensation (\$)	Total (\$)
René Sindlev	\$ 100,000	\$ —	\$ 53,396	\$ —	\$ 153,396
James Sapirstein	77,500	—	52,071	—	129,571
Carl Sandler (2)	45,000	—	52,075	—	97,075
Carol Brosgart	69,938	—	52,993	—	122,931
Gregg Alton	77,500	—	52,993	—	130,493
Henrik Grønfeldt-Sørensen	60,000	—	74,066	—	134,066
Jayne McNicol	75,000	—	53,227	—	128,227
Total	<u>\$ 504,938</u>	<u>\$ —</u>	<u>\$ 390,821</u>	<u>\$ —</u>	<u>\$ 895,759</u>

- (1) Amounts shown are not intended to reflect value actually received by the directors. Instead, the amounts shown are the total fair value of option awards granted in fiscal 2022 for financial statement reporting purposes, as determined pursuant to Financial Accounting Standards Board Accounting Standards Codification Topic 718, or ASC Topic 718. These values are amortized as equity compensation expense over the vesting period of the grants.
- (2) Mr. Carl Sandler resigned from the Board of Directors effective March 25, 2022. Compensation reflects 3 quarters of payments. Equity grants issued to Mr. Sandler during the fiscal year remain available to exercise through their expiration date.

Narrative to Director's Compensation Table

Our director compensation program reflects competitive practices for a NASDAQ listed company. The resulting compensation package for our directors and for committee service (for members who qualify as independent under the rules of The Nasdaq Capital Market) as of the date hereof is set forth in the table below. In addition, our directors are awarded annual options to purchase common stock valued at \$75,000.

Compensation Element		Value
Retainer-Board Chair	\$	100,000
Retainer-Board Members	\$	60,000
Audit Committee Chair Fee	\$	15,000
Compensation Committee Chair Fee	\$	10,000
Nominating Committee Chair Fee	\$	10,000
Audit Committee Member Fee	\$	7,500
Compensation Committee Member Fee	\$	5,000
Nominating Committee Member Fee	\$	4,000

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following sets forth information regarding the beneficial ownership of our common stock as of February 27, 2023 by:

- each person to be known by us to be the beneficial owner of more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

Beneficial ownership of the Common Stock is determined in accordance with the rules of the SEC and includes any shares of Common Stock over which a person exercises sole or shared voting or investment power, or of which a person has a right to acquire ownership at any time within 60 days. Except as otherwise indicated, we believe that the persons named in this table have sole voting and investment power with respect to all shares of Common Stock held by them. Applicable percentage ownership in the following table is based on 55,705,521 shares of Common Stock outstanding as of February 27, 2023, excluding 2,500,000 shares of Common Stock issuable only upon the exercise of warrants by other warrant holders (see footnotes 2 and 6 to the table below), plus any securities that the individuals included in this table have the right to acquire within 60 days of February 27, 2023.

To our knowledge, except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of Common Stock beneficially owned by them. Unless indicated otherwise, the address for the beneficial holders is c/o Enochian BioSciences Inc. 1927 Paseo Rancho Castilla, Los Angeles, CA, U.S.A.

Name of Beneficial Owner	Enochian BioSciences Inc.	
	Number of Shares	% Ownership
<i>Directors/Officers:</i>		
René Sindlev, Chairman of the Board (1)	9,715,490	18.31%
Mark Dybul, Chief Executive Officer (2)	1,495,937	2.75%
Luisa Puche, Chief Financial Officer (3)	96,266	*%
Francois Binette, Chief Operating Officer (7)	—	—
Carol Brosgart, Director	50,507	*%
Gregg Alton, Director	50,507	*%
James Sapirstein, Director	85,895	*%
Jayne McNicol, Director	26,498	*%
Henrik Grønfeldt-Sørensen, Director (4)	91,434	*%
<i>Directors/Officers Total (9 persons):</i>	11,612,534	21.18%
<i>5% Shareholders who are not Directors or Officers:</i>		
RS Bio ApS	9,668,351	18.24%
Serhat Gümürkücü (5)	12,526,552	23.63%
Anderson Wittekind (6)	5,352,046	10.10%
<i>5% Shareholders who are not Directors or Officers Total:</i>	27,546,949	51.97%
Total:	29,491,132	55.64%

* Indicates less than 1%.

- (1) Includes 9,668,351 shares of Common Stock owned of record by RS Bio ApS, a Danish entity, and options to purchase 47,139 shares of Common Stock exercisable within 60 days of February 22, 2023 owned of record by Mr. Sindlev. Mr. Sindlev, our Chairman of the Board, holds the sole voting and disposition power of the shares owned by RS Bio ApS.
- (2) Includes 66,481 shares of Common Stock and options to purchase 1,429,456 shares of Common Stock exercisable within 60 days of February 22, 2023.
- (3) Includes 16,266 shares of Common Stock and options to purchase 80,000 shares of Common Stock exercisable within 60 days of February 22, 2023.
- (4) Includes 50,000 shares of Common Stock and options to purchase 41,434 shares of Common Stock exercisable within 60 days of February 22, 2023. Mr. Grønfeldt-Sørensen, our Director, holds the sole voting and disposition power of the shares owned by Greenfield Holding ApS. Excludes 9,668,351 shares of Common Stock owned of record by RS Bio ApS, a Danish entity, of which Mr. Grønfeldt-Sørensen is an officer but over which he exercises no voting or disposition power. Mr. Sindlev holds the sole voting and disposition power of the shares owned by RS Bio ApS.
- (5) Includes 88,121 shares of Common Stock held in a joint investment account with his spouse, and excludes 5,352,046 shares owned by Mr. Gümürkü's spouse, to which Mr. Gümürkü disclaims beneficial ownership.
- (6) Includes 97,032 shares of Common Stock owned of record by Weird Science, LLC, and 3,615,757 shares owned of record by Mr. Wittekind, 88,121 shares held in a joint investment account with his spouse, and 1,450,568 shares held in trust over which Mr. Wittekind has sole voting and disposition power. Mr. Wittekind is a member and a manager of Weird Science and has sole voting and disposition power. Excludes 1,250,000 shares of Common Stock issuable only upon the exercise of warrants that remain outstanding as contingent consideration to Weird Science, and 12,526,552 shares of Common Stock controlled by Mr. Wittekind's spouse, to which Mr. Wittekind exercises no voting or disposition power.
- (7) Mr. Binette was appointed Chief Operating Officer on October 18, 2022.

Equity Incentive Plan Information

The following table provides information, as of June 30, 2022, regarding the number of shares of Company common stock that may be issued pursuant to our 2014 Equity Incentive Plan and 2019 Equity Incentive Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders:	4,307,820	\$ 5.37	2,835,906(1)
Equity compensation plans not approved by security holders	—	—	—
Total	4,307,820	\$ 5.37	2,835,906(1)

- (1) On February 6, 2014, the Board adopted the Company's 2014 Equity Incentive Plan (the "2014 Plan"), and the Company had reserved 1,206,000 shares of Common Stock for issuance in accordance with the terms of the Plan. On October 30, 2019, the Board approved and on October 31, 2019, the Company's stockholders adopted the Enochian BioSciences' 2019 Equity Incentive Plan (the "2019 Plan"), which became effective on December 12, 2019 (the "Effective Date") and replaced the 2014 Plan. The 2019 Plan authorized options to be awarded to not exceed the sum of (1) 6,000,000 new shares, (2) the number of shares available under the 2014 Plan for the grant of awards as of the Effective Date, and (3) shares underlying outstanding awards granted under the 2014 Plan that, after the Effective Date, expire or are terminated, surrendered or forfeited for any reason without the issuance of shares. The remaining shares available for grant related to the 2014 Plan was 655,769. As of the Effective Date, this amount along with the new 6,000,000 shares totaled 6,655,769 shares available for grant immediately after the Effective Date.

Item 13. Certain Relationships and Related Transactions and Director Independence

Transactions with Related Persons

Consulting Agreements - On July 9, 2018, the Company entered into a consulting agreement with G-Tech Bio, LLC, a California limited liability company (“G-Tech”) to assist the Company with the development of the gene therapy and cell therapy modalities for the prevention, treatment, and amelioration of HIV in humans, and with the development of a genetically enhanced Dendritic Cell for use as a wide spectrum platform for various diseases (including but not limited to cancers and infectious diseases) (the “G-Tech Agreement”). G-Tech was entitled to consulting fees for 20 months with a monthly consulting fee of not greater than \$130,000 per month. Upon the completion of the 20 months, a monthly consulting fee of \$25,000 continued for scientific consulting and knowledge transfer on existing HIV experiments until the services were no longer being rendered or the G-Tech Agreement is terminated. G Tech is controlled by certain members of Weird Science. For the years ended June 30, 2022 and 2021, \$275,000 was charged to research and development expenses in the accompanying consolidated statements of operations related to this consulting agreement. As of May 25, 2022, the consultant was no longer able to render services.

On January 31, 2020, the Company entered into a Statement of Work and License Agreement (the “HBV License Agreement”) by and among the Company, and G-Tech, and G Health Research Foundation, a not for profit entity organized under the laws of California doing business as Seraph Research Institute (“SRI”) (collectively the “Licensors”), whereby the Company acquired a perpetual, sublicensable, exclusive license (the “HBV License”) for a treatment under development (the “Treatment”) aimed to treat Hepatitis B Virus (HBV) infections.

The HBV License Agreement states that in consideration for the HBV License, the Company shall provide cash funding for research costs and equipment and certain other in-kind funding related to the Treatment over a 24 month period, and provides for an up-front payment of \$1.2 million within 7 days of January 31, 2020, along with additional payments upon the occurrence of certain benchmarks in the development of the technology set forth in the HBV License Agreement, in each case subject to the terms of the HBV License Agreement. Additionally, the HBV License Agreement provides for cooperation related to the development of intellectual property related to the Treatment and for a 2% royalty to G-Tech on any net sales that may occur under the HBV License. On February 6, 2020, the Company paid the \$1.2 million up-front payment. The HBV License Agreement contains customary representations, warranties, and covenants of the parties with respect to the development of the Treatment and the HBV License.

The cash funding for research costs pursuant to the HBV License Agreement consisted of monthly payments amounting to \$144,500 that covered scientific staffing resources to complete the project as well as periodic payments for materials and equipment needed to complete the project. There were no payments made after January 31, 2022. During the years ended June 30, 2022 and 2021, the Company paid a total of \$1,011,500 and \$2,409,000, respectively, for scientific staffing resources, R&D and IND Enabling studies. During the year ended June 30, 2022, the Company paid \$1,500,000 in August 2021 for the milestone completion of a Pre-Investigational New Drug (IND) process following receipt of written comments in accordance the HBV License Agreement. The Company has filed a claim against the Licensors, which includes certain payments it made related to this license.

On April 18, 2021, the Company entered into a Statement of Work and License Agreement (the “License Agreement”), by and among the Company, and G Tech and SRI (collectively, the “Licensors”), whereby the Company acquired a perpetual sublicensable, exclusive license (the “Development License”) to research, develop, and commercialize certain formulations which are aimed at preventing and treating pan-coronavirus or the potential combination of the pan-coronavirus and pan-influenza, including the SARS-coronavirus that causes COVID-19 and pan-influenza (the “Prevention and Treatment”).

The License Agreement was entered into pursuant to the existing Framework Agreement between the parties dated November 15, 2019. The License Agreement states that in consideration for the Development License, the Company shall provide cash funding for research costs and equipment and certain other in-kind funding related to the Prevention and Treatment over a 24-month period. Additionally, the License Agreement provides for an up-front payment of \$10,000,000 and a \$760,000 payment for expenditures to date prior to the effective date related to research towards the Prevention and Treatment within 60 days of April 18, 2021. The License Agreement provides for additional payments upon the occurrence of certain benchmarks in the development of the technology set forth in the License Agreement, in each case subject to the terms of the License Agreement.

The License Agreement provides for cooperation related to the development of intellectual property related to the Prevention and Treatment and for a 3% royalty to G Tech on any net sales that may occur under the License Agreement. For the year ended June 30, 2022 and June 30, 2021, the Company paid \$150,000 and \$10,760,000 related to the Prevention and Treatment research. The Company is no longer pursuing any product candidates that relate to this license. The Company has filed a claim against the Licensors to recover all monies it paid related to this license.

On August 25, 2021, the Company entered into an ALC Patent License and Research Funding Agreement in the HIV Field (the "ALC License Agreement") with Dr. Gümürkcü and SRI (collectively, the "Licensors") whereby the Licensors granted the Company an exclusive, worldwide, perpetual, fully paid-up, royalty-free license, with the right to sublicense, his proprietary technology subject to a U.S. patent application, to make, use, offer to sell, sell or import products for use solely for the prevention, treatment, amelioration of or therapy exclusively for HIV in humans, and research and development exclusively relating to HIV in humans; provided the Licensors retained the right to conduct HIV research in the field. Pursuant to the ALC License Agreement, the Company granted a non-exclusive license back to the Licensors, under any patents or other intellectual property owned or controlled by the Company, to the extent arising from the ALC License, to make, use, offer to sell, sell or import products for use in the diagnosis, prevention, treatment, amelioration or therapy of any (i) HIV Comorbidities and (ii) any other diseases or conditions outside the HIV Field. The Company made an initial payment to SRI of \$600,000 and agreed to fund future HIV research conducted by the Licensors, as mutually agreed to by the parties. On September 10, 2021, pursuant to the ALC License Agreement, the Company paid the initial payment of \$600,000.

G-Tech and SRI are controlled by Dr. Serhat Gümürkcü and Anderson Wittekind, shareholders of the Company.

Compensation of Named Executive Officers and Directors

For information regarding compensation of named executive officers and directors, please see "Item 11. Executive Compensation."

Except as otherwise indicated herein, there have been no other related party transactions, or any other transactions or relationships required to be disclosed pursuant to Item 404 and Item 407(a) of Regulation S-K.

Director Independence

The NASDAQ listing standards provide that an independent director is one who the Board affirmatively determines is free of any relationship that would interfere with that individual's exercise of independent judgment. The Board has determined that Mr. Sapirstein, Mr. Alton, Dr. Brosgart and Ms. McNicol are each independent as defined in the listing standards of NASDAQ. In making such determinations, the Board has concluded that none of these directors has an employment, business, family or other relationship, which, in the opinion of our Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Item 14. Principal Accounting Fees and Services

The following information sets forth fees billed to us by Sadler, Gibb & Associates, LLC ("Sadler") during the years ended June 30, 2022 and June 30, 2021 for: (i) services rendered for the audit of our annual financial statements and the review of our quarterly financial statements ("Audit Fees"), (ii) services that were reasonably related to the performance of the audit or review of our financial statements and that are not reported as Audit Fees ("Audit-Related Fees"), (iii) services rendered in connection with tax compliance, tax advice and tax planning ("Tax Fees"), and (iv) services rendered by Sadler other than the foregoing ("Other Fees").

Audit Fees

For the fiscal year ended June 30, 2022 Sadler billed an aggregate of \$86,000 in Audit Fees. For the fiscal year ended June 30, 2021, Sadler billed an aggregate of \$91,975 in Audit Fees.

Audit-Related Fees

For the fiscal year ended June 30, 2022 Sadler billed an aggregate of \$13,500 in Audit-Related Fees. For the fiscal year ended June 30, 2021, Sadler billed an aggregate of \$2,000 in Audit-Related Fees.

Tax and Other Fees

None.

Audit Committee's Pre-Approval Process

The Audit Committee, which has been in place since March 28, 2018, pre-approves all audit and permissible non-audit services on a case-by-case basis. In its review of non-audit services, the Audit Committee considers whether the engagement could compromise the independence of our independent registered public accounting firm, and whether it is in our best interests to engage our independent registered public accounting firm to perform the services. The Audit Committee does not delegate its responsibilities to pre-approve services performed by our independent registered public accounting firm to management. The Audit Committee may delegate, and has delegated, pre-approval authority to one or more of its members. The member or members to whom such authority is delegated must report any pre-approval decisions to the Audit Committee at its next scheduled meeting.

During the year ended June 30, 2022, all services performed by Sadler were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibits, Financial Statement Schedules

Exhibit No.	Description	Incorporated by Reference
3.1	Certificate of Incorporation	Incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2018.
3.2	Bylaws	Incorporated herein by reference to exhibit to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 16, 2019.
4.1	Form of Warrant	Incorporated herein by reference to Exhibit 10.2 to the Company's Form 8-K filed with the SEC on May 1, 2017.
4.2	Promissory Note	Incorporated herein by reference to Exhibit 10.2 to the Company's Form 8-K filed with the SEC on March 31, 2020.
4.3*	Amendment No.2 to Promissory Note, dated May 17, 2022	
4.4	Amendment No.3 to Promissory Note, effective December 30, 2022	Incorporated herein by reference to Exhibit 10.2 to the Company's Form 8-K filed with the SEC on February 23, 2023.
4.5	Form of Amended and Restated Senior Secured Convertible Promissory Note, amended effective December 31, 2022	Incorporated herein by reference to Exhibit 10.2 to the Company's Form 8-K filed with the SEC on February 23, 2023.
4.6	Description of Securities	Incorporated herein by reference to Exhibit 4.1 to the Company's Form 10-K filed with the SEC on September 30, 2020.
10.1	Form of License Agreement	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 17, 2018.
10.2	2019 Equity Incentive Plan	Incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on February 10, 2020.
10.3	Statement of Work and License Agreement	Incorporated herein by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on February 3, 2020.
10.4	Note Purchase Agreement	Incorporated herein by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on March 31, 2020.
10.5	Lease Agreement by and between the Company and Plaza Medical Office Building, LLC dated November 13, 2017	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 17, 2017.
10.6	General Office Lease by and between the Registrant and Century City Medical Plaza Land Co., Inc. dated June 19, 2018	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 25, 2018.
10.7	Consulting Agreement by and between the Company and G-Tech Bio, LLC July 9, 2018	Incorporated herein by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K/A filed with the SEC on September 30, 2019.

10.8	Offer Letter from the Company to Luisa Puche, dated December 28, 2018	Incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K/A filed with the SEC on September 30, 2019.
10.09	Purchase Agreement, dated July 8, 2020, by and between the Company and Lincoln Park Capital Fund, LLC	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 14, 2020.
10.10	Registration Rights Agreement, dated July 8, 2020, by and between the Company and Lincoln Park Capital Fund, LLC	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 14, 2020.
10.11	Form of Subscription Agreement	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 24, 2021.
10.12	Statement of Work and License Agreement, dated April 18, 2021, by and among the Company, G-Tech Bio, LLC, and G Health Research Foundation	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on April 22, 2021.
10.13	Employment Agreement, dated August 11, 2021, by and between the Company and Dr. Mark Dybul	Incorporated herein by reference to Exhibit to 10.1 the Company's Current Report on Form 8-K/A, filed with the SEC on August 16, 2021.
10.14	Amendment to Employment Agreement between Mark Dybul, M.D. and Enochian BioSciences Inc., dated December 12, 2022	Incorporated herein by reference to Exhibit to 10.1 the Company's Current Report on Form 8-K, filed with the SEC on December 16, 2022.
10.15	Security Agreement, effective December 30, 2022, by and between the Company and Paseco ApS	Incorporated herein by reference to Exhibit 10.2 to the Company's Form 8-K filed with the SEC on February 23, 2023.
21.1*	List of subsidiaries of the Company	
23.1*	Consent of Sadler, Gibb & Associates	
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934	
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934	
32.1**	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350	
32.2**	Certification of Chief Financial Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350	
101.INS	XBRL Instance Document*	
101.SCH	XBRL Taxonomy Extension Schema*	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase*	
101.DEF	XBRL Taxonomy Extension Definition Linkbase*	
101.LAB	XBRL Taxonomy Extension Label Linkbase*	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase*	
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) *	

* Provided herewith.

** Furnished herewith.

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.

Date: February 27, 2023

ENOCHIAN BIOSCIENCES INC.

By: /s/ Mark Dybul
Mark Dybul
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Luisa Puche
Luisa Puche
Chief Financial Officer
(Principal Financial and Accounting Officer)

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Dr. Mark Dybul</u> Dr. Mark Dybul	Chief Executive Officer (Principal Executive Officer)	February 27, 2023
<u>/s/ Luisa Puche</u> Luisa Puche	Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2023
<u>/s/ René Sindlev</u> René Sindlev	Director and Chairman of the Board	February 27, 2023
<u>/s/ Henrik Grønfeldt-Sørensen</u> Henrik Grønfeldt-Sørensen	Director	February 27, 2023
<u>/s/ Gregg Alton</u> Gregg Alton	Director	February 27, 2023
<u>/s/ Jayne McNicol</u> Ms. Jayne McNicol	Director	February 27, 2023
<u>/s/ James Sapirstein</u> James Sapirstein	Director	February 27, 2023
<u>/s/ Carol Brosgart</u> Carol Brosgart	Director	February 27, 2023

**AMENDMENT NO. 2
TO
PROMISSORY NOTE**

This Amendment No. 2 to Promissory Note (this "Amendment"), dated as of May 17, 2022 (the "Effective Date"), is entered into by and between ENOCHIAN BIOSCIENCES, INC., a Delaware corporation (the "Company"), and PASECO APS (the "Holder").

RECITALS

WHEREAS, the Company issued to the Holder that certain Promissory Note in the principal amount of \$5,000,000, dated March 30, 2020 (the "Original Note");

WHEREAS, pursuant to Section 2 of the Original Note, the note matures with the entire principal amount payable on November 30 2021;

WHEREAS, Section 7(a) of the Original Note provides that the Original Note and any provision therein may be amended by the written agreement of the Company and the Holder; and

WHEREAS, Amendment No. 1 to Promissory Note the Company and the Holder amended the Original Note to extend the maturity of the Original Note until November 30, 2022.

WHEREAS, the Company and the Holder desire to extend the maturity of the Original Note until November 30, 2023 and to amend certain other terms of the Original Note as set forth below.

NOW THEREFORE, in consideration of the mutual promises contained in this Amendment and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Holder, intending to be legally bound, hereby agree as follows:

1. Capitalized Terms. Except as may be expressly provided herein, all capitalized terms used herein shall have the meanings assigned to them in the Original Note.
2. Amendment to Section 1. The Company and the Holder desire to amend the Original Note to increase the interest accrued on the Principal to a rate of twelve percent (12%) per annum, and as such, Section 1 of the Original Note is hereby amended and shall read in its entirety as follows:

"Interest shall accrue on the Principal received by Maker from the date so received at a rate of twelve percent (12%) per annum. Interest shall be calculated on the Issue Date on the basis of the actual number of days elapsed until the Maturity Date (as defined below) and shall be subject to mandatory prepayment in-kind pursuant to Section 4 below."

3. Amendment to Section 2. The Company and the Holder desire to amend the Original Note to extend the maturity of the Original Note until November 30, 2023, and as such, Section 2 of the Original Note is hereby amended and shall read in its entirety as follows:

"The entire unpaid Principal shall be due and payable by the Maker to the Payee on November 30, 2023 (the "Maturity Date"). All payments hereunder shall be made at the Payee's address as set forth herein below or as otherwise may be designated by the Payee in writing."

4. Amendment to Section 4. Section 4 of the Original Note is hereby amended to add the following:

“Accrued Interest payable from November 30, 2022 until May 30, 2023 shall be paid by the Maker in-kind on the date hereof in fully paid and non-assessable shares of the Company’s common stock, par value \$0.0001 per share (“Common Stock”), valued at the closing sale price of the Common Stock of the Nasdaq Capital Market on the date hereof. All accrued interest payable from May 30, 2023 to the Maturity Date shall be payable by the Maker on May 30, 2023, at the option of the Holder either (i) in cash or (ii) in non-assessable shares of the Company’s Common Stock, valued at the closing sale price of the Common Stock of the Nasdaq Capital Market on May 30, 2023.”

5. Conforming Changes. All provisions in the Original Note and any amendments, attachments, schedules or exhibits thereto in conflict with this Amendment shall be and hereby are changed to conform to this Amendment.
6. Full Force and Effect. The Original Note is not amended hereby and shall remain in full force and effect, except as otherwise set forth in this Amendment. The parties hereby ratify and confirm the terms and conditions of the Original Note, as supplemented and amended by this Amendment.
7. Recitals. The Recitals above are true and correct and are hereby incorporated by reference.
8. Applicable law. The substantive laws of the applicable state, as well as terms regarding forum and jurisdiction, as originally provided in the Original Note shall govern the construction of this Agreement and the rights and remedies of the parties hereto.
9. Counterparts. This Amendment may be executed in counterparts (including by means of electronic transmission), each of which shall be deemed an original but all of which, when taken together, will constitute one and the same agreement.

*** Signature Page Follows ***

IN WITNESS WHEREOF, the Company and the Holder have made and executed this Amendment effective as of the Effective Date.

COMPANY:

ENOCHIAN BIOSCIENCES, INC.

By: /s/ Luisa Puche

Name: Luisa Puche

Title: Chief Financial Officer

HOLDER:

PASECO APS

By: /s/ Ole Abildgaard

Name: Ole Abildgaard

Title: CEO

Signature Page to Amendment No. 2 to Promissory Note

LIST OF SUBSIDIARIES

The following is a list of subsidiaries of the Company as of June 30, 2022:

<u>Subsidiary Legal Name</u>	<u>State or Other Jurisdiction of Incorporation or Organization</u>
Enochian Biopharma, Inc.	Delaware
Enochian Biosciences Denmark ApS	Denmark
Enochian Technologies, Inc.	Nevada

**Registered with the Public Company
Accounting Oversight Board**

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors
Enochian Biosciences, Inc.
Los Angeles, CA

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-239837) of Enochian Biosciences, Inc. of our report dated October XX, 2022 relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ Sadler, Gibb & Associates, LLC

Salt Lake City, UT
February 27, 2023

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mark Dybul, certify that:

1. I have reviewed this Annual Report on Form 10-K of Enochian Biosciences Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15-d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2023

By: /s/ Mark Dybul

Mark Dybul
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Luisa Puche, certify that:

1. I have reviewed this Annual Report on Form 10-K of Enochian Biosciences Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15-d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2023

/s/ Luisa Puche

Luisa Puche

Chief Financial Officer

(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Enochian Biosciences Inc. (the "Company") on Form 10-K for the year ending June 30, 2022 as filed with the Securities and Exchange Commission (the "Report"), the undersigned, Mark Dybul, as Chief Executive Officer (Principal Executive Officer) of the Company, hereby certifies as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2023

By: /s/ Mark Dybul

Mark Dybul
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Enochian Biosciences Inc. (the "Company") on Form 10-K for the year ending June 30, 2022 as filed with the Securities and Exchange Commission (the "Report"), the undersigned, Luisa Puche, as Chief Financial Officer (Principal Financial Officer) of the Company, hereby certifies as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2023

/s/ Luisa Puche

Luisa Puche
Chief Financial Officer
(Principal Financial and Accounting Officer)
