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Document Description 2	Management and Operations Agreement by and between the Company and Sheffa Enterprises, Inc., dated March 3, 2025
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2024

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

For the transition period from _____ to _____

Commission File No. 000-53002

Raphael Pharmaceutical Inc.
(Exact name of registrant as specified in its charter)

Nevada	26-0204284
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

4 Lui Paster
Tel Aviv-Jaffa, Israel 6803605
(Address of Principal Executive Offices)

Registrant's Telephone Number: (972) 52-775-5072

Securities Registered pursuant to Section 12(b) of the Act:
NONE

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

Common Stock, $0.01 par value
(Title of class)

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 checkmark if the registrant is not required to file reports pursuant to Section 13 or 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 preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark 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 definition of "large accelerated filer," "accelerated filer,'' "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filed ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was $17,188,303 based on the closing price of $1.54 per share of the registrant's common stock on June 28, 2024.

As of March 28, 2025, there were 19,626,418 shares of common stock, par value $0.01, or Common Stock, of the registrant issued and outstanding.

Documents Incorporated By Reference: None.

TABLE OF CONTENTS

Item No.	Description	Page
Cautionary Note	Regarding Forward-Looking Statements	ii
	PART I	
Item 1.	Business	1
Item 1A.	Risk Factors	23
Item 1B.	Unresolved Staff Comments	48
Item 1C	Cyber Security	48
Item 2.	Properties	48
Item 3.	Legal Proceedings	48
Item 4.	Mine Safety Disclosures	48
	PART II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	49
Item 6.	[Reserved]	49
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	49
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	56
Item 8.	Financial Statements and Supplementary Data	56
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	57
Item 9A.	Controls and Procedures	57
Item 9B.	Other Information	57
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	57
	PART III	
Item 10.	Directors, Executive Officers and Corporate Governance	58
Item 11.	Executive Compensation	61
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	63
Item 13.	Certain Relationships and Related Transactions, and Director Independence	64
Item 14.	Principal Accounting Fees and Services	65
	PART IV	
Item 15.	Exhibits and Financial Statement Schedules	66
Item 16.	Form 10-K Summary	67
Signatures		68

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or the Annual Report, contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, which includes information relating to future events, future financial performance, financial projections, strategies, expectations, competitive environment and regulation. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or management's good faith belief as of that time with respect to future events, and are subject to significant risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- the regulatory pathways that we may elect to utilize in seeking U.S. Food and Drug Administration, or FDA, European Medicines Agency, or EMA, and other regulatory approvals, if any;
- obtaining (and the cost thereof) FDA and EMA approval of, or other regulatory action in Europe or the United States, or U.S., and elsewhere with respect to our product candidates;
- the commercial launch and future sales of our product candidates and our advancement of product candidates for other indications in our pipeline;
- the potential cost of our rheumatoid arthritis product candidate, or RA, and RA product candidate, respectively, for patients;
- our expectations regarding the timing of conducting clinical trials;
- our expectations regarding the supply of the active pharmaceutical ingredient for our product candidates;
- third-party payor reimbursement for our product candidates;
- our estimates regarding anticipated expenses, capital requirements and our needs for additional financing;
- completion and receiving favorable results of clinical trials for our product candidates; and
- the filing by us, and the subsequent issuance of patents to us, by the U.S. Patent and Trademark Office, or USPTO, and other governmental patent agencies.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. Please see "Item 1A. Risk Factors" for additional risks that could adversely impact our business and financial performance.

Moreover, new risks regularly emerge and it is not possible for our management to predict or articulate all the risks we face, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this Annual Report are based on information available to us on the date of this Annual Report. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained above and throughout this Annual Report.

In this Annual Report, unless otherwise specified, all dollar amounts are expressed in U.S. dollars. Except as otherwise indicated by the context, references in this Annual Report to "Raphael," "Company", "we," "us" and "our" are references to Raphael Pharmaceutical Inc., a Nevada corporation, together with its consolidated subsidiaries.

PART I

Item 1. Business.

History

Raphael Pharmaceutical Inc. was incorporated in the State of Nevada in May 2007 and was formerly known as Easy Energy, Inc. On May 14, 2021, Raphael Pharmaceutical Ltd., or Raphael Israel, an Israeli company, and Easy Energy, Inc., a Nevada corporation, completed a share exchange agreement, or the Share Exchange, pursuant to which the shareholders of Raphael Israel became the holders of 90% of the issued and outstanding share capital of Easy Energy, Inc., while Easy Energy, Inc.'s shareholders hold, following the share exchange, 10% of Easy Energy, Inc. On May 19, 2021, as agreed by the parties to the share exchange, Easy Energy, Inc. changed its name to Raphael Pharmaceutical Inc. Raphael Israel was incorporated in 2019 in the State of Israel and has focused to date on developing its lead product candidate for the treatment of rheumatoid arthritis. Easy Energy did not have any ongoing business or operations before the Share Exchange and following the Share Exchange we adopted Raphael Israel's business plan.

Overview

We are a pharmaceutical drug research and development company focused on the discovery and clinical development of life-improving drug therapies based on cannabinoids, including cannabidiol, or CBD, oil. Unless indicated otherwise, we plan on using oil derived from CBD strains with low levels of Tetrahydrocannabinol, or THC. All references to the use of CBD in our product candidates refer to CBD strains with less than 0.3% of THC.

We have recently completed a proof-of-concept clinical study, or Study, for our lead product candidate for the treatment of RA in the U.S. Encouraged by the promising results of the Study, we will continue to investigate our product for the treatment of autoimmune diseases.

In addition, we are aiming to develop a novel treatment for asthma. At Rambam Health Care Campus, Rambam Med-Tech Ltd., or Rambam, we have successfully conducted studies using human-derived immune cells and mouse models to advance our understanding both COVID-19 and RA products. Due to the similarity of COVID-19 and asthma symptoms, such studies also advance our understanding of asthma and its treatment. Since the volume of COVID-19 testing has been decreasing, we decided to leverage our knowledge and understanding of COVID-19 to study asthma as well.

On February 9, 2022, we filed an application for a clinical trial with the Medical Cannabis Unit of the Ministry of Health of Israel, or MOH. On February 16, 2022 we submitted an application with the Helsinki Committee at Rambam for a clinical trial in COVID-19 patients.

In November 2022, we submitted a proposal to the Ministry of Health of Israel, or MOH for a clinical trial of a cannabis-based drug intended to alleviate the deterioration of COVID-19 patients.

On March 27, 2023, the MOH accepted our proposal for a clinical trial of a cannabis-based drug intended to alleviate the deterioration of COVID-19 patients.

In April 2024 we began the Study in the U.S., leveraging insights from the pre-clinical experiments we have conducted at the Rambam . This Study aimed to evaluate the Company's Cannabinoid based formula, or Raphael's Formula, in patients with active RA. The single-group Study was managed by MindMate, Inc./ dba Citruslabs, or Citruslabs, and conducted in Santa Monica, California, U.S., under Institutional Review Board, or IRB, approval, in compliance with applicable FDA regulations and in accordance with applicable industry standards and regulations. An IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects.

On December 23, 2024, upon a successful completion of the Study, we received the Study results with overall findings that emphasize the clinical potential of Raphael's Formula and suggest that it may have beneficial effects on symptom management and overall well-being for individuals with RA. For more information about the Study results, see "Item 1. Business - Research and Clinical Development Strategy".

As we move forward, our focus will be on further investigating mechanisms and refining Raphael's Formula through continued pre-clinical research. Our goal is to ensure that the formula meets all the necessary standards and regulations set forth by the FDA, allowing us to progress towards clinical treatments.

Our vision is to emerge as a pioneering company at the forefront of formulating pharmaceutical drugs that harness the potential of purified cannabinoids and full-spectrum CBD oil. Our primary mission is to cater to the unmet medical requirements of patients grappling with various disorders, with a particular focus on conditions linked to inflammation, such as autoimmune diseases, asthma, RA and COVID-19.

By leveraging our expertise in this field, we are committed to providing innovative solutions to improve the lives of those afflicted with these challenging medical conditions. Through our dedication to research, development, and compassionate care, we aim to contribute significantly to the well-being of patients worldwide, offering them much-needed relief and hope for a better future.

In order to achieve our goal, we have and will continue to build an experienced team of senior executives and scientists, with experience in all facets of pharmaceutical research and development, drug formulation, clinical trial execution and regulatory submissions. We intend to leverage the knowledge of our team in order to complete the clinical trials needed to receive approvals of our product candidates from applicable regulatory authorities.

Initially, we intend to obtain approvals for our product candidates from the FDA, and the Medical Cannabis Unit of the MOH. Upon obtaining FDA approvals, or in the event that we are not successful in obtaining such approvals, we intend to apply for European Medicines Agency, or EMA, and other countries' governmental regulatory agencies approvals for our product candidates. If we are successful in obtaining FDA approvals for our product candidates, we intend to enter into royalty agreements with good manufacturing practice, or GMP, approved medical manufactures and distributors, having them use our medical formulas for the purpose of growing, cultivating, manufacturing, and distributing Raphael Pharmaceutical medical indications in their designated territories.

For this purpose, in October 2022, we entered into an agreement with the Medical Cannabis Research Center at Rambam for the development of a new, patentable formulation that combines purified cannabinoids to treat rheumatoid diseases.

The overall objective of this study is to identify a novel cannabinoid based patentable formulation to treat Rheumatoid diseases. Specifically, to investigate combination of purified cannabinoids to downregulate inflammation related to Rheumatoid diseases. We propose to base our study on data derived from Dr. Igal Louria-Hayon's studies (Helsinki # 0442-20-RMB) on the evaluation of the immune regulation properties of cannabinoids on the immune system and the data derived from the cannabinoids receptors study (Helsinki # 0331-20-RMB). We will analyze the activation of cannabinoid receptors on mouse models and will study the role of purified cannabinoid as a potential to develop a novel patentable formulation to treat RA.

Our discovery platform currently focuses the use of CBD oil, one of the cannabinoids in cannabis plants, as the active pharmaceutical ingredient, or API, for our RA product candidate and COVID-19 product candidate. Research results published in 2018 ("Translational Investigation of the Therapeutic Potential of Cannabidiol (CBD): Toward a New Age") has shown that there may be benefits to treading medical conditions, or their effects, with cannabinoids, and more specifically, with CBD, which may help reduce chronic pain by impacting endocannabinoid receptor activity, reducing inflammation and interacting with neurotransmitters. This research has also shown that CBD may have neuroprotective properties, and could have the ability to (i) reduce anxiety and depression, (ii) alleviate cancer-related symptoms, (iii) reduce acne and (iv) benefit heart health.

Over the last few years, pharmaceutical drug products that include parts of the cannabis plant have begun to receive regulatory approvals for use in patients suffering from certain disorders, as highlighted below.

- Nabiximols, better known under the tradename Sativex, is a botanical mouth spray consisting of natural THC and CBD extracts, that received approval in the United Kingdom in 2010 for the alleviation of multiple sclerosis, or MS, symptoms like spasticity, pain and overactive bladder.

- Dronabinol, better known under the name Marinol, contains mainly THC and is a partial agonist of the cannabinoid receptor type 1, or CB1, in the nervous system and a partial agonist of the cannabinoid receptor type 2, or CB2, in the periphery that activates appetite, mood, cognition, memory and perception. Dronabinol received FDA-approval for use in the U.S. in 1985 for treatment of anorexia in acquired immunodeficiency syndrome, or AIDS, patients and for the prevention of chemotherapy-induced nausea and vomiting, or CINV. A Lack of randomized controlled trials, or RCTs, makes a recommendation for usage of dronabinol as a third-line treatment for CINV difficult. Dronabinol in the form of an oral tablet is known under the trade name Namisol. It has high bioavailability and a long shelf life and is indicated for MS, chronic pain and behavioral disturbances in dementia patients.

- Nabilone, better known under the tradename Cesamet, contains primarily THC, is approved for use as an anti-emetic and adjunctive analgesic for neuropathic pain, CINV and treatment for anorexia in AIDS patients in Canada, Mexico, the UK and the U.S. Its main usage today is as adjunct medicine for chronic pain management.

In light of the past regulatory approvals for other pharmaceutical drug products and, more specifically, the potential beneficial effects of CBD and other parts of the cannabis plant, we believe that a drug discovery platform based on CBD may offer new and differentiated treatment options for patients. Prior regulatory approvals of other companies' pharmaceutical drug products do not serve as an indication as to the ability or likelihood that we receive regulatory approval to commercialize any of our product candidates.

After four successful years of pre-clinical research at the laboratories of Rambam, which paved the way for the Study in RA patients, we are now advancing our efforts to further develop our product candidates.

Following the completion of the Study, we intend to submit an Investigational New Drug, or IND, application to the FDA and MOH. See "Item 1. Business - Research and Clinical Development Strategy - Clinical Development Plan" for additional information on the ongoing pre-clinical trial and our planned clinical trial for our RA product candidate.

In addition, with respect to our COVID-19 product candidate, our clinical research partners have been focused on the effect of cannabinoids and cannabis extracts on immune cells which induce acute inflammation. This study will begin in the pre-clinical level in immune cell models and, subject to positive results that exhibit downregulation of pro-inflammatory cytokines by cannabis extract, the study was completed successfully. Following the completion of the pre-clinical study, a mice model was conducted to analyze for acute inflammation, which resembles the immunopathology of COVID-19. The mice model was successfully completed and we have registered for a clinical trial in patients with the MOH.

As a pharmaceutical research and clinical development company we do not own or operate, and currently do not intend on creating an in-house team to manufacture and commercialize our pharmaceutical drug products, if any, that receive regulatory approval allowing for commercialization. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing of any pharmaceutical drug products for which we may receive regulatory approval. Subject to the receipt of such regulatory approvals, we intend on cooperating with manufacturers and other third parties to manufacture and commercialize approved pharmaceutical drug products.

Product Pipeline

In December, 2024, we completed the Study for our lead product candidate for the treatment of RA, and are currently developing novel asthma product candidates, which are in the pre-clinical stage.

Assuming that we successfully complete the clinical development of our RA and asthma product candidates, we intend to then turn our attention to the clinical development of cannabinoid-based drug products for the treatment of certain oncology indications. Unlike our RA and asthma product candidate, the use of our cannabinoid-based drug products for the treatment of certain oncology indications will require specific dosing and potentially, a different regulatory pathway than our existing product candidates.

We intend to apply for MOH approval, as well as the FDA and EMA approvals right afterwards, subject to the completion of the applicable clinical trials, for our RA product candidate as well as our asthma product candidate using the FDA's regulatory pathway for drug products.

Indications and Market

Rheumatoid Arthritis

RA is an autoimmune disease of unknown cause characterized by inflammation in multiple joints, including synovial inflammation with hyperplasia. Inflammation is also associated with reduced hemoglobin (anemia) and reduced albumin and changes in levels of cholesterol and triglycerides. In addition to the inflammation associated with RA, studies, including a 2018 publication entitled, "Cartilage and bone damage in rheumatoid arthritis," patients suffering from RA generally also suffer from chronic pain, fatigue, progressive joint damage, disability, hyperplasia, production of autoantibodies such as rheumatoid factor and anti-citrullinated protein antibody, cartilage damage and bone erosions.

Research has shown that in about 30% of RA patients, current conventional synthetic and biologic disease modifying anti-rheumatic drugs and targeting molecules may fail or induce only partial responses, both of which we believe are insufficient for patients suffering from RA. Using disease modified anti-rheumatic drugs, or DMARD, based treatments, as shown in a 2017 study from Sohita Dhillon, patients tend to report at follow-up meetings that pain relief is unsatisfactory and although there is an initial improvements in the average pain score, a plateau may be reached beyond which DMARDs are not able to resolve RA pain. As a result, we believe that RA patients need ongoing therapy as RA relapses are frequent. During RA flareups, patients experience acute and chronic pain, fatigue, sleep disturbances, and morning stiffness which significantly reduces their quality of life. Furthermore, damage is accumulated by long-term disease which also interferes with pain, fatigue and quality of life.

All types of pain (acute or chronic, widespread or local and nociceptive) have been reported in RA. Patients with RA may develop fibromyalgia, or FM, especially with long-term disease. Concomitant FM is a key factor for discordance between PRO and clinical outcomes in assessment of RA patients including in RCTs. Peripheral sensitization, induced by local inflammation or damage, and pain augmentation by the central nervous system, or CNS, both drives the pain problems in RA patients. Anxiety or depression, impaired sleep and fatigue all contribute to pain sensitization in RA patients. As noted in the study, "Tackling Pain Associated with Rheumatoid Arthritis: Proton-Sensing Receptors," some RA patients have allodynia and peripheral neuropathies that contribute to refractory chronic pain.

We believe that clinical studies on the use of cannabinoids in rheumatic conditions, and particularly RA, are logically advocated as possible positive effectors of the inflammatory pathway of RA, as well as symptomatic pain relievers that may have the potential to also improve fatigue, sleep disorder and tolerability of DMARDs. Through our sponsored Research Agreement (as further detailed and defined below), we believe that we have arrived at an understanding as to how cannabinoids influence inflammation. Applying immune cells models in our pre-clinical research, we identified specific strains of cannabis which reduce the capacity of the immune cells to communicate during inflammation, thus decreasing their capacity to participate in chronic inflammation. For a deeper understanding of the mechanism in which cannabinoids effect inflammation, we developed a unique, real time-Polymerase chain reaction, or RT-PCR, method to identify 10 different receptors to cannabinoids, both in human and mice models. We believe that this technology will allow us to identify which cannabinoids receptors are participating in the downregulation of inflammation, which we believe will help us develop our RA product candidate.

In 2015 alone, research conducted by the NIH National Library of Medicine showed that RA affected about 24.5 million people as of 2015, which reflected between 0.5% and 1% of adults in the developed world, with an additional 5 to 50 per 100,000 people developing the condition each year. It is believed that onset is most frequent during middle age and women are affected 2.5 times as frequently as men. Further research indicates that RA resulted in 38,000 deaths in 2013, up from 28,000 deaths in 1990.

Hyperinflammatory Syndrome Related to COVID-19

Since the first emergence of COVID-19 in December 2019 in Wuhan, China, COVID-19 has spread across more than 200 countries across the world and over 112 million cases of the virus have been reported. Most patients develop only mild symptoms of COVID-19; however, some develop severe symptoms including dyspnea, hypoxia and lung involvement which requires hospitalization. Based on research, we believe that most of the severe COVID-19 symptoms are related to hyperinflammation caused by failure of resolution of the immunological response to the infection similar as observed in cytokine release syndrome. Despite the advancements in COVID-19 vaccines and the use of anti-inflammatory or anti-viral medications worldwide according to The World Health Organization, or WHO, there was a 4% global increase in reported new cases during the 28-day period from December 11, 2023, to January 7, 2024, compared to the previous 28-day period, totaling over 1.1 million new cases. However, there was a 26% decrease in new deaths, with 8,700 reported fatalities during the same period. Globally, as of January 7, 2025, there have been over 777 million confirmed cases and over seven million deaths since the emergence of COVID-19, according to the WHO. Consequently, there is an urgent need to explore new anti-inflammatory therapies that could potentially prevent symptom deterioration.

Asthma

Asthma is a chronic inflammatory disease of the airways, marked by symptoms such as coughing, wheezing, shortness of breath, and chest tightness. According to eClinicalMedicine article (February 2025), it affects between 1% to 29% of the global population. The underlying mechanisms of asthma include persistent airway inflammation, excessive mucus production, structural changes in the airway wall, and bronchial hyper-responsiveness, or BHR, where airway smooth muscle cells overreact to various triggers like allergens and cold air. Inhaled corticosteroids, or ICS, are the primary treatment for persistent asthma, often combined with short-acting bronchodilators for immediate relief and long-acting bronchodilators for sustained symptom control. However, many patients struggle with inadequate asthma management due to refractory disease, suboptimal treatment regimens, poor adherence, and coexisting conditions, emphasizing the urgent need for more effective therapeutic options.

Together with the Cannabis Research Institute at Rambam, we explore the therapeutic potential of our specific non-psychoactive cannabis strain, or -CBD-X, extract by examining its effects on cells involved in the asthmatic process. We utilized two ex vivo cell models—primary human T-cells and neutrophils, to evaluate the anti-inflammatory properties of CBD-X. We believe that CBD-X extract inhibits the differentiation of T-cells, leading to a reduction in the secretion of pro-asthmatic cytokines. Additionally, CBD-X extract decreases the levels of pro-inflammatory cytokines in primary human neutrophils and impairs their migration towards the lungs. This reduction impairs the communication between immune cells, which we believe to be crucial in the development and exacerbation of asthma.

The global asthma therapeutics market has been experiencing steady growth, driven by the increasing prevalence of asthma and the continuous development of novel treatments. According to Global Market Insights report (March 2024), in 2023, the asthma therapeutics market size was valued at approximately $25.7 billion and is projected to grow at a compound annual growth rate, or CAGR, of 4.4% from 2024 to 2030.

Research and Clinical Development Strategy

Research and clinical development of our pharmaceutical drug product candidates is our core business. We are currently focused on developing innovative cannabinoid-based medical indications that we aim to push through Phase 2A and Phase 2B approval from both the FDA and EMA.

The research efforts that have been conducted to date by the team at Rambam are aimed at revealing the mechanism which structures the activity of cannabinoids in human cells and organs, while applying a variety of disease models. By employing our PCR method, we are able to discern various cannabinoid receptors and determine their involvement in inflammation downregulation. This approach empowers us to identify which cannabinoid receptors play a role in mitigating inflammation. Consequently, we can accurately identify the cannabinoid components within a chosen strain, enabling precise administration tailored to patient treatment. This pivotal discovery forms the scientific cornerstone for our pioneering anti-inflammatory formulas.

Research Agreement with Rambam

On July 17, 2019, we entered into a sponsored research agreement, or the Research Agreement, with Rambam, pursuant to which the Company agreed to fund a research project, to be performed by Rambam, with a research plan aimed at identifying the effects of different cannabis strains on the function of immune cells. On October 28, 2020, the Company and Rambam agreed to expand the research plan to study the anti-inflammatory activities of cannabis extracts in an RA mouse model. On February 15, 2021, the Company and Rambam agreed to further expand the research plan to study the effect of cannabis extracts on the immunopathology of the COVID-19 disease. The sponsored Researched Agreement is for an initial term of 48 months. On October 23, 2022, the Company and Rambam entered into a supplement to the Research Agreement, or the Supplement Agreement, pursuant to which the Company exercised an option to extend the Research Agreement by additional two years until December 31, 2024, which we plan to extend in 2025

Pursuant to the Research Agreement, we agreed to pay Rambam $1.4 million in four equal payments, due on the first day of August on each successive year from 2019 through 2022. Pursuant to the Supplement Agreement, we agreed to pay Rambam $960,000 plus VAT in four biannual payments from May 2023 through May 2025. Such amount was later amended to $470,000 plus VAT. Furthermore, in accordance with the terms of the Research Agreement, we and Rambam will have joint ownership of any intellectual property, or IP, created as a result of research programs covered by such agreement. In connection with the Research Agreement, Rambam agreed not to work, study or develop any technologies with other entities that compete with our work with Rambam for our COVID-19 product candidate or RA product candidate for a term of three and seven years, respectively, from the end of the parties' collaboration with respect to the COVID-19 product candidate and seven years from the end of the term of the Research Agreement with respect to the RA product candidate.

Subject to commercial sales of any product candidate using the IP created as a part of the research covered by such agreement, Raphael Israel is required to pay Rambam a royalty in an amount equal to 6% of all net sales, subject to certain deductions, such as taxes paid by any purchaser, transportation and shipping costs, and other customary deductions.

On December 25, 2023, the Company received an extension to pay the remaining $350,000 pursuant to the Research Agreement until the end of June 2024. As of the date of this Annual Report, the Company has made all four of the four equal payments due pursuant to the Research Agreement, for a total amount of $1.4 million and $295,000 for the Supplement Agreement (out of the remaining $470,000).

We and Rambam are currently focused on characterizing the activity of cannabinoids in RA and in asthma. RA is a long-term autoimmune disorder, and as such, the research conducted by Rambam has focused on identifying the effect of cannabinoids on inflammatory processes related to RA. Moreover, building on the promising findings of a mouse model study demonstrating the potential of the Company's cannabis treatment for lung inflammation, as published in *Frontiers in Immunology* in May 2022, Rambam's research team is currently studying the effects of cannabinoids on models of chronic lung inflammation, including asthma. In October 2024, their findings were published in the scientific journal- Pharmaceuticals: "CBD-X extracts in asthma management: Reducing Th2-driven cytokine secretion and Neutrophil/Eosonophils activity".

Pre-Clinical Studies for RA Product Candidate

In Vitro Study

Pursuant to the Research Agreement, the team at Rambam established a study in order to determine which cannabis strains extracts may affect inflammation. The lab applied an *in vitro* system, allowing them to screen a variety of cannabis derived oil extracts and their influence on cytokine secretion, which is a type of response to injury and infection in the body.

The researchers employed human donors neutrophils cells, which can be induced to secrete cytokines (which is aimed as serving as a bridge for cross-communication with other innate immune cells). Using this system, our partners from Rambam have established a variety of cannabinoids and studied their influence on pro-inflammatory and anti-inflammatory cytokines. Most interestingly the study has identified a CBD-X and showed that CBD-X reduced IL-6 secretion while also reducing the secretion of the pro-inflammatory chemokine IL-8, as highlighted in Figure 1 below. Based on the results from this pre-clinical study, we believe that CBD-X strain, may be a potential anti-inflammatory agent with the ability to influence both activation and migration of cells during inflammation.

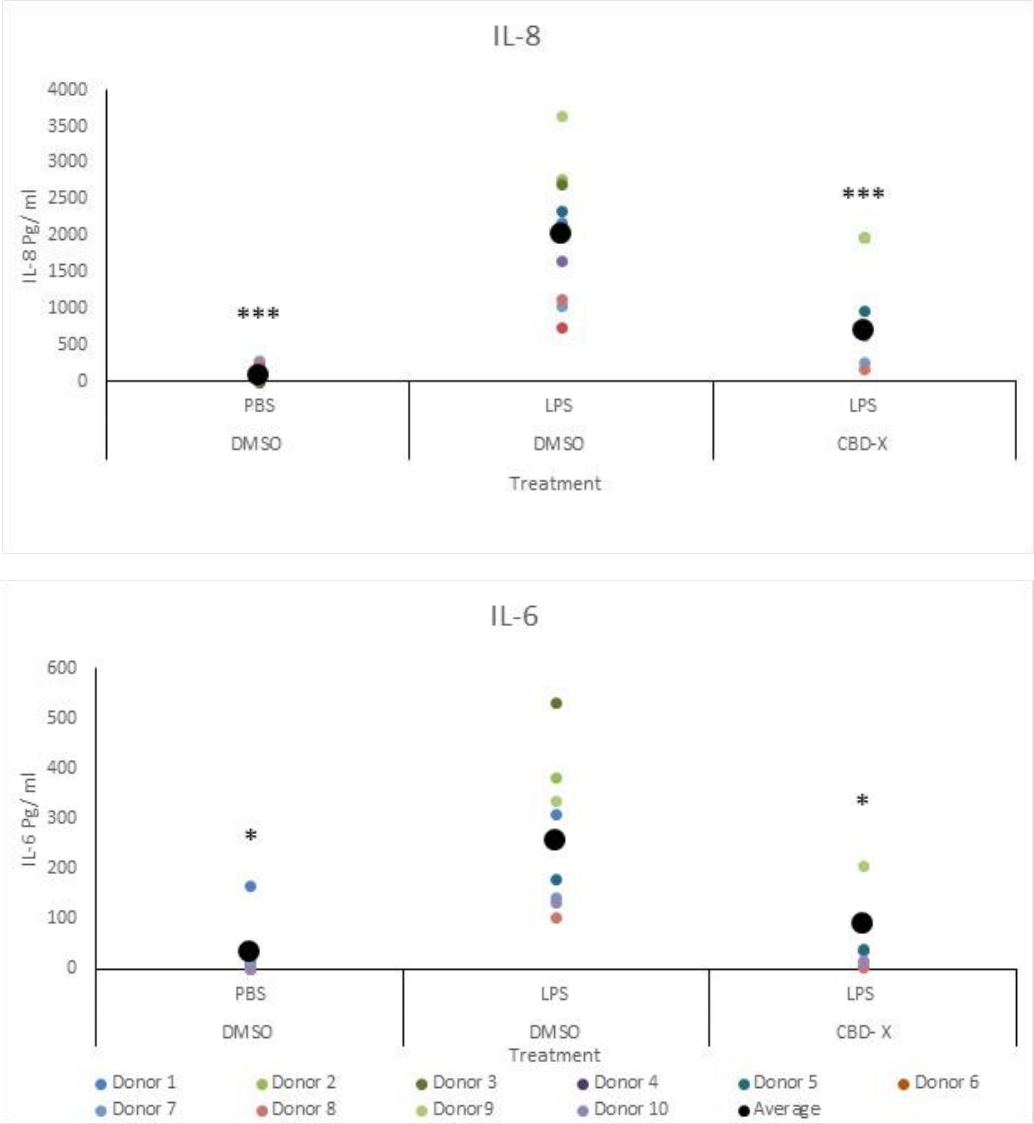

Figure 1. CBD-X strain downregulates the secretion of pro-inflammatory cytokines from human neutrophils.

Neutrophils were isolated from the blood of healthy donors by negative magnetic selection with the EasySep Direct Human Neutrophil Isolation Kit. Isolated neutrophils were treated with 2µg/ml CBD-X or DMSO (vehicle) as a control for two hours. Treated cells were activated by 100 ng/ml LPS overnight. Levels of IL-8 and IL-6 (A-B) were detected by ELISA. Each colored dot represents one donor. The means were calculated from healthy donors (black big dots) and each dot represents one case. Data were analyzed by one-way ANOVA (Fisher's LSD test with values $p < 0.05$ considered statistically significant, (***$p < 0.001$)

Pre-Clinical Study in Mice

In January 2021, we commenced a pre-clinical study in mice. Mice in our pre-clinical study are being treated with cannabis strain (CBD-X) that we previously identified in our in vitro study and other prior research as potential candidates in the cell models. Following the treatment, we expect to examine the ability of the treatment to modulate the immune function, specifically in the case of chronic inflammation, in order to optimize treatment for RA and asthma.

This pre-clinical study is expected to be focused on the following results.

- Aim 1: Evaluating the immune modulatory properties of different cannabis strains related to the immunopathology (i.e., the immune responses) in RA and asthma;
- Aim 2: Demonstrating the immunomodulatory properties of specific cannabis extracts on a mouse model for RA and asthma;
- Aim 3: Elucidating the mechanisms of action, or MOA, of cannabinoids that are involved in the regulation of inflammation in RA and asthma.
- Aim 4: Establishing a phase 1 and 2 clinical trial experiment in compliance with FDA and EMA rules and regulations to study the effect of cannabis-based medical indication on RA.

In addition, this pre-clinical study is expected to enable us to examine how we manufacture the API, the dosage design, analytical and bioanalytical method development and validation, metabolism and pharmacokinetics, toxicology, both safety and genetic toxicology and possibly safety pharmacology; and good manufacturing practice, or GMP, manufacture and documentation of drug product for use in clinical trials.

Aim 1. Evaluating the immune modulation properties of different cannabis strains

RA is an autoimmune disease that causes chronic inflammation and damage to the joints, leading to pain, stiffness, and loss of mobility. It occurs when the body's immune system mistakenly attacks the synovium, which is the lining of the joints. This can cause swelling and thickening of the synovium, which can eventually lead to erosion of the cartilage and bone within the joint. RA can also affect other parts of the body, such as the skin, eyes, lungs, and blood vessels. RA is a chronic condition that requires ongoing management to control symptoms and prevent joint damage.

Current treatments for RA have potential difficulties and side effects that need to be carefully weighed against their benefits. Some medications may lose effectiveness over time, requiring patients to switch treatments. Additionally, some medications have side effects such as gastrointestinal problems, liver damage, and increased risk of infections and cancer. There are also individual differences in patient response to treatments, highlighting the need for more personalized approaches.

It is our belief, based on the research conducted by our partners, and that or our industry peers, that cannabinoids have immunomodulatory properties, although the exact effects are not fully comprehended.

Together with the team at the Medical Cannabis Research and Innovation Center at Rambam our experiments in cells derived from human healthy donors (Helsinki Num. 044220-RNB) have revealed a specific high-CBD strain-CBD-X, that effectively reduces the capacity of immune cells: T cells and neuthrophils to be activated in response to inflammatory stimulation. The strain was found to reduce the expression levels of IL6, TNF alpha. This suggests that the strain has the potential to slow the progression of RA.

Thus, we have successfully completed the proof-of-concept phase in human derived immune cells.

Aim 2. Demonstrating the immune modulatory properties of specific cannabis extract on mouse models for RA.

Cannabis is not an isolated substance; it contains a plethora of biologically active substances. The most common substances are THC and CBD. Today more than 140 cannabinoids are known to be expressed in the plant. In addition to cannabinoids, the plants contain flavonoids and terpenes. This greatly complicates our ability to understand the effects of cannabis on the physiology because the different substances may have different (and even contradictory) effects. Therefore, the use of different cannabis varieties with diverse ingredients may produce distinct and unexpected results.

Our preclinical experiments have revealed a specific high-CBD strain – CBD-X, that effectively reduces inflammation in a mouse model of RA. The strain was found to reduce the expression levels of IL6, TNF alpha, and IL1b in the joints and peripheral blood of the mice. This suggests that the strain has the potential to slow the progression of RA.

We have successfully completed the proof-of-concept phase in mice and are now preparing to move towards clinical trials.

Aim 3. Elucidating the MOA of cannabinoids that are involved in the regulation of inflammation in RA.

Upon activation, it is the cannabinoid receptors, or CBrs, in the endocannabinoid system, or ECS, which initiate numerous regulatory functions in a mammal. CBrs have been found in a variety of species including human, monkey, pig, dog, rat and mouse. The discovery of membrane receptors found in the brain, central nervous system as well as peripheral tissues and organs that bind cannabimimetic compounds was a critical turning point that paved the way towards the pharmacological understanding of cannabis-derived compounds.

The most studied CBrs are CB1 and CB2; both belong to the G protein-coupled receptors (these cell surface receptors act like an inbox for messages in the form of light energy, peptides, lipids, sugars, and proteins), or GPCR, family. GPCRs constitute a large protein family of receptors that detect molecules outside the cell and activate internal signal transduction pathways and cellular responses. GPCRs, are called seven-transmembrane receptors because they pass through the cell membrane seven times. Heterotrimeric G proteins are activated by GPCRs and are made up of three subunits, α, β and γ. G proteins are divided into four main classes: Gαs, Gαi, Gαq and Gα12. These proteins are activated depending on the ability of the G protein α-subunit, or Gα, to cycle between an inactive guanosine diphosphate, or GDP, bound conformation and an active guanosine triphosphate, or GTP, bound conformation that can modulate the activity of downstream effector-proteins. Additional receptors have been shown to bind cannabinoids: G protein-coupled receptor 55, or GPR55, several transient receptor potential, or TRP, channels (TRPV1, TRPV2, TRPA1, TRPM8), and glycine receptors.

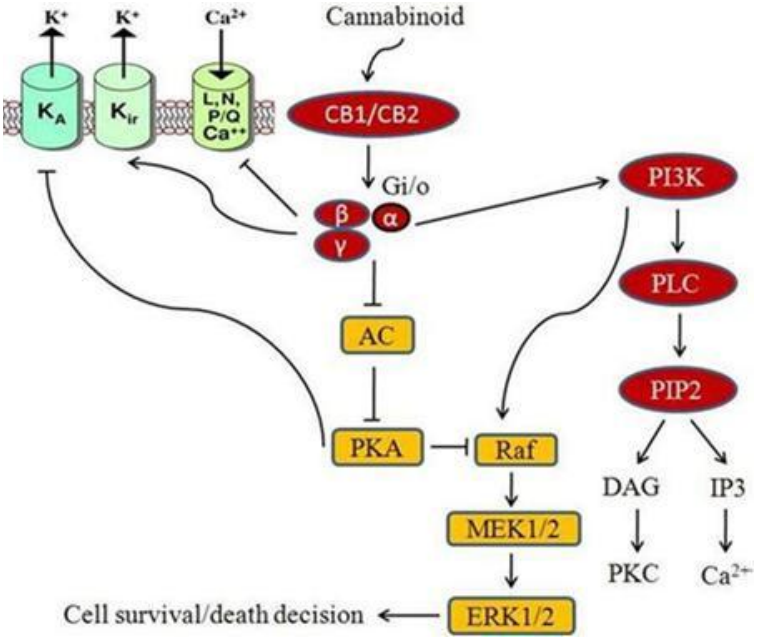

Figure 2. CB1 downstream signaling network. Adapted from Chakravarti et al., 2014.

Since most of the biological properties related to phytocannabinoids, a type of natural cannabinoid, rely on their interactions with receptors of the endocannabinoid system, it is crucial to define which receptors are expressed and activated in the target cells. As a result, we have developed a system with the capacity to identify ten cannabinoid receptors simultaneously and measure their expression levels using quantitative real-time PCR. We have applied this method in examining cells of the immune system, and more specifically, in monocytes, before and after differentiation to macrophages, or after stimulation to secrete cytokines. Using this methodology, we were able to identify a differential expression pattern of the receptors under different conditions.

To obtain a deep understanding on the mechanism of action of the cannabis strains, we applied our research system and established a unique study to research the response of 10 different receptors to Cannabis in RA patients, which aims to identify the specific cannabinoids receptors on the immune cells. The data from this study is expected to subsequently be used to set up a system for analyzing and matching the specific cannabis treatment to the specific cannabinoids receptors that are expressed in the patient's cells. We believe that if cannabinoid treatments correspond to the receptors in the patient's cells, the treatment may be more accurate for treating that specific patient's RA symptoms. We have identified cannabinoid receptors that are expressed on activated T cells from human donors (Helsinki # 033120-RNB). Our next objective is to determine the cannabinoid receptors expressed on neutrophils.

Aim 4. Establish a Phase 1 & 2B clinical trial according to FDA rules and regulations to study the effect of cannabis-based medical indications on RA.

Our goal for the treatment of RA is to achieve disease remission or low disease activity, or LDA. LDA is measured with several assessment metrics that are intended to measure the effect of the treatment on a number of physical phenomena that are connected to RA. These metrics include, but are not limited to: (i) Disease Activity Score based on assessment of 28 joints, or DAS28, patient's assessment, (ii) erythrocyte sedimentation rate (a common hematology test, and is a non-specific measure of inflammation) or C-reactive protein, or CRP, test, which is a blood test that measures the CRP in a person's blood, (iii) SDAI and CDAI (Simple and Complex Disease Activity Indices) as compared to DAS28, (iv) patient's and physician's assessment, including global assessment scores, or PtGA and PhGA, respectively (v) pain visual analogue scale and (vi) health assessment questionnaire disability index, or HAQ-DI.

Clinical Development Plan for RA Product Candidate

On December 23, 2024, we received clinical study results after a successful completion of the Study, evaluating the efficacy of the Raphael's Formula in patients with active RA. Citruslabs, a leading contract research organization, successfully completed this Study in the U.S. under IRB approval and in compliance with the FDA regulations and in accordance with applicable industry standards and regulations

The Study evaluated the impact of Raphael's Formula on RA related health outcomes in 12 adult participants, each of whom used 0.5 mL Raphael's Formula product daily over an 8-week period, completed questionnaires and attended their local diagnostics testing center for blood biomarker assessment at designated intervals. According to the Study results, the questionnaires results demonstrated significant improvement in certain health parameters, including pain levels, sleep quality and overall well-being, with certain parameters remaining significantly improved through the end of the Study.

The key findings from the Study results included a reduction in the Disease Activity Score (a comprehensive metric assessing RA disease activity), or DAS28, by 19.2%, reflecting a total decrease from high to moderate disease activity. A low DAS28 score indicates reduced disease activity and is a key goal in RA management. Additionally, the percentage of participants classified according to disease activity was evaluated and the findings included an increase in the percentage of participants classified as in remission from 0% at baseline to 16.67% at week 8, an increase in the percentage of participants classified as having low disease activity from 8.33% to 16.67% and a decreased in the percentage of participants classified as having high disease activity from 66.67% at baseline to 41.67% at week 8.

Additionally, participant perceptions were highly positive, with approximately 83.3% of participants willing to continue using the product and approximately 91.7% of participants indicating they would recommend Raphael's Formula to others with RA. Overall findings of the Study emphasize the clinical potential of Raphael's cannabinoid-based formula and suggest that it may have beneficial effects on symptom management and overall well-being for individuals with RA.

This study reinforces the Company's extensive preclinical research, which suggests that Raphael Pharmaceutical's formula effectively reduces key parameters of RA, thereby demonstrating potential to slow the progression of RA by acting as an anti-inflammatory agent.

We utilize a highly purified cannabinoid formulation derived from select non-psychoactive strains of cannabis with a anti-inflammatory potential. The formulation is designed to interact and communicate with the endocannabinoid system in the human body, activating cannabinoid receptors expressed by immune cells.

Pre-Clinical Studies for Treatment of Asthma

We are studying the potential of cannabis extracts to downregulate the hyperinflammation and the immunopathology in asthma patients. Our partners at Rambam have been conducting research on the use of cannabis to treat disorders with widespread inflammatory responses, such as RA and asthma. We hope that by decoding the cannabinoid mechanism of action during inflammatory storms, we can treat inflammation associated with asthma where conventional drugs and other therapies have failed.

In order to properly understand cannabis' effects on asthma, the Rambam team compiled its Biobank database. In generating the Biobank database, the Rambam team found what they believed to be a safe way to separate the white blood cells, including the immune cells, from verified patients. We believe that this is crucial as blood samples are the most accessible resource for continuous sampling (allowing for the understanding of biological processes during the disease) and to develop vaccines and drugs for treatment of the condition.

This study with our partners at Rambam, began in the pre-clinical level in immune cell models and, and was subject to positive results that exhibit downregulation of pro-inflammatory cytokines by cannabis extract. This study is expected to continue to a mouse model to analyze for lung inflammation, which resembles the immunopathology of asthma. We believe that our strategy to investigate the response of ex-vivo immune cells to cannabis extract together with the analysis of the *in-vivo* model for lung inflammations, will allow us to identify the medical cannabis extracts, if any, that have the potential to treat patients with asthma.

Our experiments have revealed a specific high-CBD strain-CBD-X that presents enhanced anti-inflammatory effects. Using cells derived from human donors (Helsinki Num. 044220-RNB) and a mouse model for asthma, we have found that this strain is effective in preventing cytokine storms. It reduces the secretion of IL6 and TNF alpha, as well as the inflammation in the mice's lungs, while also inhibiting the migration of immune cells to the lungs.

In October 2024, these findings were published by Rambam's research team in the scientific journal "Pharmaceuticals": "CBD-X extracts in asthma management: Reducing Th2-driven cytokine secretion and Neutrophil/Eosonophils activity".

Aim 5. Development of a new, patentable formulation that combines purified cannabinoids to treat rheumatoid diseases.

In October 2022, we entered into an agreement with Rambam for the development of a new, patentable formulation that combines purified cannabinoids to treat rheumatoid diseases.

The overall objective of this study is to identify a novel cannabinoid based patentable formulation to treat Rheumatoid diseases. Specifically, to investigate combination of purified cannabinoids to downregulate inflammation related to Rheumatoid diseases. We propose to base our study on data derived from Dr. Igal Louria-Hayon's studies (Helsinki # 0442-20-RMB) on the evaluation of the immune regulation properties of cannabinoids on the immune system and the data derived from the cannabinoids receptors study (Helsinki # 0331-20-RMB). We will analyze the activation of cannabinoid receptors on mouse models and will study the role of purified cannabinoid as a potential to develop a novel patentable formulation to treat RA.

Competition and Competitive Position

The pharmaceutical industry is characterized by rapidly advancing technologies and intense competition. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates for which we complete clinical development successfully and for which we receive marketing approval may compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have far greater marketing and research capabilities than us. We also face potential competition from academic institutions, government agencies and private and public research institutions, among others, which may in the future develop products to treat those diseases that we currently or, in the future, seek to treat. All of these companies and institutions may have product candidates in development that are or may become superior to our RA product candidate or any other product candidate that we may seek to develop. Our commercial opportunity would be reduced significantly if our competitors develop and commercialize products that are safer, more effective, and more convenient, have fewer side effects or are less expensive than our product candidates.

In addition, although our product candidates may, if approved, be considered advantageous to existing therapies, such as the use of corticosteroids and DMARDs for the treatment of RA, our target market may continue to use existing therapies.

However, we do believe, specifically with respect to our competitors not using cannabis in their pharmaceutical drug products that our use of, and experience with, cannabinoids provides us with a potential competitive advance. Our research has shown that the use of cannabinoids for the treatment of RA is justified based on its positive effect on pain, fatigue, sleep problems and its potential safety profile. Growing evidence on the anti-inflammatory effect of cannabinoids provide more strong ground for their use in the treatment of RA.

Although the use of any part of the cannabis plant in pharmaceutical drug products was once non-existent or minimal, in addition to approved pharmaceutical drug products that use parts of the cannabis plant (see "Item 1. Business - Overview" for additional information), we are aware that there is at least one plan for a multicenter randomized control trial on the use of medical cannabidiol in Danish patients with RA and Ankylosing Spondylitis (inflammatory joint and spine disease), as previously published in an issue of BMJ Open in 2019. As the medical benefits of cannabis become more well-known, we believe that we may face more competition from both new startup pharmaceutical and biotechnology companies and from well-funded and experienced organizations and it is therefore imperative that we face as few delays as possible in our pre and clinical development plan or we may otherwise face more competition.

The following table highlights the estimated cost that RA patients incur on an annual basis based on a 2017 report from the Canadian Agency for Drugs and Technologies in Health.

Drug Product	Strength	Dose Form	Price ($)	Recommended Dose	Annual Drug Cost ($)
Sarilumab (Kevzara)	150 mg/1.14 mL 200 mg/1.14 mL	Pre-filled syringe	700.0000	200 mg SC every two weeks	18,200
Abatacept SC (Orencia)	125 mg/mL	Pre-filled syringe	366.1000	125 mg weekly	19,037
Abatacept IV (Orencia)	250 mg/15 mL	Vial	490.0500	Patients < 60 kg: 500 mg Patients 60 to 100 kg: 750 mg Patients > 100 kg: 1,000 mg 500 to 1,000 mg at weeks 0, 2, and 4 then every 4 weeks	Year 1: 20,582 Thereafter: 19,112
Adalimumab SC (Humira)	40 mg/0.8 mL	Pre-filled syringe or pen	769.9700	40 mg every other week	20,019
Anakinra (Kineret)	100 mg	Pre-filled syringe	48.0571	100 mg daily	17,493
Certolizumab pegol (Cimzia)	200 mg/mL	Pre-filled syringe	664.5100	400 mg at weeks 0, 2 and 4 then 200 mg every 2 weeks	Year 1: 19,271 Thereafter: 17,277
Etanercept (Enbrel)	25 mg 50mg/mL	Vial Pre-filled syringe or auto-injector	202.9300 405.9850	50 mg weekly or two 25 mg doses on same day every week or every 3 or 4 days	21,105 21,111
Entanercept (Brenzys)	50 mg/mL	Pre-filled syringe	305.0000[d]	50 mg weekly	15,860
Golimumab SC (Simponi)	50 mg/0.5 mL	Pre-filled syringe or auto-injector	1,555.17	50 mg monthly	18,662
Golimumab IV (Simponi)	50 mg/4 mL	Vial	849.5000[b]	2 mg/kg at weeks 0 and 4, then every 8 weeks thereafter	Year 1:17,829 Thereafter: 16,565
Infliximab (Remicade)	100 mg	Vial	987.5600	3 mg/kg at weeks 0, 2, and 6, then every 8 weeks thereafter	Year 1: 23,701 Thereafter: 19,257 10 mg/kg every 4 weeks: $102,706 annually
Infliximab (Inflectra)	100 mg	Vial	525.0000	Depending on clinical response, dose can be increased to 10 mg/kg and/or up to every four weeks	Year 1: 12,600[b] Thereafter: 10,238[b] 10 mg/kg every 4 weeks: $54,600 annually[15]
Rituximab (Rituxan)	100 mg/10 mL 500 mg/50 mL	Vial	466.3200 2,331.61	A course consists of 1,000 mg infusions at weeks 0 and 2. Reassess for retreatment at week 26, no sooner than 16 weeks after previous	18,653 assumes 2 courses Per course: 9,326
Tocilizumab SC (Actemra)	162 mg/0.9 mL	Pre-filled syringe	355.0000	Patients < 100 kg: 162 mg SC every two weeks, increasing to weekly based on clinical response. Patients ≥ 100 kg: 162 mg SC weekly	Every two weeks: 9,230 Weekly: 18,460
Tocilizumab IV (Actemra)	80 mg/4 mL 200 mg/10mL 400 mg/20 mL	Vial	180.8100 452.0300 904.0600	4 mg/kg every 4 weeks followed by an increase to 8 mg/kg based on clinical response	4 mg/kg: 10,577 8 mg/kg: 17,629
Tofacitinib (Xeljanz)	5 mg	Tablet	23.5585	5 mg p.o. twice daily	17,151

IV = intravenous; p.o. = orally; SC = subcutaneous.

Although there can be no guarantee, we believe that our RA product candidate, if approved for commercialization by regulators, will be available to patients at a lower price than that of other available treatments.

With respect to our development of a product candidate to treat inflammation associated with COVID-19, we will face competition from major pharmaceutical companies that have developed or that will develop vaccines, along with other companies and organizations that have or will develop therapies or pharmaceutical drug products aimed at treating the underlying symptoms of COVID-19.

Cultivation of our API

In October 2020, we entered into an engagement agreement with Way of Life Cannabis Ltd., or Wolc, pursuant to which, subject to its completing the Share Exchange, Raphael Israel is scheduled to be provided with up to 15 liters of CBD oil, from a strain of cannabis of our selection, during a term of 18 months, to be provided in two to three deliveries of between one to seven liters of CBD oil. In accordance with the agreement with Wolc, we have agreed to issue to certain persons affiliated with Wolc 3% of our issued and outstanding share capital as of the date of the Share Exchange, to be provided in three equal issuances; provided, however, that such persons may elect to receive a cash payment of $100,000 instead of any one issuance of our shares. In addition to the issuance of shares, we have also agreed to pay Wolc a royalty fee equal to 15% of net income royalties generated from sales of our pharmaceutical drug products that are developed at Rambam in Israel.

At this time, we only require a limited amount of our API for our studies and trials and, to date, we have received oil extracted from high CBD strains, from Wolc in the amounts that we require in order to conduct our pre-clinical trials. Pursuant to our agreement with Wolc, pending FDA approval of any of our product candidates, Wolc is expected to transfer seeds used for the FDA-approved product candidate to growers in California, Colorado and Oklahoma. Wolc is a fully licensed Israeli cannabis company focused on growing, cultivating and manufacturing cannabis medical oil, located in Aviel, Israel. As an owner and operator of green houses for growing organic cannabis plants and a GMP manufacturing facility located in Netanya, Israel, we intend to utilize, pursuant to an agreement between the parties, Wolc for the growing and cultivation of the CBD oil needed for our product candidates.

We believe that our current agreement with Wolc will provide us with sufficient amounts of CBD oil in order to complete our clinical development and for initial sales of our pharmaceutical drug products. In the future, as our demand for pharmaceutical products grows, if ever, we may need to find additional partners that may provide us with sufficient amounts of CBD oil and/or amend or terminate our engagement with Wolc.

Pursuant to the agreement with Wolc, on July 27, 2022, the Company issued 100,500 shares of common stock to Wolc. The value of such issued shares was based on the value of the service provided by Wolc, which amounted to $100,000. In June 2023, the Company issued 201,000 shares of common stock to Wolc, in connection with the services agreement dated October 2020. The value of the shares issued was based on the value of the service provided, which amounted to $200,000.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities for final manufacture. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing of any pharmaceutical drug products for which we receive regulatory approval.

Commercialization Plan

Subject to the receipt of regulatory approval to commercialize our pharmaceutical product candidates, our goal is to distribute our approved formulas to good manufacturing practice, or GMP, approved medical cannabis manufacturers and global medical cannabis distributors. Depending on the expertise of the distributors, we expect the licensing agreements to provide us with royalty-based payments for the sale of each of our approved pharmaceutical drug products. In Israel, pursuant to our agreement with Wolc, the parties are expected to negotiate an exclusive distribution agreement in Israel, pursuant to which Wolc will be the exclusive supplier of any approved pharmaceutical drug products of the Company in Israel.

Although we expect government regulation of pharmaceutical products derived from cannabis to develop over the next few years, we may be limited in the manner in which we commercialize our product candidates. We fully intend on being fully complaint with local and state-wide government regulations and therefore we expect to enter into licensing agreements with vendors only if such vendor may legally distribute our product candidate within the region for which they have obtained a license from us to sell our pharmaceutical product.

Intellectual Property

We do not currently have any patents, and currently rely on our know-how and trade secrets. However, subject to the completion of our pre-clinical trial for our RA product candidate, and prior to the completion of our clinical development plan, we intend on seeking patent protection in the U.S. and/or internationally for such product candidate and, potentially for other product candidates that we may seek to develop. Our policy is to pursue, maintain and defend patent rights developed internally and to protect the technology, inventions and improvements that are commercially important to the development of our business.

Governmental Regulation

Government authorities in the U,S., at the federal, state and local levels, and in other countries and jurisdictions, including the EU, extensively regulate, among other things, the research, development, testing, manufacture, sales, pricing, reimbursement, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of biopharmaceutical products. The processes for obtaining marketing approvals in the U.S. and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

We are a research and development company collaborating with our partners at Rambam to research and develop our COVID-19, asthma and RA product candidates. We do not grow or cultivate cannabis and we have no physical connection to the raw cannabis materials, which is shipped directly to Rambam. Pre-clinical research, animal models and clinical trials are sponsored by us through our agreement with Rambam. Such research and trials are being done by Rambam's medical team, researchers, doctors and professors, as well as by Citrus Labs, which is a CRO Company and a leader in clinical trials for biotech companies, located in Las Vegas , Nevada, U.S., and conducting clinical trials under the supervision of IRB and in accordance with FDA regulations. An IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities for final manufacturing of our products. We do not distribute, and we have no plans to distribute, our products. Once we receive regulatory approval for our products, we intend to license to our future candidate partners the rights to commercialize our medical formulas. Our future candidate partners will be responsible for the manufacturing, distributing, promoting, and marketing of medical indications. We intend to engage with candidate partners that are GMP approved professionals, well established and experienced medical manufacturers and distributors in the U.S. and other countries.

Our future candidate partners will be entirely responsible and liable for regulatory compliance, including but not limited to cannabis growing and cultivation, GMP manufacturing, distribution, advertising and promotional regulations, marketing, labeling, post-market approval reporting and record keeping.

We intend to hire and train quality assurance professional that will inspect periodically the facilities of our future candidate partners as well as the methods of production, marketing and distribution under applicable governmental regulatory guidelines.

U.S. Cannabis Market

The emergence of the legal cannabis sector in the U.S., both for medical and adult use, has been rapid as more states adopt regulations for its production and sale. A majority of Americans now live in a state where cannabis is legal in some form and almost a quarter of the population lives in states in which both medical and recreational use is permitted as a matter of, and in accordance with, applicable state and local laws. According to Fortune Business Insights, the global legal marijuana market is anticipated to reach a value of $444.34 billion by the end of 2030, from $10.60 billion in 2018. The market is predicted to rise at a compounded annual growth rate of 34.03% during the period 2022 to 2030.

The use of cannabis and cannabis derivatives to treat or alleviate the symptoms of a wide variety of chronic conditions, while not recognized by the FDA, has been accepted by a majority of citizens with a growing acceptance by the medical community. A review of the research, published in 2015 in the Journal of the American Medical Association, found solid evidence that cannabis can treat pain and muscle spasms. The pain component is particularly important, because other studies have suggested that cannabis can replace pain patients' use of highly addictive, potentially deadly opiates. Although hemp, defined as cannabis and derivatives of cannabis with not more than 0.3% THC, has been descheduled from the Controlled Substances Act, the FDA has regulatory oversight over foods, drugs, cosmetics containing cannabis under the Food, Drug and Cosmetics Act of 1938. All references to the use of CBD in our product candidates refer to CBD strains with less than 0.3% of THC. It is possible that as the federal and state agencies legalize certain products, the FDA may issue rules and regulations, including good manufacturing practices related to the growth, cultivation, harvesting and processing of such products, even if they are not marketed as drugs. It is possible that the FDA would require that facilities where medical-use cannabis is grown to register with the FDA and comply with certain federally prescribed regulations, certifications, testing, or other requirements. The potential impact on the cannabis industry is uncertain and could include the imposition of new costs, requirements, and prohibitions.

Although we are not currently engaged and do not expect to be engaged in the production or distribution of medical marijuana products, the FDA has jurisdiction over our flower, oil, vape and edible products, among others. The FDA is currently taking action in the form of Warning Letters, but may also take more extreme enforcement such as recalls, disgorgement or penalties.

Polls conducted throughout the U.S. consistently show overwhelming support for the legalization of medical cannabis, together with strong majority support for the full legalization of recreational adult-use cannabis. According to a Pew Research Center survey, as of November 11, 2019, "Around nine-in-ten Americans favor legalization for recreational or medical purposes" and "Only 8% say it should not be legal." These are large increases in public support over the past 40 years in favor of legal cannabis use.

As of the date of this Annual Report, in the U.S., cannabis is legal in 40 of 50 states for medical use and 24 states for recreational use. At the federal level, cannabis is classified as a Schedule I drug under the Controlled Substances Act, or the CSA, determined to have a high potential for abuse and no accepted medical use, prohibiting its use for any purpose, according to Marijuana Policy Project. Despite this prohibition, federal law is generally not enforced against the possession, cultivation, or intrastate distribution of cannabis in states where such activity has been legalized, according to "Attorney General Merrick Garland on DOJ's New Marijuana Policy", published on March 16, 2023 in the National Law Review. The medical use of cannabis is legal with a medical recommendation in 40 states, 4 out of 5 permanently inhabited U.S. territories, and the federal District of Columbia cannabis-based products in treating or addressing therapeutic needs, and assuming that research findings demonstrate that such products are effective in doing so, management believes that the size of the U.S. medical cannabis market will also continue to grow as more states expand their medical marijuana programs and new states legalize medical marijuana.

Notwithstanding that 40 states and the District of Columbia have now legalized adult-use and/or medical cannabis, cannabis remains illegal under U.S. federal law with cannabis listed as a Schedule I drug under the CSA.

Government Regulation and Product Approval

We are a preclinical to early clinical stage pharmaceutical company that intends to engage third parties to test, register and license the rights to commercialize our products in the U.S. and other jurisdictions. Such third parties may be subject to extensive regulation by various regulatory authorities. The primary regulatory agency in the U.S. is the FDA and in Europe it is the EMA. Along with these two, there are other federal, state, and local regulatory agencies. In the U.S., the Federal Food, Drug, and Cosmetic Act of 1938, or the FDCA, and its implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. Although the discussion below focuses on regulation in the U.S., we anticipate seeking approval for, and marketing of, our products in other countries.

Generally, our activities outside the U.S. will be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences. Approval in the U.S., Canada, or Europe does not assure approval by other regulatory agencies, although often test results from one country may be used in applications for regulatory approval in another country. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way through the EMA but country specific regulation remains essential in many respects. A major difference in Europe, when compared to Canada and the U.S., is with the approval process. In Europe, there are different procedures that can be used to gain marketing authorization in the European Union. The first procedure is referred to as the centralized procedure and requires that a single application be submitted to the EMA and, if approved, allows marketing in all countries of the European Union. The centralized procedure is mandatory for certain types of medicines and optional for others. The second procedure is referred to as national authorization and has two options; the first is referred to as the mutual recognition procedure and requires that approval is gained from one member state, after which a request is made to the other member states to mutually recognize the approval, whilst the second is referred to as the decentralized procedure which requires a member state to act as the reference member state through a simultaneous application made to other member states.

The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and may not be successful. See “Item 1A. Risk Factors” for additional information.

U.S. Government Regulation

The FDA is the main regulatory body that controls pharmaceuticals in the U.S, and its regulatory authority is based in the FDCA. Pharmaceutical products are also subject to other federal, state and local statutes. A failure to comply explicitly with any requirements during the product development, approval, or post approval periods, may lead to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an IRB of a hold on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution.

The steps required before a new drug may be marketed in the U.S. generally include:

- completion of preclinical studies, animal studies and formulation studies in compliance with the FDA’s GLP regulations;
- submission to the FDA of an IND application to support human clinical testing in the U.S.;
- approval by an IRB at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with federal regulations and with GCP regulations to establish the safety and efficacy of the investigational product candidate for each target indication;
- submission of a new drug application, or NDA, to the FDA;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the investigational product candidate is produced to assess compliance with cGMP, and to assure that the facilities, methods and controls are adequate; and
- FDA review and approval of the NDA.

Clinical Trials and the FDA Approval Process

An IND is a request for authorization from the FDA to administer an investigational product candidate to humans. This authorization is required before interstate shipping and administration of any new drug product to humans in the U.S. that is not the subject of an approved NDA. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease under study, under the supervision of qualified investigators following GCPs, an international standard intended to protect the rights and health of patients with the disease under study and define the roles of clinical trial sponsors, administrators and monitors. Clinical trials are conducted under protocols that detail the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. Each protocol involving testing on patients in the U.S. and subsequent protocol amendments must be submitted to the FDA as part of the IND. Rambam has not yet submitted an IND in the U.S. for any clinical programs.

The clinical investigation of an investigational product candidate is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or some may be combined. The three phases of clinical investigation are as follows:

- Phase I. Phase I includes the initial introduction of an investigation product candidate into humans. Phase I clinical trials may be conducted in patients with the target disease or condition, or in healthy volunteers. These studies are designed to evaluate the safety, metabolism, pharmacokinetics, or “PK”, and pharmacologic actions of the investigational product candidate in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase I clinical trials, sufficient information about the investigational product candidate’s PK and pharmacological effects may be obtained to inform the design of Phase II clinical trials. The total number of participants included in Phase I clinical trials varies but is generally in the range of 20 to 80. We expect that it will take approximately 3 months for Rambam to complete Phase I.

- Phase II. Phase II includes the controlled clinical trials conducted to evaluate the effectiveness of the investigational product candidate for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the product candidate. Phase II clinical trials are typically well controlled, closely monitored, conducted in a limited subject population and usually involving no more than several hundred participants. Rambam is planning to divide Phase II into two parts:

- Phase IIa. Phase IIa will include a randomized, double-blind, placebo-controlled, multiple ascending dose study in Israel to determine the maximum CBD extract administered sublingually to assess the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy for at least 4 weeks in RA patients in the presence of concurrent active therapies, such as non-steroidal anti-inflammatory drugs, or NSAIDs, and steroids. We expect that Phase IIa will take approximately 6 months.

- Phase IIb. Phase IIb will include IND submission for randomized, multi center double blinded, placebo-controlled dose response finding, or DRF, study for at least 12 weeks with either CBD extract or placebo administered sublingually in the presence of concurrent active therapies such as NSAIDs and steroids. This study will include 300-400 patients (80-100 patients per cohort) to study safety and efficacy of the product in active RA patients. We expect that Phase IIb will take approximately 18 months.

- Phase III. Phase III clinical trials are controlled clinical trials conducted in an expanded subject population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the investigational product candidate has been obtained, are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product candidate, and to provide an adequate basis for drug approval. Phase III clinical trials usually involve several hundred to several thousand participants. In most cases, the FDA requires two adequate and well controlled Phase III clinical trials to demonstrate the efficacy of the drug.

The decision to terminate development of an investigational product candidate may be made by either a health authority body, such as the FDA or IRB/ethics committees, or by a company for various reasons. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor or the clinical monitoring board. This group provides authorization for whether or not a trial may move forward at designated check points. These decisions are based on the limited access to data from the ongoing trial. The suspension or termination of development can occur during any phase of clinical trials if it is determined that the participants or patients are being exposed to an unacceptable health risk. In addition, there are requirements for the registration of ongoing clinical trials of Product Candidates on public registries and the disclosure of certain information pertaining to the trials as well as clinical trial results after completion.

New Drug Applications

In order to obtain approval to market a drug in the U.S., a marketing application must be submitted to the FDA that provides data establishing the safety and effectiveness of the product candidate for the proposed indication. The application includes all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company sponsored clinical trials intended to test the safety and effectiveness of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational product candidate to the satisfaction of the FDA. In most cases, the NDA must be accompanied by a substantial user fee; there may be some instances in which the user fee is waived. The FDA will initially review the NDA for completeness before it accepts the NDA for filing. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. After the NDA submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review Product Candidates are reviewed within ten to twelve months. The FDA can extend this review by three months to consider certain late submitted information or information intended to clarify information already provided in the submission. The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP. The FDA may refer applications for novel Product Candidates that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. Product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA regulated products, including prescription drugs, are required to register and disclose certain clinical trial information (though not specifically required for Phase I trials) on a public website maintained by the U.S. National Institutes of Health, or "NIH". Information related to the product, patient population, phase of investigation, study sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. Disclosure of the results of these trials can be delayed until the product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the design and progress of our development programs.

Advertising and Promotion

The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling (package insert) approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses - that is, uses not approved by the FDA and, therefore, not described in the drug's labeling - because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses.

Post-Approval Regulations

After regulatory approval of a drug is obtained, a company is required to comply with a number of post-approval requirements. For example, as a condition of approval of an NDA, the FDA may require post-marketing testing, including Phase IV clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, as a holder of an approved NDA, a company would be required to report adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of its products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to assure and preserve the long-term stability of the drug or biological product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural and substantive record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Controlled Substances

The CSA and its implementing regulations establish a "closed system" of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the DEA, which is the federal agency responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

Facilities that research, manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substance schedule(s). For example, separate registrations are required for importation and manufacturing activities, and each registration authorizes which schedules of controlled substances the registrant may handle. However, certain coincident activities are permitted without obtaining a separate DEA registration, such as distribution of controlled substances by the manufacturer that produces them.

The DEA categorizes controlled substances into one of five schedules - Schedule I, II, III, IV, or V- with varying qualifications for listing in each schedule. Schedule I substances by definition have a high potential for abuse, have no currently "accepted medical use" in treatment in the U.S. and lack accepted safety for use under medical supervision. They may be used only in federally approved research programs and may not be marketed or sold for dispensing to patients in the U.S.. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence. The regulatory requirements are more restrictive for Schedule II substances than Schedule III substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist in most situations, and cannot be refilled. Once FDA has approved a medical use for Schedule I drugs, the DEA must reschedule the drug. For example, after FDA approval for Epidiolex®, a purified CBD oil, for the treatment of two rare forms of epilepsy, DEA placed it in Schedule V. Further, on April 6, 2020, GW Pharma announced that Epidiolex® was descheduled by the DEA and is no longer considered a controlled substance.

The DEA inspects all manufacturing facilities to review security, record keeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. Manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic, and submit import or export declarations for Schedule III, IV and V non-narcotics.

For drugs manufactured in the U.S., the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the U.S. based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. The quotas apply equally to the manufacturing of the API and production of dosage forms.

The states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State Authorities, including Boards of Pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

Cannabinoids as a Controlled Substance

Cannabinoids are subject to the United Nations Single Convention on Narcotic Drugs (1961) adopted by numerous countries globally, which prohibits the production and supply of specific drugs, except for scientific and research purposes. Under the current UN definition, Cannabis extracts and tinctures are controlled substances. Individual countries (and sometimes jurisdictions within countries) are rapidly changing how they interpret and apply the international rules. Currently there is a broad spectrum of legal statuses based on strength, source and intended use. We are closely monitoring these changes. We expect that there may be different requirements in each region where we have clinical sites.

Several Cannabis-related drugs were placed in lower schedules once they were approved as drugs. For example, the US DEA reduced Epidiolex® (CBD) to Schedule V after it was approved for treatment of two rare forms of childhood epilepsy. In April 2020, the DEA descheduled Epidiolex® entirely.

The passage of the Farm Bill in December 2018 legalized the cultivation of hemp in the U.S. and the production of hemp-derived non-THC cannabinoids, removing these products from the CSA. Our products use oil extracted from CBD strains, containing <0.3% THC.

We plan to engage third parties to conduct clinical trials for our product candidates outside the U.S., subject to regulatory approval. As a result, such third parties will also be subject to controlled substance laws and regulations from the various other regulatory agencies in other countries where we develop, manufacture or commercialize our product candidates in the future.

Marketing Exclusivity

Upon NDA approval of a new chemical entity, which for this purpose is defined as a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot approve any abbreviated new drug application, or ANDA, seeking approval of a generic version of that drug. Certain changes to the scope of an approval for a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA for a generic drug that includes the change. A Section 505(b)(2) NDA may be eligible for three-year marketing exclusivity, assuming the NDA includes reports of new clinical studies (other than bioequivalence studies) essential to the approval of the NDA.

An ANDA may be submitted one year before marketing exclusivity expires if a Paragraph IV certification is filed. In this case, the 30 months stay, if applicable, runs from the end of the five-year marketing exclusivity period. If there is no listed patent in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

Additionally, six months of marketing exclusivity in the U.S. is available under Section 505A of the FDCA if, in response to a written request from the FDA, a sponsor submits and the agency accepts requested information relating to the use of the approved drug in the pediatric population. This six-month pediatric exclusivity period is added to any existing patent or non-patent exclusivity period for which the drug product is eligible.

Patent Term Extension

The term of a patent that covers an FDA approved drug may be eligible for patent-term extension, which provides patent-term restoration as compensation for the patent term lost during the FDA regulatory review process. The U.S. Federal Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent-term extension of up to five years beyond the expiration of the patent. The length of the patent-term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug.

European and Other International Government Regulation

In addition to regulations in the U.S. and Canada, our third-party licensees will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, such third-party licensees must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Some countries outside of the U.S. have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed.

The UK was previously in a transition period until December 31, 2020, during which time it continued to abide by the EU regulatory processes; however, they may adopt different or additional procedures.

To obtain regulatory approval to commercialize a new drug under EU regulatory systems, it is required to submit a MAA. The MAA is similar to the NDA, with the exception of, among other things, country-specific document requirements.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with GCP, applicable regulatory requirements of each jurisdiction and the medical ethics principles that have their origin in the Declaration of Helsinki.

Compliance

During all phases of development (pre- and post-marketing), failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the FDA's imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention or refusal to permit the import or export of products, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect.

Other Special Regulatory Procedures

Priority Review (U.S.) and Accelerated Assessment (European Union)

Based on results of the Phase III clinical trial(s) submitted in an NDA, upon the request of an applicant, a priority review designation may be granted to a product by the FDA, which sets the target date for FDA action on the application at six months from the FDA's decision on priority review application, or eight months from the NDA filing. Priority review is given where preliminary estimates indicate that a product, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists, or a significant improvement compared to marketed products is possible. If criteria are not met for priority review, the standard FDA review period is ten months from the FDA's decision on priority review application, or 12 months from the NDA filing. The priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a MAA is 210 days (excluding "clock stops," when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use, or "CHMP"). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, which takes into consideration: the seriousness of the disease (e.g., disabling or life-threatening diseases); the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days.

Accelerated Approval

Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit. This approval mechanism is provided for under 21CRF314 Subpart H and 21CRF601 Subpart E. In this case, clinical trials are conducted in which a surrogate endpoint is used as the primary outcome for approval. A surrogate endpoint is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. This surrogate endpoint substitutes for a direct measurement of how a patient feels, functions, or survives and is considered reasonably likely to predict clinical benefit. Such surrogate endpoints may be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to confirm the effect on the clinical endpoint. When the Phase IV commitment is successfully completed, the biomarker is deemed to be a surrogate endpoint. Failure to conduct required post-approval studies or confirm a clinical benefit during post-marketing studies, could lead the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Other Healthcare Laws and Compliance Requirements

In the U.S., our activities are potentially subject to additional regulation by various federal, state and local authorities in addition to the FDA, including, among others, the Centers for Medicare and Medicaid Services, other divisions of HHS, the DOJ, and individual U.S. Attorney offices within the DOJ and state and local governments.

Compliance with Environmental Laws

Other than our ongoing research and development, our only operations consist of our pre-clinical trial being in conducted in Israel for RA, which may further our COVID-19 product candidate. At this time, compliance with environmental laws in Israel, where we conduct our operations, has not been a burden and has not required from us the use of material resources or capital expenditures.

Employees

As of December 31, 2024, we do not have any employees. Our officers are engaged through consulting agreements.

Corporate Information

Easy Energy was incorporated under the laws of the State of Nevada in May 2017. On May 14, 2021, Raphael Israel and Easy Energy completed the Share Exchange, pursuant to which we changed our name to Raphael Pharmaceutical Inc..Our registered address is 4 Lui Paster, Tel Aviv-Jaffa, Israel 6803605. Our website address is https://www.raphaelpharmaceutical.com/. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report, and you should not consider information on our website to be part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference. The Securities and Exchange Commission, or SEC, also maintains an Internet website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through the SEC's website at http://www.sec.gov.

Item 1A. Risk Factors.

An investment in our securities carries a significant degree of risk. You should carefully consider the following risks, as well as the other information contained in this Annual Report, including our historical financial statements and related notes included elsewhere in this Annual Report, before you decide to purchase our securities. Additional risks and uncertainties that we are unaware of may become important factors that affect us. If any of the following events occur, our business, financial conditions and operating results may be materially and adversely affected. In that event, the trading price of our common stock and warrants may decline, and you could lose all or part of your investment.

We may not be successful in preventing the material adverse effects that any of the following risks and uncertainties may cause. These potential risks and uncertainties may not be a complete list of the risks and uncertainties facing us. There may be additional risks and uncertainties that we are presently unaware of, or presently consider immaterial, that may become material in the future and have a material adverse effect on us. You could lose all or a significant portion of your investment due to any of these risks and uncertainties.

Summary Risk Factors

Our business is subject to a number of risks, including risks that may adversely affect our business, financial condition and results of operations. These risks are discussed more fully below and include, but are not limited to, risks related to:

- We have a limited operating history and we have incurred significant operating losses since our inception, and anticipate that we will incur continued losses for the foreseeable future.
- We have not generated revenue from any product candidate and may never be profitable.
- We expect that we will need to raise substantial additional funding before we can expect to complete the development of our RA product candidate or any other product candidate. This additional financing may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product candidate development efforts or other operations.
- The lack of an active trading market could adversely impact our ability to raise working capital and adversely impact our ability to continue operations.
- We are heavily dependent on the success of our product candidates, which are in various stages of pre-clinical development. We cannot give any assurance that any of our product candidates will proceed to clinical development or that they will receive regulatory approval, which is necessary before they can be commercialized.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.
- We hold no patents on our products, and our business employs proprietary technology (know-how) and information may be difficult to protect and/or infringe on the intellectual property rights of third parties.
- We manage our business through a small number of officers and key consultants.

- We will need to expand our organization and we may experience difficulties in recruiting needed additional employees and consultants, which could disrupt our operations.

- We rely on third parties to conduct our preclinical and, in the future, clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

- We will rely on third parties to grow and provide us with our active pharmaceutical ingredient, or API, and formulations. Our business could be harmed if those third parties fail to provide us with sufficient quantities of our needed supplies, or fail to do so at acceptable quality levels or prices.

- We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such product candidates and the commercialization of any products, if approved, could be stopped, delayed, or made less profitable if any such third party fails to provide with sufficient quantities of product candidates or products, or fails to do so at acceptable quality levels or prices, or fails to maintain or achieve satisfactory regulatory compliance.

- We and our collaborators and contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

- Our executive officer, directors and certain stockholders who are beneficial owners of 5% or more of our outstanding Common Stock possess the majority of our voting power, and through this ownership, have the ability to control our Company and our corporate actions.

- Investors may have difficulty in reselling their shares due to the substantial lack of liquidity of our Common Stock.

- Because we previously had our registration with the SEC revoked and because our business operations resulted from public by means of a “reverse merger,” we may not be able to attract the attention of major brokerage firms.

- As a former shell company, resales of shares of our restricted Common Stock in reliance on Rule 144 of the Securities Act are subject to the requirements of Rule 144(i).

- Our headquarters and other significant operations are located in Israel, and, therefore, our results may be adversely affected by political, economic and military instability in Israel.

- Conditions in Israel, including the armed conflict between Israel and Hamas, Hezbollah and other terrorist organizations from the Gaza Strip and Lebanon.

Risks Related to Our Financial Condition and Capital Requirements

We have a limited operating history and we have incurred significant operating losses since our inception, and anticipate that we will incur continued losses for the foreseeable future.

We are an emerging pharmaceutical research and clinical development company with a limited operating history in our industry. Before the Share Exchange, we did not have any operations dating back to 2011. To date, we have focused almost exclusively on developing our RA product candidate. Raphael Israel has funded its operations to date primarily through proceeds from investors and from its own resources. Other than the funding that Easy Energy received, and which was lent to Raphael Israel after the closing of the Share Exchange, Easy Energy has had no sources of funding since ceasing its operations in 2011. We have only a limited operating history in our current industry upon which you can evaluate our business and prospects. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical industry. To date, we have not generated revenue from the sale of our product candidates (see Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” for additional information). We incurred losses in each year since our inception and, while operational, we have never been profitable and have incurred losses since inception. We expect to continue to incur losses until, and if, a product candidate that we are developing, such as our RA product candidate, receives approval from regulators for commercialization. Our net loss attributable to holders of our ordinary shares for the years ended December 31, 2024 and 2023 was approximately $1.47 million and $1.38 million, respectively. As of December 31, 2024, we had an accumulated deficit of approximately $8.89 million. Substantially all of our operating losses resulted from costs incurred in connection with our development program and from general and administrative costs associated with our operations.

We expect our research and development expenses to increase in connection with our planned preclinical and clinical trials. In addition, even if we obtain marketing approval for any current or future product candidate, we will likely incur significant business development expenses as we seek to commercialize such products, as well as continued research and development expenses. Furthermore, we expect to incur additional costs associated with operating as a reporting company, which we estimate will be at least tens of thousands of dollars annually. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We expect to continue to incur significant losses until we are able to commercialize our product candidates, which we may not be successful in achieving. We anticipate that our expenses will increase substantially if and as we:

- continue the research and development of our RA product candidate or any other product candidate;
- expand the scope of our current clinical studies for our RA product candidate or any other product candidate;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel; and
- create additional infrastructure to support our operations as a reporting company and our product candidate development and planned future commercialization efforts.

We have not generated revenue from any product candidate yet and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. We do not expect to generate significant revenue unless or until we obtain marketing approval of, and commercialize, our RA product candidate or any other product candidate that we may seek to develop. Our ability to generate future revenue from product candidate sales depends heavily on our success in many areas, including but not limited to:

- obtaining favorable results from and progress the pre-clinical and clinical development of our product candidate(s);
- developing and obtaining regulatory approval for registration studies protocols for our product candidate(s);
- subject to successful completion of registration and clinical trials of our RA product candidate, applying for and obtaining marketing approval;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products, and at acceptable costs, to support market demand for our product candidates, if marketing approval is received;
- identifying, assessing, acquiring and/or developing new product candidate(s);
- accurately identifying demand for our product candidate(s);
- continued consumer interest in treatments to the symptoms of RA;
- obtaining market acceptance of our product candidates, if approved for marketing, as viable treatment options;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter; and
- attracting, hiring and retaining qualified personnel.

We do not believe that our current cash on hand will be sufficient to fund our projected operating requirements. This raises substantial doubt about our ability to continue as a going concern. In addition, the report of our independent registered public accounting firm contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

We do not believe that our current cash on hand will be sufficient to fund our projected operating requirements. This raises substantial doubt about our ability to continue as a going concern. In addition, the report of our independent registered public accounting firm on our audited financial statements for each of the two years ended December 31, 2024 and 2023 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. Our audited financial statements do not include any adjustments that might result from the outcome of the uncertainty regarding our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of equity or debt securities or otherwise. Further reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. If we cannot continue as a going concern, our investors may lose their entire investment in our Common Stock. Until we can generate significant revenues, if ever, we expect to satisfy our future cash needs through debt or equity financing. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate research or development plans for, or commercialization efforts with respect to our products.

We expect that we will need to raise substantial additional funding before we can expect to complete the development of our RA product candidate or any other product candidate. This additional financing may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product candidate development efforts or other operations.

As of December 31, 2024, our cash and cash equivalents were approximately $0.02 million and we had a negative working capital of $0.7 million and an accumulated deficit of $8.89 million. Based upon our currently expected level of operating expenditures, we expect that our existing cash and cash equivalents will only be sufficient to fund operations through the second quarter of 2025. In addition, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including but not limited to:

- our clinical trial results;
- the cost, timing and outcomes of seeking marketing approval of any product candidate for which we may seek marketing approval and the costs associated with our plans to have third parties commercialize any approved product candidate(s);
- the cost of filing and prosecuting patent applications and the cost of defending patents, if any;
- development of other early-stage development product candidates;
- subject to receipt of marketing approval, revenue received from sales of approved products, if any, in the future;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel; and
- the costs associated with being a reporting company.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all, during or after the COVID-19 pandemic. Moreover, the terms of any financing may adversely affect the holdings or the rights of holders of our securities and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the trading price of our shares to decline. The incurrence of indebtedness could result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable, and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Even if we believe that we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the development or commercialization, if any, of any product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

The lack of an active trading market could adversely impact our ability to raise working capital and adversely impact our ability to continue operations.

Our Common Stock is not currently traded on any national securities exchange and is traded on the over-the-counter market with quotations published on the OTC Markets Group, Inc.'s OTCQB tier Venture Market, or OTCQB, under the symbol "RAPH." Because our Common Stock is considered illiquid, we may find it more difficult to raise capital. If we are unable to raise sufficient capital in the future, we may not be able to have the resources to continue our normal operations. For additional information, see "Item 1A. Risk Factors - Risks Related to Ownership of Our Securities - Investors may have difficulty in reselling their shares due to the substantial lack of liquidity of our common stock."

Risks Related to Product Development, Regulatory Approval and Commercialization

We are heavily dependent on the success of our product candidates, which are in various stages of pre-clinical development. We cannot give any assurance that any of our product candidates will proceed to clinical development or that they will receive regulatory approval, which is necessary before they can be commercialized.

Since its inception, Raphael Israel has invested substantially all of its efforts and financial resources to design and develop its product candidates, including conducting preclinical studies and providing general and administrative support for these operations. Our future success is dependent on our ability to continue these operations, and more specifically, to successfully complete pre-clinical and clinical development of our product candidates, which will require coordination from applicable regulatory agencies, obtain regulatory approval for, and then successfully commercialize one or more product candidates for which we receive regulatory approval. We currently generate no revenue from, and we may never be able to generate revenue.

Our RA product candidate and the product candidate that we are seeking to develop for the treatment of inflammation associated with COVID-19 are both in pre-clinical development and will require clinical development (and in some cases additional pre-clinical development), management of non-clinical, clinical and manufacturing activities, regulatory approval, obtaining adequate manufacturing supply, building of a commercial organization and significant marketing efforts before we generate any revenue from product candidate sales. It may be months or years before a pivotal study is initiated, if at all. Any clinical trials in the U.S. will require the approval of an IND application by the FDA, and we cannot assure that we will obtain such approval in a timely manner, or at all. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

We as a company have never submitted marketing applications to the FDA or comparable foreign regulatory authorities. We cannot be certain that any of our product candidates will be successful in clinical studies or receive regulatory approval or what regulatory pathway the regulatory authorities shall designate for our product candidates. Further, our product candidates may not receive regulatory approval even if they are successful in clinical studies. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

We generally plan to seek regulatory approval to commercialize our product candidates in the U.S., the European Union, Israel and other foreign countries. To obtain regulatory approvals we must comply with the numerous and varying regulatory requirements of such countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical studies, commercial sales, pricing and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations would be negatively affected.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical studies and depends upon numerous factors. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's safety-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical studies;

- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of a new drug application, or NDA, in the U.S. or elsewhere;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical studies, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of pre-clinical studies and early clinical studies, if any are commenced, of our product candidates may not be predictive of the results of later-stage clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent advanced clinical studies. There is a high failure rate for drugs proceeding through clinical studies, and product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed satisfactorily through preclinical studies and initial clinical studies. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. We do not know whether any Phase 1, Phase 2, Phase 3 (if any) or other clinical studies we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain regulatory approval to market our product candidates.

We may find it difficult to enroll patients in our clinical studies. Difficulty in enrolling patients could delay or prevent clinical studies of our product candidates.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical studies if we encounter difficulties in enrollment.

Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical studies, the proximity and availability of clinical study sites for prospective patients and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential product candidates will be delayed.

If we experience delays in the completion or termination of any clinical study of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product candidate revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical studies will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product candidate sales and generate revenue. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates.

We may encounter substantial delays in our clinical studies, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, time consuming and uncertain as to outcome. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required IRB approval at each clinical study site;
- imposition of a clinical hold by regulatory agencies, after review of an IND, application, or equivalent application, or an inspection of our clinical study operations or study sites;
- delays in recruiting suitable patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's Good Clinical Practices, or GCP, requirements, or applicable regulatory guidelines in other countries;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- patients dropping out of a study;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding, or regulators requiring us, to conduct additional clinical studies or abandon product candidate development programs; and
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. We may also be required to conduct additional safety, efficacy and comparability studies before we will be allowed to start clinical studies with our repurposed drugs. Clinical study delays could also shorten any periods during which our product candidates have patent protection and may allow our competitors to bring product candidates to market before we do, which could impair our ability to obtain orphan exclusivity and successfully commercialize our product candidates and may harm our business and results of operations.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

The use of dronabinol has been associated with seizures, paranoia, rapid heart rate and unusual thoughts and behaviors. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive marketing label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Potential side effects of our cannabinoid-based treatments may include: asthenia, palpitations, tachycardia, vasodilation/facial flush, abdominal pain, nausea, vomiting, amnesia, anxiety/nervousness, ataxia, confusion, depersonalization, dizziness, euphoria, hallucinations, paranoid reaction, somnolence and abnormal thinking. Results of our studies may identify unacceptable severity and prevalence of these or other side effects. In such an event, our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications.

Drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the study or result in potential product candidate liability claims.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product candidates, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Even if we obtain regulatory approval for a product candidate, our product candidates will remain subject to regulatory scrutiny.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the U.S.. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, regulations and Quality System Regulation, or QSR. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP, QSR and adherence to commitments made in any NDA. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. We will also be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for our product candidates. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product candidate's approved label. As such, we may not promote our product candidates for indications or uses for which they do not have FDA approval. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product candidate, product candidate labeling or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our product candidates in general or in specific patient subsets. If original marketing approval were obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical study to confirm clinical benefit for our product candidates. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. Furthermore, any new legislation addressing drug safety issues could result in delays in product candidate development or commercialization or increased costs to assure compliance. Foreign regulatory authorities impose similar requirements.

If a regulatory agency discovers previously unknown problems with a product candidate, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product candidate is manufactured, or disagrees with the promotion, marketing or labeling of a product candidate, such regulatory agency may impose restrictions on that product candidate or us, including requiring withdrawal of the product candidate from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain product candidates, or require a product candidate recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

We are subject to numerous complex regulations and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.

The research, testing, development, manufacturing, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, marketing, distribution, possession and use of our product candidates, among other things, are subject to regulation by numerous governmental authorities in the U.S. and elsewhere. The FDA regulates drugs under the FDCA and implementing regulations. Noncompliance with any applicable regulatory requirements can result in refusal to approve product candidates for marketing, warning letters, product candidate recalls or seizure of product candidates, total or partial suspension of production, prohibitions or limitations on the commercial sale of product candidates or refusal to allow the entering into of federal and state supply contracts, fines, civil penalties and/or criminal prosecution. Additionally, the FDA and comparable governmental authorities have the authority to withdraw product candidate approvals that have been previously granted. Moreover, the regulatory requirements relating to our product candidates may change from time to time and it is impossible to predict what the impact of any such changes may be.

We are developing product candidates that are controlled substances as defined in the Controlled Substances Act of 1970, or CSA, which establishes, among other things, certain registration, production quotas, security, recordkeeping, reporting, import, export and other requirements administered by the Drug Enforcement Administration, or the DEA. The active ingredient in our product candidates is CBD, which, when derived from cannabis, is a Schedule V controlled substance, meaning that any drug containing it cannot be marketed before it receives regulatory approval from the FDA.

The manufacture, shipment, storage, sale and use, among other things, of controlled substances that are pharmaceutical product candidates are subject to a high degree of regulation. The DEA also conducts periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our product candidates as well. While some states automatically schedule a drug when the DEA does so, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product candidate for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product candidate. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

Our projections of both the number of people who have our target diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

We face intense competition and rapid technological change and the possibility that our competitors may discover, develop or commercialize therapies that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

The biotechnology and pharmaceutical industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our product candidates.

More established companies may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources. As a result of these factors, our competitors may have an advantage in marketing their approved products and may obtain regulatory approval of their product candidates before we are able to, which may limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and less expensive than ours, and may also be more successful than us in manufacturing and marketing their products. These advantages could materially impact our ability to develop and commercialize our product candidates successfully.

Our product candidates may also compete with medical and recreational marijuana, in markets where the recreational and/or medical use of marijuana is legal. There is support in the U.S. for further legalization of marijuana. In markets where recreational and/or medical marijuana is not legal, our product candidates may compete with marijuana purchased in the illegal drug market. We cannot assess the extent to which patients may utilize marijuana obtained illegally for the treatment of the indications for which we are developing our product candidates.

Even if we successfully develop our product candidates, and obtain marketing approval for them, other treatments or therapeutics may be preferred and we may not be successful in commercializing our product candidates or in bringing them to market.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than we do. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our product candidates will depend in part on the medical community, patients and third-party payors accepting our product candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the safety and efficacy of the product as demonstrated in clinical studies and potential advantages over competing treatments;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which approval is granted;
- relative convenience and ease of administration;
- the cost of treatment, particularly in relation to competing treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage and reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the product will not be fully known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the product candidates may require significant resources and may never be successful. If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, patients, third-party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The pricing, coverage and reimbursement of our product candidates, if approved, must be adequate to support our commercial infrastructure. Our per-patient prices must be sufficient to recover our development and manufacturing costs and potentially achieve profitability. Accordingly, the availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to be able to afford expensive treatments such as ours, assuming approval. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government authorities, private health insurers and other third-party payors. If coverage and reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the U.S., the principal decisions about coverage and reimbursement for new drugs are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for products such as ours.

Outside the U.S., international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for medicinal products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, was passed. The Affordable Care Act is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and the health insurance industry, impose new taxes and fees on the healthcare industry and impose additional health policy reforms. This law revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, the law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. While the U.S. Supreme Court upheld the constitutionality of most elements of the Affordable Care Act in 2012, other legal challenges are still pending final adjudication in several jurisdictions. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of the Affordable Care Act. At this time, it remains unclear whether there will be any changes made to the Affordable Care Act, whether to certain provisions or its entirety. We can provide no assurance that the Affordable Care Act, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

We continue to evaluate the effect that the Affordable Care Act has on our business. Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. However, the CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2031. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, on January 28, 2021, President Biden issued an executive order to initiate a special enrolment period from February 26, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. In addition, on August 16, 2022, President Biden signed the IRA into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. Affordable Care Act Additional legislative and regulatory changes and judicial challenges to the Affordable Care Act, its implementing regulations and guidance and its policies, remain possible.

It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and any healthcare reform measures of the Trump administration will impact the Affordable Care Act. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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, designed to encourage importation from other countries and bulk purchasing. The Affordable Care Act, as well as other federal, state and foreign healthcare reform measures that have been and may be adopted in the future, could harm our future revenues.

Risks Related to our Business and Operations

Reduced funding for the FDA and other government agencies and/or potentially shifting priorities under the new administration could hinder the FDA's and/or those other government agencies' ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products, provide feedback on clinical trials and development programs, meet with sponsors and otherwise review regulatory submissions 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, among other factors. Average review times at the agency may fluctuate as a result. In addition, government funding of other government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also increase the time necessary for new drugs to be reviewed and/or approved by necessary government agencies or to otherwise respond to regulatory submissions, which would adversely affect our business. For example, the Trump Administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs or treatments. Additionally, over the last several years, the US government has shut down multiple times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If funding for the FDA is reduced, FDA priorities change, or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We hold no patents on our products, and our business employs proprietary technology (know-how) and information may be difficult to protect and/or infringe on the intellectual property rights of third parties.

Raphael has no patents and therefore, as a result of the Share Exchange, we did not acquire any patents. As such, we currently rely on trade secrets, proprietary know-how, and technology methods that we seek to protect, in part, by confidentiality agreements. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets and proprietary know-how will not otherwise become known or be independently discovered by others. We currently do not hold patents from the USPTO.

We cannot assure you that the patents of others will not have an adverse effect on our ability to conduct our business, that any of our trade secrets and applications will be protected, that we will develop additional proprietary technology (know-how) or methods that is defensible against theft or will provide us with competitive advantages or will not be challenged by third parties.

We manage our business through our three executive officers and key consultants and are highly dependent upon our Chief Technology Officer.

Key service providers are serving as our Chief Executive Officer, Chief Financial Officer and Chief Technology Officer and other scientific services consultants. Due to the lean nature of our operations and our current operations which mainly consist of outsourcing services, we are highly dependent upon our Chief Technology Officer. If our Chief Technology Officer, and to a lesser extent, any key consultants, resigns, this could adversely affect our ability to execute our business plan and harm our operating results. We do not currently carry "key person" insurance on the lives of members of management.

We will need to expand our organization and we may experience difficulties in recruiting needed additional employees and consultants, which could disrupt our operations.

As our development and commercialization plans and strategies develop and because we are so leanly staffed, we will need additional managerial, operational, sales, marketing, financial, legal and other resources. The competition for qualified personnel in the pharmaceutical field is intense. Due to this intense competition, we may be unable to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, 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 additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We may not be successful in our efforts to identify, license or discover additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of our existing product candidates, the success of our business also depends in part upon our ability to identify, license or discover additional product candidates. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license or discover additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the U.S., our operations may be directly or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, and marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;

- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the federal physician sunshine requirements under the Affordable Care Act requires manufacturers of drugs, devices and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, 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 providers 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 providers 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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the U.S. or Israel.

Other than our headquarters and other operations which are located in Israel (as further described below), we currently have limited international operations, but our business strategy incorporates potentially significant international expansion, particularly in anticipation of approval of our product candidates. We plan to maintain sales representatives and conduct physician and patient association outreach activities, as well as clinical trials, outside of the U.S. and Israel. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts, business operations and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

The use of any of our product candidates could result in product liability or similar claims that could be expensive, damage our reputation and harm our business.

Our business exposes us to an inherent risk of potential product liability or similar claims. The pharmaceutical industry has historically been litigious, and we face financial exposure to product liability or similar claims if the use of any of our products were to cause or contribute to injury or death. There is also the possibility that defects in the design or manufacture of any of our products might necessitate a product recall. Although we plan to maintain product liability insurance, the coverage limits of these policies may not be adequate to cover future claims. In the future, we may be unable to maintain product liability insurance on acceptable terms or at reasonable costs and such insurance may not provide us with adequate coverage against potential liabilities. A product liability claim, regardless of merit or ultimate outcome, or any product recall could result in substantial costs to us, damage to our reputation, customer dissatisfaction and frustration and a substantial diversion of management attention. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical and, in the future, clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and, in the future, clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors will be required to comply with current cGMP, GCP, QSR and Good Laboratory Practices, or GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, and comparable foreign regulatory authorities for any product candidates that move into clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the clinical data generated in our clinical studies may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical studies before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical studies comply with GCP regulations. In addition, our clinical studies must be conducted with product candidates which are produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical studies may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which could materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We will rely on third parties to grow and provide us with our active pharmaceutical ingredient, or API, and formulations. Our business could be harmed if those third parties fail to provide us with sufficient quantities of our needed supplies, or fail to do so at acceptable quality levels or prices.

We do not have the infrastructure or capability internally to manufacture the API formulations, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We plan to rely on third parties for such supplies. In addition, we are reliant on one third party for the CBD that we intend to use in our preclinical studies, which, has caused us to rely on their cooperation to meet their contractual obligations, but there can be no guarantee that we are able to meet such obligations. In addition, there may be a need to identify alternate manufacturers to prevent a possible disruption of our clinical studies. Any significant delay or discontinuity in the supply of these components could considerably delay completion of our preclinical studies, product candidate testing and potential regulatory approval of our product candidates, which could harm our business and results of operations.

We and our collaborators and contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or a product candidate used in late-stage clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational product candidates and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaborators or our contract manufacturers must supply all necessary documentation in support of an NDA, or Marketing Authorization Application, or MAA, on a timely basis and must adhere to GLP and cGMP QSR regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaborators and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the product candidates may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product candidate for sale, if ever, audit the manufacturing facilities of our collaborators and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product candidate specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical study or commercial sales, or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we, our collaborators, or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product, withdrawal of an approval or suspension of production. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA or MAA amendment, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and, if we commence clinical development, could cause the delay or termination of clinical studies, regulatory submissions, required approvals or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

Risks Related to Ownership of Our Securities

Our executive officer, directors and certain stockholders who are beneficial owners of 5% or more of our outstanding Common Stock possess the majority of our voting power, and through this ownership, have the ability to control our Company and our corporate actions.

Following the Share Exchange, our current executive officer, directors and certain stockholders who are beneficial owners of 5% or more of our outstanding Common Stock hold approximately 54.0% of the issued and outstanding voting power of the Company's outstanding shares. These persons have a controlling influence in determining the outcome of any corporate transaction or other matters submitted to our stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets, election of directors, and other significant corporate actions. As such, our directors and executive officer may have the power, acting alone or together, to prevent or cause a change in control; therefore, without their consent we could be prevented from entering into transactions that could be beneficial to us. The interests of our executive officer may give rise to a conflict of interest with the Company and the Company's shareholders.

In addition, we have a number of stockholders who are beneficial owners of more than 5% of our outstanding Common Stock, as of March 28, 2025, including our Chief Executive Officer who beneficially owns approximately 24.5% of our issued and outstanding shares, and as such, also may have the ability to prevent us from entering into transactions that could be beneficial to us and/or other shareholders. In addition, we have one additional non-affiliated stockholder who is a beneficial owner of more than 5% of our outstanding Common Stock. Although this non-affiliated stockholder currently does not have a controlling influence in determining the outcome of any corporate transaction or other matters submitted to our stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets, election of directors, and other significant corporate actions, obtaining its vote on certain matters may be necessary to effect certain actions that our management and directors otherwise deem to be in the best interests of the Company.

For additional details concerning beneficial ownership of our securities, please refer to the section below entitled "Beneficial Ownership of the Company's Common Stock" and with respect to voting power, please refer to the section below entitled "Description of Securities."

Investors may have difficulty in reselling their shares due to the substantial lack of liquidity of our Common Stock.

Our Common Stock is traded on the over-the-counter market with quotations published on the OTC Markets Group, Inc.'s OTCQB tier Venture Market, under the symbol "RAPH." The trading volume of our Common Stock historically has been limited and sporadic. As a result of the limited and sporadic trading activity, the quoted price for our Common Stock on the over-the-counter market is not necessarily a reliable indicator of its fair market value. The price at which our Common Stock will trade in the future may be highly volatile and may fluctuate as a result of a number of factors, including, without limitation, any potential business combination that we announce, as well as the number of shares available for sale in the market.

The trading volume of our Common Stock may be limited and sporadic. This situation is attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give you any assurance that a broader or more active public trading market for our Common Stock will develop or be sustained, or that current trading levels will be sustained. As a result of such trading activity, the quoted price for our Common Stock on the OTCQB may not necessarily be a reliable indicator of our fair market value. In addition, if our shares of Common Stock cease to be quoted, holders would find it more difficult to dispose of or to obtain accurate quotation as to the market value of, our Common Stock and as a result, the market value of our Common Stock likely would decline.

Other factors that could have a similar impact include, but are not limited to:

- limited "public float" in the hands of a small number of persons whose sales or lack of sales could result in positive or negative pricing pressure on the market price for our Common Stock;
- variations in quarterly operating results from the expectations;
- revisions in securities analysts' estimates or reductions;
- our ability to obtain working capital financing;
- announcements of new products or services by us or our competitors and changes in our industry;
- reductions in the market share of our products;
- announcements by us or our competitors of significant strategic acquisitions;
- loss of any strategic relationship;
- regulatory developments;
- general technological, market or economic trends;
- investor perception of our industry or prospects;
- insider selling or buying;
- investors entering into short sale contracts;
- regulatory developments affecting our industry; and
- additions or departures of key personnel.

Many of these factors are beyond our control and may decrease the market price of our Common Stock, regardless of our operating performance. We cannot make any predictions or projections as to what the prevailing market price for our Common Stock will be at any time, including as to whether our Common Stock will sustain current market prices, or as to what effect that the sale of shares or the availability of Common Stock for sale at any time will have on the prevailing market price.

Our Common Stock may never be listed on a major stock exchange.

While we may seek the listing of our Common Stock on a national or other securities exchange at some time in the future, we currently do not satisfy the initial listing standards and cannot ensure that we will be able to satisfy such listing standards or that our Common Stock will be accepted for listing on any such exchange. Should we fail to satisfy the initial listing standards of such exchanges, or our Common Stock is otherwise rejected for listing, the trading price of our Common Stock could suffer, the trading market for our Common Stock may be less liquid, and our Common Stock price may be subject to increased volatility.

As a former shell company, resales of shares of our restricted Common Stock in reliance on Rule 144 of the Securities Act are subject to the requirements of Rule 144(i).

We previously were a "shell company" and, as such, sales of our securities pursuant to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, cannot be made unless, among other things, at the time of a proposed sale, we are subject to the reporting requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, and have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 as amended, as applicable, during the preceding 12 months, other than Form 8-K reports. Because, as a former shell company, the reporting requirements of Rule 144(i) will apply regardless of holding period, restrictive legends on certificates for shares of our Common Stock cannot be removed except in connection with an actual sale that is subject to an effective registration statement under, or an applicable exemption from the registration requirements of, the Securities Act. Because our unregistered securities cannot be sold pursuant to Rule 144 unless we continue to meet such requirements, any unregistered securities we issue will have limited liquidity unless we continue to comply with such requirements.

The securities issued in connection with the Share Exchange are restricted securities and may not be transferred in the absence of registration or the availability of a resale exemption.

The shares of Common Stock issued in connection with the Share Exchange were issued in reliance on an exemption from the registration requirements under Section 4(a)(2) of the Securities Act. Consequently, these securities are subject to restrictions on transfer under the Securities Act and may not be transferred in the absence of registration or the availability of a resale exemption. In particular, in the absence of registration, such securities cannot be resold to the public until certain requirements under Rule 144 promulgated under the Securities Act have been satisfied, including certain holding period requirements. As a result, a purchaser who receives any such securities issued in connection with the Share Exchange may be unable to sell such securities at the time or at the price or upon such other terms and conditions as the purchaser desires, and the terms of such sale may be less favorable to the purchaser than might be obtainable in the absence of such limitations and restrictions.

We do not plan to declare or pay any dividends to our stockholders in the near future.

We have not declared any dividends in the past, and we do not intend to distribute dividends in the near future. The declaration, payment and amount of any future dividends will be made at the discretion of our board of directors, or Board, and will depend upon, among other things, the results of operations, cash flows and financial condition, operating and capital requirements, and other factors as the Board considers relevant. There is no assurance that future dividends will be paid, and if dividends are paid, there is no assurance with respect to the amount of any such dividend.

The requirements of being a reporting company may strain our resources and distract management.

As a reporting company, we are subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. These requirements are extensive. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting.

We may incur significant costs associated with our public company reporting requirements and costs associated with applicable corporate governance requirements. We expect all of these applicable rules and regulations to significantly increase our legal and financial compliance costs and to make some activities more time consuming and costly. This may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition and results of operations. We also expect that these applicable rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our Board or as executive officers. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

We are required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes- Oxley Act, subject to certain exceptions. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and to obtain attestations of the effectiveness of internal controls by independent auditors.

If we fail to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act, we could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock and could negatively impact our business.

If material weaknesses or deficiencies in our internal controls exist and go undetected or unremedied, our financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

If in the future there is a trading market for our Common Stock, "penny stock" rules may make buying or selling our Common Stock difficult.

The SEC has adopted regulations that generally define a penny stock to be any equity security that has a market price of less than $5.00 per share, subject to certain exceptions. These rules require that any broker-dealer that recommends our Common Stock to persons other than prior customers and accredited investors, must, prior to the sale, make a special written suitability determination for the purchaser and receive the purchaser's written agreement to execute the transaction. Unless an exception is available, the regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the risks associated with trading in the penny stock market. In addition, broker-dealers must disclose commissions payable to both the broker-dealer and the registered representative and current quotations for the securities they offer. The additional burdens imposed upon broker-dealers by such requirements may discourage broker-dealers from effecting transactions in our Common Stock, which could severely limit the market price and liquidity of our Common Stock.

The sales practice requirements of the Financial Industry Regulatory Authority, or FINRA, may also limit a stockholder's ability to buy and sell our stock.

In addition to the "penny stock" rules described above, FINRA has adopted Rule 2111 that requires a broker-dealer to have reasonable grounds for believing that an investment is suitable for a customer before recommending the investment. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. The FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy the Company's Common Stock, which may limit your ability to buy and sell the Company's stock and have an adverse effect on the market for our shares.

Because we are a "smaller reporting company," we will not be required to comply with certain disclosure requirements that are applicable to other public companies, and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our Common Stock less attractive to investors.

We are a "smaller reporting company," as defined in Item 10(f)(1) of Regulation S-K under the Securities Act. As a smaller reporting company, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies, including, but not limited to:

- Reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements;
- Not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002; and
- Reduced disclosure obligations for our annual and quarterly reports, proxy statements and registration statements.

We will remain a smaller reporting company until the end of the fiscal year in which (1) we have a public common equity float of more than $250 million, or (2) we have annual revenues for the most recently completed fiscal year of more than $100 million plus we have any public common equity float or public float of more than $700 million. We also would not be eligible for status as smaller reporting company if we become an investment company, an asset-backed issuer or a majority-owned subsidiary of a parent company that is not a smaller reporting company.

Risks Related to our Operations in Israel

Our headquarters and other significant operations are located in Israel, and, therefore, our results may be adversely affected by political, economic and military instability in Israel.

Our executive offices are located in Tel Aviv-Jaffa, Israel. In addition, the majority of our officers and directors are residents of Israel. If these or any future facilities in Israel were to be damaged, destroyed or otherwise unable to operate, whether due to war, acts of hostility, earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages or otherwise, or if performance of our research and development is disrupted for any other reason, such an event could delay our clinical trials or, if our product candidates are approved and we choose to manufacture all or any part of them internally, jeopardize our ability to manufacture our products as promptly as our prospective customers will likely expect, or possibly at all. If we experience delays in achieving our development objectives, or if we are unable to manufacture an approved product within a timeframe that meets our prospective customers' expectations, our business, prospects, financial results and reputation could be harmed.

Conditions in Israel, including the armed conflict between Israel and Hamas, Hezbollah and other terrorist organizations from the Gaza Strip and Lebanon.

On October 7, 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. Following the attack, Israel's security cabinet declared war against Hamas and the Israeli military began to call-up reservists for active duty. At the same time, and because of the war declaration against Hamas, the clash between Israel and Hezbollah in Lebanon has escalated to an armed conflict and there is a possibility that it will turn into a greater regional conflict in the future.

As of the date of this Annual Report, there has been no material impact on the Company's operations. According to the recent guidelines of the Israeli government, the Company's offices are open and functioning as usual. However, if the war will escalate and expand further to the Northern border with Lebanon, and the Israeli government will impose additional restrictions on movement and travel, our management and employees' ability to effectively perform their daily tasks might be temporarily disrupted, which may result in delays in some of our operations.

Any hostilities involving Israel, terrorist activities, political instability or violence in the region, or the interruption or curtailment of trade or transport between Israel and its trading partners could make it more difficult for us to raise capital, if needed in the future, and adversely affect our operations and results of operations and the market price of our common shares.

Our insurance does not cover damage or losses that may occur as a result of the war or terrorists events. Although the Israeli government is currently committed to covering the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained or, if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business, financial condition, and results of operations.

Further, many Israeli citizens are obligated to perform several days, and in some cases, more, of annual military reserve duty each year until they reach the age of 40 (or older for certain reservists) and, in the event of an escalated military conflict, may be called to active duty. In response to the series of attacks on civilian and military targets in October 2023, there have been significant call-ups of military reservists. As of March 28, 2025, none of our officers and none of our consultants or service providers have been called up to military service. However, if there will be call-ups for reservists in our Company, our operations could be disrupted by such call-ups.

It is currently not possible to predict the duration or severity of the ongoing conflict or its effects on our business, operations and financial condition. The ongoing conflict is rapidly evolving and developing, and could disrupt our business and operations, and adversely affect our ability to raise additional funds or sell our securities, among other impacts.

Our operations are subject to currency and interest rate fluctuations.

Although our functional currency is the U.S. dollar, and our financial records are maintained in U.S. dollars, we also incur expenses in Euros and New Israeli Shekels. In the future, we expect that a substantial portion of our revenues will be generated in U.S. dollars, Euros and other foreign currencies, although we currently incur a significant portion of our expenses in currencies other than U.S. dollars, mainly New Israeli Shekels. As a result, we are affected by foreign currency exchange fluctuations through both translation risk and transaction risk, and our financial results may be affected by fluctuations in the exchange rates of currencies in the countries in which our prospective product candidates may be sold. We currently partially hedge our foreign currency exchange rate risk to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies.

It may be difficult to enforce a judgment of a U.S. court against us and our executive officers and directors and the Israeli experts named in this Annual Report in Israel or the U.S., to assert U.S. securities laws claims in Israel or to serve process on our executive officers and directors and these experts.

We were incorporated in Israel. Substantially all of our executive officers and directors reside outside of the U.S., and all of our assets and most of the assets of these persons are located outside of the U.S. Therefore, a judgment obtained against us, or any of these persons, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the U.S. and may not be enforced by an Israeli court. It also may be difficult for you to effect service of process on these persons in the U.S. or to assert U.S. securities law claims in original actions instituted in Israel. Additionally, it may be difficult for an investor, or any other person or entity, to initiate an action with respect to U.S. securities laws in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a U.S. or foreign court. See “Enforceability of Civil Liabilities” for additional information on your ability to enforce a civil claim against us and our executive officers or directors named in this Annual Report.

General Risk Factors

Future changes in financial accounting standards or practices may cause adverse unexpected financial reporting fluctuations and affect reported results of operations.

A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct business.

Raising additional capital would cause dilution to our existing shareholders, and may affect the rights of existing shareholders.

We may seek additional capital through a combination of private and public equity offerings, debt financings and collaborations and strategic and licensing arrangements. To the extent that we raise additional capital through the issuance of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder.

Failure in our information technology systems, including by cybersecurity attacks or other data security incidents, could significantly disrupt our operations.

Our operations depend, in part, on the continued performance of our information technology systems. Our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptions. Failure of our information technology systems could adversely affect our business, profitability and financial condition. Although we have information technology security systems, a successful cybersecurity attack or other data security incident could result in the misappropriation and/or loss of confidential or personal information, create system interruptions, or deploy malicious software that attacks our systems. It is possible that a cybersecurity attack might not be noticed for some period of time. The occurrence of a cybersecurity attack or incident could result in business interruptions from the disruption of our information technology systems, or negative publicity resulting in reputational damage with our shareholders and other stakeholders and/or increased costs to prevent, respond to or mitigate cybersecurity events. In addition, the unauthorized dissemination of sensitive personal information or proprietary or confidential information could expose us or other third parties to regulatory fines or penalties, litigation and potential liability, or otherwise harm our business.

We may be subject to securities litigation, which is expensive and could divert management attention.

In the past, companies that have experienced volatility in the market price of their shares have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could seriously hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

The requirements associated with being a reporting company will require significant company resources and management attention.

We are subject to the reporting requirements of the Exchange Act. The Exchange Act requires that we file periodic reports with respect to our business and financial condition and maintain effective disclosure controls and procedures and internal control over financial reporting. In addition, subsequent rules implemented by the SEC may also impose various additional requirements on reporting companies. We estimate that these expenses will be at least several tens of thousand dollars annually. Further, the need to maintain the corporate infrastructure demanded of a reporting company may divert management's attention from implementing our development plans. We have made changes to our corporate governance standards, disclosure controls and financial reporting and accounting systems to meet our reporting obligations. The measures we take, however, may not be sufficient to satisfy our obligations as a public company, which could subject us to fines, sanctions and other regulatory action and potentially civil litigation.

Item 1B. Unresolved Staff Comments.

Not applicable to smaller reporting companies.

Item 1C. Cyber Security.

The Company maintains cybersecurity procedures to mitigate risk and to ensure compliance with security, availability, and confidentiality. The cybersecurity process is integrated into the Company's overall risk management system and is solely internally managed. The Company's Chief Financial Officer is responsible for identifying risks that threaten achievement of the control activities made by the Company. The risk assessment occurs as business needs change and covers identification of risks that could act against the company's objectives.

The level of each identified risk is determined by the Company' Chief Financial Officer, considering the impact of the risk itself and the likelihood of the risk materializing.

As of the date of this Annual Report, we are not aware of any material risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition.

Cyber Security Risk Management and Strategy

As part of the Company's cybersecurity risk management program, we are focused on the following key areas:

- Governance: As discussed in more detail under the heading "Governance" below, as part of its general oversight duties, the Board oversees the Company's risk management, including the cyber security risks.
- Technical Safeguards: The Company deploys commensurate technical safeguards, including firewalls, encryption, network segmentation, real-time monitoring, intrusion prevention systems, anti-malware, and access controls.
- Continuous Review: The Company regularly reviews its cybersecurity standards, and procedures and evaluates the effectiveness of implemented security controls. The Company adjusts its cybersecurity standards and programs as necessary.

Governance

The Board oversees our risk management process and receive regular updates and information on cybersecurity risks, if any, which address recent developments, evolving standards, the threat environment, technological trends and information security considerations arising with respect to our peers and third parties. The Board also receive timely information regarding any cybersecurity incident that meets established reporting thresholds, as well as ongoing updates regarding any such incident until it has been addressed.

Item 2. Properties.

Our principal executive office is currently located at 4 Lui Paster, Tel Aviv-Jaffa, Israel 6803605.

Item 3. Legal Proceedings.

We are not currently a party to or subject to any material legal proceedings.

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.

Since December 7, 2022 our Common Stock has been quoted on the OTCQB under the symbol "RAPH." On March 28, 2025, the last reported sale price of our Common Stock on OTCQB was $1 per share. As of March 28, 2025, there were 200 holders of record of our Common Stock. This figure includes an indeterminate number of stockholders who hold their shares in "street name."

We have not declared any cash dividends on our common stock, and do not intend to declare dividends in the foreseeable future. Management intends to use all available funds for the development of our plan of operation.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our audited annual consolidated financial statements as of December 31, 2024 and December 31, 2023 and accompanying notes appearing elsewhere in this Annual Report. This discussion and analysis contain forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth under "Risk Factors" and elsewhere in this Annual Report. All amounts are in U.S. dollars and rounded.

Company Overview

We are a pharmaceutical drug research and development company focused on the discovery and clinical development of life-improving drug therapies based on cannabinoids, including CBD oil. Unless indicated otherwise, we plan on using oil derived from CBD strains with low levels of THC. All references to the use of CBD in our product candidates refer to CBD strains with less than 0.3% of THC.

We have recently completed a Study, for our lead product candidate for the treatment of RA in the U.S. Encouraged by the promising results of the Study, we will continue to investigate our product for the treatment of autoimmune diseases.

In addition, we are aiming to develop a novel treatment for asthma. At Rambam, we have successfully conducted studies using human-derived immune cells and mouse models to advance our understanding of both COVID-19 and RA products. Due to the similarity of COVID-19 and asthma symptoms, such studies also advance our understanding of asthma and its treatment. Since the volume of COVID-19 testing has been decreasing, we decided to leverage our knowledge and understanding of COVID-19 to study asthma as well.

On February 9, 2022, we filed an application for a clinical trial with the Medical Cannabis Unit of the MOH. On February 16, 2022 we submitted an application with the Helsinki Committee at Rambam for a clinical trial in COVID-19 patients.

In November 2022, we submitted a proposal to the MOH for a clinical trial of a cannabis-based drug aimed at mitigating the deterioration of COVID-19 patients.

On March 27, 2023, the MOH, accepted our proposal for a clinical trial aimed at preventing the deterioration of hospitalized COVID-19 patients.

In April 2024 we began the Study in the U.S., leveraging insights from the pre-clinical experiments we have conducted at the Rambam. This Study aimed to evaluate the Company's Cannabinoid based formula, or Raphael's Formula, in patients with active RA. The single-group Study was managed by MindMate, Inc./ dba Citruslabs, or Citruslabs, and conducted in Santa Monica, California, U.S., under IRB approval, in compliance with the FDA regulations and in accordance with applicable industry standards and regulations.

On December 23, 2024, upon a successful completion of the Study, we received the Study results with overall findings that emphasize the clinical potential of Raphael's Formula and suggest that it may have beneficial effects on symptom management and overall well-being for individuals with RA. For more information about the Study results see "Item 1. Business - Research and Clinical Development Strategy".

As we move forward, our focus will be on further investigating and refining the formula through continued pre-clinical research. Our goal is to ensure that the formula meets all the necessary standards and regulations set forth by the FDA, allowing us to progress towards clinical treatments.

Our vision is to emerge as a pioneering company at the forefront of formulating pharmaceutical drugs that harness the potential of purified cannabinoids and full-spectrum CBD oil. Our primary mission is to cater to the unmet medical requirements of patients grappling with various disorders, with a particular focus on conditions linked to inflammation, such as autoimmune diseases, asthma, RA and COVID-19.

By leveraging our expertise in this field, we are committed to providing innovative solutions to improve the lives of those afflicted with these challenging medical conditions. Through our dedication to research, development, and compassionate care, we aim to contribute significantly to the well-being of patients worldwide, offering them much-needed relief and hope for a better future.

In order to achieve our goal, we have and will continue to build an experienced team of senior executives and scientists, with experience in all facets of pharmaceutical research and development, drug formulation, clinical trial execution and regulatory submissions. We intend to leverage the knowledge of our team in order to complete the clinical trials needed to receive approvals of our product candidates from applicable regulatory authorities.

Initially, we intend to obtain approvals for our product candidates from the FDA and the Medical Cannabis Unit of the MOH. Upon obtaining FDA approvals, or in the event that we are not successful in obtaining such approvals, we intend to apply for EMA and other countries' governmental regulatory agencies approvals for our product candidates. If we are successful in obtaining FDA approvals for our product candidates, we intend to enter into royalty agreements with GMP approved medical manufactures and distributors, having them using our medical formulas strains for the purpose of growing, cultivating, manufacturing, and distributing Raphael Pharmaceutical medical indications in their designated territories.

For this purpose, in October 2022, we entered into an agreement with the Medical Cannabis Research Center at Rambam=for the development of a new, patentable formulation that combines purified cannabinoids to treat rheumatoid diseases.

The overall objective of this study is to identify a novel cannabinoid based patentable formulation to treat Rheumatoid diseases. Specifically, to investigate combination of purified cannabinoids to downregulate inflammation related to Rheumatoid diseases. We propose to base our study on data derived from Dr. Igal Louria-Hayon's studies (Helsinki # 0442-20-RMB) on the evaluation of the immune regulation properties of cannabinoids on the immune system and the data derived from the cannabinoids receptors study (Helsinki # 0331-20-RMB). We will analyze the activation of cannabinoid receptors on mouse models and will study the role of purified cannabinoid as a potential to develop a novel patentable formulation to treat RA.

Our discovery platform currently focuses the use of CBD oil, one of the cannabinoids in cannabis plants, as the active pharmaceutical ingredient, or API, for our RA product candidate and COVID-19 product candidate. Research results published in 2018 ("Translational Investigation of the Therapeutic Potential of Cannabidiol (CBD): Toward a New Age") has shown that there may be benefits to treading medical conditions, or their effects, with cannabinoids, and more specifically, with CBD, which may help reduce chronic pain by impacting endocannabinoid receptor activity, reducing inflammation and interacting with neurotransmitters. This research has also shown that CBD may have neuroprotective properties, and could have the ability to (i) reduce anxiety and depression, (ii) alleviate cancer-related symptoms, (iii) reduce acne and (iv) benefit heart health.

Over the last few years, pharmaceutical drug products that include parts of the cannabis plant have begun to receive regulatory approvals for use in patients suffering from certain disorders, as highlighted below.

- Nabiximols, better known under the tradename Sativex, is a botanical mouth spray consisting of natural THC and CBD extracts, that received approval in the United Kingdom in 2010 for the alleviation of multiple sclerosis, or MS, symptoms like spasticity, pain and overactive bladder.

- Dronabinol, better known under the name Marinol, contains mainly THC and is a partial agonist of the cannabinoid receptor type 1, or CB1, in the nervous system and a partial agonist of the cannabinoid receptor type 2, or CB2, in the periphery that activates appetite, mood, cognition, memory and perception. Dronabinol received FDA-approval for use in the U.S. in 1985 for treatment of anorexia in acquired immunodeficiency syndrome, or AIDS, patients and for the prevention of chemotherapy-induced nausea and vomiting, or CINV. A Lack of randomized controlled trials, or RCTs, makes a recommendation for usage of dronabinol as a third-line treatment for CINV difficult. Dronabinol in the form of an oral tablet is known under the trade name Namisol. It has high bioavailability and a long shelf life and is indicated for MS, chronic pain and behavioral disturbances in dementia patients.

- Nabilone, better known under the tradename Cesamet, contains primarily THC, is approved for use as an anti-emetic and adjunctive analgesic for neuropathic pain, CINV and treatment for anorexia in AIDS patients in Canada, Mexico, the UK and the U.S. Its main usage today is as adjunct medicine for chronic pain management.

In light of the past regulatory approvals for other pharmaceutical drug products and, more specifically, the potential beneficial effects of CBD and other parts of the cannabis plant, we believe that a drug discovery platform based on CBD may offer new and differentiated treatment options for patients. Prior regulatory approvals of other companies' pharmaceutical drug products do not serve as an indication as to the ability or likelihood that we receive regulatory approval to commercialize any of our product candidates.

After four successful years of pre-clinical research at the laboratories of Rambam, which paved the way for the Study in RA patients, we are now advancing our efforts to further develop our product candidates.

Following the completion of the Study, we intend to submit an IND application to the FDA and MOH. See "Item 1. Business - Research and Clinical Development Strategy - Clinical Development Plan" for additional information on the ongoing pre-clinical trial and our planned clinical trial for our RA product candidate.

In addition, with respect to our COVID-19 product candidate, our clinical research partners have been focused on the effect of cannabinoids and cannabis extracts on immune cells which induce acute inflammation. This study will begin in the pre-clinical level in immune cell models and, subject to positive results that exhibit downregulation of pro-inflammatory cytokines by cannabis extract, the study was completed successfully. Following the completion of the pre-clinical study, a mice model was conducted to analyze for acute inflammation, which resembles the immunopathology of COVID-19. The mice model was successfully completed and we have registered for a clinical trial in patients with the MOH.

As a pharmaceutical research and clinical development company we do not own or operate, and currently do not intend on creating an in-house team to manufacture and commercialize our pharmaceutical drug products, if any, that receive regulatory approval allowing for commercialization. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing of any pharmaceutical drug products for which we may receive regulatory approval. Subject to the receipt of such regulatory approvals, we intend on cooperating with manufacturers and other third parties to manufacture and commercialize approved pharmaceutical drug products.

Components of Operating Results

Operating Expenses

Our current operating expenses consist of two components - research and development expenses, and general and administrative expenses. To date, we have not generated any revenues. We do not expect to receive any revenue from our product candidate unless and until we obtain regulatory approval and commercialize our product candidate or enter into agreements with third parties to commercialize them. There can be no assurance that we will receive such regulatory approvals, and if our product candidate is approved, that we will be successful in commercializing them.

Research and Development Expenses

Research and development activities are our primary focus. Products in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase as we prepare for, and commence, registrational clinical trials of our RA and COVID-19 product candidates. A key activity in progressing our product candidates toward registrational trials is the development of large-scale manufacturing processes that are tailored specifically to our product candidate. In order to confirm the suitability of a new manufacturing facility and/or process, numerous experiments are needed. Moreover, the regulatory requirements in preparation for manufacturing a drug to be used in a registrational trial or for commercial use involve validation activities and extensive updates to our regulatory files, all of which are lengthy and costly activities. For these reasons, the development of manufacturing processes currently represents the largest portion of our research and development expenses. Research and development expenses include, but are not limited to, the following:

- employee-related expenses, such as salaries and share-based compensation;
- expenses of developing manufacturing processes;
- expenses relating to outsourced and contracted services, such as external laboratories and consulting and advisory services;
- costs associated with pre-clinical activities;
- patent application and maintenance expenses;
- expenses incurred in operating our laboratories and small-scale equipment; and
- clinical development expenses.

General and Administrative Expenses

General and administrative expenses consist primarily of employee related expenses, including salaries, benefits, and equity-based compensation, for personnel in executive, finance, accounting, business development and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters, and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities, potential commercialization of our product candidates and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses. We also anticipate increased expenses related to the reimbursements of third-party patent related expenses in connection with the ongoing interference proceeding with respect to certain of our in-licensed intellectual property. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with SEC requirements and insurance costs.

Comparison of the Year Ended December 31, 2024 to the year ended December 31, 2023

Results of Operations

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023
	U.S. dollars in thousands (except for share and per share data)	
Operating expenses:		
Research and development expenses	$ (776)	$ (569)
General and administrative expenses	(733)	(763)
Operating loss	(1509	(1332)
Financial expense, net	(10)	(12)
Net loss and comprehensive loss	$ (1519)	$ (1334)
Basic and diluted net loss per share	$ (0.08)	$ (0.08)
Weighted average number of shares of ordinary shares used in computing basic and diluted net loss per share	18,674,136	16,716,905

Research and Development Expenses

Our research and development expenses totaled $776 thousand for the year ended December 31, 2024, representing an increase of $207 thousand, or 36.3%, compared to $569 thousand for the year ended December 31, 2023. The increase was primarily attributable to one time share based compensation to one of our executives, which was offset by a lower investment in development activity as a result of lower fund raising during the year.

General and Administrative Expenses

Our general and administrative expenses totaled $733 thousand for the year ended December 31, 2024, representing a decrease of $30 thousand, or 3.9%, compared to $763 thousand for the year ended December 31, 2023. The decrease was primarily attributable to lower professional services fees.

Operating Loss

As a result of the foregoing, our operating loss totaled $1,509 thousand for the year ended December 31, 2024, representing an increase of $177 thousand, or 13.3%, compared to $1,332 thousand for the year ended December 31, 2023.

Financing expense, Net

We recognized financing expense, net of $10 thousand for the year ended December 31, 2024, representing a decrease of $2 thousand, or 16.6%, compared to finance expense, net of $12 thousand for the year ended December 31, 2023. The decrease was considered immaterial.

Net and Comprehensive Loss

As a result of the foregoing, our loss totaled $ 1,519 thousand for the year ended December 31, 2024, representing a increase of $175 thousand, or 13%, compared to $1,344 thousand for the year ended December 31, 2023.

Critical Accounting Estimates

Our consolidated financial statements are prepared in accordance with US GAAP. There are no critical accounting estimates for the years ended December 31, 2024 and 2023. Please see Note 2(a) of our Consolidated Financial Statements for the summary of significant accounting policies.

Liquidity and Capital Resources

The Company has funded its operations to date primarily through equity financing and the issuance of a loan. Additional funding will be required to complete the Company's research and development and clinical trials, to attain regulatory approvals, to begin the commercialization efforts of the Company's product and to achieve a level of sales adequate to support the Company's cost structure. As of December 31, 2024, we had approximately $19 thousand in cash and cash equivalents, and have invested most of our available cash funds in ongoing cash accounts.

Overview

The table below presents our cash flows for the periods indicated:

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023
	U.S. dollars in thousands	
Cash used in operating activities	$ (532)	$ (1,203)
Cash provided by investing activities	$ -	$ -
Cash provided by financing activities	$ 321	$ 1,145
Net increase (decrease) in cash and cash equivalents	$ (211)	$ (58)

Net cash used in operating activities was $532 thousand for the year ended December 31, 2024, compared with net cash used in operating activities of $1,203 thousand for the year ended December 31, 2023. The $671 thousand decrease in the net cash used in operating activities during 2024, compared to 2023, was mainly from lower investment in development activity.

Net cash used in investing activities for the year ended December 31, 2024 was $0 compared to $0 thousand for the year ended December 31, 2023.

Net cash provided by financing activities for the year ended December 31, 2024 was $321 thousand compared to $1,145 thousand for the year ended December 31, 2023. The decrease of $824 thousand in net cash provided by financing activities during 2024 compared to 2023 was mainly due to lower financing activity in 2024.

Current Outlook

We have financed our operations to date primarily through proceeds from founder's capital and issuance of shares and warrants. We have incurred losses and generated negative cash flows from operations since inception. To date we have not generated revenue, and we do not expect to generate significant revenues from the sale of our products in the near future.

We do not believe that our current cash on hand will be sufficient to fund our projected operating requirements. This raises substantial doubt about our ability to continue as a going concern. At this time, there is no guarantee that we will be able to obtain an adequate level of financial resources required for the short and long-term support of our operations or that we will be able to obtain additional financing as needed, or meet the conditions of such financing, or that the costs of such financing may not be prohibitive. These conditions raise substantial doubt about our ability to continue as a going concern for a period within one year from the date of the financial statements included elsewhere in this Annual Report.

As of December 31, 2024, our cash and cash equivalents were $19 thousand. We believe that our existing cash and cash equivalents will be sufficient to fund our projected cash requirements through the second quarter of 2025. Therefore, we will require significant additional financing in the near future to fund our operations. We currently anticipate that we will require approximately $500 thousand for research and development activities over the course of the next 12 months. We also anticipate that we will require approximately $700 thousand for capital expenditures over such 12-month period, which consists primarily of expenditures for clinical trials and general Company operating costs.

In addition, our operating plans may change as ae result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future capital requirements will depend on many factors, including:

- our research and development efforts, including our ability to finish research and development projects or product development within the allotted or expected timeline;
- the cost, timing and outcomes of seeking to commercialize our products in a timely manner;
- our ability to generate cash flows;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- government regulation in our industry, and more specifically, the costs and timing of obtaining regulatory approval or permits to launch our technology in various geographical markets; and
- The costs of, and timing for, strengthening our manufacturing agreements for production of our wave energy systems.

Until we can generate significant revenues, if ever, we expect to satisfy our future cash needs through our existing cash, cash equivalents and short-term deposits, loans, or debt or equity financings. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate research or development plans for, or commercialization efforts with respect to, one or more applications of our products. This may raise substantial doubts about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

Rambam Research Agreement

On July 17, 2019, we entered into a sponsored Research Agreement with Rambam, pursuant to which the Company agreed to fund a research project, to be performed by Rambam, with a research plan aimed at identifying the effects of different cannabis strains on the function of immune cells. On October 28, 2020, the Company and Rambam agreed to expand the research plan to study the anti-inflammatory activities of cannabis extracts in an RA mouse model. On February 15, 2021, the Company and Rambam agreed to further expand the research plan to study the effect of cannabis extracts on the immunopathology of the COVID-19 disease. The sponsored Researched Agreement is for an initial term of 48 months. On October 23, 2022, the Company and Rambam entered into a supplement to the Research Agreement, or the Supplement Agreement, pursuant to which the Company exercised an option to extend the Research Agreement by additional two years until December 31, 2024, which we plan to extend in 2025.

Pursuant to the Research Agreement, we agreed to pay Rambam $1.4 million in four equal payments, due on the first day of August on each successive year from 2019 through 2022. Pursuant to the Supplement Agreement, we agreed to pay Rambam $960,000 plus VAT in four biannual payments from May 2023 through December 2024. Such amount was later amended to $470,000 plus VAT. Furthermore, in accordance with the terms of the Research Agreement, we and Rambam will have joint ownership of any IP created as a result of research programs covered by such agreement. In connection with the Research Agreement, Rambam agreed not to work, study or develop any technologies with other entities that compete with our work with Rambam for our COVID-19 product candidate or RA product candidate for a term of three and seven years, respectively, from the end of the parties' collaboration with respect to the COVID-19 product candidate and seven years from the end of the term of the Research Agreement with respect to the RA product candidate.

Subject to commercial sales of any product candidate using the IP created as a part of the research covered by such agreement, Raphael Israel is required to pay Rambam a royalty in an amount equal to 6% of all net sales, subject to certain deductions, such as taxes paid by any purchaser, transportation and shipping costs, and other customary deductions.

On December 25, 2023, the Company received an extension to pay the remaining $350,000 pursuant to the Research Agreement until the end of June 2024. As of the date of this Annual Report, the Company has made all four of the four equal payments due pursuant to the Research Agreement, for a total amount of $1.4 million and $295,000 for the Supplement Agreement (out of the remaining $470,000).

Way of Life Cannabis Agreement

In October 2020, Raphael Israel entered into an engagement agreement with Wolc, pursuant to which, subject to its completing the Share Exchange with Easy Energy, Raphael Israel will be provided with up to 15 liters of CBD oil, from a strain of cannabis during a term of 18 months, to be provided in two to three deliveries of between one to seven liters of CBD oil. In accordance with Raphael Israel's agreement with Wolc, Raphael Israel has agreed to issue to certain persons affiliated with Wolc 3% of Raphael's issued and outstanding share capital as of the date of the Share Exchange, to be provided in three equal issuances; provided, however, that such persons may elect to receive a cash payment of $100,000 instead of any one issuance of Raphael's shares. In addition to the issuance of shares, Raphael Israel has also agreed to pay Wolc a royalty fee equal to 15% of the net royalties generated from sales of Raphael Israel's pharmaceutical drug products that are developed at Rambam l in Israel.

On July 27, 2022, the Company issued 100,500 shares of common stock to Wolc in connection with the engagement agreement. The value of such issued shares was based on the value of the service provided, which amounted to $100,000. In June 2023, the Company issued 201,000 shares of common stock to Wolc, in connection with the services agreement dated October 2020. The value of the shares issued was based on the value of the service provided, which amounted to $200,000.

Service Agreement with our Chief Technology Officer

Our Chief Technology Officer, Dr. Igal Louria Hayon, provides services to our Company pursuant to a service agreement, by and between the Company and Dr. Igal Louria Hayon. Pursuant to the terms thereof Dr. Hayon provides consulting services the Company to engage with an array of science consultants and to coordinate collaborations with hospitals on medical cannabis research. Pursuant to such agreement, we agreed to pay our Chief Technology Officer 15% of the Company's net royalty's income from worldwide sales of any of the Company's cannabis-based medical indications treating COVID-19. Pursuant to Dr. Hayon's service agreement, in the event we will apply for any clinical trial of cannabis-based treatment or will begin any other new cannabis related research, the Corporation will grant Dr. Hayon warrants to purchase up to 350,000 shares of Common Stock at an exercise price of $0.01. On May 1, 2024, the milestone was met and the Company granted to Dr. Igal Louria Hayon warrants to purchase up to 350,000 shares of Common Stock of the Company at an exercise price of $0.01. The warrants expire on April 30, 2026. On March 3, 2025, we entered into a new service agreement with our Chief Technology Officer, substantially on the same terms as the agreement described above, effective as of January 1, 2025 Pursuant to such service agreement, we agreed to pay our Chief Technology Officer a monthly fee of $24,000 and to reimburse him with certain expenses related to his scientific work.

The Company may terminate the service agreement prior to the expiration of its term upon 120 days advance notice and the payment to Dr. Hayon of a termination fee equal to the monthly fees payable through the expiration of its term.

Except for the above, we have not engaged in any off-balance sheet arrangements, such as the use of unconsolidated subsidiaries, structured finance, special purpose entities or variable interest entities.

We do not believe that our off-balance sheet arrangements and commitments have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Item 7A. Quantitative and Qualitative Disclosure about Market Risk

Not applicable to smaller reporting companies.

Item 8. Financial Statements and Supplementary Data.

All information required by this item is included in Item 15 of Part IV of this Annual Report and is incorporated into this item by reference.

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

None.

Item 9A. Controls and Procedures

Management's Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

As of December 31, 2024, we conducted an evaluation, under the supervision and participation of management including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended). There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level as of December 31, 2024.

Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the U.S. of America.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even internal controls determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. The effectiveness of our internal control over financial reporting is subject to various inherent limitations, including cost limitations, judgments used in decision making, assumptions about the likelihood of future events, the possibility of human error, and the risk of fraud. The projection of any evaluation of effectiveness to future periods is subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies may deteriorate. Because of these limitations, there can be no assurance that any system of internal control over financial reporting will be successful in preventing all errors or fraud or in making all material information known in a timely manner to the appropriate levels of management.

This Annual Report does not include an attestation report of the company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the company's registered public accounting firm pursuant to rules of the SEC that exempt from this requirement issuers that are neither accelerated filers nor large accelerated filers.

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

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

Our directors and executive officers and their ages as of March 28, 2025, are set forth in the following table:

Name	Age	Position
Ajay Kumar Dhadha	79	Director and Chairman of the Board of Directors
Shlomo Pilo	71	Chief Executive Officer and Director
Guy Ofir	52	Chief Financial Officer and Director
Dr. Igal Louria Hayon	52	Chief Technology Officer and Director
Dr. Yehuda Eliya	51	Director

Ajay Kumar Dhadha, has been a member of our Board and Chairman of the Board since January 8, 2025. Mr. Dhadha is a diamond dealer and a member of the Israel Diamond Exchange, residing in Israel for the last 45 years. Mr. Dhadha is the founder and owner and Chief Executive Officer of Shanti Gems (1982) Ltd. in Israel, which exports and sells diamonds.

Shlomo Pilo, has been our Chief Executive Officer and a member of our Board since the Share Exchange and previously served in such capacity with Raphael Israel from July 2019. In addition, following the founding of Sheffa Enterprises Inc. in 2009, Mr. Pilo is also engaged in providing food brokering services, representing seven food manufacturers in Europe and North America. Before founding Sheffa Enterprises Inc., Mr. Pilo served as VP Sales & Marketing of Alle Processing Corporation, the world's largest Glatt Kosher food manufacturer.

Guy Ofir, has been our Chief Financial Officer and a member of our Board since September 27, 2021. Mr. Ofir is a qualified lawyer in Israel and the owner of "Guy Ofir Adv" law firm since 2000, with a main practice in civil and business law. In 2007 he established and registered a company named Easy Energy Inc. that developed a green energy patent. Mr. Ofir owns an investment company, which has invested in land and construction in Romania since 2005.

Dr. Igal Louria-Hayon, has been our Chief Technology Officer and member of our Board since September 27, 2021. Dr. Louria-Hayon serves as a scientific director of the Medical Cannabis Research and Innovation Center at Rambam and Head of the Leukemia & Immunotherapy Research Laboratory in the Clinical Research Institute at Rambam. In addition, Dr. Louria-Hayon served as Senior Research Fellow in the Technion's Cannabinoid Research Laboratory.

Dr. Yehuda Eliya, has been a member of our Board since September 27, 2021. Dr. Eliya is a partner at one of the largest accounting firms in Israel and the owner of a law firm. Dr. Eliya is the Vice President of the Chamber of Internal Auditors in Israel. In addition, Dr. Eliya is a member of the presidency of ZAKA, a series of volunteer community emergency response teams in Israel, a parliamentary adviser to the Republic of Abkhazia and serves as a director in several non-profit organizations in Israel.

Scientific Advisory Board

Professor Alexandra Balbir-Gurman, Frontline Director of Clinical Trials (Rambam) and Director of the B. Shine Rheumatology Unit at Rambam, a member of the Executive Committee of the Israeli Society of Rheumatology, an active member of the Scleroderma Research Group (EUSTAR) and a member of the EULAR Target US initiative.

Dr. Shachar Eduardo, Frontline Director of Clinical Trials (Rambam), is the Director of the Clinical Immunology Unit at Rambam.

Prof. Shai Israeli, Head of the Division of Pediatric Hematology-Oncology Center, Schneider Children's' Medical Center of Israel (affiliated to Tel Aviv University), is a member of the executive Board of the European Hematology Association (EHA).

Family Relationship

There is no family relationship among the directors and officers of the Company.

Involvement in Certain Legal Proceedings

Over the past ten (10) years, none of our directors or our executive officer have been (i) involved in any petition under Federal bankruptcy laws or any state insolvency law, (ii) convicted in a criminal proceeding or is a named subject of a pending criminal proceeding (excluding traffic violations and other minor offenses), (iii) subject of any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining him from (a) acting as a futures commission merchant, introducing broker, commodity trading advisor, commodity pool operator, floor broker, leverage transaction merchant, any other person regulated by the Commodity Futures Trading Commission, or an associated person of any of the foregoing, or as an investment adviser, underwriter, broker or dealer in securities, or as an affiliated person, director or employee of any investment company, bank, savings and loan association or insurance company, or engaging in or continuing any conduct or practice in connection with such activity, (b) engaging in any type of business practice, or (c) engaging in any activity in connection with the purchase or sale of any security or commodity or in connection with any violation of Federal or State securities laws or Federal commodities laws, or (d) subject of any order, judgment or decree, not subsequently reversed, suspended or vacated, of any Federal or State authority barring, suspending or otherwise limiting for more than 60 days the right to engage in any activity described in (iii)(a), (iv) found by a court of competent jurisdiction in a civil action or by the SEC to have violated any Federal or State securities law, and the judgment in such civil action or finding by the SEC has not been subsequently reversed, suspended, or vacated, (v) found by a court of competent jurisdiction in a civil action or by the Commodity Futures Trading Commission to have violated any Federal commodities law, and the judgment in such civil action or finding by the Commodity Futures Trading Commission has not been subsequently reversed, suspended or vacated. (vi) subject of, or a party to, any Federal or State judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of (a) any Federal or State securities or commodities law or regulation, (b) any law or regulation respecting financial institutions or insurance companies, or (c) any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity, or (vii) the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act (15 U.S.C. 78c(a)(26))), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act (7 U.S.C. 1(a)(29))), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member. Except as set forth in our discussion below in “Transactions with Related Persons; Promoters and Certain Control Persons; Director Independence,” none of our directors, director nominees or executive officers has been involved in any transactions with us or any of our directors, executive officers, affiliates or associates which are required to be disclosed pursuant to the rules and regulations of the SEC.

Code of Ethics

On March 5, 2025, our Board adopted a Code of Business Conduct and Ethics that applies to, among other persons, members of our Board, our employees (if applicable), officers including our Chief Executive Officer, our Chief Financial Officer and persons performing similar functions. A copy of the Code of Business Conduct and Ethics is filed as Exhibit 14.1 to this Form 10-K.

Our Code of Business Conduct and Ethics is posted on our internet website at www.raphaelpharmaceutical.com. The information on our website is not incorporated by reference into this Annual Report. We intend to satisfy the disclosure requirement under Item 5.05 of a Current Report on Form 8-K regarding amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on the website address specified above.

Insider Trading Policy

On March 5, 2025, we have adopted an insider trading policy governing the purchase, sale and other transactions in our securities that applies to our directors, officers, employees (if applicable), consultants, and other covered persons, including immediate family members and entities controlled by any of the foregoing persons, as well as by the Company itself.

The insider trading policy prohibits, among other things, insider trading and certain speculative transactions in our securities and establishes a regular blackout period schedule during which directors, executive officers, employees, and other covered persons may not trade in the Company's securities.

The Company believes that the insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to the Company. A copy of the insider trading policy is filed as Exhibit 19.1 to this Form 10-K.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of our common stock, to file reports regarding ownership of, and transactions in, our securities with the SEC and to provide us with copies of those filings.

We have reviewed all forms provided to us or filed with the SEC. Based on that review and on written information given to us by our executive officers and directors, we believe that all Section 16(a) filings during the past fiscal year were filed on a timely basis and that all directors, executive officers and 10% beneficial owners have fully complied with such requirements during the past fiscal year.

Committees of the Board of Directors

We do not have an audit or compensation committee and have no independent directors that examine related party transactions. Our Board performs these functions as a whole. Thus, there is a potential conflict in that Board members who are also part of management will participate in discussions concerning management compensation and audit issues that may affect management decisions. To the extent possible, a majority of the disinterested members of our Board will approve future affiliated transactions. Additionally, because the Company's Common Stock is not listed for trading or quotation on a national securities exchange, we are not required to have such committees.

Nominees to the Board of Directors

During the Company's 2024 fiscal year, there were no material changes to the procedures by which security holders may recommend nominees to the Board.

Item 11. Executive Compensation.

Summary Compensation Table

The following sets forth the compensation of our Chief Executive Officer and Chief Financial Officer during the fiscal year ended December 31, 2024, and the other persons who served as executive officers during the Company's fiscal year ended December 31, 2024. Unless otherwise noted, the amounts shown represent what was earned in the Company's fiscal year ended December 31, 2024.

Summary Compensation Table - Fiscal Year Ended December 31, 2024

Name and principal position	Year (1)	Salary ($)	Bonus ($)	Stock awards ($)	Option awards ($)	Non-equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation ($)	Total ($)
Shlomo Pilo	2024	$ 240,000			$ -				$ 240,000
	2023	$ 244,000			$ -				$ 244,000
Guy Ofir	2024	$ 144,000		$ -	$ -				$ 144,000
	2023	$ 149,000		$ -	$ -				$ 149,000
Dr. Igal Louria-Hayoun	2024	$ -			$ 350,000(2)				$ 350,000
	2023	$ -			$ -				$ -

(1) The information is provided for each fiscal year, which begins on January 1 and ends on December 31.

(2) Relates to warrants to purchase up to 350,000 common stock of the Company, which were granted during 2024 according to a service agreement.

Service Agreements

During fiscal year 2024, we had the following written agreements with our executive officers, including our Chief Executive Officer, Chief Financial Officer and Chief Technology Officer, who are also members of our Board.

Management and Operations Agreement with our Chief Executive Officer

Our Chief Executive Officer provides services to our Company pursuant to a management and operations agreement between the Company and Sheffa Enterprises, Inc., a New Jersey corporation. Since January 1, 2023, we have paid our Chief Executive Officer a monthly fee of $20,000 for his services. In addition, we issued Mr. Pilo warrants to purchase up to 1,000,000 shares of Common Stock, at an exercise price of $1.12 per share, which shall expire on December 31, 2025. On March 3, 2025, we entered into a new management and operations agreement with our Chief Executive Officer, substantially on the same terms as the agreement described above, effective as of January 1, 2025. The management and operations agreement expires on December 31, 2025.

The Company may terminate the management and operations agreement prior to the expiration of its term upon 120 days advance notice and the payment of a termination fee equal to the lesser of (i) $360,000, or (ii) the monthly fees payable through the expiration of its term. Furthermore, as disclosed in the agreement, We have undertaken to indemnify Sheffa Enterprises, Inc. against and in respect of any and losses arising out of or due to the operation of the business by Raphael Israel, its affiliates, agents, servants and/or employees.

Operations Agreement with our Chief Financial Officer

Our Chief Financial Officer provides services to our Company pursuant to an operations agreement between the Company, Model Engineering &Investments SRL, a Romanian Company, and Guy Ofir. Since January 1, 2023, we have paid our Chief Financial Officer a monthly fee of $12,000. In addition, we granted Mr. Ofir 1,000,000 restricted shares of Common Stock and warrants to purchase up to 1,000,000 shares of Common Stock, at an exercise price of $1.00 per share, which shall expire on December 31, 2025. On March 3, 2025, we entered into a new operations agreement with our Chief Financial Officer, substantially on the same terms as the agreement described above, effective as of January 1, 2025 The operations agreement expires on December 31, 2025.

The Company may terminate the operations agreement prior to the expiration of its term upon 120 days advance notice and the payment to Mr. Ofir of a termination fee equal to the lesser of (i) $120,000, or (ii) the monthly fees payable through the expiration of its term.

Service Agreement with our Chief Technology Officer

Our Chief Technology Officer provides services to our Company pursuant to a service agreement, by and between the Company and Dr. Igal Louria Hayon. Pursuant to the terms thereof Dr. Hayon provides consulting services the Company to engage with an array of science consultants and to coordinate collaborations with hospitals on medical cannabis research. Pursuant to such agreement, we agreed to pay our Chief Technology Officer 15% of the Company's net royalty's income from worldwide sales of any of the Company's cannabis-based medical indications treating COVID-19. Pursuant to Dr. Hayon's service agreement, in the event we will apply for any clinical trial of cannabis-based treatment or will begin any other new cannabis related research, the Corporation will grant Dr. Hayon warrants to purchase up to 350,000 shares of Common Stock at an exercise price of $0.01. On May 1, 2024, the milestone was met and the Company granted to Dr. Igal Louria Hayon warrants to purchase up to 350,000 shares of Common Stock of the Company at an exercise price of $0.01. The warrants expire on April 30, 2026. On March 3, 2025, we entered into a new service agreement with our Chief Technology Officer, substantially on the same terms as the agreement described above, effective as of January 1, 2025 Pursuant to such service agreement, we agreed to pay our Chief Technology Officer a monthly fee of $24,000 and to reimburse him with certain expenses related to his scientific work.

The Company may terminate the service agreement prior to the expiration of its term upon 120 days advance notice and the payment to Dr. Hayon of a termination fee equal to the monthly fees payable through the expiration of its term.

The Company has no stock option, retirement, pension, or profit-sharing programs for the benefit of directors, officers or other employees, but our Board may recommend adoption of one or more such programs in the future.

See "Item 13. Certain Relationships and Related Transactions, and Director Independence" below for additional information.

Restricted Stock Awards

During 2024, we did not grant any restricted stock awards.

Outstanding Equity Awards at Fiscal Year End

The following table provides information regarding equity awards held by the named executive officers that were outstanding as of December 31, 2024:

	Equity Awards				
Name	**Grant Date**	**Number of Securities Underlying Unexercised Options / Warrants Exercisable [1] [2] (#)**	**Number of Securities Underlying Unexercised Options / Warrants Unexercisable (#)**	**Option / Warrants Exercise Price ($)**	**Option / Warrants Expiration Date**
Shlomo Pilo	12/5/2022	1,000,000	-	1.12	12/31/2025
Guy Ofir	12/5/2022	1,000,000	-	1.00	12/31/2025
Igal Louria Hayon	05/01/2024	350,000	-	0.01	04/30/2026

(1) Amounts in this column represent warrants granted to each of the directors pursuant to their respective service agreements.

(2) Unless otherwise indicated, all of the warrants vested upon granting and are exercisable immediately.

Director Compensation

The Company did not pay any fees to their respective directors for attendance at meetings of the Board; however, the Company may adopt a policy of making such payments in the future. The Company may reimburse out-of-pocket expenses incurred by directors in attending Board and committee meetings.

The following table sets forth information concerning compensation accrued or paid to our non-employee directors during the year ended December 31, 2024 for their service on our Board.

Name	Fees earned or paid in cash ($)	Option / Warrant Awards ($)[1]	All other compensation ($)	Total ($)
Igal Louria Hayon	-	$ 350,000	-	$ 350,000

(1) Amounts in this column represent the grant date fair value of warrants granted to each of the directors pursuant to their respective service agreements.

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

Security Ownership of Certain Beneficial Owners

The following table sets forth information regarding beneficial ownership of our Common Stock as of March 28, 2025 by:

- each person, or group of affiliated persons, known to us to be the beneficial owner of at least 5% of our outstanding Common Stock;
- each of our directors and executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to Common Stock. Percentage of shares beneficially owned is based on 19,626,418 shares outstanding on March 28, 2025.

Except as indicated in footnotes to this table, we believe that the shareholders named in this table have sole voting and investment power with respect to all shares shown to be beneficially owned by them, based on information provided to us by such shareholders. Unless otherwise noted below, each beneficial owner's address is: 4 Lui Paster, Tel Aviv-Jaffa, Israel 6803605.

	No. of Shares Beneficially Owned	Percentage Owned
Holders of more than 5% of our voting securities:		
Haim Castro	1,255,325	6.4%
Directors and executive officers:		
Guy Ofir	2,312,156	11.2%
Shlomo Pilo	5,083,701	24.5%
Dr. Igal Louria Hayon	1,349,000	6.8%
Dr. Yehuda Eliya	-	-%
Ajay Kumar Dhadha	1,004,820	5.1%
All directors and executive officers as a group (5 persons)	11,005,002	54.0%

Changes in Control

There are no arrangements known to the Company, including any pledge by any person of securities of the Company, the operation of which may at a subsequent date result in a change in control of the Company.

Equity Compensation Plan Information

Currently, there is no equity compensation plan in place.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Transactions with Related Persons

Service Agreements with Non-Employee Directors

During fiscal year 2024, we entered into written service agreements with our non-employee directors.

On July 5, 2022 we entered into a service agreement with Yehuda Eliya, pursuant to which Mr. Eliya will serve as a member of our Board. Pursuant to the service agreement, we granted Mr. Eliya warrants to purchase up to 202,000 shares of common stock, at an exercise price of $1.12 per share, which expired unexercised during 2024. On December 25, 2023, we amended Mr. Eliya's service agreement to extend its expiry date to December 31, 2024. On March 10, 2025, we entered into a new service agreement with Mr. Eliya, substantially on the same terms, effective as of January 1, 2025 Pursuant to such service agreement, we have granted Mr. Eliya warrants to purchase up to 200,000 shares of Common Stock, at an exercise price of $1.0 per share. The warrants will expire on March 10, 2026.

On March 5, 2025, we entered into a service agreement with Ajay Kumar Dhadha, pursuant to which Mr. Dhadha will serve as a member of our Board and as chairman of the Board. Pursuant to the service agreement, on March 5, 2025, we granted Mr. Dhadha 350,000 restricted shares of the Company's Common Stock and warrants to purchase up to 250,000 shares of Common Stock at an exercise price of $1.00 per share. The warrants will expire on December 31, 2026.

Indemnification Agreements

We have entered into indemnification agreements with our directors pursuant to which we agreed to indemnify each director for any liability he or she may incur by reason of the fact that he or she serves as our director, to the maximum extent permitted by law.

Policies and Procedures for Related-Party Transactions

Our Company does not have any formal written policies or procedures for related party transactions, however in practice, our Board's reviews and approves all related party transactions and other matters pertaining to the integrity of management, including potential conflicts of interest and adherence to standards of business conduct. We have two independent directors on our Board. See Item 13. Certain Relationships and Related Transactions, and Director Independence" for further information.

Director Independence

None of our securities are listed or trade on any securities or currency exchange or other established public trading market. However, the members of our Board have reviewed their relationship with the Company in conjunction with Nasdaq Listing Rule 5605(a)(2) that provides that an "independent director" is 'a person other than an executive officer or employee of the Company or any other individual having a relationship which, in the opinion of the Company's Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.' Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, our Board has affirmatively determined that each of Ajay Kumar Dhadha, Prof. Press and Dr. Eliya has no relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and is independent within the meaning of the director independence standards of the Nasdaq rules and the SEC. Our members of the Board have determined that Dr. Louria-Hayon, Mr. Ofir and Mr. Pilo do not qualify as independent directors pursuant to the standards described above.

Our Company does not have a separately designated audit, nominating or compensation committee or committee performing similar functions; therefore, our full Board of directors currently serves in these capacities.

Item 14. Principal Accounting Fees and Services.

We were billed the following fees for professional services rendered by our auditor Elkana Amitai CPA and Weinstein International CPA, or our Former Auditor, for the years ended December 31, 2024 and 2023.

	2024	2023
	U.S. dollars in thousands	
Elkana Amitai CPA (1)		
Audit fees (2)	29,500	-
Audit - related fees	-	-
Tax fees	-	-
All other fees	-	-
Total	33,500	-
Weinstein International CPA (3)		
Audit fees (4)	11,000	30,000
Audit -related fees	-	-
Tax fees	-	-
All other fees	-	-
Total	11,000	30,000

(1) On September 11, 2024, our Board approved the engagement with Elkana Amitai CPA as the Company's new independent registered public accounting firm.

(2) Consists of fees for audit of the Company's annual financial statements, audit of the financial statements of acquired subsidiaries, the review of interim financial statements included in the Company's quarterly reports, consents, and the review of other documents filed with the SEC.

(3) On September 11, 2024, our Board dismissed Weinstein International CPA as the Company's independent registered public accounting firm, effective September 5, 2024. During the fiscal years ended December 31, 2022 and 2023, and the subsequent interim period through September 5, 2024, there were (i) no "disagreements" (as that term is defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) between the Company and the Former Auditor on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of the Former Auditor, would have caused the Former Auditor to make reference to the subject matter of the disagreement in its reports on the Company's financial statements and (ii) no "reportable events" (as that term is defined in Item 304(a)(1)(v) of Regulation S-K and the related instructions).

(4) Consists of fees for audit of the Company's annual financial statements, audit of the financial statements of acquired subsidiaries, the review of interim financial statements included in the Company's quarterly reports, consents, and the review of other documents filed with the SEC

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Financial Statements.

RAPHAEL PHARMACEUTICAL INC. AND ITS SUBSIDIARY

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2024

U.S. DOLLARS IN THOUSANDS

INDEX

	Page
Report of independent Registered Public Accounting Firm (PCAOB ID No. 681600001)	F-2
Consolidated Balance Sheets	F-4
Consolidated Statements of Comprehensive Loss	F-5
Consolidated Statements of Changes in Stockholders' Equity (Deficit)	F-6
Consolidated Statements of Cash Flows	F-7
Notes to Consolidated Financial Statements	F-8 - F-23

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Raphael Pharmaceutical Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Raphael Pharmaceutical Inc. and its subsidiary (the “Company”) as of December 31, 2024 and 2023, the related consolidated statements of comprehensive loss, changes in stockholders’ equity (deficit) and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023 and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

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.

Going Concern

The accompanying financial statements have been prepared to assume that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, as of December 31, 2024, The Company suffered losses from operations and further losses are anticipated in the development of its business. These and other factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plan regarding these matters is also described in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. This matter is also described in the "Critical Audit Matters" section of our report.

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) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Going Concern- Refer to Note 1 to the financial statements

Critical Audit Matter Description

The Company raised substantial doubt about the entity's ability to continue as a going concern for a reasonable period of time. The financial statements for the years under audit have been prepared to assume that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We have identified the Going Concern as a critical audit matter because of the significant estimates and assumptions made by management. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the reasonableness of the Company's assessment of Going Concern. See the explanatory paragraph of the opinion paragraph.

How the Critical Audit Matter Was Addressed in the Audit

(i) We evaluate whether there is substantial doubt about the entity's ability to continue as a going concern for a reasonable period of time. (ii) We obtained information about management's plans that are intended to mitigate the effect of such conditions or events, and assess the likelihood that such plans can be effectively implemented. (iii) We added an explanatory paragraph to the audit report.

/s/ Elkana Amitai CPA

We have served as the Company's auditor since 2024

Mitzpe Netofa, Israel

March 31, 2025

RAPHAEL PHARMACEUTICAL INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

U.S dollars in thousands (except for share and per share data)

	Note	As of December 31, 2024	2023
Assets			
Current assets:			
Cash and cash equivalents		$ 19	$ 230
Other current assets	3	6	7*
Total current assets		25	237*
Non-Current assets:			
Fixed asset, net		2	2
Total assets		$ 27	$ 239*
Liabilities and stockholders' equity (deficit)			
Current liabilities:			
Other accounts payable and accrued expenses	4	500	94*
Short term loan	5	41	-
Payable to related party		228	38
Total current liabilities		769	132*
Stockholders' equity (deficit):			
Common stock, $0.01 par value: Authorized: 21,020,560 shares; Issued and outstanding: 18,701,418 and 18,502,918 as of December 31, 2024 and December 31, 2023, respectively		187	185
Receivable on account of shares		-	(100)*
Additional paid-in capital		7,960	7,392
Accumulated deficit		(8,889)	(7,370)*
Total stockholders' equity (deficit)		(742)	107*
Total liabilities and stockholders' equity		$ 27	$ 239

(*) reclassified.

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

RAPHAEL PHARMACEUTICAL INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

U.S dollars in thousands (except for share and per share data)

	Note	For the year ended December 31, 2024	2023
Research and development expenses	11a	$ 776	$ 569
General and administrative expenses	11b	733	763*
Operating loss		1,509	1,332*
Total financial expense, net	11c	10	12
Net loss and comprehensive loss		1,519	1,344*
Basic and diluted net loss per share		0.08	0.08
Weighted average number of common shares used in computing basic and diluted net loss per share		18,674,136	16,716,905

(*) reclassified.

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

RAPHAEL PHARMACEUTICAL INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES STOCKHOLDERS' IN EQUITY (DEFICIT)

U.S dollars in thousands (except for share and per share data)

	Common stock		Additional paid-in capital	Receivable on account of shares	Accumulated deficit	Total equity
	Number	Amount				
Balance as of January 1, 2023	15,624,040	$ 157	$ 5,975	$ -	$ (6,026)	$ 106
Issuance of common stock and warrants	2,677,878	26	1,219	(100)	-	1,145
Issuance of common stock in exchange for services	201,000	2	198	-	-	200
Net loss	-	-	-	-	(1,344) **	(1,344) **
Balance as of December 31, 2023	18,502,918	$ 185	$ 7,392	$ (100)	$ (7,370) **	$ 107**

	Common stock		Additional paid-in capital	Receivable on account of shares	Accumulated deficit	Total equity
	Number	Amount				
Balance as of January 1, 2024	18,502,918	$ 185	$ 7,392	$ (100)	$ (7,370) **	$ 107**
Issuance of common stock and warrants	158,500	2	178	100	-	280
Issuance of common stock in exchange for services	40,000	(*	40	-	-	40
Share based compensation expenses	-	-	350	-	-	350
Net loss	-	-	-	-	(1,519)	(1,519)
Balance as of December 31, 2024	18,701,418	187	$ 7,960	$ -	$ (8,889)	$ (742)

(*) less than 1 thousand.
(**) reclassified.

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

RAPHAEL PHARMACEUTICAL INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S dollars in thousands (except for share and per share data)

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (1,519)	$ (1,344) **
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based payment in exchange for services	40	200
Share-based compensation	350	-
Depreciation	*)	*)
Changes in:		
Other current assets	1	36
Related parties	190	35
Other accounts payables and accrued expenses	406	(130) **
Net cash used in operating activities	(532)	(1,203)
Cash flows from investing activities		
Purchase of fixed assets	-	-
Net cash provided by investing activities	-	-
Cash flows from financing activities		
Receipt of a loan	41	-
Proceeds from issuance of common stock and warrants	280	1,145
Net cash provided by financing activities	321	1,145
Change in cash and cash equivalents	(211)	(58)
Cash and cash equivalents at the beginning of the year	230	288
Cash and cash equivalents at the end of the year	$ 19	$ 230
Non cash supplement		
Issuance of shares for past services (Note 7i)	$ -	$ 200
Exercise of warrants (Note 7n)	$ -	$ 100

(*) less than 1 thousand.
(**) reclassified.

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

NOTE 1:- GENERAL

a. Raphael Pharmaceutical Inc (formerly Easy Energy, Inc.) ("Raphael", or the "Company") was incorporated under the laws of the State of Nevada on May 17, 2007. The Company is headquartered in Tel Aviv-Jaffa, Israel. From April 1, 2011 until December 31, 2019, the Company was not active.

On October 8, 2020, the Company and its stockholders entered into a Share Exchange Agreement (the "Share Exchange") with an Israeli pharmaceutical company ("Raphael"), according to which, among other matters, all shareholders of Raphael will sell and convey the entire holdings in Raphael to the Company such that following the Share Exchange, the shareholders of Raphael will hold 90% of the issued and outstanding common stock of the Company, and the existing shareholders of the Company will hold the remaining 10% of the issued and outstanding common stock.

On May 14, 2021, the Company's board of directors and stockholders approved a 1-for-100 reverse split of the Company's common stock, which was implemented and became effective as of May 14, 2021. The reverse split combined each one hundred (100) shares of the Company's issued and outstanding Common stock into one share of common stock. No fractional shares were issued in connection with the reverse split, and any fractional shares resulting from the reverse split were rounded up to the nearest whole share.

On May 14, 2021, Raphael and the Company, completed the Share Exchange pursuant to which 9,459,253 common stock were issued to the shareholders of Raphael so that they became the holders of 90% of the issued and outstanding common stock of the Company immediately after the Share Exchange while the Company's shareholders hold, following the Share Exchange, 1,051,028 common stock which represents 10% of the Company. On May 19, 2021, as agreed by the parties to the Share Exchange, the Company changed its name to Raphael Pharmaceutical Inc. Following such Share Exchange, Raphael's activities are the sole activities of the Company.

The Share Exchange was accounted for as a reverse recapitalization which is outside the scope ASC 805, "Business Combinations" ("ASC 805"), as the Company, the legal acquirer, is considered a non-operating public shell, and is therefore not a business as defined in ASC 805. As the shareholders of Raphael received the largest ownership interest in the Company, Raphael was determined to be the "accounting acquirer" in the Share Exchange. As a result, the historical financial statements of the Company were replaced with the financial statement of Raphael for all periods presented.

Company's common stock began public trading on the over the counter market in the U.S. in January 2023 under the symbol "RAPH".

b. Going concern and management plans

The accompanying consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Since its inception, the Company has devoted substantially all of its efforts to research and development, clinical trials, and raising capital. The Company is still in its development and pre-clinical stage and has not yet generated revenues. The extent of the Company's future operating losses and the timing of becoming profitable are uncertain. As of December 31, 2024, the Company's accumulated deficit was $8,889, the net loss for the year then ended was $1,519 and the net cash used in operating activities was $532.

NOTE 1:- GENERAL (Cont.)

The Company has funded its operations to date primarily through equity financing.

Additional funding will be required to complete the Company's research and development and clinical trials, to attain regulatory approvals, to begin the commercialization efforts of the Company's product and to achieve a level of sales adequate to support the Company's cost structure.
Management's plans include, but are not limited to, raising capital in the United States. There can be no assurance that it will be able to successfully raise additional financing, including in a public offering, or obtain additional financing on a timely basis or on terms acceptable to the Company, or at all.

Management expects that the Company will continue to generate losses from the development, clinical development and regulatory activities of its product, which will result in negative cash flow from operating activity. This has led management to conclude that substantial doubt about the Company's ability to continue as a going concern exists in the event that additional funding does not occur. If such sufficient financing is not received timely, the Company will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated and would then need to pursue a plan to license its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection. The Company's financial statements do not reflect any adjustments that might result from the outcome of this uncertainty.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation:

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

The consolidated financial statements include the accounts of the Company and its subsidiary. Intercompany accounts and transactions have been eliminated upon consolidation.

b. Use of estimate in preparation of the consolidated financial statements:

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company evaluates on an ongoing basis its assumptions. The Company's management believes that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Actual results could differ from those estimates.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

c. Consolidated financial statements in United States dollars:

The Company's functional currency is the U.S. dollar ("dollar" or "$") since the dollar is the currency of the primary economic environment in which the Company has operated and expects to continue to operate in the foreseeable future. Transactions and balances denominated in dollars are presented at their original amounts. Transactions and balances denominated in currencies other than dollars have been re-measured to dollars. All transaction gains and losses from re-measurement of monetary balance sheet items denominated in currencies other than dollars are reflected in the statements of comprehensive loss as financial expenses, net.

d. Cash and cash equivalents:

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with original maturities of three months or less as of the date acquired and that are exposed to insignificant risk of change in value.

e. Fair value measurements:

The carrying values of Company's financial assets and liabilities, including cash and cash equivalents, other current assets, related parties, accounts payable and accrued expenses approximate their fair value due to the short-term maturity of these instruments.

f. Research and development expenses:

Research and development expenses are charged to the statements of comprehensive loss as incurred.

g. Income taxes:

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes". ASC 740 prescribes the use of the liability method whereby deferred tax assets and liability account balances are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances in respect of deferred tax assets are provided for, if necessary, to reduce deferred tax assets to amounts more likely than not to be realized. As of December 31, 2024, and 2023, the Company had a full valuation allowance on its deferred tax assets.

h. Basic and diluted net loss per share:

Earnings or loss per share ("EPS") is the amount of earnings attributable to each share of common stock. For convenience, the term is used to refer to either earnings or loss per share. EPS is computed pursuant to ASC 260-10-45. Pursuant to ASC 260-10-45-10 through 260-10-45-16 Basic EPS is computed by dividing income available to common stockholders (the numerator) by the weighted-average number of common shares outstanding (the denominator) during the period. Loss available to common stockholders shall be computed by deducting both the dividends declared in the period on preferred stock (whether or not paid) from loss from operating loss (if that amount appears in the statements of comprehensive loss) and also from net loss.

U.S dollars in thousands (except for share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

The computation of diluted EPS is similar to the computation of basic EPS except that the denominator is increased to include the number of additional common shares that would have been outstanding if the dilutive potential common stock had been issued during the period to reflect the potential dilution that could occur from common shares issuable through contingent shares issuance arrangement, stock options or warrants.

The net loss per share and the weighted average number of shares used in computing basic and diluted net loss per share is as follows:

	For the Year Ended December 31,	
	2024	**2023**
Numerator:		
Net loss applicable to common stockholders	$ (1,519)	$ (1,344)
Denominator:		
Number of shares of common stock used in computing basic and diluted net loss per share	18,674,136	16,716,905
Net loss of shares of common, basic and diluted	$ (0.08)	$ (0.08)

i. Leases

In February 2016, the Financial Accounting Standards Borad (“FASB”) issued ASU 2016-02, Leases (Topic 842) (“ASU 2016-02”). ASU 2016-02 requires lessees to recognize their leases contracts as assets and liabilities in the consolidated financial statements. Furthermore, the ASU requires the Company to continue recognizing expenses but recognize expenses on their statements of comprehensive loss in a manner similar to current lease accounting. The amendments in this ASU are effective January 1, 2019. In July 2018, the FASB issued ASU 2018-11, Leases - Targeted Improvements, to allow a company to elect an optional modified retrospective transition method that applies the new lease requirements through a cumulative-effect adjustment in the period of adoption.

Effective January 2019, the Company adopted the new lease accounting standard. The Company elected to apply the practical expedients permitted under the transition guidance within the new standard. As such, there was no impact on the Company’s consolidated financial statements as a result of adopting ASU 2016-02. See note 6a for more details.

U.S dollars in thousands (except for share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

j. Recently adopted accounting pronouncements:

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures, which expands public entities' segment disclosures primarily by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items. The guidance is in effect for the Company for annual periods beginning January 1, 2024 and will be in effect for the interim periods beginning January 1, 2025. Early adoption is permitted. The Company has adopted this standard for the fiscal year 2024 annual financial statements and interim financial statements thereafter and has applied this standard retrospectively for all prior periods presented in the financial statements. See Note 10 – Segment Reporting for further information.

k. Recently issued accounting pronouncements not yet adopted

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740), Improvements to Income Tax Disclosures, which requires disaggregated information about the effective tax rate reconciliation as well as information on income taxes paid. The guidance will be in effect for the Company for annual periods beginning January 1, 2025, with early adoption permitted. The Company is currently evaluating the impact on its financial statement disclosures.

In November 2024, the FASB issued ASU 2024-03 "Income Statement (Topic 220): Reporting Comprehensive Income - Expense Disaggregation Disclosures" ("ASU 2024-03"), which requires more detailed information about specified categories of expenses presented on the face of the income statement, in addition to disclosures about selling expenses. ASU 2024-03 will be in effect for fiscal years beginning after December 15, 2026, with early adoption permitted. The amendment may be applied either prospectively to financial statements issued for reporting periods after the effective date or retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating ASU 2024-03 to determine the impact it may have on its consolidated financial statements and related disclosures.

NOTE 3:- OTHER CURRENT ASSETS

	As of December 31,	
	2024	**2023**
Receivables on account of shares	$ -	$ -*
Receivables from governmental authorities	2	7
Prepaid expenses	4	-
	$ 6	$ 7*

(*) reclassified.

U.S dollars in thousands (except for share and per share data)

NOTE 4:- OTHER ACCOUNTS PAYABLE AND ACCRUED EXPENSES

	As of December 31,	
	2024	2023
Account payables	$ 125	$ 69*
Accrued expenses	375	25
	$ 500	$ 94*

(*) reclassified.

NOTE 5:- SHORT TERM LOAN

On December 24, 2024, the Company received a short term loan from certain lender in a total of NIS 150 thousand ($41). The loan will be repaid in 4 months including a risk premium of NIS 12 thousand + VAT. The Company's chief executive officer ("CEO") and chief financial officer ("CFO") are guarantees for the repayment of the loan.

NOTE 6:- CONTINGENT LIABILITIES AND COMMITMENTS

a. Lease commitments:

Starting February 1, 2022, the Company began renting its offices from a third party for a rental monthly fee of approximately $1 per month. The rent period is for a period of one month which renews on a monthly basis.

The Company elected to apply the practical expedients permitted under the transition guidance within the new standard, and the Company also elected not to apply the recognition requirements in the lease standard to short-term leases (less than 12 months) as of the adoption date. As such, there was no impact on the Company's consolidated financial statements as a result of adopting ASU 2016-02.

b. Rambam research agreement

On July 17, 2019, we entered into a sponsored research agreement, (the "Research Agreement"), with Rambam Med-Tech Ltd. ("Rambam MT"), pursuant to which the Company agreed to fund a research project, to be performed by Rambam MT, with a research plan aimed at identifying the effects of different cannabis strains on the function of immune cells. On October 28, 2020, the Company and Rambam MT agreed to expand the research plan to study the anti-inflammatory activities of cannabis extracts in an RA mouse model. On February 15, 2021, the Company and Rambam MT agreed to further expand the research plan to study the effect of cannabis extracts on the immunopathology of the COVID-19 disease. The Research Agreement is for an initial term of 48 months. On October 23, 2022, the Company and Rambam MT entered into a supplement to the Research Agreement, or the Supplement Agreement, pursuant to which the Company exercised an option to extend the Research Agreement by additional two years until December 31, 2024.

As of December 31, 2024 the Company paid $1,400.

NOTE 6:- CONTINGENT LIABILITIES AND COMMITMENTS (Cont.)

In October 2022, the Company and Rambam signed a supplement to the Research Agreement, according to which the objective of the new study will be to identify a novel cannabinoid based patentable formulation to treat RA diseases. The total cost of the new study will be $800 + $160 (overhead) + VAT (which consist of $700 + VAT pre-clinical lab research cost, $120 + VAT Mouse model for systemic inflammation and $140 + VAT Mouse model for Rheumatoid Arthritis). The Company's payments will be according to the payment schedule stipulated in the supplement and will begin in May 2023.

As of December 31, 2024 the Company paid $120.

c. Way of Life Cannabis research agreement

In October 2020, Raphael entered into an engagement agreement with Way of Life Cannabis Ltd. ("WOLC"), pursuant to which, subject to its completing the Share Exchange with Easy Energy, Raphael will be provided with up to 15 liters of CBD oil, from a strain of cannabis during a term of 18 months, to be provided in two to three deliveries of between one to seven liters of CBD oil.

In accordance with Raphael's agreement with WOLC, Raphael has agreed to issue to certain persons affiliated with WOLC 3% of Raphael's issued and outstanding share capital as of the date of the Share Exchange, to be provided in three equal issuances; provided, however, that such persons may elect to receive a cash payment of $100 instead of any one issuance of Raphael's shares. In addition to the issuance of shares, Raphael has also agreed to pay WOLC a royalty fee equal to 15% of the net royalties generated from sales of Raphael's pharmaceutical drug products that are developed at Rambam hospital in Israel. In February 2023, the Company and WOLC signed an appendix to the research agreement, according to which the parties agreed that WOLC provided to the Company 12 out of 15 liters of CBD oil, from a strain of cannabis and the Company will transfer to WOLC the remaining stock per research agreement. In addition, WOLC will transfer the remaining 3 liters of CBD oil to the Company upon Company's request.

On July 27, 2022, the Company issued 100,500 shares of common stock to WOLC in connection with the engagement agreement. The value of such issued shares was based on the value of the service provided, which amounted to $100. In June 2023, the Company issued the remaining 201,000 shares of common stock to WOLC in connection with the services agreement dated October 2020. The value of the shares issued was based on the value of the service provided, which amounted to $200.

d. Service agreement with executive officers:

During fiscal year 2024, we had the following written agreements with our executive officers, including our CEO, CFO and Chief Technology Officer, who are also members of our Board.

- Our Chief Executive Officer provides services to our Company pursuant to a management and operations agreement between the Company and Sheffa Enterprises, Inc., a New Jersey corporation. Since January 1, 2023, we have paid our Chief Executive Officer a monthly fee of $20,000 for his services. In addition, we issued Mr. Pilo warrants to purchase up to 1,000,000 shares of Common Stock, at an exercise price of $1.12 per share, which shall expire on December 31, 2025. On March 3, 2025, we entered into a new management and operations agreement with our Chief Executive Officer, substantially on the same terms as the agreement described above, effective as of January 1, 2025. The management and operations agreement expires on December 31, 2025.

  The Company may terminate the management and operations agreement prior to the expiration of its term upon 120 days advance notice and the payment of a termination fee equal to the lesser of (i) $360,000, or (ii) the monthly fees payable through the expiration of its term. Furthermore, as disclosed in the agreement, We have undertaken to indemnify Sheffa Enterprises, Inc. against and in respect of any and losses arising out of or due to the operation of the business by Raphael Israel, its affiliates, agents, servants and/or employees

NOTE 6:- CONTINGENT LIABILITIES AND COMMITMENTS (Cont.)

- Our Chief Financial Officer provides services to our Company pursuant to an operations agreement between the Company, Model Engineering &Investments SRL, a Romanian Company, and Guy Ofir. Since January 1, 2023, we have paid our Chief Financial Officer a monthly fee of $12,000. In addition, we granted Mr. Ofir 1,000,000 restricted shares of Common Stock and warrants to purchase up to 1,000,000 shares of Common Stock, at an exercise price of $1.00 per share, which shall expire on December 31, 2025. On March 3, 2025, we entered into a new operations agreement with our Chief Financial Officer, substantially on the same terms as the agreement described above, effective as of January 1, 2025 The operations agreement expires on December 31, 2025.

  The Company may terminate the operations agreement prior to the expiration of its term upon 120 days advance notice and the payment to Mr. Ofir of a termination fee equal to the lesser of (i) $120,000, or (ii) the monthly fees payable through the expiration of its term.

- Our Chief Technology Officer provides services to our Company pursuant to a service agreement, by and between the Company and Dr. Igal Louria Hayon. Pursuant to the terms thereof Dr. Hayon provides consulting services the Company to engage with an array of science consultants and to coordinate collaborations with hospitals on medical cannabis research. Pursuant to such agreement, we agreed to pay our Chief Technology Officer 15% of the Company's net royalty's income from worldwide sales of any of the Company's cannabis-based medical indications treating COVID-19. Pursuant to Dr. Hayon's service agreement, in the event we will apply for any clinical trial of cannabis-based treatment or will begin any other new cannabis related research, the Corporation will grant Dr. Hayon warrants to purchase up to 350,000 shares of Common Stock at an exercise price of $0.01. On May 1, 2024, the milestone was met and the Company granted to Dr. Igal Louria Hayon warrants to purchase up to 350,000 shares of Common Stock of the Company at an exercise price of $0.01. The warrants expire on April 30, 2026. On March 3, 2025, we entered into a new service agreement with our Chief Technology Officer, substantially on the same terms as the agreement described above, effective as of January 1, 2025 Pursuant to such service agreement, we agreed to pay our Chief Technology Officer a monthly fee of $24,000 and to reimburse him with certain expenses related to his scientific work.

  The Company may terminate the service agreement prior to the expiration of its term upon 120 days advance notice and the payment to Dr. Hayon of a termination fee equal to the monthly fees payable through the expiration of its term.

NOTE 7:- STOCKOLDERS' EQUITY

a. On November 4, 2022, the Company signed an agreement to raise $100 and to issue 80,000 shares of common stock and 20,000 warrants to purchase common stock at an exercise price of $1.5 per share to certain investor of the Company. The warrants are exercisable until September 30, 2023. The shares of common stock were issued on January 10, 2023.

b. In December 2022, the Company signed an agreement to raise $20 and to issue 15,750 shares of common stock and 47,250 warrants to purchase common stock at an exercise price of $1.25 per share to certain investor of the Company. The warrants are exercisable until December 31, 2024. The shares of common stock were issued on January 10, 2023.

c. In December 2022, the Company signed an agreement to raise $200 and to issue 160,000 shares of common stock and 40,000 warrants to purchase common stock at an exercise price of $1.5 per share to certain investor of the Company. The warrants are exercisable until December 31, 2023. The shares of common stock were issued on January 10, 2023.

d. On December 30, 2022, the Company signed an agreement to raise $7.5 and to issue 6,000 shares of common stock and 18,000 warrants to purchase common stock at an exercise price of $1.25 per share to certain investor of the Company. The warrants are exercisable until February 28, 2024. The investment above and share issuance took place in January 2023.

e. In January 2023, the Company issued 255,750 shares of common stock following certain share purchase agreements dated November and December 2022.

NOTE 7:- STOCKOLDERS' EQUITY (Cont.)

f. On January 8, 2023, certain investor of the Company and the Company signed an agreement to raise $250 and to issue 250,000 shares of common stock and 100,000 warrants to purchase common stock at an exercise price of $1.13 per share following the exercise of an option for additional investment. The warrants are exercisable until April 30, 2024. In January 2023, the investor and the Company agreed to raise $117 out of the $250 investment. As a result, the Company received $117 and issued 117,000 shares of common stock and the issuance of 100,000 warrants to purchase common stock of the Company were cancelled.

g. From March through June, 2023, certain investors of the Company and the Company signed an agreement to raise $198 and to issue 170,378 shares of common stock. The shares were issued in April 2023.

h. In May 2023, certain investor of the Company and the Company signed an agreement to exercise investors warrants into Company's common stock. In May 2023, the investor transferred $123.

i. In June 2023, the Company issued 201,000 shares of common stock to Way of Life Cannabis Ltd., or WOLC, in connection with the services agreement dated October 2020. The value of the shares issued was based on the value of the service provided and amounted to $200.

j. From July through September, 2023, certain investors of the Company exercised their warrants into shares and as such, the Company received $480 (including $123 which was received in May 2023) and issued 1,454,250 shares of common stock.

k. In September 2023, certain investor of the Company and the Company signed an agreement to raise $50 and to issue 100,000 shares of common stock.

l. In September 2023, certain investor of the Company and the Company signed an agreement to exercise investors warrants into Company's common stock for an amount of $180. In September and December 2023, the investor transferred $180 and the Company issued 180,000 shares.

m. In November 2023, certain investor of the Company and the Company signed an investment agreement according to which the investors transferred $116 and the Company issued 200,500 shares.

U.S dollars in thousands (except for share and per share data)

NOTE 7:- STOCKOLDERS' EQUITY (Cont.)

n. In December 2023, certain investors of the Company and the Company signed an agreement to exercise investors warrants into Company's common stock for an amount of $100. In December 2023, the Company issued 200,000 shares.

As of December 31, 2023, the consideration for the warrant exercise above was recorded as receivables from issuance of shares.

o. In January 2024, the Company and certain investors signed an investment agreement according to which the investors transferred $80 and the Company issued 58,500 shares.

p. In January 2024, the Company signed an agreement to raise $100 and to issue 100,000 shares of common stock and 100,000 warrants to purchase common stock at an exercise price of $1 per share to certain investor of the Company. The warrants were exercisable until December 31, 2024.

q. In January 2024, the Company received $100 from certain shareholder as part of shareholders' warrants exercise which occurred in December 2023.

r. In May 2024, the Company issued 40,000 shares in connection with service agreement with certain service provider.

s. In May 2024, the Company signed an agreement to raise 350,000 warrants to purchase common stock at an exercise price of $0.01 per share to certain investor of the Company.

The following table summarizes information regarding outstanding warrants to purchase the Company's ordinary shares as of December 31, 2024:

Issuance date	Number of outstanding Warrants	Exercise price per warrant
July 2022	1,000,000	$ 1
July 2022	1,000,000	$ 1.12
May 2024	350,000	$ 0.01
	2,350,000	

U.S dollars in thousands (except for share and per share data)

NOTE 7:- STOCKOLDERS' EQUITY (Cont.)

	Number of warrants
Outstanding at December 31, 2022	4,341,250
Grants	20,000
Exercised	(1,984,250)
expired	(70,000)
Outstanding at December 31, 2023	2,307,000
Grants	450,000
Exercised	-
expired	(407,000)
Outstanding at December 31, 2024	2,350,000

NOTE 8:- RELATED PARTIES BALANCES AND TRANSACTIONS

A. Balances

The following related party payables are included in accounts payable and accrued expenses.

	As of December 31,	
	2024	2023
Payables to related party - Officers (*)	228	38
	228	38

(*) Relates to CEO's and CFO's services

U.S dollars in thousands (except for share and per share data)

NOTE 8:- RELATED PARTIES BALANCES AND TRANSACTIONS (Cont.)

The Company's CEO and CFO are guarantees for the repayment of the loan (see note 5).

B. Transactions

	Year ended December 31,	
	2024	2023
Consulting services (*)	240	244
Stock-based compensation	350	
CFO fee (**)	144	149
	734	393

(*) Including salary expenses to the Company's CEO and CFO. For further details on the consulting agreement with Company's CEO, refer to Note 6d.
(**) Including legal services provided to Company's subsidiary by Company's CFO with respect to an agreement between the Company and its CFO.

NOTE 9:- TAXES ON INCOME

Income tax rates applicable to the Company in 2024 and 2023 was 21%.

b. Foreign income tax:

1. Income tax rates:

Presented hereunder are the income tax rates relevant to the Company's Israeli subsidiary

2023 - 23%
2024 - 23%

2. As of December 31, 2024, the Company had U.S. federal net operating loss carryforwards of approximately $3,210 available to reduce future taxable income. There is a limitation on the amount of taxable income that can be offset by carryforwards after a change in control (generally greater than a 50% change in ownership). Losses from 2018 and forward that can only offset 80% of taxable income in a future year.

The Company's Israeli subsidiary have estimated total available carryforward operating tax losses for Israeli income tax purposes of approximately $3,755 as of December 31, 2024.

U.S dollars in thousands (except for share and per share data)

NOTE 9:- TAXES ON INCOME (Cont.)

c. Deferred income taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

	As of December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carry forward	$ 6,965	$ 5,741
Deferred tax asset before valuation allowance	1,538	1,270
Valuation allowance	(1,538)	(1,270)
Net deferred tax asset	$ -	$ -

d. Reconciliation of the theoretical tax expense to the actual tax expense:

The main reconciling item between the statutory tax rate of the Company and the effective tax rate is the recognition of valuation allowance in respect of deferred taxes relating to accumulated net operating losses carried forward due to the uncertainty of the realization of such deferred taxes.

	Year ended December 31,	
	2024	2023
Net loss, as reported in the consolidated statements of comprehensive loss	$ 1,519	$ 1,344*
Statutory tax rate	21%	21%
Computed "expected" tax income	319	282*
Valuation allowance	(319)	(282*)
Taxes on income	$ -	$ -

(*) reclassified.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S dollars in thousands (except for share and per share data)

NOTE 10:- SEGMENT REPORTING

ASC 280, "Segment Reporting," establishes standards for reporting information about operating segments. Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker ("CODM") in deciding how to allocate resources and in assessing performance. The Company's business is comprised of one operating segment.

The Company's CODM is its Chief Executive Officer, who reviews financial information presented on a consolidated basis.

The CODM uses consolidated net loss to assess financial performance and allocate resources. These financial metrics are used by the CODM to make key operating decisions, such as the allocation of budget between Research and development and General and Administrative expenses. Segment assets that are reviewed by the CODM are reported within the Consolidated Balance Sheet as consolidated total assets.

The table below summarizes the significant expense categories regularly reviewed by the CODM for the years ended December 31, 2024 and 2023:

	For the Year Ended December 31	
	2024	2023
Clinical developments	$ 776	569
Other segments expenses	743	775*
	$ 1,519	$ 1,344*

(*) reclassified.

NOTE 11:- SELECTED STATEMENTS OF COMPREHENSIVE LOSS DATA

a. Research and development expenses:

	For the Year Ended December 31	
	2024	2023
Subcontractors and consultants	$ 415	$ 530
Share based payment	350	-
Laboratory services	11	39
	$ 776	$ 569

U.S dollars in thousands (except for share and per share data)

NOTE 11:- SELECTED STATEMENTS OF COMPREHENSIVE LOSS DATA (Cont.)

b. General and administrative expenses:

	For the Year Ended December 31	
	2024	2023
Professional services	$ 483	$ 501*
Consulting services	244	255
Rent and office maintenance	3	6
Others	3	1
	$ 733	$ 763*

(*) reclassified.

c. Financial expenses, net:

	For the Year Ended December 31	
	2024	2023
Bank fees	$ 2	$ 3
Exchange rate differences	8	9
Total financial expenses, net	$ 10	$ 12

NOTE 12:- EXPLANATION OF RECLASSIFICATION FOR DECEMBER 31, 2023

	For the Years Ended December 31, 2024		
	Original	Change	Restated
Other current assets	$ 107	$ (100)	$ 7
Receivable on account of shares	-	(100)	(100)
Other accounts payable and accrued expenses	34	60	94
Accumulated deficit	(7310)	(60)	(7,370)
General and administrative expenses	703	60	763
Operating loss	(1,272)	(60)	(1,332)
Net loss	(1,284)	(60)	(1,344)
Changes in Other accounts payables and accrued expenses	(190)	60	(130)

NOTE 13:- SUBSEQUENT EVENTS

On January 16, 2025, the Company signed an agreement to raise $90 and to issue 115,000 shares of common stock and 55,000 warrants to purchase common stock at an exercise price of $1 per share to certain investor of the Company. The warrants will expire on July 15, 2026.

On January 30, 2025, the Company signed an agreement to raise $50 and to issue 200,000 shares of common stock.

On March 2, 2025, the Company signed an agreement to raise $100 and to issue 200,000 shares of common stock and 100,000 warrants to purchase common stock at an exercise price of $1 per share to Company's chief executive officer. The warrants will expire on July 15, 2026.

On March 21, 2025, the Company signed an agreement to raise $25 and to issue 50,000 shares of common stock and 10,000 warrants to purchase common stock at an exercise price of $1 per share to certain investor of the Company. The warrants will expire on March 15, 2026.

In February 2025, the Company issued 40,000 shares in connection with a service agreement with a certain service provider.
On March 5, 2025, the Company entered into a service agreement with Ajay Kumar Dhadha, pursuant to which Mr. Dhadha will serve as a member of our Board and as chairman of the Board. Pursuant to the service agreement, on March 5, 2025, the Company granted Mr. Dhadha 350,000 restricted shares of the Company’s Common Stock and warrants to purchase up to 250,000 shares of Common Stock at an exercise price of $1.00 per share. The warrants will expire on December 31, 2026.

On March 10, 2025, the Company updated a service agreement with one of Company's directors and extended the service term until December 31, 2025. As compensation for the services, the director will be granted with warrants to purchase up to 200,000 of the Company's common stock at an exercise price of $1 per share. The warrants will expire on December 31, 2025. The warrants weren't granted yet.

On March 21, 2025, the Company signed an agreement to raise $10 and to issue 10,000 shares of common stock and warrants to purchase up to 5,000 of the Company’s common stock at an exercise price of $2.5 per share to a certain investor of the Company. The warrants will expire on March 15, 2026.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation (incorporated by reference from Amendment No. 2 to our registration statement on Form 10 filed September 23, 2021).
3.2	Bylaws (incorporated by reference from Amendment No. 2 to our registration statement on Form 10 filed September 23, 2021).
4.1	Description of Securities (incorporated by reference from our Annual Report on Form 10-K filed March 30, 2022).
10.1	Contractual Agreement between Raphael Pharmaceutical Ltd. and Way of Life Cannabis Ltd. (incorporated by reference from Amendment No. 2 to our registration statement on Form 10 filed September 23, 2021).
10.2	Sponsored Research Agreement with Rambam Med-Tech Ltd. (incorporated by reference from Amendment No. 2 to our registration statement on Form 10 filed September 23, 2021).
10.3	Supplement to Sponsored Research Agreement with Rambam Med-Tech Ltd. (incorporated by reference from our quarterly report on Form 10-Q filed November 14, 2022)
10.4	English Translation of the Amendment to the Service Agreement by and between the Company and Yehuda Eliya, dated December 25, 2023 (incorporated by reference from our Annual Report on Form 10-K filed March 28, 2024).
10.5*	Management and Operations Agreement by and between the Company and Sheffa Enterprises, Inc., dated March 3, 2025.
10.6*	Operations Agreement by and between the Company and Model Engineering & Investments SRL and Guy Ofir, dated March 3, 2025.
10.7*	Service Agreement by and between the Company and Dr. Igal Louria Hayon, dated March 3, 2025.
10.8*	Service Agreement by and between the Company and Prof. Eliya Yehuda, dated March 10, 2025.
10.9*	Director and Chairman of the Board Service Agreement by and between the Company and Ajay Kumar Dhadha, dated March 5, 2025.
14.1*	Code of Business Conduct and Ethics.
16.1	Letter from Weinstein International CPA, addressed to the Securities and Exchange Commission, dated September 11, 2024 (incorporated by reference from our Current Report on Form 8-K filed September 11, 2024).
19.1*	Insider Trading Policy.
21.1	List of Subsidiaries of the Company (incorporated by reference from Amendment No. 2 to our registration statement on Form 10 filed September 23, 2021).
31.1*	Certification of Chief Executive Officer pursuant to Sec. 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Sec. 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101*	The following materials from the Company's Annual Report on Form 10-K for the period ended December 31, 2024 formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Comprehnesive Loss, (iii) the Statements of Changes in Stockholders' Equity (Deficit), (iv) the Consolidated Statements of Cash Flows and (v) related notes to these financial statements, tagged as blocks of text and in detail.**
104*	Cover Page Interactive Data File

* Filed herewith.
** Furnished herewith.

Item 16. Form 10-K Summary.

None.

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.

RAPHAEL PHARMACEUTICAL INC.

Date: March 31, 2025

By: /s/ Shlomo Pilo
Shlomo Pilo
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Guy Ofir
Guy Ofir
Chief Financial Officer
(Principal Financial Officer and Principal 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.

Date: March 31, 2025

By: /s/ Ajay Kumar Dhadha
Ajay Kumar Dhadha
Chairman of the Board of Directors

Date: March 31, 2025

By: /s/ Shlomo Pilo
Shlomo Pilo
Chief Executive Officer (Principal Executive Officer)

Date: March 31, 2025

By: /s/ Guy Ofir
Guy Ofir
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Date: March 31, 2025

By: /s/ Yehuda Eliya
Yehuda Eliya
Director

Date: March 31, 2025

By: /s/ Igal Louria Hayon
Igal Louria Hayon
Chief Technology Officer and Director

Exhibit 10.5

This MANAGEMENT AND OPERATIONS AGREEMENT (this "Agreement") is made as of March 3rd 2025, by and between **Raphael Pharmaceutical ltd**. (the "Company"), and **Sheffa Enterprises, INC., a New Jersey corporation/ Shlomo Pilo,** an Individual residing at Israel **(the "Manager").**

RECITALS

WHERES, the parties signed a management agreement on 1st June 2019 ("so call: "the previous agreement";

WHERES, the parties agreed to cancel the previous agreement and to engage the following agreement;

WHEREAS, the Company desires to engage the Manager to manage its Business, and the Manager desires to retain, operate and manage the Business on the terms set forth herein;

NOW, THEREFORE, in consideration of the mutual covenants, agreements, representations and warranties contained herein, and intending to be legally bound hereby, the parties hereto hereby agree as follows:

1. Appointment of Manager; Relationship of Company and the Manager.

Manager shall provide management and operational support services to the Company, as hereinafter provided. Manager, at all times, shall be independent of the Company. Nothing contained herein shall be deemed to make or render the Company a partner, co-venturer or other participant in the business or operations of the Manager, or in any manner to render Company liable, as principal, surety, guarantor, and agent or otherwise for any of the debts, obligations or liabilities of Manager. Similarly, nothing contained herein shall be deemed to make or render the Manager a partner, co-venturer or other participant in the business or operations of the Company, or in any manner to render Manager liable, as principal, surety, guarantor, and agent or otherwise for any of the debts, obligations or liabilities of Company.

2. Management Services.

Commencing on the date of this Agreement, Manager will provide, supply and render such management and operational support services as are necessary to provide service to the Company and, as more specifically described below, shall:

a. Administer and supervise all of the finances of the Business, including payroll, taxes, accounting, bookkeeping, record keeping, managing or accounts payable, and accounts receivable, banking, financial records and reporting functions as they pertain to the business of the Company, with the power to make such changes therein, in its sole discretion, and to incorporate such functions into systems used by Manager. Manager shall prepare and maintain financial statements for the Business according to generally accepted accounting principles consistently applied and shall provide the Company with weekly operating reports and statements including but not limited to cash flow statements, income statements, accounts payable and accounts receivable reports and such other reports and information as may be requested by Company from time to time.

b. Select and employ all personnel necessary to service the Business of the Company.

c. Supervise and control the purchase of all materials and supplies, and acquire, lease, dispose of and repair equipment and facilities necessary to provide safe and adequate service to the business of the Company.

d. Manage all costs and all pricing on a customer-by-customer basis, estimate all costs on new contracts, bid on and enter into new contracts, and control all costs for contracts in progress.

e. Commence, defend and control all legal actions, arbitrations, investigations and proceedings that arise due to events occurring in connection with the business of the Company during the term of this Agreement.

f. Maintain the assets of the Company in good repair, order and condition, normal and reasonable wear and tear excepted.

g. At the Manager's expense, provide the Company with office or storage space in **Lui Paster 4 Tel Aviv-Jaffa, Israel** sufficient to maintain the Company's files and administrative personnel.

Notwithstanding the foregoing, the Manager shall not have the authority, without the express written consent of the board of the directors of the Company, to purchase in the name of the Company, or for use by the Company in the Business, any assets outside the ordinary course of business, or incur any indebtedness outside the ordinary course of business.

3. Obligations of the Company.

Prior to the expiration of this Agreement, the Company shall provide the Manager with true and correct information relating to all functions for which the Manager has responsibility hereunder, and shall not take any action to interfere with the Manager's performance of its duties hereunder.

4. Additional Agreements of the Manager.

The Manager agrees that at all times during the term of this Agreement it shall, to the extent the Company has adequate funds thereto:

(a) Do nothing, and permit nothing to be done (which is within the control of the Manager), which will or might cause the Company to operate in an improper or illegal manner.

(b) Not cause a default in any of the terms, conditions and obligations of any of the contracts and other agreements of the Company.

(c) To the extent permissible by law, maintain in full force its licenses and permits in the State of Israel and comply fully with all laws respecting its formation, existence, activities and operations.

(d) Allow the Company and the employees, attorneys, accountants and other representatives of the Company, full and free access to its books and records, and all of the facilities of the Company relating to the Business.

5. General and Administrative Activities.

To the extent that Manager shall deem it necessary or desirable, Manager shall have the power and authority to combine and integrate, at its own office (including those of an affiliate), the "general and administrative" (as such term is used in accounting practice) activities of the Business, including, but not limited to, all accounting, bookkeeping, record-keeping, paying, receiving and other fiscal or financial activities, with those of Manager, provided that any obligation of the Company to share or defer costs of such office shall but subject to the subsequent agreement of the Company.

6. Location.

During the term of this Agreement, the business of the Company will be serviced by Manager from the Manager's office in Lui-Paster 4 Tel Aviv Jaffa, Israel or any other location selected by Manager.

7. Compensation.

a. Base Compensation

While Manager is employed by the Company hereunder and as otherwise provided in this Agreement, the Company shall pay to Manager a monthly fee in the amount of $20,000, payable in advance, with the first payment being due and payable on January 1st, 2025, and each succeeding payment being due and payable on the first day of each succeeding calendar quarter during the term of this Agreement.

b. Expenses

While Manager is employed by the Company hereunder, the Company shall reimburse Manager for all reasonable and necessary out-of-pocket business, travel and entertainment expenses incurred by it in the performance of its duties and responsibilities hereunder, subject to the Company's normal policies and procedures for expense verification and documentation.

8. Term of Agreement; Termination of Rights.

(a) The term of this Agreement shall commence on its execution, and expire, unless terminated or extended in writing, on December 31, 2025. Upon termination of this Agreement, all books and records relating to the operation of the Business shall be immediately returned to the Company. Notwithstanding the foregoing, the Company may terminate this Agreement prior to the expiration of its term upon one hundred & twenty (120) days advance notice and the payment to the Manager of a termination fee equal to the lesser of a) $360,000, or b) the monthly management fee paid or payable to the Manager pursuant to Paragraph 7 herein for the remaining this Agreement.

(b) Company may, at its option, upon ten (10) days' written notice terminate this Agreement (if such default is not cured within such ten (10) day period or such longer period as required to effect a cure if a cure is commenced within 10 days and diligently prosecuted): (i) if Manager shall violate any material provision of this Management Agreement; (ii) if Manager shall violate or be in material breach of any provision, representation, warranty, covenant or undertaking herein; or (iii) if Manager (a) makes an assignment for the benefit of creditors, (b) is adjudicated a bankrupt, (c) files or has filed against it any bankruptcy, reorganization, liquidation or similar petition or any petition seeking the appointment of a receiver, conservator or other representative, or (d) proposes a composition arrangement with creditors. The date on which this Agreement is terminated pursuant to Section 8(a) above or this Section 8(b) is hereinafter referred to as the "Expiration Date".

9. Indemnification.

The Company shall indemnify the Manager in his capacity as a director of the company to the fullest extent permitted by applicable law against all debts, judgements, costs, charges or expenses incurred or sustained by the Manger in connection with any action, suit or proceeding to which the Manager may be made a party by reason of his being or having been a director of the company, or because of actions taken by the Manager which were believed by the Manager to be in the best interests of the company, and the Manager shall be entitled to be covered by any director's liability insurance policies which the company may maintain for the benefit of its Directors and Officers, subject to the limitations of any such policies.

10. Additional Provisions.

(a) This Agreement sets forth the entire understanding and agreement among the parties hereto with reference to the subject matter hereof and may not be modified, amended, discharged or terminated except by a written instrument signed by the parties hereto.

(b) This Agreement replaced the previous agreement& the parties see the previous agreement as void.

(c) This Agreement shall be governed by, and construed in accordance with, the laws of the State of ISRAEL applicable to agreements made, delivered and to be performed within such State.

(c) This Agreement may not be assigned by Company or Manager, except that Manager may in its sole discretion assign this Agreement to a properly licensed affiliate performing similar types of services. Upon any assignment Manager shall remain primarily liable and also be jointly and severally liable to Company for performance of Manager's duties herein.

(d) All of the terms and provisions of this Management Agreement shall be binding upon, inure to the benefit of, and be enforceable by each of the parties hereto and their respective successors and assigns. Except for affiliates of the Company and Manager and their respective shareholders, officers, directors, employees and agents, no person other than the parties hereto shall be a third party beneficiary of this Agreement or have any rights hereunder.

(e) If any provision of this Agreement shall be determined by a court of competent jurisdiction to be invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement, all of which shall remain in full force and effect.

(f) This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which shall constitute one and the same instrument.

(g) The headings in this Agreement are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Management Agreement as of the date first above written.

Signed this 3rd day of March, 2025.

/s/ Guy Ofir	**/s/ Shlomo Pilo**
COMPANY	**MANAGER**
by: Guy Ofir, CFO & Director	**by: Shlomo Pilo, CEO**

Exhibit 10.6

This OPERATIONS AGREEMENT (this "Agreement") is made as of March, 3rd ,2025, by and between **Raphael Pharmaceutical ltd**. (the "Company"), and Model Engineering & Investments. SRL a **Romanian Company no. J40/1123/2007 AND/OR ADV' GUY OFIR I.D. 172910400069, an Individual residing at Romaina (the "CFO, Legal Adviser & Director").**

RECITALS

WHEREAS, the Company desires to engage the CFO into this agreement, and the CFO desires & agree to all the terms set forth herein;

NOW, THEREFORE, in consideration of the mutual covenants, agreements, representations and warranties contained herein, and intending to be legally bound hereby, the parties hereto hereby agree as follows:

1. Appointment of CFO, Legal Adviser & Director and it's relationship with the Company.

CFO shall provide CFO, Legal Advises & Director Services to the Company, as hereinafter provided. CFO, at all times, shall be independent of the Company. Nothing contained herein shall be deemed to make or render the Company a partner, co-venturer or other participant in the business or operations of the CFO, or in any manner to render Company liable, as principal, surety, guarantor, and agent or otherwise for any of the debts, obligations or liabilities of CFO. Similarly, nothing contained herein shall be deemed to make or render the CFO a partner, co-venturer or other participant in the business or operations of the Company, or in any manner to render CFO liable, as principal, surety, guarantor, and agent or otherwise for any of the debts, obligations or liabilities of Company.

2. CFO Services.

Commencing on the date of this Agreement, CFO will provide, supply and render such services and operational support services as are necessary to provide service to the Company and, as more specifically described below, shall:

a. CFO SERVICES TO THE COMPANY.

b. Legal Advice to the company.

c. Serve as a Director of the Company.

3. Obligations of the Company.

Prior to the expiration of this Agreement, the Company shall provide the CFO with true and correct information relating to all functions for which the CFO has responsibility hereunder, and shall not take any action to interfere with the CFO's performance of its duties hereunder.

4. Additional Agreements of the CFO.

The CFO agrees that at all times during the term of this Agreement it shall, to the extent the Company has adequate funds thereto:

(a) Do nothing, and permit nothing to be done (which is within the control of the CFO), which will or might cause the Company to operate in an improper or illegal manner.

(b) Not cause a default in any of the terms, conditions and obligations of any of the contracts and other agreements of the Company.

(c) To the extent permissible by law, maintain in full force its licenses and permits in the State of Israel and comply fully with all laws respecting its formation, existence, activities and operations.

(d) Allow the Company and the employees, attorneys, accountants and other representatives of the Company, full and free access to its books and records, and all of the facilities of the Company relating to the Business.

5. General and Administrative Activities.

To the extent that CFO shall deem it necessary or desirable, CFO shall have the power and authority to combine and integrate, at its own office (including those of an affiliate), the "general and administrative" (as such term is used in accounting practice) activities of the Business, including, but not limited to, all accounting, bookkeeping, record-keeping, paying, receiving and other fiscal or financial activities, with those of CFO, provided that any obligation of the Company to share or defer costs of such office shall but subject to the subsequent agreement of the Company.

6. Location.

During the term of this Agreement, the business of the Company will be serviced by CFO from the Manager's (CEO) office in Lui-Paster 4 Tel Aviv Jaffa, Israel or any other location selected by Manager (CEO).

7. Compensation.

a. Base Compensation:

While CFO is employed by the Company hereunder and as otherwise provided in this Agreement, the Company shall pay to CFO a monthly fee in the amount of $12,000, payable in advance, with the first payment being due and payable on January 1st, 2025, and each succeeding payment being due and payable on the first day of each succeeding calendar quarter during the term of this Agreement.

b. Expenses:

While CEO is employed by the Company hereunder, the Company shall reimburse CFO for all reasonable and necessary out-of-pocket business, travel and entertainment expenses incurred by it in the performance of its duties and responsibilities hereunder, subject to the Company's normal policies and procedures for expense verification and documentation.

8. Term of Agreement; Termination of Rights.

(a) The term of this Agreement shall commence on its execution, and expire, unless terminated or extended in writing, on December 31, 2025. Upon termination of this Agreement, all books and records relating to the operation of the Business shall be immediately returned to the Company. Notwithstanding the foregoing, the Company may terminate this Agreement prior to the expiration of its term upon one hundred & twenty (120) days advance notice and the payment to the CFO of a termination fee equal to the lesser of a) $120,000, or b) the monthly CFO's fee paid or payable to the CFO pursuant to Paragraph 7 herein for the remaining this Agreement.

(b) Company may, at its option, upon ten (10) days' written notice terminate this Agreement (if such default is not cured within such ten (10) day period or such longer period as required to effect a cure if a cure is commenced within 10 days and diligently prosecuted): (i) if CFO shall violate any material provision of this Agreement; (ii) if CFO shall violate or be in material breach of any provision, representation, warranty, covenant or undertaking herein; or (iii) if CFO (a) makes an assignment for the benefit of creditors, (b) is adjudicated a bankrupt, (c) files or has filed against it any bankruptcy, reorganization, liquidation or similar petition or any petition seeking the appointment of a receiver, conservator or other representative, or (d) proposes a composition arrangement with creditors. The date on which this Agreement is terminated pursuant to Section 8(a) above or this Section 8(b) is hereinafter referred to as the "Expiration Date".

9. Indemnification.

The Company shall indemnify the CFO in his capacity as a director of the company to the fullest extent permitted by applicable law against all debts, judgements, costs, charges or expenses incurred or sustained by the CFO in connection with any action, suit or proceeding to which the CFO may be made a party by reason of his being or having been a director of the company, or because of actions taken by the CFO which were believed by the CFO to be in the best interests of the company, and the CFO shall be entitled to be covered by any director's liability insurance policies which the company may maintain for the benefit of its Directors and Officers, subject to the limitations of any such policies.

10. Additional Provisions.

(a) This Agreement sets forth the entire understanding and agreement among the parties hereto with reference to the subject matter hereof and may not be modified, amended, discharged or terminated except by a written instrument signed by the parties hereto.

(b) This Agreement shall be governed by, and construed in accordance with, the laws of the State of ISRAEL applicable to agreements made, delivered and to be performed within such State.

(c) This Agreement may not be assigned by Company or CFO, except that CFO may in its sole discretion assign this Agreement to a properly licensed affiliate performing similar types of services. Upon any assignment CFO shall remain primarily liable and also be jointly and severally liable to Company for performance of CFO's duties herein.

(d) All of the terms and provisions of this Agreement shall be binding upon, inure to the benefit of, and be enforceable by each of the parties hereto and their respective successors and assigns. Except for affiliates of the Company and CFO and their respective shareholders, officers, directors, employees and agents, no person other than the parties hereto shall be a third party beneficiary of this Agreement or have any rights hereunder.

(e) If any provision of this Agreement shall be determined by a court of competent jurisdiction to be invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement, all of which shall remain in full force and effect.

(f) This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which shall constitute one and the same instrument.

(g) The headings in this Agreement are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

Signed this 3rd day of March, 2025.

/s/ Shlomo Pilo	**/s/ Guy Ofir**
"COMPANY"	**"CFO"**
by: SHLOMO PILO, CEO	**by: GUY OFIR, CFO**

Exhibit 10.7

This SERVICE AGREEMENT (this "Agreement") is made as of 3RD of March, 2025, by and between **Raphael Pharmaceutical INC**. (the "Company"), and **DR. IGAL LOURIA HAYON**, an Individual residing at Israel **(the "CTO"/so called "IGAL").**

RECITALS

WHEREAS, the Company desires to engage IGAL to be the Chief Technology officer (so called: "CTO") & DIRECTOR of the company, and IGAL desires to be the CTO & board Member on the terms set forth herein;

NOW, THEREFORE, in consideration of the mutual covenants, agreements, representations and warranties contained herein, and intending to be legally bound hereby, the parties hereto hereby agree as follows:

1. Appointment of IGAL to be CTO & DIRECTOR; Relationship of Company and IGAL.

Igal shall provide technological operational support services to the Company, as hereinafter provided. Igal, at all times, shall be independent of the Company. Nothing contained herein shall be deemed to make or render the Company a partner, co-venturer or other participant in the business or operations of Igal, or in any manner to render Company liable, as principal, surety, guarantor, and agent or otherwise for any of the debts, obligations or liabilities of Igal. Similarly, nothing contained herein shall be deemed to make or render Igal a partner, co-venture or other participant in the business or operations of the Company, or in any manner to render Igal liable, as principal, surety, guarantor, and agent or otherwise for any of the debts, obligations or liabilities of Company.

2. Services Descriptions.

Commencing on the date of this Agreement, Igal will provide, supply and render such services, advices and operational support services as are necessary to provide service to the Company and, as more specifically described below, shall:

a. Serve as the Chief Technology Officer & Director of the company.

b. Represent the company in the Stock Exchange & the SEC in all Technology maters.

c. Give the company Medical Advice Services & also sit as a member of its Medical Committee.

d. Represent the company in any Health Ministry Country around the world such as the USA FDA & ISRAELI HEALTH MINISTRY.

It should be noted that Igal services to the company will not be contradict or in any conflict of interest to his work in Rambam Health Care Campus.

3. Obligations of the Company.

Igal is the head of the scientific board and will have the right for final scientific decision,

Including but not limited to appointing the scientific board members, hiring other consulting or CRO services by the company.

Prior to the expiration of this Agreement, the Company shall provide Igal with true and correct information relating to all functions for which Igal has responsibility hereunder, and shall not take any action to interfere with Igal's performance of its duties hereunder.

4. Location.

During the term of this Agreement, the business of the Company will be serviced by Igal from the company's office in Haifa, Israel or any other location selected by the company and is agreed by Igal.

5. Compensation.

a. Compensation

While Igal is employed by the Company hereunder and as otherwise provided in this Agreement, the Company shall pay Igal a monthly fee in the amount of $24,000+expenses related to his science work payable in advance, with the first payment being due and payable on January 1st, 2025, and each succeeding payment being due and payable on the first day of each succeeding calendar quarter during the term of this Agreement.

b. **It should be stated that the compensation will be changed in the future according to the Board of Directors of the company decisions, in such a way as it can increase the amount of fee and/or grant Igal other benefits.**

c. In addition to the CTO capacity as the Company's R&D consultant for medical Cannabis at the Rambam medical center, the company appoints Igal to be the company's COVID-19 project manager. The parties agreed that the project manager will be entitled, in addition to the above considerations, 15% of the net Royalties income that the company will get for its medical Cannabis oil indications sold worldwide for the treatment of COVID-19 patient, and 15% of the net Royalties income that the company will get for its medical cannabis indication molecules based, for treating Rheumatoid Arthritis (RA) and other diseases.

6. Term of Agreement; Termination of Rights.

(a) The term of this Agreement shall commence on its execution, and expire, unless terminated or extended in writing, on December 31, 2025. Upon termination of this Agreement, all books and records relating to the operation of the Business shall be immediately returned to the Company. Notwithstanding the foregoing, the Company or Igal may terminate this Agreement prior to the expiration of its term upon one hundred & twenty (120) days advance notice and the payment to Igal of a termination fee equal to three years the fee paid or payable to Igal pursuant to Paragraph 5 herein for the remaining this Agreement.

(b) Company may, at its option, upon ten (10) days' written notice terminate this Agreement (if such default is not cured within such ten (10) day period or such longer period as required to effect a cure if a cure is commenced within 10 days and diligently prosecuted): (i) if Igal shall violate any material provision of this Agreement; (ii) if Igal shall violate or be in material breach of any provision, representation, warranty, covenant or undertaking herein; or (iii) if Igal (a) makes an assignment for the benefit of creditors, (b) is adjudicated a bankrupt, (c) files or has filed against it any bankruptcy, reorganization, liquidation or similar petition or any petition seeking the appointment of a receiver, conservator or other representative, or (d) proposes a composition arrangement with creditors. The date on which this Agreement is terminated pursuant to Section 6(a) above or this Section 6(b) is hereinafter referred to as the "Expiration Date".

(c) Igal may, at his option, upon ten (10) days' written notice terminate this Agreement (if such default is not cured within such ten (10) day period or such longer period as required to effect a cure if a cure is commenced within 10 days and diligently prosecuted): (i) if Company shall violate any material provision of this Agreement; (ii) if Company shall violate or be in material breach of any provision, representation, warranty, covenant or undertaking herein; or (iii) if Company (a) makes an assignment for the benefit of creditors, (b) is adjudicated a bankrupt, (c) files or has filed against it any bankruptcy, reorganization, liquidation or similar petition or any petition seeking the appointment of a receiver, conservator or other representative, or (d) proposes a composition arrangement with creditors. The date on which this Agreement is terminated pursuant to Section 6(a or b) above or this Section 6 (c) is hereinafter referred to as the "Expiration Date".

7. Indemnification.

The Company shall indemnify the CTO in his capacity as a director of the company to the fullest extent permitted by applicable law against all debts, judgements, costs, charges or expenses incurred or sustained by the CTO in connection with any action, suit or proceeding to which the CTO may be made a party by reason of his being or having been a director of the company, or because of actions taken by the CTO which were believed by the CTO to be in the best interests of the company, and the CTO shall be entitled to be covered by any director's liability insurance policies which the company may maintain for the benefit of its Directors and Officers, subject to the limitations of any such policies.

8. Additional Provisions.

(a) This Agreement sets forth the entire understanding and agreement among the parties hereto with reference to the subject matter hereof and may not be modified, amended, discharged or terminated except by a written instrument signed by the parties hereto.

(b) This Agreement shall be governed by, and construed in accordance with, the laws of the State of ISRAEL applicable to agreements made, delivered and to be performed within such State.

(c) This Agreement may not be assigned by Company or Igal.

(d) All of the terms and provisions of this Agreement shall be binding upon, inure to the benefit of, and be enforceable by each of the parties hereto and their respective successors and assigns.

(e) If any provision of this Agreement shall be determined by a court of competent jurisdiction to be invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement, all of which shall remain in full force and effect.

(f) This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which shall constitute one and the same instrument.

(g) The headings in this Agreement are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Service Agreement as of the date first above written.

Signed this 3rd day of March, 2025.

/s/ Shlomo Pilo	**/s/ Dr. Igal Louria Hayon**
COMPANY	**CHIEF TECHNOLOGY OFFICER**
by: SHLOMO PILO, CEO	**by: Dr. Igal Louria Hayon**

Exhibit 10.8

This SERVICE AGREEMENT (this "Agreement") is made as of March 10, 2025, by and between **Raphael Pharmaceutical INC**. (the "Company"), and **Prof. ELIYA YEHUDA** I.D 025721069**, an Individual residing in Israel (the "Director"/so called "Yehuda").**

RECITALS

WHEREAS the Company desires to engage Yehuda to be a director of the company, and Yehuda desires to be the director on the terms set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants, agreements, representations and warranties contained herein, and intending to be legally bound hereby, the parties hereto hereby agree as follows:

1. Appointment of Director; Relationship of Company and Yehuda:

Yehuda shall serve as a director of the Company, as hereinafter provided. The Director, always, shall be independent of the Company. Nothing contained herein shall be deemed to make or render the Company a partner, co-venturer or other participant in the business or operations of Yehuda, or in any manner to render Company liable, as principal, surety, guarantor, and agent or otherwise for any of the debts, obligations, or liabilities of Yehuda. Similarly, nothing contained herein shall be deemed to make or render Yehuda a partner, co-venturer or other participant in the business or operations of the Company, or in any manner to render Yehuda liable, as principal, surety, guarantor, and agent or otherwise for any of the debts, obligations, or liabilities of Company.

2. Services Descriptions.

Commencing on the date of this Agreement, Yehuda will serve as a director in its board of directors.

3. Obligations of the Company.

Prior to the expiration of this Agreement, the Company shall provide Yehuda with true and correct information relating to all functions for which Yehuda has responsibility hereunder and shall not take any action to interfere with Yehuda's performance of its duties hereunder.

4. Location.

During the term of this Agreement, the business of the Company will be serviced by Yehuda from the company's office Haifa, Israel or any other location in other country selected by company (subject to the CEO decision).

5. Compensation.

The company will grant Yehuda 200,000 Warrants for 1 year at an execution price of $1.0 per share.

It should be noted that the compensation will be changed in the future according to the Board of Directors of the company decisions, in such a way as it can propose Yehuda fees and/or grant Yehuda other benefits.

6. Term of Agreement; Termination of Rights.

(a) The term of this Agreement shall commence on its execution, and expire, unless terminated or extended in writing, on December 31, 2025.

(b) Company may, at its option, upon ten (10) days' written notice terminate this Agreement (if such default is not cured within such ten (10) day period or such longer period as required to effect a cure if a cure is commenced within 10 days and diligently prosecuted): (i) if Yehuda shall violate any material provision of this Agreement; (ii) if Yehuda shall violate or be in material breach of any provision, representation, warranty, covenant or undertaking herein; or (iii) if Yehuda (a) makes an assignment for the benefit of creditors, (b) is adjudicated a bankrupt, (c) files or has filed against it any bankruptcy, reorganization, liquidation or similar petition or any petition seeking the appointment of a receiver, conservator or other representative, or (d) proposes a composition arrangement with creditors. The date on which this Agreement is terminated pursuant to Section 6(a) above or this Section 6(b) is hereinafter referred to as the "Expiration Date".

7. The Company shall indemnify the Director in his capacity as a director of the company to the fullest extent permitted by applicable law against all debts, judgements, costs, charges or expenses incurred or sustained by the Director in connection with any action, suit or proceeding to which the Director may be made a party by reason of his being or having been a director of the company, or because of actions taken by the Director which were believed by the Director to be in the best interests of the company, and the Director shall be entitled to be covered by any director's liability insurance policies which the company may maintain for the benefit of its Directors and Officers, subject to the limitations of any such policies.

8. Additional Provisions.

(a) This Agreement sets forth the entire understanding and agreement among the parties hereto with reference to the subject matter hereof and may not be modified, amended, discharged or terminated except by a written instrument signed by the parties hereto.

(b) This Agreement shall be governed by, and construed in accordance with, the laws of the State of ISRAEL applicable to agreements made, delivered and to be performed within such State.

(c) This Agreement may not be assigned by Company or Yehuda.

(d) All of the terms and provisions of this Agreement shall be binding upon, inure to the benefit of, and be enforceable by each of the parties hereto and their respective successors and assigns.

(e) If any provision of this Agreement shall be determined by a court of competent jurisdiction to be invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement, all of which shall remain in full force and effect.

(f) This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which shall constitute one and the same instrument.

(g) The headings in this Agreement are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Service Agreement as of the date first above written.

Signed this 10 day of March 2025.

/s/ Shlomo Pilo	**/s/ Yehuda Eliya**
COMPANY **by: SHLOMO PILO, CEO**	**Director** **by: Yehuda Eliya**

Exhibit 10.9

DIRECTOR AND CHAIRMAN OF THE BOARD SERVICES AGREEMENT

This DIRECTOR AND CHAIRMAN OF THE BOARD SERVICES AGREEMENT (this "Agreement") is made as of 8TH of January, 2025 (the "Effective Date"), by and between Raphael Pharmaceutical Inc. (the "Company"), and Ajay Kumar Dhadha, an individual residing in Israel (the "Chairman of the Board" or "Shanti").

WHEREAS, the Company desires to appoint Shanti as a member of the Board of Directors of the Company (the "Board") and as the Chairman of the Board, and Shanti desires to be appointed as a member of the Board and as Chairman of the Board, subject to the terms set forth herein;

NOW, THEREFORE, for consideration and as set forth herein, the parties hereto hereby agree as follows:

1. Election as Director, Appointment as Chairman of the Board.

Subject to the Company's Bylaws, as may be amended from time to time (the "Bylaws") and the approval of the Board, Shanti accepts the appointment to serve as a director of the Board and as Chairman of the Board. The management of the Company will be responsible for reporting to the Board and its Chairman all the necessary information regarding the functions of the Company.

2. Services Descriptions.

In addition to Shanti's responsibilities as Chairman of the Board, Shanti shall have all responsibilities of a Director of the Company imposed by the Company's Certificate of Incorporation, as may be amended from time to time (the "Certificate of Incorporation"), the Bylaws, and Nevada or other applicable law. These responsibilities shall include, but shall not be limited to: (i) providing leadership and oversight to the Board; (ii) the attendance at scheduled meetings of the Board, (iii) representing the stockholders and the interests of the Company as a fiduciary, and (iv) participating as a full voting member of the Board in setting overall objectives, approving plans and programs of operation, formulating general policies, offering advice and counsel, serving on Board Committees from time to time, and reviewing the Company's management performance.

3. Obligations of the Company.

Prior to the expiration of this Agreement, the Company shall provide Shanti with true and correct information relating to all functions for which Shanti has responsibility hereunder, and shall not take any action to interfere with Shanti's performance of its duties hereunder.

4. Location.

During the term of this Agreement, the business of the Company will be serviced by Shanti from the company's office in Tel-Aviv, Israel or any other location selected by company.

5. Compensation - Equity & Warrants Only.

In consideration for Shanti's service, the Company will grant Shanti 350,000 restricted shares of the Company's common stock, par value $0.01 per share (the "Common Stock") and warrants to purchase up to 250,000 shares of the Company's Common Stock, at an exercise price of $2.00 per share, which shall expire on December 31, 2026.

6. No Employment Relationship.

This Agreement is not intended to create an employment relationship between the Company and Shanti. Rather, it is the parties' intention that Shanti shall be an independent contractor of the company. Shanti shall be solely responsible to for the payment of all income taxes derives from the compensation above.

7. Term of the Agreement

(a) Shanti shall continue to serve as a member of the Board from the Effective Date until the date upon which Shanti is not re-elected as a director by the stockholders of the Company, pursuant to the Company's Certificate of incorporation and Bylaws, or upon his earlier removal or resignation (such time period, the "Term").

(b) Shanti shall continue to serve as Chairman of the board from the Effective Date until December 31, 2025, unless this Agreement is extended by a mutual written agreement of the parties hereto.

8. Indemnification.

The Company shall indemnify the Chairman of the Board in his capacity as a director of the company to the fullest extent permitted by applicable law against all debts, judgements, costs, charges or expenses incurred or sustained by the Chairman of the Board in connection with any action, suit or proceeding to which the Chairman of the Board may be made a party by reason of his being or having been a director of the company, or because of actions taken by the Chairman which were believed by the Chairman to be in the best interests of the company, and the Chairman shall be entitled to be covered by any of the Company's directors' liability insurance policies which the Company may maintain for the benefit of its directors and officers, subject to the limitations of any such policies.

9. Additional Provisions.

(a) This Agreement sets forth the entire understanding and agreement among the parties hereto with reference to the subject matter hereof and may not be modified, amended, discharged or terminated except by a written instrument signed by the parties hereto.

(b) This Agreement shall be governed by, and construed in accordance with, the laws of the State of Israel, applicable to agreements made, delivered and to be performed within such State.

(c) This Agreement may not be assigned by the Company or by Shanti.

(d) All of the terms and provisions of this Agreement shall be binding upon, inure to the benefit of, and be enforceable by each of the parties hereto and their respective successors and assigns.

(e) If any provision of this Agreement shall be determined by a court of competent jurisdiction to be invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement, all of which shall remain in full force and effect.

(f) This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which shall constitute one and the same instrument.

(g) The headings in this Agreement are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first set forth above.

/s/ Shlomo Pilo	/s/ Ajay Kumar Dhadha
RAPHAEL PHARMACEUTICALS INC.	DIRECTOR AND CHAIRMAN OF THE BOARD
by: SHLOMO PILO, CEO	by: AJAY KUMAR DHADHA

Signature Page to Chairman of the Board Services Agreement

Exhibit 14.1

RAPHAEL PHARMACEUTICALS INC.

CODE OF ETHICS AND BUSINESS CONDUCT

Dated March 5, 2025

This Code of Ethics and Business Conduct (the "Code") of Raphael Pharmaceuticals Inc. (the "Company") applies to the Chief Executive Officer, Chief Financial Officer and persons performing similar functions (collectively, the "Senior Officers") along with all directors and other employees of the Company (the Senior Officers, directors and employees are hereinafter collectively referred to as the "Covered Persons"). This Code covers a wide range of business practices and procedures. It does not cover every issue that may arise, but it sets out basic principles to guide all Covered Persons. All Covered Persons should conduct themselves accordingly and seek to avoid the appearance of improper behavior in any way relating to the Company.

Any Covered Person who has any questions about the Code should consult with the Chief Executive Officer, Chief Financial Officer or the Company's board of directors (the "Board").

The Company has adopted the Code for the purpose of promoting:

- honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- full, fair, accurate, timely and understandable disclosure in all reports and documents that the Company files with, or submits to, the Securities and Exchange Commission ("SEC") and in other public communications made by the Company that are within the Covered Persons' area of responsibility;
- compliance with applicable governmental laws, rules and regulations;
- the prompt internal reporting of violations of the Code; and
- accountability for adherence to the Code.

HONEST AND ETHICAL CONDUCT

Each Senior Officer and member of the Board owes a duty to the Company to act with integrity. Integrity requires, among other things, being honest and candid. Covered Persons must adhere to a high standard of business ethics and are expected to make decisions and take actions based on the best interests of the Company, as a whole, and not based on personal relationships or benefits. Generally, a "conflict of interest" occurs when a Covered Person's personal interests is, or appears to be, inconsistent with, interferes with or is opposed to the best interests of the Company or gives the appearance of impropriety.

Business decisions and actions must be made in the best interests of the Company and should not be influenced by personal considerations or relationships. Relationships with the Company's stakeholders, for example suppliers and customers, should not in any way affect a Covered Person's responsibility and accountability to the Company. Conflicts of interest can arise when a Covered Person or a member of his or her family receive improper gifts, entertainment or benefits as a result of his or her position in the Company. Specifically, each Covered Person must:

1. act with integrity, including being honest and candid, while still maintaining the confidentiality of information when required or consistent with the Company's policies;
2. avoid violations of the Code, including actual or apparent conflicts of interest with the Company in personal and professional relationships;

3. disclose to the Board any material transaction or relationship that could reasonably be expected to give rise to a breach of the Code, including actual or apparent conflicts of interest with the Company;

4. obtain approval from the Board before making any decisions or taking any action that could reasonably be expected to involve a conflict of interest or the appearance of a conflict of interest;

5. observe both the form and spirit of laws and governmental rules and regulations, accounting standards and Company policies;

6. maintain a high standard of accuracy and completeness in the Company's financial records;

7. ensure full, fair, timely, accurate and understandable disclosure in the Company's periodic reports;

8. report any violations of the Code to the Board;

9. proactively promote ethical behavior among peers in his or her work environment; and

10. maintain the skills appropriate and necessary for the performance of his or her duties.

DISCLOSURE OF COMPANY INFORMATION

As a result of the Company's status as a public company, it is required to file periodic and other reports with the SEC. The Company takes its public disclosure responsibility seriously to ensure that these reports furnish the marketplace with full, fair, accurate, timely and understandable disclosure regarding the financial and business condition of the Company. All disclosures contained in reports and documents filed with or submitted to the SEC, or other government agencies, on behalf of the Company, or contained in other public communications made by the Company, must be complete and correct in all material respects and understandable to the intended recipient.

The Senior Officers, in relation to his or her area of responsibility, must be committed to providing timely, consistent and accurate information, in compliance with all legal and regulatory requirements. It is imperative that this disclosure be accomplished consistently during both good times and bad and that all parties in the marketplace have equal or similar access to this information.

All of the Company's books, records, accounts and financial statements must be maintained in reasonable detail, must appropriately reflect the Company's transactions, and must conform both to applicable legal requirements and to the Company's system of internal controls. Unrecorded or "off the book" funds, assets or liabilities should not be maintained unless permitted by applicable law or regulation. Senior Officers involved in the preparation of the Company's financial statements must prepare those statements in accordance with generally accepted accounting principles, consistently applied, and any other applicable accounting standards and rules so that the financial statements materially, fairly and completely reflect the business transactions and financial statements and related condition of the Company. Further, it is important that financial statements and related disclosures be free of material errors.

Specifically, each Senior Officer must:

1. familiarize himself or herself with the disclosure requirements generally applicable to the Company;

2. not knowingly misrepresent, or cause others to misrepresent, facts about the Company to others, including the Company's independent auditors, governmental regulators, self-regulating organizations and other governmental officials;

3. to the extent that he or she participates in the creation of the Company's books and records, promote the accuracy, fairness and timeliness of those records; and

4. in relation to his or her area of responsibility, properly review and critically analyze proposed disclosure for accuracy and completeness.

CONFIDENTIAL INFORMATION

Covered Persons must maintain the confidentiality of confidential information entrusted to them by the Company of its customers, suppliers, joint venture partners, or others with whom the Company is considering a business or other transaction, except when disclosure is authorized by a Senior Officer or required or mandated by laws or regulations. Confidential information includes all non-public information that might be useful or helpful to competitors or harmful to the Company or its customers or suppliers, if disclosed. It also includes information that suppliers, customers and other parties have entrusted to the Company. The obligation to preserve confidential information continues even after employment ends.

Records containing personal data about employees or private information about customers and their employees are confidential. They are to be carefully safeguarded, kept current, relevant and accurate. They should be disclosed only to authorized personnel or as required by law.

All inquiries regarding the Company from non-employees, such as financial analysts and journalists, should be directed to a Senior Officer or to the Board. The Company's policy is to cooperate with every reasonable request of government investigators for information. At the same time, the Company is entitled to all the safeguards provided by law for the benefit of persons under investigation or accused of wrongdoing, including legal representation. If a representative of any government or government agency seeks an interview or requests access to data or documents for the purposes of an investigation, the Covered Person should refer the representative to a Senior Officer or to the Board. Covered Persons also should preserve all materials, including documents and e-mails, that might relate to any pending or reasonably possible investigation.

COMPLIANCE WITH LAWS

Covered Persons must respect and obey all applicable foreign, federal, state and local laws, rules and regulations applicable to the business and operations of the Company.

Covered Persons who have access to, or knowledge of, material nonpublic information from or about the Company are prohibited from buying, selling or otherwise trading in the Company's stock or other securities. "Material nonpublic information" includes any information, positive or negative, that has not yet been made available or disclosed to the public and that might be of significance to an investor, as part of the total mix of information, in deciding whether to buy or sell stock or other securities.

Covered Persons also are prohibited from giving "tips" on material nonpublic information, that is directly or indirectly disclosing such information to any other person, including family members, other relatives and friends, so that they may trade in the Company's stock or other securities.

Furthermore, if, during the course of a Covered Person's service with the Company, he or she acquires material nonpublic information about another company, such as one of the Company's customers or suppliers, or if he or she learns that the Company is planning a major transaction with another company (such as an acquisition), the Covered Person is restricted from trading in the securities of the other company. The Company also maintains an Insider Trading Policy, which each Covered Person must review and comply with.

REPORTING ACTUAL AND POTENTIAL VIOLATIONS OF THE CODE AND ACCOUNTABILITY FOR COMPLIANCE WITH THE CODE

The Company, through the Board, is responsible for applying this Code to specific situations in which questions may arise and has the authority to interpret this Code in any particular situation.

This Code is not intended to provide a comprehensive guideline for Covered Persons in relation to their business activities with the Company. Any Covered Person may seek clarification on the application of this Code from the Board.

Each Covered Person must:

1. notify the Company of any existing or potential violation of this Code, and failure to do so is itself a breach of the Code; and

2. not retaliate, directly or indirectly, or encourage others to do so, against any Covered Person for reports, made in good faith, of any misconduct or violations of the Code solely because that Covered Person raised a legitimate ethical issue.

Employees may report compliance concerns by sending an e-mail to the following e-mail address: gyofir@gmail.com.

The Board will take all actions it considers appropriate to investigate any breach of the Code reported to it. All Covered Persons are required to cooperate fully with any such investigations and to provide truthful and accurate information. If the Board determines that a breach has occurred, it will take or authorize disciplinary or preventative action as it deems appropriate, after consultation with the Company's legal counsel if warranted, up to and including termination of employment. Where appropriate, the Company will not limit itself to disciplinary action but may pursue legal action against the offending Covered Person involved. In some cases, the Company may have a legal or ethical obligation to call violations to the attention of appropriate enforcement authorities.

Compliance with the Code may be monitored by audits performed by the Board, the Company's counsel and/or by the Company's outside auditors. All Covered Persons are required to cooperate fully with any such audits and to provide truthful and accurate information.

Any waiver of this Code for any Covered Person may be made only by the Board and will be promptly disclosed to stockholders and others, as required by applicable law. The Company must disclose changes to and waivers of the Code in accordance with applicable law.

Exhibit 19.1

RAPHAEL PHARMACEUTICALS INC.

INSIDER TRADING POLICY
AND GUIDELINES WITH RESPECT TO
CERTAIN TRANSACTIONS IN COMPANY SECURITIES

Date: March 5, 2025

This Insider Trading Policy (the "**Policy**") provides guidelines to directors, officers, employees and other related persons of Raphael Pharmaceuticals Inc. (the "**Company**"), a company incorporated under the laws of the State of Nevada, with respect to transactions in the Company's securities. The Company has adopted this Policy in order to ensure compliance with securities laws and to avoid even the appearance of improper conduct by anyone associated with the Company. Failure to comply with these procedures could result in a serious violation of the securities laws by you and/or the Company and can result in both civil penalties and criminal fines and imprisonment. We have all worked hard to establish the Company's reputation for integrity and ethical conduct, and we are all responsible for preserving and enhancing this reputation. The appearance of insider trading can cause a substantial loss of confidence in the Company and its shares on the part of the public and the securities markets. This could result in an adverse impact on the Company and its shareholders. Accordingly, avoiding the appearance of engaging in share transactions on the basis of material undisclosed information can be as important as avoiding a transaction actually based on such information. The Company has appointed its Chief Financial Officer, or in his or her absence, the Company's Chief Executive Officer (the "**Compliance Officer**," as the case may be), as the Company's Insider Trading Compliance Officer.

I. Applicability of Policy

This Policy applies to all transactions in the Company's securities, including ordinary shares, options, warrants and any other securities the Company may issue from time to time, such as preferred shares, notes and convertible debentures, as well as to derivative securities relating to the Company's shares, whether or not issued by the Company, such as exchange-traded options and debt securities. It applies to all officers of the Company, all members of the Company's Board of Directors, and all employees of, and consultants and contractors to, the Company and its subsidiaries/branches who receive or have access to Material Nonpublic Information (as defined below) regarding the Company (collectively, "**Company Affiliated Persons**"). Company Affiliated Persons, members of their immediate families (which include spouse and minor children), members of their households, other family members living with them or who are supported by them, are sometimes referred to in this Policy as "**Insiders**". This Policy also applies to any trust or other estate in which an Insider has a substantial beneficial interest or as to which he or she serves as trustee or in a similar fiduciary capacity, and to any trust, corporation, partnership or other entity which the Insider controls, including venture capital partnerships. This Policy also applies to any person who receives Material Nonpublic Information from any Insider.

Any person who possesses Material Nonpublic Information regarding the Company is an Insider for so long as the information is not publicly known. Any employee can be an Insider from time to time, and would at those times be subject to this Policy.

The Policy imposes additional restrictions upon Insiders who have routine access to Material Nonpublic Information, referred to as "**Access Insiders**." Access Insiders are: (1) members of the board of directors, (2) the executive officers, (3) the controller, if applicable, and (4) the investor relations department of the Company, if applicable. In addition, other employees of the Company who have routine access to Material Nonpublic Information as determined by the Compliance Officer, who were notified that these additional restrictions apply to them shall also be Access Insiders until otherwise determined by the Compliance Officer.

In addition, the Company itself must comply with securities laws applicable to its own securities trading activities, and must not engage in any transaction involving a purchase or sale of its securities, including any offer to purchase or offer to sell or other disposition of its securities, when it is in possession of Material Nonpublic Information concerning the Company, other than in compliance with applicable law, subject to the policies and procedures adopted by the Company and the exceptions listed in Section XII of this Policy to the extent applicable.

II. General Policy

It is the policy of the Company to oppose the unauthorized disclosure of any nonpublic information acquired in the work-place and the misuse of Material Nonpublic Information in securities trading.

III. Specific Policies

1. Trading on Material Nonpublic Information. No Insider shall engage in any transaction involving a purchase or sale of the Company's securities, including any offer to purchase or offer to sell or other disposition of the Company's securities, during any period commencing with the time that he or she first receives Material Nonpublic Information concerning the Company, and ending at the close of business on the second Trading Day following the date of public disclosure of that information, or at such time as such nonpublic information is no longer material. As used herein, the term "**Trading Day**" shall mean a day on which the OTCQB Market or any other trading market on which the Company's securities trade is open for trading.

2. Tipping. No Insider shall disclose (sometimes called a "**Tip**") Material Nonpublic Information to any other person (including family members) where such information may be used by such person to his or her profit by trading in the securities of companies to which such information relates, nor shall such Insider or related person make recommendations or express opinions on the basis of Material Nonpublic Information as to trading in the Company's securities.

3. Confidentiality of Nonpublic Information. Nonpublic information relating to the Company is the property of the Company and the unauthorized disclosure of such information is forbidden. In the event any officer, director or employee of the Company receives any inquiry from outside the Company, such as a stock analyst, for information (particularly financial results and/or projections) that may be Material Nonpublic Information, the inquiry should be referred to the Compliance Officer, and to the other appropriate Company officers, as provided for in the Disclosure Policy of the Company, if any, as may be in place from time to time.

IV. Potential Criminal and Civil Liability and/or Disciplinary Action

1. Liability for Insider Trading. In the United States and many other countries, the personal consequences to an Insider of illegally trading securities while in possession, or on the basis of, Material Nonpublic Information can be quite severe. In the United States there are substantial civil penalties and criminal sanctions which may be assessed for insider trading. Civil penalties are a payment of a penalty of up to three times the illicit windfall. In addition, Insiders may be subject to criminal fines of up to $5,000,000 and up to twenty years in prison for engaging in transactions in the Company's securities at a time when they have knowledge of Material Nonpublic Information regarding the Company.

If you are located or engaged in dealings outside the U.S., be aware that laws regarding insider trading and similar offenses differ from country to country. Employees must abide by the laws in the country where located. However, you are required to comply with this Policy even if local law is less restrictive. If a local law conflicts with this Policy, you must consult the Compliance Officer.

If securities transactions ever become the subject of scrutiny, they are likely to be viewed after-the-fact with the benefit of hindsight. As a result, before engaging in any transaction an Insider should carefully consider how the transaction may be construed in the bright light of hindsight. If you have any questions or uncertainties about this Policy or a proposed transaction, please ask the Compliance Officer.

2. Liability for Tipping. Insiders may also be liable for improper transactions by any person (commonly referred to as a "**Tippee"**) to whom they have disclosed Material Nonpublic Information or any person to whom the Tippee discloses such Material Nonpublic Information regarding the Company or to whom they have made recommendations or expressed opinions on the basis of such information as to trading in the Company's securities. The civil penalties and criminal sanctions for tipping by an Insider are the same as the ones for an Insider conducting insider trading, even if the disclosing person did not profit from the trading. The U.S. Securities and Exchange Commission (the "**SEC**"), the Financial Industry Regulatory Authority ("**FINRA**") and the stock exchanges use sophisticated electronic surveillance techniques to uncover insider trading.

3. Possible Disciplinary Actions. The seriousness of securities law violations is reflected in the penalties and criminal sanctions such violations carry. These violations may also create negative publicity for the Company and a director's resignation may be sought, or an officer or other employee will be subject to possible Company disciplinary action including ineligibility for future participation in the Company's equity incentive plans or termination of employment.

V. Individual Responsibility

Every Company Affiliated Person has the individual responsibility to comply with this Policy against insider trading, regardless of whether the Company has recommended a trading window to that person or any other Insiders of the Company. The guidelines set forth in this Policy are not intended to provide a conclusive solution for all circumstances, and appropriate judgment should be exercised in connection with any trade in the Company's securities.

An Insider may, from time to time, have to forego a proposed transaction in the Company's securities even if he or she planned to make the transaction before learning of the Material Nonpublic Information and even though the Insider believes he or she may suffer an economic loss or forego anticipated profit by waiting.

VI. Applicability of Policy to Inside Information Regarding Other Companies

This Policy and the guidelines described herein also apply to Material Nonpublic Information relating to other companies, including the Company's customers, vendors or suppliers ("**Business Partners**"), when that information is obtained in the course of employment with, or other services performed on behalf of, the Company. Civil penalties and criminal sanctions, and termination of employment, may result from trading on inside information regarding the Company's Business Partners. All employees should treat Material Nonpublic Information about the Company's Business Partners with the same care required with respect to information related directly to the Company.

VII. Dissemination of Company Information

The prohibition of the disclosure of Material Nonpublic Information applies to all contacts made within and outside the Company. Care should be taken to prevent the disclosure of Material Nonpublic Information during all contact including phone calls and casual conversation. If in doubt about whether information falls into the category of Material Nonpublic Information, then the information should not be disclosed.

Prior to disclosure to any third party, any officer, director or employee of the Company who is aware of any Material Nonpublic Information concerning the Company that has not been disclosed to the public should report the intention to disclose such information promptly to the Compliance Officer and obtain approval to do so, or otherwise act in accordance with the Company's Disclosure Policy, if any, as may be in place from time to time.

VIII. Definition of Material Nonpublic Information

Material Nonpublic Information is information which is material, and that has not been disclosed or otherwise made available to the general public by the Company.

It is not possible to define all categories of material information. Generally, information should be regarded as material if a reasonable investor would consider it important in making an investment decision regarding the purchase or sale of the Company's securities or the information, if made public, would likely affect the market price of the Company's securities. Either positive or negative information may be material. Information may be material even if it relates to future, speculative or contingent events and even if it is significant only when considered in combination with publicly available information. Nonpublic information can be material even with respect to companies that do not have publicly traded stock, such as those with outstanding bonds or bank loans.

While it may be difficult under this standard to determine whether particular information is material, there are various categories of information that are particularly sensitive and, as a general rule, should always be considered material. If any Insider has questions as to the materiality of information, he or she should contact the Compliance Officer for clarification. Examples of information which is deemed to be material include:

- Financial results;
- Projections of future earnings or losses;
- News of a pending or proposed merger or acquisition;
- New product or project announcements of a significant nature;
- Expansion or curtailment of operations or the gain or loss of a substantial customer;
- Changes in control of the Company or major changes in senior management;
- Significant new joint ventures, alliances, or strategic partnerships or material developments in existing arrangements;
- Impending bankruptcy or financial liquidity problems;
- Significant product defects or modifications;
- Significant pricing changes;
- Events regarding the Company's securities (e.g. stock splits, repurchases, or changes in dividend policy);
- Changes in auditors or auditor notification that the Company may no longer rely on an audit report;
- A significant purchase or sale of assets or disposition of a subsidiary or division;
- New equity or debt offerings, significant borrowings, or other material financial transactions;
- Significant litigation exposure due to actual or threatened litigation;
- Significant actions by regulatory bodies;
- Receipt, cancellation or deferral of significant purchase orders;
- Cyber attacks;
- Proposed payment of a dividend; and
- Any of the above with respect to a subsidiary, or other affiliate of the Company.

Nonpublic information is information that has not been previously disclosed to the general public and is otherwise not available to the general public. It is important to note that information is not necessarily public merely because it has been discussed in the press, which will sometimes report rumors. You should presume that information is nonpublic unless you can point to its official release by the Company in at least one of the following ways:

1. Information contained in publicly available documents filed with securities regulatory authorities (e.g., filings with the SEC);
2. Issuance of press releases; or
3. Meetings with members of the press and the public.

IX. Additional Circumstances Where No Exceptions Apply

There are almost no exceptions to the prohibition against insider trading. For example, it does not matter that the transactions in question may have been planned before the Insider came into possession of the undisclosed material information, regardless of the economic loss that the person may believe he or she might suffer as a consequence of not trading.

As noted above, the definition of Insiders, to which this Policy applies, includes immediate family members of Company Affiliated Persons. Although immediate family is narrowly defined, a Company Affiliated Person should be especially careful with respect to family members or to unrelated persons living in the same household.

Finally, there are no limits on the size of a transaction that will trigger insider trading liability; relatively small trades have in the past occasioned investigations and lawsuits.

X. Trading Window

The period beginning two weeks before the end of the last month of each calendar quarter and ending two Trading Days following the date of public disclosure of the financial results for that quarter, is a particularly sensitive period of time for transactions in the Company's shares from the perspective of compliance with applicable securities laws. This sensitivity is due to the fact that directors, officers and certain other employees will, during that period, often possess Material Nonpublic Information about the expected financial results for the quarter.

Accordingly, to ensure compliance with this Policy and applicable federal and state securities laws, it is the Company's policy that all directors, officers and employees refrain from conducting transactions involving the purchase or sale of the Company's securities other than during the period (the "**Trading Window**") commencing at the close of business on the second Trading Day following the date of public disclosure of the financial results for a particular fiscal quarter or year and continuing until the day that is two weeks before the last day of the last month of the next fiscal quarter. As a courtesy to the persons subject to this Policy, the Company may provide advance notice before the Trading Window opens.

From time to time, the Company may also notify that directors, officers, selected employees and others are required to suspend trading because of developments known to the Company and not yet disclosed to the public. In such event, such persons are advised not to engage in any transaction involving the purchase or sale of the Company's securities during such period and should not disclose to others the fact of such suspension of trading.

The purpose behind the self-imposed Trading Window period is to help establish a diligent effort to avoid any improper transaction. It should be noted, however, that even during the Trading Window, any person possessing Material Nonpublic Information concerning the Company may not attempt to "beat the market" by trading simultaneously with, or shortly after, the official release of Material Nonpublic Information. Although there is no fixed period for how long it takes the market to absorb information, out of prudence a person aware of Material Nonpublic Information should refrain from any trading activity for at least two full Trading Days following its official release, whether or not the Company has recommended a suspension of trading to that person.

NOTWITHSTANDING THESE TIMING GUIDELINES, IT IS ILLEGAL FOR ANY PERSON TO TRADE WHILE IN POSSESSION OF MATERIAL NONPUBLIC INFORMATION, INCLUDING SITUATIONS IN WHICH THE PERSON IS AWARE OF MAJOR DEVELOPMENTS THAT HAVE NOT YET BEEN PUBLICLY ANNOUNCED BY THE COMPANY. TRADING IN THE COMPANY'S SECURITIES DURING THE TRADING WINDOW SHOULD NOT BE CONSIDERED A "SAFE HARBOR," AND ALL DIRECTORS, OFFICERS AND OTHER INSIDERS SHOULD USE GOOD JUDGMENT AT ALL TIMES.

XI. Inquiries

All Insiders should review this Policy carefully and contact the Compliance Officer if they have a concern that a contemplated transaction in the Company's securities might not conform with this Policy.

XII. Certain Exceptions

For purposes of this Policy, the Company considers that the exercise of share options for cash under the Company's share option plans or the purchase of shares under employee purchase plans that exist and are in effect at the time of the adoption of this Policy and that may be adopted in the future (but not the sale of any such shares) is exempt from this Policy, since the other party to the transaction is the Company itself and the price does not vary with the market but is fixed by the terms of the option agreement or the plan. Accordingly, cashless exercises of options are subject to the Policy when they involve the sale of shares into the public marketplace.

Bona fide gifts of securities are not deemed to be transactions for the purposes of this Policy. Whether a gift is truly bona fide will depend on the circumstances surrounding each gift. The more unrelated the donee is to the donor, the more likely the gift would be considered "bona fide" and not a "transaction." For example, gifts to charities, religious institutions and service organizations would likely not be "transactions." On the other hand, gifts to dependent children followed by a sale of the "gift" securities in close proximity to the time of the gift may imply some economic benefit to the donor and, therefore, make the gift non-bona fide.

The restrictions in this Policy shall not apply to purchases or sales made pursuant to a Qualified Plan. For purposes of this exception, a "**Qualified Plan**" is a written plan for purchasing or selling the Company's securities which meets each of the following requirements: (1) the plan is adopted by the Insider during a Trading Window; (2) the plan is adopted in good faith by the Insider when he or she is not in possession of material non-public information; (3) the plan is adhered to strictly by the Insider; (4) the plan either (a) specifies the amount of securities to be purchased or sold and the date on which the securities are to be purchased or sold, (b) includes a written formula or algorithm, or computer program, for determining the amount of securities to be purchased or sold and the price at which and the date on which the securities are to be purchased or sold, or (c) does not permit the Insider to exercise any subsequent influence over how, when, or whether to effect purchases or sales; provided, in addition, that any other person who, pursuant to the plan, does exercise such influence must not have been aware of the material nonpublic information when doing so; and (5) at the time it is adopted the plan conforms to all other requirements of Rule 10b5-1(c)(1)(C) under the U.S. Securities Exchange Act of 1934 as then in effect.

In addition to the above requirements, a Qualified Plan shall be signed and dated by the Insider, and submitted to the Compliance Officer at least two (2) trading days before it is filed with the broker who executes it. The Company shall have the right, at all time, to suspend purchases or sales under a Qualified Plan, for instance in the event that the Company needs to comply with requirements by underwriters for "lock-up" agreements in connection with an underwritten public offering of the Company's securities. A Qualified Plan cannot be canceled, suspended, expanded or otherwise modified by the Insider who signed it more than once during a fiscal quarter (or as further limited by Rule 10b5-1). Any cancellation, suspension, expansion or other modification of a Qualified Plan by the Insider who established it must: (1) be in writing, signed and dated by such Insider, (2) be submitted to the Compliance Officer within two (2) trading days after the cancellation, suspension, expansion or other modification was reduced to writing, and (3) be made during a Trading Window, and when the Insider who established it has no Nonpublic Material Information about the Company.

XIII. Preclearance of Trades

The Company has determined that all Access Insiders should refrain from trading in the Company's securities, even during the Trading Window, without first complying with the Company's "preclearance" process. Each Access Insider should contact the Compliance Officer prior to commencing any trade in the Company's securities. At the time of executing a trade in the Company's securities, such individuals will be responsible for verifying that the Company has not imposed any restrictions on their ability to engage in trades. If the individual has not completed the trade within ten (10) trading days of notification of the intention to trade, then the individual must again notify the Compliance Officer that he or she intends to execute a trade and re-verify the nonexistence of any restrictions on such trade. For the avoidance of doubt, this paragraph shall not apply to a Qualified Plan, after it has been set up.

Before each transaction in the Company's securities, each officer and director should contact the Compliance Officer regarding compliance with Rule 144 under the U.S. Securities Act of 1933, as amended ("**Rule 144**"), which contains guidelines for the sale of privately issued shares and sales by affiliates of the Company, if such sales are not covered by an effective registration statement, to the extent applicable.

XIV. Specific Requirements

1. **Speculative Trading**. No Insider may engage in transactions of a speculative nature at any time. All Insiders are prohibited from short-selling the Company's securities or engaging in transactions involving the Company's based derivative securities. A short sale, for these purposes, means any transaction whereby one may benefit from a decline in the price of the Company's securities. "**Derivative Securities**" are options, warrants, stock appreciation rights or similar rights whose value is derived from the value of an equity security, such as the Company's common stock. This prohibition includes, but is not limited to, trading in the Company's based put and call option contracts, transacting in straddles, hedging or monetization transaction with respect to the Company's securities, and the like. In addition, no Insider shall engage in a transaction with respect to securities of the Company if he or she owns the security, but does not deliver it against such sale (a "short sale against the box") within twenty days thereafter, or does not within five days after such sale deposit it in the mails or other usual channels of transportation. The above does not derogate from Insiders' right to hold and exercise options or other derivative securities granted under the Company's employee share option or equity incentive plans as long as such exercise is not prohibited by this Policy.

2. **Margin Accounts and Pledges**. Securities held in a margin account may be sold by the broker without the consent of the owner thereof if such owner fails to meet a margin call. Similarly, securities pledged as collateral for a loan may be sold if the owner thereof defaults on the loan. In case of an owner who is subject to this Policy, these sales may occur at a time when such person is aware of material, non-public information or otherwise not permitted to trade such securities. Therefore, this policy prohibits holding any Company securities in a margin account or pledging any Company securities as collateral for a loan.

3. **Post-Termination Transactions.** If an Insider is aware of Material Nonpublic Information at the time such Insider's association with the Company is terminated, whether by the Insider or the Company, the Insider may not trade in Company securities until such information is no longer material or until two Trading Days after such information has become public. In addition, if the Company is not in a Trading Window at the time such association with the Company is terminated, the Insider may not trade in Company securities until two Trading Days after the next announcement of quarterly earnings or of the material, non-public information.

4. **Ad hoc Restrictions**. The Compliance Officer has the authority to impose restrictions on trading in the Company's securities by appropriate individuals at any time. In such event, the Compliance Officer will notify the affected individuals, either personally, by email or by voicemail, to inform them of the restrictions.

5. **Open Orders**. Any Insider who has placed a limit order or open instruction to buy or sell the Company's securities shall bear responsibility for canceling such instructions immediately upon becoming in possession of Material Nonpublic Information.

XV. Acknowledgement

Please sign the attached acknowledgement form and return it to the Compliance Officer.

If you have any questions with respect to this Policy, please contact the Company's Compliance Officer, at gyofir@gmail.com or at +972-5051505.

ACKNOWLEDGEMENT

I have received, read and understand the Insider Trading Policy and Guidelines with Respect to Certain Transactions in Company Securities of Raphael Pharmaceuticals Inc., a copy of which is attached hereto, and agree to comply with the provisions thereof.

Date: March 5, 2025

/s/ Guy Ofir
Signature

Guy Ofir
Name

Chief Financial Officer
Title

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Shlomo Pilo, certify that:

1. I have reviewed this Annual Report on Form 10-K of Raphael Pharmaceutical 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 15d-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: March 31, 2025

By: /s/ Shlomo Pilo
Shlomo Pilo
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Guy Ofir, certify that:

1. I have reviewed this Annual Report on Form 10-K of Raphael Pharmaceutical 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 15d-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: March 31, 2025

By: /s/ Guy Ofir
Guy Ofir
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the annual report of Raphael Pharmaceutical Inc., or the Company, on Form 10-K for the period ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Shlomo Pilo, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) 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.

Dated: March 31, 2025

/s/ Shlomo Pilo
Shlomo Pilo
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the annual report of Raphael Pharmaceutical Inc., or the Company, on Form 10-K for the period ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Guy Ofir, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) 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.

Dated: March 31, 2025

/s/ Guy Ofir
Guy Ofir
Chief Financial Officer
(Principal Financial Officer)