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, 2022

OR

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

For the transition period from _____ to _____

Commission File No. 001-27072

AIM IMMUNOTECH INC.
(Exact name of registrant as specified in its charter)

Delaware	52-0845822
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
2117 SW Highway 484, Ocala FL	34473
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (352) 448-7797

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	AIM	NYSE American

Securities registered pursuant to Section 12(g) of the Act:
(Title of Each Class)
NONE

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

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

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

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

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

☐ Large accelerated filer	☐ Accelerated filer
☒ 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 pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by checkmark 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 ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates at June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter was $36,254,483.

The number of shares of the registrant's Common Stock outstanding as of March 28, 2023 was 48,407,326.

DOCUMENTS INCORPORATED BY REFERENCE: None.

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PART I

ITEM 1. Business

GENERAL

AIM ImmunoTech Inc. and its subsidiaries (collectively, "AIM", "Company", "we" or "us") are an immuno-pharma company headquartered in Ocala, Florida, and focused on the research and development of therapeutics to treat multiple types of cancers, viral diseases and immune-deficiency disorders. We have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of nucleic acids and natural interferon to enhance the natural antiviral defense system of the human body, and to aid the development of therapeutic products for the treatment of certain cancers and chronic diseases.

Our flagship products are Ampligen® (rintatolimod) — a first-in-class drug of large macromolecular RNA (ribonucleic acid) molecules — and Alferon N Injection® (Interferon alfa-n3). Ampligen has not been approved by the FDA or marketed in the United States. Ampligen is approved for commercial sale in the Argentine Republic for the treatment of severe CFS.

Our primary present business focus involves Ampligen. Ampligen represents a dsRNA being developed for globally important cancers, viral diseases and disorders of the immune system.

We currently are proceeding primarily in four areas:

- Conducting a randomized, controlled study to evaluate efficacy and safety of Ampligen compared to a control group to treat locally advanced pancreatic cancer patients.
- Evaluating Ampligen in other cancers, as a potential therapy that modifies the tumor microenvironment with the goal of increasing anti-tumor responses to check point inhibitors.
- Exploring Ampligen's antiviral activities and potential use as a prophylactic or treatment for existing viruses, new viruses and mutated viruses thereof.
- Evaluating Ampligen as a treatment for myalgic encephalomyelitis/chronic fatigue syndrome ("ME/CFS") and fatigue and/or Post-COVID conditions of fatigue.

We are prioritizing our activities in an order related to the stage of development, with those clinical activities such as pancreatic cancer, ME/CFS and Post-COVID conditions having priority over antiviral experimentation. We intend that priority clinical work be conducted in FDA- or EMA-authorized trials which could support a potential future NDA. However, our antiviral experimentation is designed to accumulate additional preliminary data supporting our hypothesis that Ampligen is a powerful, broad-spectrum prophylaxis and early-onset therapeutic that may confer enhanced immunity and cross-protection. Accordingly, we will conduct our antiviral programs in those venues most readily available and able to generate valid proof-of-concept data, including foreign venues.

Immuno-Oncology.

We are focused on pancreatic cancer because testing results, to date, primarily conducted in the Netherlands, have been very promising. The Netherlands study generated statistically significant data indicating that Ampligen extended survival well beyond the Standard of Care ("SOC"), when compared to well-matched historical controls. These data support the proposition that Ampligen, when administered to either patients with locally advanced or metastatic pancreatic cancer after systemic chemotherapy showed a statistically significant increase in survival rate. In October 2021, we and our Contract Research Organization, Amarex, submitted an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for a planned Phase 2 study of Ampligen as a therapy for locally advanced or metastatic late-stage pancreatic cancer. In August 2022, we received Institutional Review Board ("IRB") approval of the trial protocol and so announced the trial's commencement. Assuming this trial and subsequent planned clinical trials confirm the existing data, our goal is to then submit an NDA for use of Ampligen in pancreatic cancer patients.

Because of the differences in the scale of necessary trials, our initial primary focus when it comes to pancreatic cancer will be cases that are locally advanced, rather than metastatic. The number of different approaches to treating metastatic pancreatic cancer — approaches which would be determined by treating physicians — would require a much larger, far more expensive trial than would a trial for locally advanced pancreatic cancer. Therefore, we are focusing on patients who have completed FOLFIRINOX and have stable disease. Ampligen has also demonstrated in the clinic the potential for standalone efficacy in a number of other solid tumors. We have also seen success in increasing survival rates and efficacy in the treatment of animal tumors when Ampligen is used in combination with checkpoint blockade therapies. In fact, in March 2022 we announced interim data from an investigator-initiated, Phase 2, single-arm, efficacy/safety trial to evaluate the effectiveness of combining intensive locoregional intraperitoneal (IP) chemoimmunotherapy of cisplatin with IP Ampligen (TLR-3 agonist) and IV infusion of the checkpoint inhibitor pembrolizumab for patients with recurrent platinum-sensitive ovarian cancer. We believe that data from the study, which is being conducted by the University of Pittsburgh Medical Center and funded by a Merck grant, demonstrated that when combining three drugs – Ampligen and pembrolizumab, which are both immune therapies, with cisplatin, a chemotherapy – evidence of increased biomarkers associated with T cell chemotaxis and cytolytic function has been seen. Importantly, increases of these biomarkers in the tumor microenvironment have been correlated with favorable tumor responses. These successes in the field of immuno-oncology have guided our efforts toward the potential use of

Ampligen as a combinational therapy for the treatment of a variety of solid tumor types. The first of our patent applications in this space was granted by the Netherlands on March 15, 2021.

Please see "*Immuno-Oncology*" below.

Ampligen as an Antiviral.

We have a research and pre-clinical history that indicates broad-spectrum antiviral capability of Ampligen in animals. We hope to demonstrate that it has the same effect in humans. To do this, among other things, we need a population infected with a virus. That is why we have spent significant resources on COVID-19 (the disease caused by SARS-CoV-2) which is active and still infecting many subjects. While much would need to be done to get Ampligen to market as a broad-spectrum antiviral, we believe that it is important to focus our efforts first and foremost on thoroughly proving the concept, especially while there is still a large COVID-19-infected population. Previously, animal studies were conducted that yielded positive results utilizing Ampligen to treat numerous viruses, such as Western Equine Encephalitis Virus, Ebola, Vaccinia Virus (which is used in the manufacture of smallpox vaccine) and SARS-CoV-1. We have conducted experiments in SARS-CoV-2 showing Ampligen has a powerful impact on viral replication. The prior studies of Ampligen in SARS-CoV-1 animal experimentation may predict similar protective effects against SARS-CoV-2.

The FDA has requested that we provide additional data to assist the agency in evaluating the potential risks and benefits of administering Ampligen to asymptomatic and mild COVID-19 individuals. However, as discussed in more detail below, where the threat to the patient from COVID-19 is high, the FDA has already authorized Ampligen in a clinical trial of patients with COVID-19 who have a pre-existing cancer. We have also elected to explore studies (initially with healthy volunteers) outside the United States and have already conducted a study in the Netherlands to determine the safety profile of the intranasal delivery of Ampligen.

In this regard, CHDR, a foundation located in Leiden in the Netherlands, managed a Phase 1 randomized, double-blind study for us to evaluate the safety, tolerability and biological activity of repeated administration of Ampligen intranasally. A total of 40 healthy subjects received either Ampligen or a placebo in the trial, with the Ampligen given at four escalating dosages across four cohorts, to a maximum level of 1,250 micrograms. All patients had completed study by June 2021 and the study is completed. The Final Safety Report reported no Serious or Severe Adverse Events at any dosage level.

Today, over two years after COVID-19 first appeared, the world has a number of vaccines and some promising therapeutics. Our quest to prove the antiviral activities of Ampligen continues. If Ampligen has the broad-spectrum antiviral properties that we believe that it has, it could be a very valuable tool in treating variants of existing viral diseases, including COVID-19, or novel ones that arise in the future. Unlike most developing therapeutics which attack the virus, Ampligen works differently. We believe that it activates antiviral immune system pathways that fight not just a particular virus or viral variant, but other similar viruses as well.

In October 2022, our IND application cleared the FDA approval process and we are proceeding with a Phase 2 study evaluating Ampligen as a therapeutic for patients with post-COVID conditions ("AMP-518"). Additional comments were received from the FDA, which have been addressed in an amended protocol approved by the IRB on March 30, 2023.

Please see "*Ampligen as a Potential Antiviral*" below.

Ampligen as a treatment for ME/CFS and Post-COVID Conditions

We have long been focused on seeking the FDA's approval for the use of Ampligen to treat myalgic encephalomyelitis/chronic fatigue syndrome ("ME/CFS"). In fact, in February 2013, we received a Complete Response letter ("CRL") from the FDA for our Ampligen NDA for ME/CFS, stating that we should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses.

While developing a comprehensive response to the FDA and a plan for a confirmatory trial for the FDA NDA, we proceeded independently in Argentina and, in August 2016, we received approval of an NDA from ANMAT for commercial sale of Ampligen in the Argentine Republic for the treatment of severe CFS. In September 2019, we received clearance from the FDA to ship Ampligen to Argentina for the commercial launch and subsequent sales. On June 10, 2020, we received import clearance from ANMAT to import the first shipment of commercial grade vials of Ampligen into Argentina. The next steps in the commercial launch of Ampligen include ANMAT conducting a final inspection of the product and release tests before granting final approval to begin commercial sales. This testing and approval process is currently delayed due to ANMAT's internal processes and the ongoing effects of COVID-19 and. Once final approval by ANMAT is obtained, GP Pharm will be responsible for distributing Ampligen in Argentina.

The FDA authorized an open-label treatment protocol ("AMP-511") allowing patient access to Ampligen for treatment in a study under which severely debilitated CFS patients have the opportunity to be on Ampligen to treat this very serious and chronic condition. The data collected from the AMP-511 protocol through a consortium group of clinical sites provide safety information regarding the use of Ampligen in patients with CFS. The AMP-511 protocol is ongoing. In October 2020, we received IRB approval for the expansion of the AMP-511 protocol to include patients previously diagnosed with SARS-CoV-2 following clearance of the virus, but who still demonstrate chronic fatigue-like symptoms that we refer to as Post-COVID conditions. As of December 31, 2022, there were 10 patients enrolled in this open-label expanded access treatment protocol (including two patients with Post-COVID-19 Conditions). As of January 31, 2023, there have been seven such Post-COVID patients treated in the study. AIM previously reported positive preliminary results based on data from the first four Post-COVID Condition patients enrolled in the study. The data show that, by week 12, compared to baseline, there was what the investigators considered a clinically significant decrease in fatigue-related measures.

We plan on a comprehensive follow through with the FDA regarding the use of Ampligen as a treatment for ME/CFS. We have learned a great deal since the FDA's CRL and plan to adjust our approach to concentrate on specific ME/CFS symptoms. Responses to the CRL and a proposed confirmatory trial are being worked on now by our R&D team and consultants.

Please see "*Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)*" below.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND SUMMARY RISK FACTORS

Certain statements in this Report contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. These statements are based on our management's current beliefs, expectations and assumptions about future events, conditions and results and on information currently available to us. Discussions containing these forward-looking statements may be found, among other places, in this Report in Part I, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations"; Part II, Item 1. "Legal Proceedings"; and Part II, Item 1A. "Risk Factors", as well as the following sections of our Annual Report on Form 10-K for the year ended December 31, 2021: Item 1. "Business", Part I; Item 1A. "Risk Factors", Part I; Item 3. "Legal Proceedings", Part I and Part II; Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations".

All statements, other than statements of historical fact, included or incorporated herein regarding our strategy, future operations, financial position, future revenues, projected costs, plans, prospects and objectives are forward-looking statements. Words such as "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate," "think," "may," "could," "will," "would," "should," "continue," "potential," "likely," "opportunity" and similar expressions or variations of such words are intended to identify forward-looking statements but are not the exclusive means of identifying forward-looking statements and their absence does not mean that a statement is not forward-looking. Our forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such statements due to risks and uncertainties.

Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to adequately fund our projects as we will need additional funding to proceed with our objectives; the potential therapeutic effect of our products; the possibility of obtaining regulatory approval; our ability to find senior co-development partners with the capital and expertise needed to commercialize our products and to enter into arrangements with them on commercially reasonable terms; our ability to manufacture and sell any products; our ability to enter into arrangements with third party vendors; market acceptance of our products; our ability to earn a profit from sales or licenses of any drugs; our ability to discover new drugs in the future, changing market conditions, changes in laws and regulations affecting our industry; and future matters related to our New Jersey facility, which by definition we cannot define at this time.

We are in various stages of seeking to determine whether Ampligen will be effective in the treatment of multiple types of viral diseases, cancers, and immune-deficiency disorders. We discuss in this Report our current and anticipated future activities, all of which are subject to change for a number of reasons. Significant testing and trials will be required to determine whether Ampligen will be effective in the treatment of these conditions. Results obtained in animal models do not necessarily predict results in humans. Human clinical trials will be necessary to prove whether or not Ampligen will be efficacious in humans. No assurance can be given as to whether current or planned clinical trials will be successful or yield favorable data and the trials are subject to many factors including lack of regulatory approval(s), lack of study drug, or a change in priorities at the institutions sponsoring other trials. We cannot assure that the clinical studies will be successful or yield any useful data or require additional funding.

With the outbreak of the COVID-19 coronavirus and our prior research into Ampligen's antiviral activity against Severe Acute Respiratory Syndrome, or SARS, we have been focused on the potential role that Ampligen could play in the treatment of SARS-CoV-2 — from a protective prophylaxis/early-onset therapeutic to a treatment for post-COVID conditions. Our beliefs rely on a number of studies. No assurance can be given that future studies will not result in findings that are different from those reported in the studies we refer to. The pandemic is disrupting world health and world economies and most likely will continue to do so for a long time. While we are able to continue to operate, clearly, like all businesses, we are unable to gauge how bad this pandemic will affect our operations in the future. We reached out to numerous foreign governments related to COVID-19 and, if successful, may be working in these countries. Operating in foreign countries carries with it a number of risks, including potential difficulties in enforcing intellectual property rights. We cannot assure that our potential operations in foreign countries will not be adversely affected by these risks. We have filed provisional patent applications related to the COVID-19 coronavirus. However, these filings do not assure that patents will ultimately be granted.

In February 2013, we received a Complete Response Letter (CRL) from the Food and Drug Administration, or FDA, for our Ampligen New Drug Application, or NDA, for the treatment of CFS. The FDA communicated that we should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses. Accordingly, the remaining steps to potentially gain FDA approval of the Ampligen NDA, the final results of these and other ongoing activities could vary materially from our expectations and could adversely affect the chances for approval of the Ampligen NDA. These activities and the ultimate outcomes are subject to a variety of risks and uncertainties, including but not limited to risks that (i) the FDA may ask for additional data, information or studies to be completed or provided; and (ii) the FDA may require additional work related to the commercial manufacturing process to be completed or may, in the course of the inspection of manufacturing facilities, identify issues to be resolved. A proposed confirmatory trial and responses to the CRL are being worked on now by our R&D team and consultants.

In August 2016, we received approval of our NDA from Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica ("ANMAT"), for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of severe CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America. We believe, but cannot assure, that this approval provides a platform for potential sales in certain countries within the European Union under regulations that support cross-border pharmaceutical sales of licensed drugs. In Europe, approval in a country with a stringent regulatory process in place, such as Argentina, should add further validation for the product as the Early Access Program, or EAP, as discussed below and underway in Europe in pancreatic cancer. ANMAT approval is only an initial, but important, step in the overall successful commercialization of our product. There are a number of actions that must occur before we could be able to commence commercial sales in Argentina. In September 2019, we received clearance from the FDA to ship Ampligen to Argentina for the commercial launch and subsequent sales. In June 2020, we received import clearance from ANMAT to import the first shipment of commercial grade vials of Ampligen into Argentina. We are currently working with GP Pharma on the commercial launch of Ampligen in Argentina. Commercialization in Argentina will require, among other things, an appropriate reimbursement level, appropriate marketing strategies, completion of manufacturing preparations for launch and ANMAT conducting a final inspection of the product and release tests before granting final approval to begin commercial sales. This testing and approval process is currently delayed due to the COVID-19 pandemic and ANMAT's internal processes. Approval of rintatolimod for severe CFS in the Argentine Republic does not in any way suggest that the Ampligen NDA in the United States or any comparable application filed in the European Union or elsewhere will obtain commercial approval.

In May 2016, we entered into a five-year agreement with myTomorrows, a Netherlands based company, for the commencement and management of an EAP in Europe and Turkey related to CFS. Pursuant to the agreement, myTomorrows, as our exclusive service provider and distributor in this territory, is performing EAP activities. In January 2017, the EAP was extended to pancreatic cancer patients beginning in the Netherlands. In February 2018, we signed an amendment to extend the territory to cover Canada to treat pancreatic cancer patients, pending government approval. In March 2018, we signed an amendment to which myTomorrows will be our exclusive service provider for special access activities in Canada for the supply of Ampligen for the treatment of CFS. MyTomorrows provides services related to the supply and distribution of Ampligen to patients in Early Access Programs (EAPs) which are initiated through a physician's request; there have been no physician requests that have led to government approval, therefore no patients have been treated under an EAP for either pancreatic cancer or CFS in Canada. No assurance can be given that we can sufficiently supply product should we experience an unexpected demand for Ampligen in our clinical studies, the commercial launch in Argentina or pursuant to the EAPs. No assurance can be given that Ampligen will prove effective in the treatment of pancreatic cancer. The agreement was automatically extended for one year periods on May 20, 2021 and 2022, and is anticipated to extend again on May 20, 2023.

Multiple Ampligen clinical trials are underway, in various phases of development and activity, with subjects enrolled at university cancer centers testing whether tumor microenvironments can be reprogrammed to increase the effectiveness of cancer immunotherapy, including checkpoint blockade. One site of clinical trials is Roswell Park and the other is the University of Pittsburgh Medical Center. (See: "Research and Development; Immuno-oncology"). No assurance can be given as to the results of these underway trials. No assurance can be given as to whether some or all of the planned additional oncology clinical trials will occur and they are subject to many factors, including lack of regulatory approval(s), lack of study drug, or a change in priorities at the sponsoring universities or cancer centers. Even if these additional clinical trials are initiated, as we are not the sponsor, we cannot assure that these clinical studies or the studies underway will be successful or yield any useful data. In addition, initiation of planned clinical trials may not occur secondary to many factors including lack of regulatory approval(s) or lack of study drug.

Our overall objectives include plans to continue seeking approval for commercialization of Ampligen in the United States and abroad as well as seeking to broaden commercial therapeutic indications for Alferon N Injection presently approved in the United States and Argentina. We continue to pursue senior co-development partners with the capital and expertise needed to commercialize our products and to enter into arrangements with them on commercially reasonable terms. Our ability to commercialize our products, widen commercial therapeutic indications of Alferon N Injection and/or capitalize on our collaborations with research laboratories to examine our products are subject to a number of significant risks and uncertainties including, but not limited to our, ability to enter into more definitive agreements with some of the research laboratories and others that we are collaborating with, to fund and conduct additional testing and studies, whether or not such testing is successful or requires additional testing and meets the requirements of the FDA and comparable foreign regulatory agencies. We do not know when, if ever, our products will be generally available for commercial sale for any indication.

We strived to maximize the outsourcing of certain components of our manufacturing, quality control, marketing and distribution while maintaining control over the entire process through our quality assurance and regulatory groups. We cannot provide any guarantee that the facility or our contract manufacturers will pass an FDA pre-approval inspection for Alferon N Injection manufacturing.

In May 2021, we exercised our option to re-purchase the New Brunswick manufacturing facility, pursuant to the terms of the March 2018 sale and lease-back agreement. We thereafter sold certain equipment and machinery that we determined to be obsolete and no longer needed for current or future manufacturing. On March 3, 2022, we entered into an Agreement of Sale and Purchase with Acellories, Inc. to purchase the property for an estimated $3.9 million, with AIM's intention to keep some space specifically for its Alferon activity. The sale was finalized on November 1, 2022, for $3.7 million net of normal closing cost.

In June 2022 we entered into a lease agreement with the New Jersey Economic Development Authority for a 5,210 square-foot, state-of-the-art R&D facility at the New Jersey Bioscience Center ("NJBC"), primarily consisting of two separate laboratory suites. The facility is AIM's operations, research and development center.

The production of new Alferon N Injection Active Pharmaceutical Ingredient, or API, is currently on hold. The New Brunswick facility is approved by the FDA under the Biological License Application, or BLA, for Alferon N Injection. While we have sold the New Brunswick facility, we maintain a certain amount of space at that facility for Alferon activities, the sale of the facility will move up the timeline for contracting with a CMO, or CMOs, capable of producing Alferon, and receiving FDA approval to do so, prior to commercial sale of newly produced inventory product. If and when we obtain a reaffirmation of FDA BLA status and have begun production of new Alferon N Injection API, it will need FDA approval as to the quality and stability of the final product before commercial sales can resume. We may need additional funds to finance the validation process. If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon N Injection inventory, our operations most likely will be materially and/or adversely affected. In light of these contingencies, there can be no assurances that the approved Alferon N Injection product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

In December 2020, we added Pharmaceutics International Inc. ("Pii") as a "Fill & Finish" provider to enhance our capacity to produce Ampligen. This addition amplifies our manufacturing capability by providing redundancy and cost savings. The contracts augment our active and in-process fill and finish capacity.

Due to continuing delays and other obstacles related to importing Ampligen to China, on August 10, 2022, we ended our contract with Shenzhen Smoore Technology for the development of an Ampligen delivery device for the treatment of SARS-CoV-2.

We believe, and are investigating, Ampligen's potential role in enhancing the activity of influenza vaccines. While certain studies involving rodents, non-human primates (monkeys) and healthy human subjects indicate that Ampligen may enhance the activity of influenza vaccines by conferring increased cross-reactivity or cross-protection, further studies will be required and no assurance can be given that Ampligen will assist in the development of a universal vaccine for influenza or other viruses.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

This Report also refers to estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

SUMMARY RISK FACTORS

General Risk Related to our Business

- The COVID-19 coronavirus could adversely impact our business, including our clinical trials. We cannot predict the ultimate effects of the Covid-19 pandemic on our business
- We may require additional financing which may not be available.
- We may continue to incur substantial losses and our future profitability is uncertain.
- Our drug and related technologies are investigational and subject to regulatory approval. If we are unable to obtain regulatory approval in a timely manner, or at all, our operations will be materially harmed and our stock adversely affected.
- We may be subject to product liability claims from the use of Ampligen, Alferon N Injection, or other of our products which could negatively affect our future operations. We have limited product liability and clinical trial insurance.
- Uncertainty of health care reimbursement for our products.
- There are risks of liabilities associated with handling and disposing of hazardous materials.
- We rely upon information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.
- The loss of services of key personnel could hurt our chances for success.
- Our financial statements are prepared in accordance with GAAP. GAAP requires estimates, judgements and assumptions which inherently contain uncertainties.

Risks Associated with Our Products

- Possible side effects from the use of Ampligen or Alferon N Injection could adversely affect potential revenues and physician/patient acceptability of our product.

Risks Related to our activities associated with Ampligen's potential effectiveness as a treatment for SARS-CoV-2

- It is not possible to predict the future of the ongoing SARS-CoV-2 global pandemic or the development of potential treatments. There are available a couple of treatments for COVID-19. No assurance can be given that Ampligen will aid in or be applied to the treatment of this virus.

- Operating in foreign countries carries with it many risks.

Risks Associated with Our Intellectual Property

- We may not be profitable unless we can protect our patents and/or receive approval for additional pending patents.

- The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves complex legal and factual questions.

- There can be no assurance that we will be able to obtain necessary licenses if we cannot enforce patent rights we may hold. In addition, the failure of third parties from whom we currently license certain proprietary information or from whom we may be required to obtain such licenses in the future, to adequately enforce their rights to such proprietary information, could adversely affect the value of such licenses to us.

- There is no guarantee that our trade secrets will not be disclosed or known by our competitors.

Risks Associated with Our R&D

- We cannot predict what additional studies and/or additional testing or information may be required by the FDA. Accordingly, we are unable to estimate the nature, timing, costs and necessary efforts to complete these projects nor the anticipated completion dates. In addition, we have no basis for estimating when material net cash inflows may commence. We have yet to generate significant revenues from the sale of these developmental products.

Risks Associated with Our Manufacturing

- Our Alferon N Injection Commercial Sales were halted due to lack of finished goods inventory. If we are unable to gain the necessary FDA approvals related to Alferon N Injection, or if we are unable to identify a CMO or CMOs that meet our requirements, then our operations would most likely be materially and/or adversely affected.

- There are no long-term agreements with suppliers of required materials and services for Ampligen and there are a limited number of raw material suppliers. If we are unable to obtain the required raw materials and/or services, we may not be able to manufacture Ampligen.

- There are a limited number of organizations in the United States available to provide the final manufacturing steps of formulation, fill, finish and packing sets for Alferon N Injection and Ampligen.

- There is no assurance that upon successful manufacture of a drug on a limited scale basis for investigational use will lead to a successful transition to commercial, large-scale production.

- We have limited manufacturing experience for Ampligen and Alferon N Injection. We may not be profitable unless we can produce Ampligen, Alferon N Injection or other products in commercial quantities at costs acceptable to us.

Risks Associated with Our Licensing/Collaborations/Joint Ventures

- If we are unable to achieve licensing, collaboration and/or joint ventures, our marketing strategy for Ampligen will be part of the differing health care systems around the world along with the different marketing and distribution systems that are used to supply pharmaceutical products to those systems.

Risks Associated with Our Marketing and Distribution

- We have limited marketing and sales capability. If we are unable to obtain additional distributors and our current and future distributors do not market our products successfully, we may not generate significant revenues or become profitable.

Risks Associated with Our Competition

- Rapid technological change may render our products obsolete or non-competitive.

- Our products may be subject to substantial competition.

Risks Associated with an Investment in Our Common Stock

- The market price of our stock may be adversely affected by market volatility

- Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock.

- Provisions of our Certificate of Incorporation and Delaware law could defer a change of our Management which could discourage or delay offers to acquire us.

- Our business, financial condition and operating results could be negatively affected as a result of actions by activist investors. In this regard, an activist stockholder unsuccessfully attempted to take control of us by proposing director nominees at our last annual stockholders meeting.

AVAILABLE INFORMATION

We file electronically with the United States Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our website at www.ao-inc.com free of charge, copies of these reports as soon as reasonably practicable after filing these reports with, or furnishing them to, the SEC.We are subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, we file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information are available for inspection and copying at the website of the SEC www.sec.gov. You also may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and amendments to those reports on the day of filing with the SEC on our website at http://www.aimimmuno.com under the Investor Relations tab for SEC Filings or by contacting the Investor Relations Department by calling (833) 475-8247 or (352) 448-7797 or sending an e-mail message to AIM@jtcir.com. Our Internet website and the information contained on that website, or accessible from our website, is not intended to be incorporated into this Annual Report on Form 10-K or any other filings we make with the SEC.

OUR PRODUCTS

Our primary pharmaceutical product platform consists of Ampligen (rintatolimod), a first-in-class drug of large macromolecular double-stranded (ds) RNA (ribonucleic acid) molecules, and our FDA-approved natural alpha-interferon product, Alferon N Injection.

Ampligen®

Ampligen is approved for sale in Argentina (to 2026) for severe CFS and is an experimental drug in the United States currently undergoing clinical development for the treatment of certain cancers and ME/CFS. Over its developmental history, Ampligen has received various designations, including Orphan Drug Product Designation (FDA and EMA), Treatment protocol (e.g., "Expanded Access" or "Compassionate" use authorization) with Cost Recovery Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports ("AHRQ" or Agency for Healthcare Research and Quality). Based on the results of published, peer-reviewed pre-clinical studies and clinical trials, we believe that Ampligen may have broad-spectrum antiviral and anti-cancer properties.

We believe that nucleic acid compounds represent a potential new class of pharmaceutical products designed to act at the molecular level for treatment of many human diseases. Ampligen represents the first drug in the class of large (macromolecular) dsRNA molecules to apply for NDA review. There are two forms of nucleic acids: deoxyribonucleic acid ("DNA") and ribonucleic acid ("RNA"). DNA is a group of naturally occurring molecules found in chromosomes, the cell's genetic machinery. RNA is a group of naturally occurring informational molecules which orchestrate a cell's behavior which, in turn, regulates the action of groups of cells, including the cells which comprise the body's immune system. RNA directs the production of proteins and regulates certain cell activities including the activation of an otherwise dormant cellular defense against viruses and tumors. Our drug technology utilizes specifically configured RNA and is a selective Toll-like Receptor 3 ("TLR3") agonist that can be administered intravenously, intranasally and intraperitoneally. Ampligen has been assigned the generic name rintatolimod by the United States Adopted Names Council ("USANC") and has the chemical designation poly(I):poly(C_{12}U).

Expanded Access Program/Early Access Programs/clinical trials of Ampligen that have been conducted or that are ongoing include studies of the potential treatment of patients with pancreatic cancer, renal cell carcinoma, malignant melanoma, non-small cell lung cancer, ovarian cancer, breast cancer, colorectal cancer, prostate cancer, ME/CFS, Hepatitis B, HIV, COVID-19 and Post-COVID conditions.

We have received approval of our NDA from ANMAT for the commercial sale of Ampligen in the Argentine Republic for the treatment of severe CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America. Shipment of the drug product to Argentina was initiated in 2018 to complete the release testing by ANMAT needed for commercial distribution. In September 2019, we received clearance from the FDA to ship Ampligen to Argentina for the commercial launch and subsequent sales. In June 2020, we received import clearance from ANMAT to import the first shipment of commercial grade vials of Ampligen into Argentina. We are currently working with GP Pharm on the commercial launch of Ampligen in Argentina. Commercialization in Argentina will require, among other things, GP Pharm to establish disease awareness, medical education, creation of an appropriate reimbursement level, design of marketing strategies and completion of manufacturing preparations for launch and ANMAT conducting a final inspection of the product and release tests before granting final approval to begin commercial sales. AIM has supplied GP Pharm with the Ampligen required for testing and ANMAT release. This testing and approval process is currently delayed due to ANMAT's internal processes and the ongoing effects of COVID-19. Once final approval by ANMAT is obtained, GP Pharm will be responsible for distributing Ampligen in Argentina. We continue to pursue our Ampligen NDA, for the treatment of CFS with the FDA.

The FDA has authorized an open-label expanded access treatment protocol (fAMP-511) allowing patient access to Ampligen in a study under which severely debilitated CFS patients have the opportunity to be on Ampligen to treat this very serious and chronic condition. The AMP-511 protocol started in the 1990s and is ongoing. The data collected from the AMP-511 protocol through clinical sites provide safety information regarding the use of Ampligen in patients with CFS. We are establishing an enlarged database of clinical safety information which we believe will provide further documentation regarding the absence of autoimmune disease associated with Ampligen treatment. We believe that continued efforts to understand existing data, and to advance the development of new data and information, will ultimately support our future filings for Ampligen and/or the design of future clinical studies that the FDA requested in a CRL. The FDA approved an increased reimbursement level from $200 to $345 per 200 mg vial of Ampligen, due to increased production costs; which was re-authorized in 2021 and again in 2022. At this time, we do not plan on passing this adjustment along to the patients in this program. In October 2020, we received IRB approval for the expansion of the AMP-511 Expanded Access Program clinical trial for ME/CFS to include patients previously diagnosed with SARS-CoV-2 following clearance of the virus, but who still demonstrate chronic fatigue-like symptoms that we refer to as Post-COVID conditions. As of December 31, 2022, there were 10 patients enrolled in this open-label expanded access treatment protocol), with seven Post-COVID patients receiving or having received treatment. AIM previously reported positive preliminary results based on data from the first four Post-COVID Condition patients enrolled in the study. The data show that, by week 12, compared to baseline, there was what the investigators considered a clinically significant decrease in fatigue-related measures.

In May 2016, we entered into a five-year agreement with myTomorrows, a Netherlands based company, for the commencement and management of an Early Access Program ("EAP") in Europe and Turkey related to ME/CFS. Pursuant to the agreement, as amended, myTomorrows also is managing all Early Access Programs and Special Access Programs in Europe, Canada and Turkey to treat pancreatic cancer and ME/CFS patients. The agreement was automatically extended for a period of 12 months on May 20, 2021, and again for an additional period of 12 months on May 20, 2022.

In June 2018, Ampligen was cited as outperforming two other TLR3 agonists — poly IC and natural double stranded RNA — in creating an enhanced tumor microenvironment for checkpoint blockade therapy in the journal of *Cancer Research* (http://cancerres.aacrjournals.org/content/early/2018/05/31/0008-5472.CAN-17-3985).In a head-to-head study in explant culture models, Ampligen activated the TLR3 pathway and promoted an accumulation of killer T cells but, unlike the other two TLR3 agonists, it did so without causing regulatory T cell (Treg) attraction. These findings were considered important because they indicate that Ampligen selectively reprograms the tumor microenvironment by inducing the beneficial aspects of tumor inflammation (attracting killer T cells), without amplifying immune-suppressive elements such as regulatory T cells. The study was conducted at the University of Pittsburgh and Roswell Park as a part of the NIH-funded P01 CA132714 and Ovarian Cancer Specialized Program of Research Excellence ("SPORE").

In 2018, we completed production of two commercial-size batches of more than 16,000 vials of Ampligen, following its "Fill & Finish" at Jubilant HollisterStier, the Contract Manufacturing Organization. These lots passed all required testing for regulatory release for human use and are being used for multiple programs, including: the treatment of ME/CFS; the pancreatic cancer EAP in the Netherlands; and will continue to be used for ongoing and future clinical studies in oncology. Additionally, two lots of Ampligen were manufactured in December 2019 and January 2020 at Jubilant HollisterStier. The current manufactured lots of Ampligen have been fully tested and released for commercial product launch in Argentina and for clinical trials. Additionally, in December 2020, we added Pii as a "Fill & Finish" provider. The contracts augment our active and in-process fill and finish capacity.

Alferon N Injection®

Alferon N Injection is the registered trademark for our injectable formulation of natural alpha interferon. Alferon N Injection is the only natural-source, multi-species alpha interferon currently approved for sale in the United States and Argentina for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or recurring external genital warts in patients 18 years of age or older. Alferon N Injection is also approved in Argentina for the treatment of refractory patients that failed or were intolerant to treatment with recombinant interferons. Certain types of human papilloma viruses ("HPV") cause genital warts, a sexually transmitted disease ("STD"). According to the CDC, HPV is the most common sexually transmitted infection, with approximately 79 million Americans — most in their late teens and early 20s — infected with HPV. In fact, the CDC states that "HPV is so common that nearly all sexually active men and women get the virus at some point in their lives." Although they do not usually result in death, genital warts commonly recur, causing significant morbidity and entail substantial health care costs.

Interferons are a group of proteins produced and secreted by cells to combat diseases. Researchers have identified four major classes of human interferon: alpha, beta, gamma and omega. Alferon N Injection contains a multi-species form of alpha interferon. The worldwide market for injectable alpha interferon-based products has experienced rapid growth and various alpha interferon injectable products are approved for many major medical uses worldwide. Alpha interferons are manufactured commercially in three ways: by genetic engineering, by cell culture, and from human white blood cells. All three of these types of alpha interferon are or were approved for commercial sale in the United States. Our natural alpha interferon is produced from human white blood cells. The potential advantages of natural alpha interferon over recombinant (i.e., synthetic) interferon produced and marketed by other pharmaceutical firms may be based upon their respective molecular compositions. Natural alpha interferon is composed of a family of proteins containing many molecular species of interferon. In contrast, commercial recombinant alpha interferon products each contain only a single species. Researchers have reported that the various species of interferons may have differing antiviral activity depending upon the type of virus. Natural alpha interferon presents a broad complement of species, which we believe may account for its higher activity in laboratory studies. Natural alpha interferon is also glycosylated (i.e., partially covered with sugar molecules). Such glycosylation is not present on the currently U.S.-marketed recombinant alpha interferons. We believe that the absence of glycosylation may be in part responsible for the production of interferon-neutralizing antibodies seen in patients treated with recombinant alpha interferon. Although cell culture-derived interferon is also composed of multiple glycosylated alpha interferon species, the types and relative quantity of these species are different from our natural alpha interferon.

Alferon N Injection [Interferon alfa-n3 (human leukocyte derived)] is a highly purified, natural-source, glycosylated, multi-species alpha interferon product. There are essentially no neutralizing antibodies observed against Alferon N Injection to date and the product has a relatively low side-effect profile. The recombinant DNA derived alpha interferon formulations have been reported to have decreased effectiveness after one year of treatment, probably due to neutralizing antibody formation (See "Manufacturing" and "Marketing/Distribution" sections below for more details on the manufacture and marketing/distribution of Alferon N Injection).

PATENTS AND NON-PATENT EXCLUSIVITY RIGHTS

We consider patent exclusivity as a crucial component of our business. As of December 31, 2022, we had 46 patents worldwide with 68 additional pending patent applications comprising our intellectual property.

We continually review our patents to determine if they have continuing value. Please see "Note 4: Patents, Trademark Rights and Other Intangibles (FASB ASC 350 General Intangibles Other than Goodwill)" under Notes to the Consolidated Financial Statements for more information on these patents.

There are no current patent litigation proceedings involving us.

Orphan drug designation

U.S. Orphan drug designation qualifies sponsors for incentives including:

- Tax credits for qualified clinical trials
- Exemption from user fees
- Potential seven years of market exclusivity after FDA approval

We have received Orphan Drug Designation (ODD) from the FDA for Ampligen used in the treatment of Chronic Fatigue Syndrome, HIV, Metastatic Melanoma, Renal Cell Carcinoma, Pancreatic Adenocarcinoma and Ebola Virus Disease.

In the European Union, ODD carries ten years of market exclusivity after receiving marketing authorization. We have received ODD from the EU for Ampligen used in the treatment of Ebola Virus Disease and Pancreatic Adenocarcinoma and for Alferon used in the treatment of Middle East Respiratory Syndrome.

RESEARCH AND DEVELOPMENT ("R&D")

Our general focus during the past several fiscal years has been on expanding the market potential of Ampligen through investigation of efficacy (in vitro and in vivo) in different immune-based disorders including cancer and CFS. While we have previously estimated milestone dates when significant progress could be reported, the reality of the ongoing SARS-CoV-2 pandemic could mean the re-direction of resources away from ongoing clinical trials and toward the research and development of potential treatments for the coronavirus. In this regard, we have widened our focus to include research and development of potential prophylactic and therapeutic applications for the treatment of COVID-19, including the long-term effects of COVID-19.

Immuno-Oncology

The potential of Ampligen as an immuno-oncology therapeutic has been a major focus of AIM since our current leadership took over in 2016. We have been working with the University of Pittsburgh's chemokine modulation research initiative, which includes the use of Ampligen as a potential adjuvant to modify the tumor microenvironment ("TME") with the goal of increasing anti-tumor responses to check point inhibitors ("CPI"). As part of this collaboration, we have supplied Ampligen to the University. The study, under the leadership of Robert P. Edwards, MD, chair of gynecologic services at Magee-Women's Hospital of the University of Pittsburgh School of Medicine, and Professor of Surgery Pawel Kalinski, M.D., Ph.D., at Roswell Park, Buffalo, N.Y., involved the chemokine modulatory regimen developed by Dr. Kalinski's group and successfully completed the Phase 1 dose escalation in patients with resectable colorectal cancer.

Multiple Ampligen clinical trials are underway or recently completed at major university cancer centers testing whether tumor microenvironments can be reprogrammed to increase the effectiveness of cancer immunotherapy, including checkpoint inhibitors. The underway trials include:

- **Pancreatic Cancer Trial** - The Phase 2 AMP-270 clinical trial is a randomized, open-label, controlled, parallel-arm study with the primary objective of comparing the efficacy of Ampligen versus a no treatment control group following FOLFIRINOX for subjects with locally advanced pancreatic adenocarcinoma. Secondary objectives include comparing safety and tolerability. The AMP-270 is expected to enroll approximately 90 subjects in up to 30 centers across the U.S. and Europe. The Buffett Cancer Center at the University of Nebraska Medical Center (UNMC) and Erasmus MC in the Netherlands are expected to be the primary study sites. In March 2022, the FDA granted clearance to proceed with the study. In April 2022, we executed a work order with Amarex to manage the clinical trial. In August 2022, we received IRB approval of the trial protocol and so announced the trial's commencement. (https://clinicaltrials.gov /ct2/show/NCT05494697). For the year ended December 31, 2022, we incurred expense of approximately $1,730,000.

  See "Immuno-Oncology; Additional Progress and Analysis Related to Pancreatic Cancer" for more analysis.

- **Advanced Recurrent Ovarian Cancer**

    - Results of the Phase 1 portion of a Phase 1/2 study of intraperitoneal chemo-immunotherapy in advanced recurrent ovarian cancer were published in the American Association for Cancer Research publication, Clinical Cancer Research (Clin Cancer Res January 19, 2022 DOI: 10.1158/1078-0432.CCR-21-3659). The study results represent an important extension of prior studies using human tumor explants that showed Ampligen's potentially important role as a TLR3 agonist acting synergistically with high-dose IFNα and celecoxib to selectively enhance Teff cell-attractants while suppressing Treg-attractants in the tumor microenvironment with a concomitant increase in the Teff/Treg ratio. The importance of boosting the Teff/Treg ratio in the tumor microenvironment is that it is associated with the conversion of 'cold' tumors into 'hot' tumors, which have an increased sensitivity to chemo-immunotherapy and an improved chance of showing tumor regression. The Phase 1 portion was designed to establish intraperitoneal safety. The Phase 2 portion of the study is planned to be conducted in the future. https://clinicaltrials.gov/ct2/show/NCT02432378

    - A Phase 2 study of advanced recurrent ovarian cancer using cisplatin, pembrolizumab, plus Ampligen; up to 45 patients to be enrolled; enrollment has commenced, and numerous patients have commenced treatment. We announced interim data from the study demonstrating that evidence of increased biomarkers associated with T cell chemotaxis and cytolytic function was seen when combining Ampligen, pembrolizumab and cisplatin. Increases of these biomarkers in the tumor microenvironment have been correlated with favorable tumor responses. Interim results announced March 2022 detailed an observed clinical response rate of 61% includes two complete and three partial tumor responses, plus three patients with stable disease among the 13 evaluable patients. An important priority will be to confirm these findings through continuing to enroll patients onto this study. https://clinicaltrials.gov/ct2/show/NCT03734692

In March 2021, we were granted a patent by the Netherlands Patent Office with granted patent claims that include, but are not limited to, the use of Ampligen as a combination cancer therapy with checkpoint blockade inhibitors (e.g. pembrolizumab, nivolumab). Interim data from an investigator-initiated, Phase 2, single-arm, efficacy/safety trial demonstrated that evidence of increased biomarkers associated with T cell chemotaxis and cytolytic function was seen when combining Ampligen, pembrolizumab and cisplatin. It is critical to note that increases of these biomarkers in the tumor microenvironment have been correlated with favorable tumor responses. All told, the study has seen an Objective Response Rate (ORR) 38.5%; a study of pembrolizumab alone in the treatment of advanced recurrent ovarian cancer found ORR of 8.1% and 9.9% across two cohorts. We believe that the positive data makes this patent have heightened potential. Similar patents are pending in other countries.

- **Stage 4 Metastatic Triple Negative Breast Cancer** - Phase 1 study of metastatic triple-negative breast cancer using chemokine modulation therapy, including Ampligen and pembrolizumab. Eight patients were enrolled and 6 patients were evaluable. https://www.clinicaltrials.gov/ct2/show/NCT03599453. The key findings announced April 2022 included:

    - The pre-determined primary endpoint of efficacy was met (increase in CD8 in TME).

    - Uniform increase of immune markers upon treatment was observed: CD8 mRNA (6.1-fold; p-0.034), GZMB mRNA (3.5-fold; p=0.058), ratios of CD8 /FOXP3 and GZMB/FOXP3 (5.7-fold; p=0.036, and 7.6-fold; p=0.024 respectively), thus successfully meeting the pre-determined primary endpoint in the study (increase in CD8 in TME).

    - In addition, an increase in CTL attractants CXCL10 (2.6-fold; p=0.104) and CCL5 (3.3-fold; p=0.019) was observed. In contrast, Treg marker FOXP3 or Treg attractants CCL22 or CXCL12 were not enhanced.

    - Three patients had stable disease lasting 2.4, 2.5 and 3.8 months, as of data cut off September 1, 2021.

    - An additional patient (non-evaluable) had a partial response (breast tumor autoamputation) with massive tumor necrosis in the post-CKM biopsy.

- **Stage 4 Colorectal Cancer Metastatic to the Liver** - Phase 2a study of Ampligen as a component of chemokine modulatory regimen on colorectal cancer metastatic to liver; recruitment has been completed; 19 patients were enrolled and 12 patients were evaluable for the primary endpoint https://clinicaltrials.gov/ct2/show/NCT03403634. The key findings announced April 2022 included:

    - The study's primary endpoint was met, evidenced by increased CD8a expression post-treatment (p=0.046).

    - Saw increase in the CD8a/CD4 (p=0.03), CD8a/FOXP3 (p<0.01) and GZMB/FOXP3 (p<0.01) ratios.

    - The expression of CTL-attracting chemokines CCL5 (p=0.08), CXCL9 (p=0.05), and CXCL10 (p=0.06) were increased, while expression of the Treg/MDSC attractant CXCL12 (p=0.07) was decreased post-treatment.

- Median OS was 10.5 (90% CI 2.2-15.2) months, and the median PFS was 1.5 (90% CI 1.4, 1.8) months.

- No tumor responses were seen. The treatment was well tolerated. Of all enrolled patients (N=19), adverse events were noted in 74% of patients, with the most common being fatigue (58%). Grade 3 or higher adverse events were rare (5%).

- **Early-Stage Prostate Cancer** - Phase 2 study investigating the effectiveness and safety of aspirin and Ampligen with or without interferon-alpha 2b (Intron A) compared to no drug treatments in a randomized three-arm study of patients with prostate cancer before undergoing radical prostatectomy. Patient enrollment has been initiated in this study designed for up to 45 patients. https://clinicaltrials.gov/ct2/show/NCT03899987

- **Early-Stage Triple Negative Breast Cancer** - Phase 1 study of chemokine modulation plus neoadjuvant chemotherapy in patients with early-stage triple negative breast cancer has received FDA authorization; the objective of this study is to evaluate the safety and tolerability of a combination of Ampligen, celecoxib with or without Intron A, when given along with chemotherapy; the goal of this approach is to increase survival. Interim results announced in March 2022 detailed data gathered from evaluating paclitaxel's impact on chemokine production in the human breast tumor microenvironment (TME) and the ability of a chemokine modulatory regimen (CKM) of Ampligen and Interferon-α to mitigate potentially undesirable aspects of taxane chemotherapy. Based on the results, we believe that the combination chemokine modulatory regimen including Ampligen has the potential to mitigate undesirable aspects of taxane chemotherapy. Investigators are currently analyzing data. https://clinicaltrials.gov/ct2/show/NCT04081389

- **Refractory Melanoma** — Roswell Park Comprehensive Cancer Center ("Roswell Park"), in a clinical trial fully funded by the National Cancer Institute (NCI), has commenced patient enrollment in its Phase 2 study in subjects with primary PD-1/PD-L1 resistant melanoma. The Phase 2 study will evaluate type-1 polarized dendritic cell (αDC1) vaccine in combination with tumor-selective chemokine modulation ("CKM") comprised of Interferon alpha 2b, Ampligen (rintatolimod) and Celecoxib. Up to 24 patients are to be enrolled (See: https://www.clinicaltrials.gov/show/NCT04093323).

Additional Progress and Analysis Related to Pancreatic Cancer

In January 2017, the EAP established under our agreement with myTomorrows to enable access of Ampligen to ME/CFS patients was extended to pancreatic cancer patients beginning in the Netherlands. myTomorrows is our exclusive service provider in Europe and Turkey and will manage all EAP activities relating to the pancreatic cancer extension of the program. In February 2018, the agreement with myTomorrows was extended to cover Canada to treat pancreatic cancer patients, pending government approval. There have been no physician requests to date that would cause the program to move forward with the approval process.

A total of 42 pancreatic cancer patients initially received treatment with Ampligen immuno-oncology therapy under the EAP program at Erasmus MC in the Netherlands; that initial program has since continued to expand and proceed with additional patients to be treated with Ampligen Supervised by Prof. C.H.J. van Eijck, MD. The team at Erasmus MC in September 2020 reported data which demonstrated a statistically significant positive survival benefit when using Ampligen in patients with locally advanced or metastatic pancreatic cancer after systemic chemotherapy, compared with historical control patients. We are working with our Contract Research Organization, Amarex Clinical Research LLC, to seek FDA "fast-track." We have applied for fast-track status; have received denials to date; and are currently working through the FDA process to provide all the materials and information required to achieve fast-track status. The IND authorization to proceed with the Phase 2 pancreatic cancer clinical trial has been received with potential sites in the Netherlands at Erasmus MC under Prof. C.H.J. van Eijck, and also at major cancer research centers in the United States such as The Buffett Cancer Center at the University of Nebraska Medical Center (UNMC).

In January 2023, we entered into an external sponsored collaborative clinical research agreement with Erasmus MC and AstraZeneca. Under the agreement, Erasmus MC is planning to perform an investigator-initiated clinical study, entitled "Combining anti-PD-L1 immune checkpoint inhibitor durvalumab with TLR-3 agonist rintatolimod in patients with metastatic pancreatic ductal adenocarcinoma for therapy effect. DURIPANC Study," in which it will use both study drugs provided by AstraZeneca and AIM ImmunoTech.

Additionally:

- In December 2020, the FDA granted Ampligen Orphan Drug Designation status for the treatment of pancreatic cancer. The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the treatment, prevention or diagnosis of a rare disease or condition, which is one that affects less than 200,000 persons in the United States or meets cost recovery provisions of the act. The status helps incentivize the treatment of therapies to treat unmet medical needs by providing a company with seven years of exclusivity rights once a drug reaches market.

- In February 2021, our subsidiary, NV Hemispherx Biopharma Europe, received formal notification from the European Commission ("EC") granting Orphan Medicinal Product Designation for Ampligen as a treatment for pancreatic cancer. Orphan products, once commercially approved in the European Union ("EU"), receive benefits including up to ten years of protection from market competition from similar medicines with similar active component and indication for use that are not shown to be clinically superior.

In June 2021, Ampligen was featured in a publication containing state-of-the-art methodologies in the peer-reviewed medical journal *Cancers* as a potential treatment option for cancer patients who are infected with SARS-CoV-2. The study's authors stated that Ampligen has the potential to reduce the severity of the deadly respiratory disease COVID-19. According to laboratory data presented in the publication, "Rintatolimod [Ampligen] activated the innate and the adaptive immune systems by activating a cascade of actions in human pancreatic cancer cells", including:

- Stimulation of interferon regulatory factors and activation of the interferon signaling pathway,
- Production of immunomodulatory activity and
- Induction of the expression of MHC class I and II histocompatibility

The full journal article is titled: "Rintatolimod Induces Antiviral Activities in Human Pancreatic Cancer Cells: Opening for an Anti-COVID-19 Opportunity in Cancer Patients?" *Cancers* is a peer-reviewed, open access journal of oncology published semimonthly online by MDPI. The study's authors include Prof. C.H.J. van Eijck, MD, PhD, the lead investigator at Erasmus Medical Center in the Netherlands.

In October 2021, we and Amarex submitted an IND application with the FDA for a planned Phase 2 study of Ampligen as a therapy for locally advanced or metastatic late-stage pancreatic cancer. In December 2021, the FDA responded with a Clinical Hold on the proposed study. We submitted our response to the FDA in February 2022. In March 2022, we received notification from the FDA that the Clinical Hold was released and cleared, meaning that we are now able to proceed with the study specifically to treat locally advanced pancreatic cancer patients. In August 2022, we received IRB approval of the trial protocol and so announced the trial's commencement.

Positive data was published in March 2022 in a manuscript titled, "Rintatolimod (Ampligen®) enhances numbers of peripheral B cells and is associated with longer survival in patients with locally advanced and metastasized pancreatic cancer pre-treated with FOLFIRINOX: a single-center named patient program," in *Cancers Special Issue: Combination and Innovative Therapies for Pancreatic Cancer*. In the single-center, named-patient program, patients with locally advanced pancreatic cancer (LAPC) or metastatic disease were treated with Ampligen for 6 weeks, at 2 doses per week with 400 mg per infusion. The study found that Ampligen improved the median survival of these patients. The study's primary endpoints were the Systemic Immune-Inflammation Index (SIII), the Neutrophils to Lymphocyte Ratio (NLR), and absolute counts of 18 different populations of circulating immune cells as measured by flow cytometry. Secondary endpoints were progression-free survival (PFS) and overall survival (OS). The median overall survival in the Ampligen group was 19 months, compared to a historical control group and subgroup (7.5 and 12.5, respectively) that did not receive Ampligen.

Also in March 2022, we announced that study data evaluating the direct effects of Ampligen on human pancreatic ductal adenocarcinoma (PDAC) cells was accepted for presentation at the 15th Annual International Hepato-Pancreato-Biliary Association World Congress in New York, NY. For the study, three PDAC cell lines (CFPAC-1, MIAPaCa-2, and PANC-1) were treated with various concentrations of Ampligen and their corresponding vehicle control. The proliferation and migration effects were examined using in-vitro assays and the molecular effect was examined by targeted gene expression profiling. Additionally human PDAC samples were used to validate the expression of toll-like receptor 3 (TLR3) by immunohistochemistry. Results from the study demonstrated Ampligen decreased the proliferation and migration ability of CFPAC-1 cells. In addition, it decreased the proliferation of MIAPaCa-2 cells and the migration of PANC-1 cells. However, it did not have a dual effect in MIAPaCa-2 and PANC-1 cells. Interestingly, TLR3 was highly expressed in CFPAC-1 cells, low expressed in MIAPaCa-2 and not expressed in PANC-1. Gene expression analysis revealed the upregulation of interferon-related genes, chemokines, interleukins and cell cycle regulatory genes. The heterogeneity of TLR3 expression was confirmed in human PDAC samples. Based on these results, treating pancreatic cancer with Ampligen may have a direct anti-tumor effect in pancreatic cancer cells expressing TLR-3.

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), also known as Chronic Fatigue Immune Dysfunction Syndrome ("CFIDS") and Chronic Fatigue Syndrome (CFS), is a serious and debilitating chronic illness and a major public health problem. ME/CFS is recognized by both the government and private sector as a significant unmet medical need, including the U.S. National Institutes of Health ("NIH"), FDA and the CDC. The CDC states on its website at https://www.cdc.gov/me-cfs/ that "*Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is a serious, long-term illness that affects many body systems. People with ME/CFS are often not able to do their usual activities. At times, ME/CFS may confine them to bed. People with ME/CFS have severe fatigue and sleep problems. ME/CFS may get worse after people with the illness try to do as much as they want or need to do. This symptom is called post-exertional malaise (PEM). Other symptoms can include problems with thinking and concentrating, pain, and dizziness.*"

Many severe ME/CFS patients become completely disabled or totally bedridden and are afflicted with severe pain and mental confusion even at rest. ME/CFS is characterized by incapacitating fatigue with profound exhaustion and extremely poor stamina, sleep difficulties and problems with concentration and short-term memory. It is also accompanied by flu-like symptoms, pain in the joints and muscles, tender lymph nodes, sore throat and new headaches. A distinctive characteristic of the illness is a worsening of symptoms following physical or mental exertion, which do not subside with rest.

The high number of younger people being hospitalized for COVID-19 suggests considerable numbers of people in the prime of their lives may have a COVID-induced ME/CFS-like illness in their future. According to a 2016 journal article, the estimated annual cost of lost productivity related to ME/CFS was $9-37 billion in the United States, and for direct medical costs it was $9-14 billion.

In June of 2020, we filed a provisional patent application for, among other discoveries, the use of Ampligen as a potential early-onset therapy for the treatment of COVID-19 induced chronic fatigue.

Many survivors of the first SARS-CoV-1 epidemic in 2003 continued to report chronic fatigue, difficulty sleeping and shortness of breath months after recovering from the acute illness. "After one year, 17% of patients had not returned to work and 9% more had not returned to their pre-SARS work levels," according to Simmaron Research. Now there is increasing evidence that patients with COVID-19 can develop a similar, ME/CFS-like illness. These patients are commonly referred to as "Long Haulers."

In October 2020, we received IRB approval for the expansion of the AMP-511 Expanded Access Program clinical trial for ME/CFS to include patients previously diagnosed with SARS-CoV-2 following clearance of the virus, but who still demonstrate chronic fatigue-like symptoms. For more information on our AMP-511 Expanded Access Program, please see "*OUR PRODUCTS: Ampligen*" above.

In November 2020, we announced the publication of statistically significant data detailing how Ampligen could have a considerable positive impact on people living with ME/CFS when administered in the early stages of the disease. The data were published in *PLOS ONE*, a peer-reviewed open access scientific journal published by the Public Library of Science. AIM researchers found that the TLR3 agonist Ampligen substantially improved physical performance in a subset of ME/CFS patients.

As noted above in *Overview; General; Ampligen as a treatment for ME/CFS and Post-COVID Conditions*, we have long been focused on seeking the FDA's approval for the use of Ampligen to treat ME/CFS. In fact, in February 2013, we received a CRL from the FDA for our Ampligen NDA for ME/CFS, stating that we should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses.

While developing a comprehensive response to the FDA and a plan for a confirmatory trial for the FDA NDA, we proceeded independently in Argentina and, in August 2016, we received approval of an NDA from ANMAT for commercial sale of Ampligen in the Argentine Republic for the treatment of severe CFS. In September 2019, we received clearance from the FDA to ship Ampligen to Argentina for the commercial launch and subsequent sales. On June 10, 2020, we received import clearance from ANMAT to import the first shipment of commercial grade vials of Ampligen into Argentina. The next steps in the commercial launch of Ampligen include ANMAT conducting a final inspection of the product and release tests before granting final approval to begin commercial sales. This testing and approval process is currently delayed due to the COVID-19 pandemic and ANMAT's internal processes. The ongoing impact of COVID-19 in Argentina is taxing the nation's health care system and is, understandably, the main priority of its regulators. Once final approval by ANMAT is obtained, GP Pharm will begin distributing Ampligen in Argentina.

We plan on a comprehensive follow through with the FDA regarding the use of Ampligen as a treatment for ME/CFS. We have learned a great deal since the FDA's CRL and plan to adjust our approach to concentrate on specific ME/CFS symptoms. Responses to the CRL and a proposed confirmatory trial are being worked on now by our R&D team and consultants.

Ampligen as a Potential Antiviral

Following the SARS-CoV-1 outbreak in 2002-03, Ampligen exhibited excellent antiviral properties and protective survival effect in NIH-contracted studies of SARS-CoV-1-infected mice, which is very similar to SARS-CoV-2, the novel virus that causes COVID-19.

- The Barnard 2006 study (https://journals.sagepub.com/doi/abs/10.1177/095632020601700505) found that Ampligen reduced virus lung levels to below detectable limits.

- The Day 2009 study (https://www.sciencedirect.com/science/article/pii/S0042682209005832) found that, instead of 100% mortality, there was 100% protective survival using Ampligen.

We compared key transcription regulatory sequences of SARS-CoV-1 to SARS-CoV-2 and found significant similarities, suggesting highly probable extension of the antiviral effects of Ampligen in the earlier NIH-contracted SARS experiments to COVID-19. The SARS-CoV-2 virus – which causes COVID-19 – shares important genomic and pathogenic similarities with SARS-CoV-1 (hence its name). Since Ampligen has shown antiviral activity against more distantly related coronaviruses, there was a reasonable probability that the antiviral effects of Ampligen against SARS-CoV-1 will likely extend to SARS-CoV-2, and as discussed below, recently, Ampligen has demonstrated ex vivo antiviral activity against SARS-CoV-2. We believe that this creates a compelling case for clinical trials to evaluate Ampligen as a potential tool in the fight against COVID-19.

Since the late 2019 outbreak of SARS-CoV-2, we have been actively engaged in determining whether Ampligen could be an effective treatment for this virus or could be part of a vaccine. We believe that Ampligen has the potential to be both an early-onset treatment for and prophylaxis against SARS-CoV-2. We believe that prior studies of Ampligen in SARS-CoV-1 animal experimentation may predict similar protective effects against the new virus.

In February 2020, we filed three provisional patent applications related to Ampligen in our efforts toward joining the global health community in the fight against the deadly coronavirus (See: https://aimimmuno.com/press-release/aim-immunotech-files-provisional-patent-application-for-the-use-of-ampligenr-as-a-potential-therapy-for-covid-19-induced-chronic- fatigue/). Our three provisional patent applications include: 1) Ampligen as a therapy for the coronavirus; 2) Ampligen as part of a proposed intranasal universal coronavirus vaccine that combines Ampligen with inactivated coronavirus, conveying immunity and cross-protection and; 3) a high-volume manufacturing process for Ampligen. Under the Patent Cooperation Treaty of 1970, which provides international protections for patents, these three provisional patent applications were converted in to two international patent applications based on the date of their filings.

In April 2020, we entered into a Material Transfer and Research Agreement ("MTA") with Shenzhen Smoore Technology to study the utilization of an innovative Smoore inhalation delivery device and Ampligen as a potential treatment approach for the SARS-CoV-2 pandemic. The MTA was extended for two years in May 2021. Due to continuing delays and other obstacles related to importing Ampligen to China, we ended our contract with Smoore on August 10, 2022.

In August 2020, we contracted Amarex to act as our Clinical Research Organization and provide regulatory support with regard to a possible clinical trial testing Ampligen's potential as a COVID-19 prophylaxis via intranasal delivery.

Beginning in April 2020, we entered into confidentiality and non-disclosure agreements with numerous companies for the potential outsourcing of the production of polymer, enzyme, placebo as well as Ampligen, and one Contract Research Organization, Amarex, which will provide regulatory and monitoring support related to a clinical trial testing Ampligen's intranasal safety and potential as a COVID-19 prophylaxis via intranasal delivery.

In May 2020, the FDA authorized an IND for Roswell Park to conduct a Phase 1/2a study of a regimen of Ampligen and interferon alpha in cancer patients with COVID-19 infections. This clinical trial, sponsored by Roswell Park in collaboration with us, will test the safety of this combination regimen in patients with cancer and COVID-19, and the extent to which this therapy will promote clearance of the SARS-CoV-2 virus from the upper airway. Several subjects have been treated. It is planned that the phase 1/2a study will enroll up to 44 patients in two stages. Phase 1 will see 12-24 patients receiving both Ampligen and interferon alpha-2b at escalating doses. Once that initial phase is complete, further study participants will be randomized to two arms: one receiving the two-drug combination and a control group who will not receive Ampligen or interferon alpha but will receive best available care. We are a financial sponsor of the study and will provide Ampligen at no charge for this study. In November 2020, the first patient in the study had been enrolled and treated. This study was amended to add 20 patients, with 10 randomized to receive a single dose of Ampligen and 10 patients to receive current best therapies. (See clinicaltrials.gov/NCT04379518). Due to a shortage of qualifying subjects with COVID-19 and cancer as a result of the positive impact of vaccinations and treatments for COVID-19, Roswell is seeking approval to expand the qualifying subject criteria to include other diseases lethal to immuno-compromised cancer patients, such as influenza. Accordingly, the study is temporarily suspended while seeking said approvals.

We also entered into a specialized services agreement with Utah State University and have supplied Ampligen to support the University's Institute for Viral Research in its research into SARS-CoV-2. The Utah State results show that Ampligen was able to decrease SARS-CoV-2 infectious viral yields by 90% at clinically achievable intranasal Ampligen dosage levels.

In October 2020, we received IRB approval for the expansion of the AMP-511 Expanded Access Program clinical trial for ME/CFS to include patients previously diagnosed with SARS-CoV-2, but who still demonstrate chronic fatigue-like symptoms. Patients in the trial are treated with our flagship pipeline drug Ampligen. In January 2021, we commenced with the treatment of the first previously diagnosed COVID-19 patient

with long-COVID symptoms (i.e., Long Hauler) also known as Post-COVID Conditions in the AMP-511 study. Enrollment of post-COVID patients continues in the study.

In January 2021, we entered into a Sponsor Agreement with CHDR to manage a Phase 1 randomized, double-blind study to evaluate the safety and activity of repeated intranasal administration of Ampligen. AIM funded and sponsored the study. This study was designed to assess the safety, tolerability and biological activity of repeated administration of Ampligen intranasally. A total of 40 healthy subjects received either Ampligen or a placebo in the trial, with the Ampligen given at four escalating dosages across four cohorts, to a maximum level of 1,250 micrograms. All patients had completed the study by June 2021 and the study is completed. The Final Safety Report reported no Serious or Severe Adverse Events at any dosage level. We believe that the trial is a critical step in our ongoing efforts to develop Ampligen as a potential prophylaxis or treatment for COVID-19 and other respiratory viral diseases. Amarex provided us with monitoring support during the trial.

Additionally, we filed two COVID-19-related provisional patent applications in the third quarter of 2021. In August, we filed an application for Ampligen as both an intranasal and an intravenous therapy for what we describe as Post-COVID conditions. The people suffering from Post-COVID conditions, including some young adults, can be afflicted with severe difficulties in concentrating; serious memory problems; and the inability to live an active lifestyle, to work and even to perform everyday tasks. Early data has demonstrated that patients with symptoms of Post-COVID conditions being treated with Ampligen in the ongoing AMP-511 Expanded Access Program have reported improvements in fatigue symptoms. Similarly, in ME/CFS, data supports the claim that Ampligen improves fatigue symptoms. Then in September, we filed a patent application for Ampligen as a potential early-onset intranasal therapy designed to enhance and expand infection-induced immunity, epitope spreading, cross-reactivity and cross-protection in patients exposed to a wide range of RNA respiratory viruses, such as influenza, Rhinoviruses and SARS-CoV-2.

In addition to securing these two provisional patent applications, we also moved forward with proposed studies in these areas and with Pre-Investigational New Drug Applications in September 2021. One pre-IND was for a Phase 2, two-arm, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of Ampligen in patients experiencing Post-COVID conditions (originally referred to as Post-COVID Cognitive Dysfunction (PCCD) and being revised to Post-COVID conditions).

In October 2022, our IND application cleared the FDA approval process and we are proceeding with a Phase 2 study evaluating Ampligen as a therapeutic for patients with post-COVID conditions (“AMP-518”). Additional comments were received from the FDA, which have been addressed in an amended protocol approved by the IRB on March 30, 2023.

Other Diseases

In Europe, the EMA has approved the Orphan Medicinal Products Designation for Ampligen as a potential treatment of Ebola virus disease and for Alferon N Injection as a potential treatment of MERS.

We concluded our series of collaborations designed to determine the potential effectiveness of Ampligen and Alferon N Injection as potential preventive and/or therapeutic treatments for Ebola-related disorders. Although we believe that the threat of both MERS and Ebola globally may reemerge in the future, it appears that the spread of these disorders has diminished.

In April 2021, we entered into an MTA with the University of Cagliari Dipartimento di Scienze della Vita e dell’Ambiente (“UNICA”), an educational institution, under the laws of Italy, located in Monserrato (Cagliari), Italy. The MTA relates to the research and development of the effects of Ampligen and its ability to induce interferon production in several cell lines, and also on the ability of the Ebola virus protein VP35 to bind to viral dsRNA and impede interferon’s upregulation and activity, and on Ampligen’s ability to reverse VP35 inhibition of interferon production in biological systems. The research is active and ongoing.

In May 2021, we filed a U.S. Provisional Patent Application for Ampligen as a potential therapeutic to possibly slow, halt, or reverse the progression of Alzheimer’s disease.

In November 2022, we received notice that the FDA had granted Orphan Drug Designation to Ampligen for the treatment of Ebola virus disease.

Alferon N Injection®

Alferon N Injection is the registered trademark for our injectable formulation of natural alpha interferon. Alferon N Injection is the only natural-source, multi-species alpha interferon currently approved for sale in the United States and Argentina for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or recurring external genital warts in patients 18 years of age or older. Alferon N Injection is also approved in Argentina for the treatment of refractory patients that failed or were intolerant to treatment with recombinant interferons. Certain types of human papilloma viruses ("HPV") cause genital warts, a sexually transmitted disease ("STD"). According to the CDC, HPV is the most common sexually transmitted infection, with approximately 79 million Americans — most in their late teens and early 20s — infected with HPV. In fact, the CDC states that "HPV is so common that nearly all sexually active men and women get the virus at some point in their lives." Although they do not usually result in death, genital warts commonly recur, causing significant morbidity and entail substantial health care costs.

Interferons are a group of proteins produced and secreted by cells to combat diseases. Researchers have identified four major classes of human interferon: alpha, beta, gamma and omega. Alferon N Injection contains a multi-species form of alpha interferon. The worldwide market for injectable alpha interferon-based products has experienced rapid growth and various alpha interferon injectable products are approved for many major medical uses worldwide. Alpha interferons are manufactured commercially in three ways: by genetic engineering, by cell culture, and from human white blood cells. All three of these types of alpha interferon are or were approved for commercial sale in the United States. Our natural alpha interferon is produced from human white blood cells. The potential advantages of natural alpha interferon over recombinant (i.e., synthetic) interferon produced and marketed by other pharmaceutical firms may be based upon their respective molecular compositions. Natural alpha interferon is composed of a family of proteins containing many molecular species of interferon. In contrast, commercial recombinant alpha interferon products each contain only a single species. Researchers have reported that the various species of interferons may have differing antiviral activity depending upon the type of virus. Natural alpha interferon presents a broad complement of species, which we believe may account for its higher activity in laboratory studies. Natural alpha interferon is also glycosylated (i.e., partially covered with sugar molecules). Such glycosylation is not present on the currently U.S.-marketed recombinant alpha interferons. We believe that the absence of glycosylation may be in part responsible for the production of interferon-neutralizing antibodies seen in patients treated with recombinant alpha interferon. Although cell culture-derived interferon is also composed of multiple glycosylated alpha interferon species, the types and relative quantity of these species are different from our natural alpha interferon.

Alferon N Injection [Interferon alfa-n3 (human leukocyte derived)] is a highly purified, natural-source, glycosylated, multi-species alpha interferon product. There are essentially no neutralizing antibodies observed against Alferon N Injection to date and the product has a relatively low side-effect profile. The recombinant DNA derived alpha interferon formulations have been reported to have decreased effectiveness after one year of treatment, probably due to neutralizing antibody formation (See "Manufacturing" and "Marketing/Distribution" sections below for more details on the manufacture and marketing/distribution of Alferon N Injection). The production of new Alferon N Injection Active Pharmaceutical Ingredient, or API, is currently on hold. We do not know when, if ever, our products will be generally available for commercial sale for any indication.

MANUFACTURING

ANMAT in Argentina approved Ampligen for commercial distribution for the treatment of CFS in 2016. Shipment of the drug product to Argentina was initiated in 2018 to complete the release testing by ANMAT needed for commercial distribution. In September 2019, we received clearance from the FDA to ship Ampligen to Argentina for the commercial launch and subsequent sales. In June 2020, we received import clearance from ANMAT to import the first shipment of commercial grade vials of Ampligen into Argentina. We are currently working with GP Pharm on the commercial launch of Ampligen in Argentina (See "Our Products; Ampligen" above).

Following our approval in Argentina, in 2017 we engaged Jubilant HollisterStier ("Jubilant") to be our authorized CMO for Ampligen. Two lots of Ampligen consisting of more than 16,000 units were manufactured and released in 2018; these lots have been designated for human use in the United States in the cost recovery CFS program and for expanded oncology clinical trials. The production of additional polymer (Ampligen intermediates) took place in 2019 at our New Brunswick facility. Additionally, Jubilant manufactured two more lots of Ampligen in December 2019 and January 2020. The current manufactured lots of Ampligen have been fully tested and released for commercial product launch in Argentina and for clinical trials. In addition, we have supplied GP Pharm with the Ampligen required for testing and ANMAT release. Once final approval by ANMAT is obtained, we anticipate that GP Pharm will begin distributing Ampligen in Argentina.

In December 2020, we added Pii as a "Fill & Finish" provider to enhance our capacity to produce Ampligen. This addition amplifies our manufacturing capability by providing redundancy and cost savings. The contracts augment our existing fill and finish capacity. We are prepared to initiate the production of additional Ampligen when and if needed.

In May 2021, we exercised our option to re-purchase the New Brunswick manufacturing facility, pursuant to the terms of the March 2018 sale and lease-back agreement. We thereafter sold certain equipment and machinery that we determined to be obsolete and no longer needed for current or future manufacturing. On March 3, 2022, we entered into an Agreement of Sale and Purchase with Acellories, Inc. as purchaser pursuant to which we would sell our property for $3.9 million; we have kept some space specifically for Alferon activity. The sale was completed on November 1, 2022 for $3.7 million net of normal closing cost.

In June 2022 we entered into a lease agreement with the New Jersey Economic Development Authority for a 5,210 square-foot, state-of-the-art R&D facility at the New Jersey Bioscience Center (NJBC), primarily consisting of two separate laboratory suites. The lease commenced on July 1, 2022, and runs through August 31, 2027, but can be extended for an additional five-year period. The facility is AIM's operations, research and development center.

Our business plan calls for the utilization of one or more CMOs to produce Ampligen API. While we believe we have sufficient Ampligen API to meet our current needs, we are also continually exploring new efficiencies so as to maximize our ability to fulfill future obligations. In this regard, in April 2021, we approved a proposal from Polysciences for the manufacture of our Poly I and Poly $C_{12}U$ polynucleotides and associated test methods at Polysciences' Warrington, PA location to enhance our capacity to produce the polymer precursors to the drug Ampligen. We are utilizing Polysciences' expertise to refine our approach to polymer production. Additionally, we continue to be open to the possibility of agreements with other CMOs, so as to create redundancy and to meet the potential need for larger quantities of API.

Our second product, Alferon N Injection, is approved by the FDA for commercial sales in the United States for the treatment of genital warts. It is also approved by ANMAT in Argentina for commercial sales for the treatment of genital warts and in patients who are refractory to treatment with recombinant interferons. Commercial sales of Alferon N Injection in the United States will not resume until new batches of commercial filled and finished product are produced and released by the FDA. While our New Brunswick facility has FDA approval under the Biologics License Application ("BLA") for Alferon N Injection, and we maintain a certain amount of space at this facility, we will need the FDA's approval to release commercial product once we have identified our new manufacturing approach and submitted satisfactory stability and quality release data; the FDA has conducted any required inspections; and the FDA has approved our new manufacturing process. Currently, we are not manufacturing Alferon N Injection and there is no definitive timetable to resume production.

LICENSING/COLLABORATIONS/JOINT VENTURES

To enable potential availability of Ampligen to patients on a worldwide basis, we have embarked on a strategy to license the product and/or to collaborate and/or create a joint venture with companies that have the demonstrated capabilities and commitment to successfully gain approval and commercialize Ampligen in their respective global territories of the world. Ideal partners would have the following characteristics: well-established global and regional experience and coverage; robust commercial infrastructure; a strong track record of successful development and registration of in-licensed products; and a therapeutic area fit (ME/CFS, immuno-oncology, e.g.).

MARKETING/DISTRIBUTION

In May 2016, we entered into a five-year exclusive Renewed Sales, Marketing, Distribution and Supply Agreement (the "Agreement") with GP Pharm. Under this Agreement, GP Pharm was responsible for gaining regulatory approval in Argentina for Ampligen to treat severe CFS in Argentina and for commercializing Ampligen for this indication in Argentina. We granted GP Pharm the right to expand rights to sell this experimental therapeutic into other Latin America countries based upon GP Pharm achieving certain performance milestones. We also granted GP Pharm an option to market Alferon N Injection in Argentina and other Latin America countries (See "Our Products; Ampligen" above). The GP Pharm contract was extended in May 2021, and will now end on May 24, 2024. In August 2021, ANMAT granted a five-year extension to a previous approval to sell and distribute Ampligen to treat severe CFS in Argentina. This extends the approval until 2026.

In May 2016, we entered into a five-year agreement (the "Impatients Agreement") with Impatients, N.V. ("myTomorrows"), a Netherlands-based company, for the commencement and management of an EAP in Europe and Turkey (the "Territory") related to ME/CFS. Pursuant to the agreement, myTomorrows, as our exclusive service provider and distributor in the Territory, is performing EAP activities. These activities will be directed to (a) the education of physicians and patients regarding the possibility of early access to innovative medical treatments not yet the subject of a Marketing Authorization (regulatory approval) through named-patient use, compassionate use, expanded access and hospital exemption, (b) patient and physician outreach related to a patient-physician platform, (c) the securing of Early Access Approvals (exemptions and/or waivers required by regulatory authorities for medical treatments prior to Marketing Authorization) for the use of such treatments, (d) the distribution and sale of such treatments pursuant to such Early Access Approvals, (e) pharmacovigilance (drug safety) activities and/or (f) the collection of data such as patient-reported outcomes, doctor-reported experiences and registry data. We are supporting these efforts and supplying Ampligen to myTomorrows at a predetermined transfer price. In the event that we receive Marketing Authorization in any country in the Territory, we will pay myTomorrows a royalty on products sold. Pursuant to the Impatients Agreement, the royalty would be a percentage of Net Sales (as defined in the Impatients Agreement) of Ampligen sold in the Territory where Marketing Authorization was obtained. The formula to determine the percentage of Net Sales will be based on the number of patients that are entered into the EAP. We believe that disclosure of the exact maximum royalty rate and royalty termination date could cause competitive harm. However, to assist the public in gauging these terms, the actual maximum royalty rate is somewhere between 2% and 10% and the royalty termination date is somewhere between five and fifteen years from the First Commercial Sale of a product within a specific country. The parties established a Joint Steering Committee comprised of representatives of both parties to oversee the EAP. No assurance can be given that activities under the EAP will result in Marketing Authorization or the sale of substantial amounts of Ampligen in the Territory. The agreement was automatically extended for a period of 12 months on May 20, 2021, and again for an additional 12 months on May 20, 2022.

In January 2017, ANMAT granted a five-year extension to a previous approval to sell and distribute Alferon N Injection (under the brand name "Naturaferon") in Argentina. This extends the approval until 2022. A request to extend the approval beyond 2022 has been filed and is still under review. In February 2013, we received ANMAT approval for the treatment of refractory patients that failed or were intolerant to treatment with recombinant interferon, with Naturaferon in Argentina.

In January 2017, the EAP through our agreement with myTomorrows designed to enable access of Ampligen to ME/CFS patients was extended to pancreatic cancer patients beginning in the Netherlands. myTomorrows is our exclusive service provider in the Territory and will manage all EAP activities relating to the pancreatic cancer extension of the program.

In August 2017, we extended our agreement with Asembia LLC, formerly Armada Healthcare, LLC, to undertake the marketing, education and sales of Alferon N Injection throughout the United States. This agreement has expired. We are in discussions with Asembia about the possibility of continuing the relationship, while also exploring the possibility of working with other, similar companies. However, we do not foresee an immediate need for this service and so may push this search further out in our expected timeline.

In February 2018, we signed an amendment to the EAP with myTomorrows. This amendment extended the Territory to cover Canada to treat pancreatic cancer patients, pending government approval. In March 2018, we signed an amendment to the EAP with myTomorrows, pursuant to which myTomorrows will be our exclusive service provider for special access activities in Canada for the supply of Ampligen for the treatment of ME/CFS.

In December 2020, we entered into a signed Letter of Agreement with myTomorrows for the delivery of Ampligen for the treatment of up to 16 pancreatic cancer patients. In November 2021, we entered into a signed Letter of Agreement with myTomorrows for the delivery of Ampligen for the treatment of up to an additional 5 pancreatic cancer patients. In March 2022, we entered into a signed Letter of Agreement with myTomorrows for the delivery of Ampligen for the treatment of up to an additional 10 pancreatic cancer patients. In November 2022, we entered into a signed Letter of Agreement with myTomorrows for the delivery of Ampligen for the treatment of up to an additional 10 pancreatic cancer patients.

COMPETITION

The major pharmaceutical competitors for Ampligen include Pfizer, GlaxoSmithKline, Merck & Co., Novartis and AstraZeneca. Biotech competitors include Baxter International, Fletcher/CSI, AVANT Immunotherapeutics, AVI BioPharma and Genta.

GOVERNMENT REGULATION

Regulation by governmental authorities in the U.S. and foreign countries is and will be a significant factor in the manufacture and marketing of Alferon N Injection products and our ongoing research and product development activities. Ampligen and other products developed from the ongoing research and product development activities will require regulatory clearances prior to commercialization. In particular, new drug products for humans are subject to rigorous pre-clinical and clinical testing as a condition for clearance by the FDA and by similar authorities in foreign countries. The process of seeking these approvals, and the ongoing process of compliance with applicable statutes and regulations, has and will continue to require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect the marketing of any products developed by us and our ability to receive product or royalty revenue. We have received Orphan Drug designation for certain therapeutic indications, which we believe might under certain conditions help to accelerate the process of drug development and commercialization. Alferon N Injection is only approved for use in intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection for other applications requires regulatory approval.

We are subject to various federal, state and local laws, regulations and recommendations relating to such matters as safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use of and disposal of hazardous or potentially hazardous substances, including infectious disease agents, used in connection with our research work.

For more information about the current status of Alferon N Injection and Ampligen, please see "Our Products" above.

HUMAN CAPITAL

As of December 31, 2022, we had personnel consisting of 22 full-time employees and two part-time employees. Five of the combined personnel are engaged in our research, development, clinical and manufacturing efforts, with 17 performing regulatory, general administration, data processing, including bio-statistics, financial and investor relations functions. We have no union employees.

Employee Engagement

Our business results depend in part on our ability to successfully manage our human capital resources, including attracting, identifying, and retaining key talent. Factors that may affect our ability to attract and retain qualified employees include employee morale, our reputation, competition from other employers, and availability of qualified individuals. We believe our commitment to our human capital resources is an important component of our mission. We provide all employees with the opportunity to share their opinions in open dialogues with our human resources department and senior management.

Compensation, Benefits and Wellness

We offer fair, competitive compensation and benefits that support our employees' overall wellness. Further, the health and wellness of our employees are critical to our success. While we have been successful in attracting skilled and experienced scientific personnel, there can be no assurance that we will be able to attract or retain the necessary qualified employees and/or consultants in the future.

ITEM 1A: Risk Factors

The following cautionary statements identify important factors that could cause our actual results to differ materially from those projected in the forward-looking statements made in this Form 10-K. Please see "Special Note Regarding Forward Looking Statements and Summary Risk Factors" above.

Risks Associated with Our Business

The COVID-19 coronavirus or other global pandemics could adversely impact our business, including our clinical trials. We cannot predict the ultimate effects of the Covid-19 pandemic on our business.

The COVID-19 pandemic had and continues to have a major disruptive effect in the US and worldwide, including in countries in which there are planned or active clinical trial sites studying Ampligen. The COVID-19 pandemic or a future major pandemic could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in issuing reports, results and publishing papers;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

As noted elsewhere in this Report, progress of our commercial launch in Argentina has been delayed due to pandemic factors. The ongoing impact of COVID-19 in Argentina is taxing the nation's health care system and is, understandably, a main priority of its regulators.

While we are not able to estimate the effects of the COVID-19 outbreak or future pandemics, they may have a material adverse effect on our results of future operations, financial position and liquidity.

We may require additional financing which may not be available.

The development of our products requires the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of December 31, 2022 we had approximately $34,190,000 in cash and cash equivalents. We believe, based on our current financial condition, that we have adequate funds to meet our anticipated operational cash needs and fund current clinical trials over approximately the next sixteen months. At present we do not generate any material revenues from our operations and we do not anticipate doing so in the near future. We may need to obtain additional funding in the future for new studies and/or if current studies do not yield positive results, require unanticipated changes and/or additional studies. In February 2022, the SEC declared our universal shelf registration statement on Form S-3 effective. Pursuant to that registration statement, we can sell up to $100 million of our securities and raise additional capital as needed in the future. No assurance can be given as to the amount of funds that could be raised pursuant to this registration statement or the potential dilution to current stockholders.

We will need to allocate capital to eventually commercialize and sell Ampligen and/or recommence sales of Alferon N Injection.

We believe, based on our current financial condition, that we have adequate funds to meet our anticipated operational cash needs and fund current clinical trials over approximately the next sixteen months. If our funds are not adequate, and we are subsequently unable to obtain additional funding, through joint venturing, sales of securities and/or otherwise, our ability to develop our products, commercially produce inventory or continue our operations may be materially adversely affected.

We may continue to incur substantial losses and our future profitability is uncertain.

As of December 31, 2022, our accumulated deficit was approximately $380,308. As with many biotechnology companies, we have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

Our drug and related technologies are investigational and subject to regulatory approval. If we are unable to obtain regulatory approval in a timely manner, or at all, our operations will be materially harmed and our stock adversely affected.

While we have received regulatory approval for the commercialization of Ampligen in Argentina (pending additional release testing and subsequent steps), all of our drugs and associated technologies, other than Alferon N Injection, are investigational in the U.S. and must receive prior regulatory approval by appropriate regulatory authorities for commercial distribution and sale and are currently legally available only through clinical trials in the U.S. with specified disorders. At present, Alferon N Injection is approved for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. However, it is not at present available for purchase on the market. Use of Alferon N Injection for other indications will require regulatory approval in the United States and abroad.

Our products, including Ampligen, are subject to extensive regulation by numerous governmental authorities in the U.S. and other countries, including, but not limited to, the U.S. FDA, the Health Protection Branch (“HPB”) of Canada, the Agency for the European Medicines Agency (“EMA”) in Europe; and the Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica (“ANMAT”) in Argentina. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen will ultimately be demonstrated to be safe and efficacious. While Ampligen is authorized for use in clinical trials in the U.S., we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. In addition, although Ampligen has been authorized by the FDA for treatment use under certain conditions, including provision for cost recovery, there can be no assurance that such authorization will continue in effect.

While we received approval of our Argentinian NDA from ANMAT for commercial sale of rintatolimod (U.S. tradename: Ampligen) in the Argentine Republic for the treatment of severe ME/CFS, ANMAT approval is only an initial, but important, step in the overall successful commercialization of our product. In September 2019, we received clearance from the FDA to ship Ampligen to Argentina for the commercial launch and subsequent sales. However, there are a number of additional actions that must occur before we would be able to commence commercial sales in Argentina. For example, Ampligen is still in the process of release testing the product that has already been sent.

The FDA's regulatory review and approval process is extensive, lengthy, expensive and inherently uncertain. To receive approval for a product candidate, we must, among other things, demonstrate to the FDA's satisfaction with substantial evidence from well-controlled pre-clinical and clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. Before we can sell Ampligen for any use or promote Alferon N Injection for any use other than as Alferon N Injection for treatment of refractory or recurring genital warts, we will need to file the appropriate NDA with the FDA in the U.S. and the appropriate regulatory agency outside of the U.S. where we intend to market and sell such products. At present the only NDA we have filed with the FDA is the NDA for the use of Ampligen to treat CFS. The FDA issued a Complete Response Letter ("CRL") in February 2013 for this NDA and provided recommendations to address certain outstanding issues before they could approve Ampligen for Commercial Sales. The Agency stated that the submitted data do not provide substantial evidence of efficacy of Ampligen for the treatment of CFS and that the data do not provide sufficient information to determine whether the product is safe for use in CFS due to the limited size of the safety database and multiple discrepancies within the submitted data. The FDA indicated that we needed to conduct additional work. Therefore, ultimate FDA approval, if any, may be delayed indefinitely and may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA for approval or even to make our applications approvable. If any of these outcomes occur, we may be forced to abandon one or more of our future applications for approval, which might significantly harm our business and prospects. As a result, we cannot predict if or when we might receive regulatory approval for the use of Ampligen to treat CFS or for the use of any other products. Even if regulatory approval from the FDA is received for the use of Ampligen to treat CFS or eventually, for the use of any other product, any approvals that we obtain could contain significant limitations in the form of narrow indications, patient populations, warnings, precautions or contra-indications or other conditions of use, or the requirement that we implement a risk evaluation and mitigation strategy. In such an event, our ability to generate revenues from such products could be greatly reduced and our business could be harmed.

If we are unable to gain necessary FDA approvals related to Ampligen and Alferon N Injection on a timely basis, or we are unable to generate the additional data, successfully complete inspections or obtain approvals as required by the FDA on a timely manner, or at all, or determine that any of our clinical studies are not cost/justified to undertake or if, for that or any other reason, Ampligen, Alferon N Injection or one of our other products or production processes do not receive necessary regulatory approval in the U.S. or elsewhere, our operations most likely will be materially and/or adversely affected.

Generally, obtaining approval of an NDA by the FDA, or a comparable foreign regulatory authority, is inherently uncertain. Even after completing clinical trials and other studies, a product candidate could fail to receive regulatory approval for many reasons, including the following:

- not be able to demonstrate to the satisfaction of the FDA that our product candidate is safe and effective for any indication;
- the FDA may disagree with the design or implementation of our clinical trials or other studies;
- the results of the clinical trials or other studies may not demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from clinical trials or other studies;
- the data collected from clinical trials and other studies of a product candidate may not be sufficient to support the submission of an NDA;
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical and other study data insufficient for approval; and
- the FDA may not approve the proposed manufacturing processes and facilities for a product candidate.

We may be subject to product liability claims from the use of Ampligen, Alferon N Injection, or other of our products which could negatively affect our future operations. We have limited product liability and clinical trial insurance.

We maintain a limited amount of Products Liability and Clinical Trial insurance coverage worldwide for Ampligen and Alferon N Injection due to the minimal amount of historical loss claims regarding these products in the marketplace. Any claims against our products, Ampligen and Alferon N Injection, could have a materially adverse effect on our business and financial condition.

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligen, Alferon N Injection or other of our products results in adverse effects. This liability might result from claims made directly by patients, hospitals, clinics or other consumers, or by pharmaceutical companies or others manufacturing these products on our behalf. Our future operations may be negatively affected from the litigation costs, settlement expenses and lost product sales inherent to these claims. While we will continue to attempt to take appropriate precautions, we cannot assure that we will avoid significant product liability exposure.

Uncertainty of health care reimbursement for our products.

Our ability to successfully commercialize our products will depend, in part, on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and from time to time legislation is proposed, which, if adopted, could further restrict the prices charged by and/or amounts reimbursable to manufacturers of pharmaceutical products. We cannot predict what, if any, legislation will ultimately be adopted or the impact of such legislation on us. There can be no assurance that third party insurance companies will allow us to charge and receive payments for products sufficient to realize an appropriate return on our investment in product development.

There are risks of liabilities associated with handling and disposing of hazardous materials.

Our business involves the controlled use of hazardous materials, carcinogenic chemicals, and flammable solvents. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with the standards prescribed by applicable regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident or the failure to comply with applicable regulations, we could be held liable for any damages that result. However, we have obtained insurance coverage to mitigate any potential significant loss in this area.

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

Our operations could be disrupted if our information systems fail, if we are unsuccessful in implementing necessary upgrades or if we are subject to cyber-attacks. Our business depends on the efficient and uninterrupted operation of our computer and communications systems and networks, hardware and software systems and our other information technology. We collect and maintain information, which includes confidential and proprietary information, as well as personal information regarding our customers and employees, in digital form. Data maintained in digital form is subject to risk of cyber-attacks, which are increasing in frequency and sophistication. Cyber-attacks could include the deployment of harmful malware, viruses, worms, and other means to affect service reliability and threaten data confidentiality, integrity and availability. Despite our efforts to monitor and safeguard our systems to prevent data compromise, the possibility of a future data compromise cannot be eliminated entirely, and risks associated with intrusion, tampering, and theft remain. In addition, we do not have insurance coverage with respect to system failures or cyber- attacks. A failure of our systems, or an inability to successfully expand the capacity of these systems, or an inability to successfully integrate new technologies into our existing systems could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

The Company and its vendors' sophisticated information technology operations are spread across multiple, sometimes inconsistent, platforms, which pose difficulties in maintaining data integrity across systems. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional or improper dissemination or destruction of confidential information stored in the Company's systems.

Any breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology or information and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business and reputational harm to our company and could have a material adverse effect on our business, financial condition, results of operations, cash flows and stock price.

The loss of services of key personnel could hurt our chances for success.

Our success is dependent on the continued efforts of our staff, especially certain doctors and researchers. The loss of the services of personnel key to our operations could have a material adverse effect on our operations and chances for success. The loss of key personnel or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

GAAP requires estimates, judgements and assumptions which inherently contain uncertainties.

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with GAAP. Any future changes in estimates, judgments and assumptions used or necessary revisions to prior estimates, judgments or assumptions could lead to a restatement of our results.

The financial statements included in this Annual Report on Form 10-K are prepared in accordance with GAAP. This involves making estimates, judgments and assumptions that affect reported amounts of assets (including intangible assets), liabilities, mezzanine equity, stockholders' equity, operating revenues, costs of sales, operating expenses, other income, and other expenses. Estimates, judgments, and assumptions are inherently subject to change in the future and any necessary revisions to prior estimates, judgments or assumptions could lead to a restatement. Any such changes could result in corresponding changes to the amounts of assets (including goodwill and other intangible assets), liabilities, mezzanine equity, stockholders' equity, operating revenues, costs of sales, operating expenses, other income and other expenses.

We currently, and may in the future, have assets held at financial institutions that may exceed the insurance coverage offered by the Federal Deposit Insurance Corporation ("FDIC"), and the loss of such assets would have a severe negative affect on our operations and liquidity.

On March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. A statement by the Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts. Although we do not have any funds deposited with SVB and Signature Bank, We currently have deposits with Bank of America and Truist Bank, each exceeding $250,000. In the future, we may maintain our cash assets at these and other financial institutions in the United States in amounts that may be in excess of the FDIC insurance limit of $250,000. In the event of a failure of any of these financial institutions where we maintain our deposits or other assets, we may incur a loss to the extent such loss exceeds the FDIC insurance limitation, which could have a material adverse effect upon our liquidity, financial condition and our results of operations.

Risks Associated with Our Products

In addition to the risks disclosed above, the development of Ampligen is subject to a number of significant risks. Ampligen may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale, be uneconomical to market or be precluded from commercialization by proprietary right of third parties. Our investigational products are in various stages of clinical and pre-clinical development and require further clinical studies and appropriate regulatory approval processes before any such products can be marketed. We do not know when, if ever, Ampligen or our other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale.

To the extent that we are required by the FDA, pursuant to the Ampligen NDA, to conduct additional studies and take additional actions, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA for approval or even to make our applications approvable. If any of these outcomes occur, we may be forced to abandon one or more of our future applications for approval, which might significantly harm our business and prospects. As a result, we cannot predict when or whether regulatory approval will be obtained for any product candidate we develop.

If approved, one or more of the potential side effects of the drug might deter usage of Ampligen in certain clinical situations and, therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

Although Alferon N Injection is approved for marketing in the United States for intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older, to date it has not been approved for other indications.

Possible side effects from the use of Ampligen or Alferon N Injection could adversely affect potential revenues and physician/patient acceptability of our product.

Ampligen. We believe that Ampligen has been generally well tolerated with a low incidence of clinical toxicity, particularly given the severely debilitating or life-threatening diseases that have been treated. A mild flushing reaction has been observed in approximately 15-20% of patients treated in our various studies. This reaction is occasionally accompanied by a rapid heartbeat, a tightness of the chest, urticaria (swelling of the skin), anxiety, shortness of breath, subjective reports of "feeling hot", sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by reducing the rate of infusion. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, visual disturbances, slow or irregular heart rate, decreases in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months.

The FDA in its February 1, 2013, CRL, provided recommendations to address certain outstanding issues before they could approve Ampligen for Commercial Sales. The Agency stated that the submitted data do not provide sufficient information to determine whether the product is safe for use in CFS due to the limited size of the safety database and multiple discrepancies within the submitted data.

If approved, one or more of the potential side effects of the drug might deter usage of Ampligen in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

Alferon N Injection. At present, Alferon N Injection is approved for the intralesional (within the lesion) treatment of refractory or recurring external genital warts in adults. In clinical trials conducted for the treatment of genital warts with Alferon N Injection, patients did not experience serious side effects; however, there can be no assurance that unexpected or unacceptable side effects will not be found in the future for this use or other potential uses of Alferon N Injection which could threaten or limit such product's usefulness.

Risks Related to our activities associated with Ampligen's potential effectiveness as a treatment for COVID-19

It is not possible to predict the future of the ongoing SARS-CoV-2 global pandemic or the development of potential treatments. No assurance can be given that Ampligen will aid in or be applied to the treatment of this virus.

Significant additional testing and trials will be required to determine whether Ampligen will be effective in the treatment of COVID-19 and no assurance can be given that it will be the case. We base our belief that Ampligen may be effective in the treatment of COVID-19 on the result of studies that we reviewed and referenced. No assurance can be given that future studies will not result in findings that are different from those in the studies that we have relied upon. We are one of many companies working to develop a treatment for this virus, most of whom have far greater resources than us. This includes research into a range of COVID-19-related circumstances, from prophylactic and early-onset treatments to therapies for Post-COVID conditions. If one of these companies develops an effective treatment along the same lines as a therapy being developed by AIM, the development of Ampligen for this virus most likely will be adversely affected. Moreover, there already are available treatments.

Operating in foreign countries carries with it many risks.

Some of our studies are being conducted in the Netherlands and we may conduct other studies and or we may enter into agreements such as supply agreements. Operating in foreign countries carries with it a number of risks, including potential difficulties in enforcing intellectual property rights. We cannot assure that our potential foreign operations will not be adversely affected by these risks.

Risks Associated with Our Intellectual Property

We may not be profitable unless we can protect our patents and/or receive approval for additional pending patents.

We need to preserve and acquire enforceable patents covering the use of Ampligen for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen for such disease. We obtained all rights to Alferon N Injection, and we plan to preserve and acquire enforceable patents covering its use for existing and potentially new diseases once we have had a successful FDA Pre Approval Inspection. Our success depends, in large part, on our ability to preserve and obtain patent protection for our products and to obtain and preserve our trade secrets and expertise. Certain of our know-how and technology is not patentable, particularly the procedures for the manufacture of our experimental drug, Ampligen. We also have been issued a patent which affords protection on the use of Ampligen in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen as a sole treatment for any of the cancers which we have sought to target. For more information on Patents, please see PART I, Item 1 "Business; Patents".

We cannot assure that our competitors will not seek and obtain patents regarding the use of similar products in combination with various other agents, for a particular target indication prior to our doing so. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional patents, we may not be able to successfully market our products.

The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves complex legal and factual questions.

To date, no consistent policy has emerged regarding the breadth of protection afforded by pharmaceutical and biotechnology patents. There can be no assurance that new patent applications relating to our products, process or technology will result in patents being issued or that, if issued, such patents will afford meaningful protection against competitors with similar technology. It is generally anticipated that there may be significant litigation in the industry regarding patent and intellectual property rights. Such litigation could require substantial resources from us and we may not have the financial resources necessary to enforce the patent rights that we hold. No assurance can be made that our patents will provide competitive advantages for our products, process and technology or will not be successfully challenged by competitors. No assurance can be given that patents do not exist or could not be filed which would have a materially adverse effect on our ability to develop or market our products or to obtain or maintain any competitive position that we may achieve with respect to our products. Our patents also may not prevent others from developing competitive products or processes using related technology.

There can be no assurance that we will be able to obtain necessary licenses if we cannot enforce patent rights we may hold. In addition, the failure of third parties from whom we currently license certain proprietary information or from whom we may be required to obtain such licenses in the future, to adequately enforce their rights to such proprietary information, could adversely affect the value of such licenses to us.

If we cannot enforce the patent rights we currently hold we may be required to obtain licenses from others to develop, manufacture or market our products. There can be no assurance that we would be able to obtain any such licenses on commercially reasonable terms, if at all. We currently license certain proprietary information from third parties, some of which may have been developed with government grants under circumstances where the government maintained certain rights with respect to the proprietary information developed. No assurances can be given that such third parties will adequately enforce any rights they may have or that the rights, if any, retained by the government will not adversely affect the value of our license.

There is no guarantee that our trade secrets will not be disclosed or known by our competitors.

To protect our rights, we require all employees and certain consultants to enter into confidentiality agreements with us. There can be no assurance that these agreements will not be breached, that we would have adequate and enforceable remedies for any breach, or that any trade secrets of ours will not otherwise become known or be independently developed by competitors.

Risks Associated with Our R&D

Due to the inherent uncertainty involved in the design and conduct of clinical trials and the applicable regulatory requirements, including the factors discussed above in "Our Products", we cannot predict what additional studies and/or additional testing or information may be required by the FDA. In addition, most of our studies to date have involved only a small group of participants and positive results in such a small group does not mean that such results will prove true in studies with a much larger group of participants. Accordingly, we are unable to estimate the nature, timing, costs and necessary efforts to complete these projects nor the anticipated completion dates. In addition, we have no basis for estimating when material net cash inflows may commence. We have yet to generate significant revenues from the sale of these developmental products. As of December 31, 2022, we had approximately $34,190,000 in Cash, Cash Equivalents. Please see "*We may require additional financing which may not be available*" above.

Risks Associated with Our Manufacturing

Our Alferon N. Injection commercial sales were halted due to lack of finished goods inventory. If we are unable to gain the necessary FDA approvals related to Alferon N Injection, our operations most likely will be materially and/or adversely affected.

We are exploring engaging a Contract Manufacturing Organization ("CMO") to produce Alferon API. At present, we do not have a supply of Alferon N Injection or the requisite API. Additionally, although our old New Brunswick facility was FDA approval under the BLA for Alferon N Injection and we intend to maintain a certain amount of space at that facility, this status will need to be reapproved when a CMO or a new facility is identified for the production of the drug. We cannot provide any guarantee that a CMO or other future facility will pass an FDA pre-approval inspection for Ampligen or Alferon N Injection manufacture.

If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon N Injection inventory or contract with a CMO, our operations most likely will be materially adversely affected. For more information on Alferon N Injection regarding potential commercial sales, please see PART I, Item 1 - "Business; Manufacturing".

There are no long-term agreements with suppliers of required materials and services for Ampligen and there are a limited number of raw material suppliers. If we are unable to obtain the required raw materials and/or services, we may not be able to manufacture Ampligen.

A number of essential raw materials are used in the production of Ampligen as well as packaging materials utilized in the fill and finish process. We do not have, but continue to work toward having, long-term agreements for the supply of such materials, when possible. There can be no assurance we can enter into long-term supply agreements covering essential materials on commercially reasonable terms, if at all.

There are a limited number of suppliers in the United States and abroad available to provide the raw and packaging materials/reagents for use in manufacturing Ampligen and Alferon N Injection. At present, we do not have any agreements with third parties for the supply of any of these materials or we are relying on a limited source of reagent suppliers necessary for the manufacture of Alferon N Injection. Jubilant HollisterStier LLC has manufactured batches of Ampligen for us pursuant to purchase orders. We anticipate, but cannot assure, that additional orders will be placed upon approved quotes and purchase orders provided by us to Jubilant. On December 22, 2020, we added Pharmaceutics International Inc. ("Pii") as a "Fill & Finish" provider to enhance our capacity to produce the drug Ampligen. This addition amplifies our manufacturing capability by providing redundancy and cost savings. The contracts augment our existing fill and finish capacity. If we are unable to place adequate acceptable purchase orders with Jubilant or Pii in the future at acceptable prices upon acceptable terms, we will need to find another manufacturer. If we need to find another contract manufacturer to produce Ampligen, it would create a significant delay and expense to get the manufacturer up and running. The costs and availability of products and materials we would need for the production of Ampligen are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, ownership of intellectual property, FDA and other governmental regulations. There can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all.

While we have produced limited quantities of active pharmaceutical ingredients ("API") for our products in our old New Brunswick, NJ facility, the sale of this facility necessitates our exploring the engagement of a CMO to produce API for both Ampligen and Alferon. While we believe we have sufficient API to meet our current Ampligen needs, we are also continually exploring new efficiencies so as to maximize our ability to fulfill future obligations. Currently, the Alferon N Injection manufacturing process is on hold and there is no definitive timetable for its restart. Please see "*Our Alferon N. Injection commercial sales were halted due to lack of finished goods inventory. If we are unable to gain the necessary FDA approvals related to Alferon N Injection, our operations most likely will be materially and/or adversely affected*" above.

If we are unable to obtain or manufacture the required materials/reagents, and/or procure services needed in the final steps in the manufacturing process, we may be unable to manufacture Ampligen. The costs and availability of products and materials we need for the production of Ampligen are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, ownership of intellectual property, FDA and other governmental regulations. There can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all. For more information on Ampligen manufacturing, please see PART I, Item 1 - "Business; Our Products; Manufacturing" above.

There are a limited number of organizations in the United States available to provide the final manufacturing steps of formulation, fill, finish and packing sets for Alferon N Injection and Ampligen.

There are a limited number of organizations in the United States available to provide the final steps in the manufacturing for Alferon N Injection and Ampligen. To formulate, fill, finish and package our products ("fill and finish"), we require an FDA approved third party CMO.

In January 2017, we approved a quote and provided a purchase order with Jubilant HollisterStier LLC pursuant to which Jubilant manufactured batches of Ampligen for us. We anticipate, but cannot assure, that additional orders will be placed upon approved quotes and purchase orders provided by us to Jubilant. If we are unable to place adequate acceptable purchase orders with Jubilant in the future at acceptable prices upon acceptable terms our business would be materially and adversely affected. Please see the prior risk factor.

In December 2020, we added Pii as a "Fill & Finish" provider to enhance our capacity to produce the drug Ampligen. This addition amplifies our manufacturing capability by providing redundancy and cost savings. The contracts augment our existing fill and finish capacity.

Should there be an unanticipated delay in receiving new product or should we experience an unexpected demand for Ampligen, our ability to supply Ampligen most likely will be adversely affected. If we are unable to procure services needed in the final steps in the manufacturing process, we may be unable to manufacture Alferon N Injection and/or Ampligen. The costs and availability of products and materials we need for the production of Ampligen and the commercial production of Alferon N Injection and other products which we may commercially produce are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, and FDA and other governmental regulations and there can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all. For more information on Ampligen and Alferon N Injection manufacturing, please see PART I, Item 1 - "Business; Our Products; Manufacturing" above.

There is no assurance that, upon successful, manufacture of a drug on a limited-scale basis for investigational use will lead to a successful transition to commercial, large-scale production.

Changes in methods of manufacturing, including commercial scale-up, may affect the chemical structure of Ampligen and other RNA drugs, as well as their safety and efficacy. The transition from limited production of pre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges, and may require additional management, technical personnel and capital. While we intend to identify a CMO (or CMOs) with a state-of-the-art facility capable of meeting potential increased demand for Ampligen, there can be no assurance that our manufacturing will be successful or that any given product will be determined to be safe and effective, or capable of being manufactured under applicable quality standards, economically, and in commercial quantities, or successfully marketed.

We have limited manufacturing experience for Ampligen and Alferon N Injection. We may not be profitable unless we can produce Ampligen, Alferon N Injection or other products in commercial quantities at costs acceptable to us.

Ampligen has been produced to date in limited quantities for use in our clinical trials, Early Access Program and Expanded Access Program. In addition, in Argentina, Ampligen is still in the process of release testing the product that has already been sent. To be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. We believe, but cannot assure, that it will not be necessary to increase our current product plans to meet our production obligations. We intend to utilize third-party facilities if and when the need arises. We will need to comply with regulatory requirements for such facilities, including those of the FDA pertaining to cGMP requirements or maintaining our BLA status. There can be no assurance that such facilities can be used, built, or acquired on commercially acceptable terms, or that such facilities, if used, built, or acquired, will be adequate for the production of our proposed products for large-scale commercialization or our long-term needs.

We have never produced Ampligen, Alferon N Injection or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen and/or Alferon N Injection, or continue to maintain third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. If and when the Ampligen NDA is approved, we may need to find an additional vendor to manufacture the product for commercial sales. Also, each production lot of Alferon N Injection is subject to FDA review and approval prior to releasing the lots to be sold. This review and approval process could take considerable time, which would delay our having product in inventory to sell, nor can we provide any assurance as to the receipt of FDA approval of our finished inventory product. There can be no assurances that the Ampligen and/or Alferon N Injection can be commercially produced at costs acceptable to us.

Risks Associated with Our Licensing/Collaborations/Joint Ventures

If we are unable to achieve licensing, collaboration and/or joint ventures, our marketing strategy for Ampligen will be part of the differing health care systems around the world along with the different marketing and distribution systems that are used to supply pharmaceutical products to those systems.

We have received approval of our NDA from ANMAT for commercial sale of rintatolimod (U.S. tradename: Ampligen) in the Argentine Republic for the treatment of severe CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America. In September 2019, we received clearance from the FDA to ship Ampligen to Argentina for the commercial launch and subsequent sales. We are currently working with GP Pharma on the commercial launch of Ampligen in Argentina. Commercialization in Argentina will require, among other things, GP Pharm to establish disease awareness, medical education, creation of an appropriate reimbursement level, design of marketing strategies and completion of manufacturing preparations for launch.

The next steps in the commercial launch of Ampligen include ANMAT conducting a final inspection of the product and release tests before granting final approval to begin commercial sales. This testing and approval process is currently delayed due to the COVID-19 pandemic and ANMAT's internal processes. Once final approval by ANMAT is obtained, GP Pharm will begin distributing Ampligen in Argentina. We continue to pursue our Ampligen NDA, for the treatment of CFS with the FDA.

Risks Associated with Our Marketing and Distribution

We have limited marketing and sales capability. If we are unable to obtain additional distributors and our current and future distributors do not market our products successfully, we may not generate significant revenues or become profitable.

We have limited marketing and sales capability. We are dependent upon existing, and possibly future, marketing agreements and third-party distribution agreements for our products in order to generate significant revenues and become profitable. As a result, any revenues received by us will be dependent in large part on the efforts of third parties, and there is no assurance that these efforts will be successful.

Our commercialization strategy for Ampligen, if and when it is approved for marketing and sale by the FDA, may include licensing/co-marketing agreements utilizing the resources and capacities of a strategic partner(s). We continue to seek a world-wide marketing partner with the goal of having a relationship in place before approval is obtained. In parallel to partnering discussions, appropriate pre-marketing activities will be undertaken. It is our current intention to control manufacturing of Ampligen on a world-wide basis.

Our commercialization strategy for Alferon N Injection may include the utilization of internal functions and/or licensing/co-marketing agreements that would utilize the resources and capacities of one or more strategic partners.

We cannot assure that our U.S. or foreign marketing strategy will be successful or that we will be able to establish future marketing or third-party distribution agreements on terms acceptable to us, or that the cost of establishing these arrangements will not exceed any product revenues. Our inability to establish viable marketing and sales capabilities would most likely have a materially adverse effect on us. There can be no assurances that the approved Alferon N Injection product will be returned to prior sales levels.

Risks Associated with Our Competition

Rapid technological change may render our products obsolete or non-competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Most of these entities have significantly greater research and development capabilities than us, as well as substantial marketing, financial and managerial resources, and represent significant competition for us. There can be no assurance that developments by others will not render our products or technologies obsolete or noncompetitive, or that we will be able to keep pace with technological developments.

Our products may be subject to substantial competition.

Ampligen. Our flagship product, Ampligen is being evaluated as a potential treatment for COVID-19, myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) and COVID-induced CFS symptoms ("Long Haulers"); as well as multiple types of cancers. With regard to COVID-19, multiple global companies are actively working to develop therapies for COVID-19, including several companies which have successfully developed vaccines and treatments. It is possible that these or other companies may be developing therapies that are similar to that which we are attempting to develop, and could therefore develop them first. Some of these potential products may have an entirely different approach or means of accomplishing similar therapeutic effects to products being developed by us. These competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments may offer competition to our products. Furthermore, many of our competitors have significantly greater experience than we do in preclinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, The Health Protection Branch of the Canada Department of National Health and Welfare (HPB) and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating CFS in the United States, and standard of care is to focus on symptom relief, such as addressing pain specifically or depression specifically The dominant competitors with drugs to treat disease indications which we plan to address include Pfizer, GlaxoSmithKline, Merck & Co., Novartis and AstraZeneca. Biotech competitors include Baxter International, Fletcher/CSI, AVANT Immunotherapeutics, AVI BioPharma and Genta. These potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Although we believe our principal advantage is the unique mechanism of action of Ampligen on the immune system, we cannot assure that we will be able to compete.

Alferon N Injection. Our competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Alferon N Injection currently competes with Merck's injectable recombinant alpha interferon product (Intron® A) for the treatment of genital warts. In addition, other pharmaceutical firms offer self-administered topical cream, for the treatment of external genital and perianal warts such as Graceway Pharmaceuticals (Aldara®), Perrigo Company (Imiquimod Cream - Generic Equivalent to Aldara®), Watson Pharma (Condylox®) and MediGene (Veregen®). Alferon N Injection also competes with surgical, chemical, and other methods of treating genital warts. We cannot assess the impact products developed by our competitors, or advances in other methods of the treatment of genital warts, will have on the commercial viability of Alferon N Injection. If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our competitors have developed or may develop products (containing either alpha or beta interferon or other therapeutic compounds) or other treatment modalities for those uses. There can be no assurance that, if we are able to obtain regulatory approval of Alferon N Injection for the treatment of new indications, we will be able to achieve any significant penetration into those markets. In addition, because certain competitive products are not dependent on a source of human blood cells, such products may be able to be produced in greater volume and at a lower cost than Alferon N Injection. Currently, our wholesale price on a per unit basis of Alferon N Injection is higher than that of the competitive recombinant alpha and beta interferon products. Please see risk factor "We may not be profitable unless we can protect our patents and/or receive approval for additional pending patents" above for additional information.

Other companies may succeed in developing products earlier than we do, obtaining approvals for such products from the FDA more rapidly than we do, or developing products that are more effective than those we may develop. While we will attempt to expand our technological capabilities in order to remain competitive, there can be no assurance that research and development by others or other medical advances will not render our technology or products obsolete or non-competitive or result in treatments or cures superior to any therapy we develop.

Risks Associated with an Investment in Our Common Stock:

The market price of our stock may be adversely affected by market volatility

The market price of our common stock has been and is likely to be volatile. This is especially true given the current significant instability in the financial markets, in part caused by the COVID-19 coronavirus and the major adverse effects it has had and will continue to have on U.S. and worldwide economies and markets as well as the adverse effects and disruptions caused by the war in the Ukraine. Should our progress slow or results of testing or activities by others negatively impact our efforts, it is just as likely that our stock price will be significantly adversely affected, and in such case, investors could sustain substantial losses. In addition to the foregoing and, general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- announcements of availability or projections of our products for commercial sale;
- announcements of legal actions against us and/or settlements or verdicts adverse to us;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency comments regarding the safety or effectiveness of our products, or the adequacy of the procedures, facilities or controls employed in the manufacture of our products;
- changes in U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third-party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards;
- overall investment market fluctuation;
- restatement of prior financial results;
- notice of NYSE American non-compliance with requirements; and
- occurrence of any of the risks described in these risk factors and the risk factors incorporated by reference herein.

Our common stock is listed for quotation on the NYSE American. For the year ended December 31, 2022, the trading price of our common stock has ranged from $0.31 to $1.03 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock.

We may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or Directors. We have registered securities for public sale pursuant to a universal shelf registration statement which will allow us to raise additional capital as needed in the future from the sale of our securities.

We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur as a result of our utilization of our shelf registration statement or otherwise could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of our common stock or the market perception that we are permitted to sell a significant number of our securities would have on the market price of our common stock. Please see Item 7- "Management's Discussion and Analysis of Financial Condition and Result of Operations; Liquidity and Capital Resources" in PART II.

Provisions of our Certificate of Incorporation and Delaware law could defer a change of our Management which could discourage or delay offers to acquire us.

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in Management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. On November 14, 2017, at the direction of the Board, we amended and restated the Rights Agreement between us and, American Stock Transfer & Trust Company, LLC, its current Rights Agent. Pursuant to the original Rights Agreement, our Board of Directors declared a dividend distribution of one Right for each outstanding share of common stock to stockholders of record at the close of business on November 29, 2002. Each Right entitles the registered holder to purchase from us a unit consisting of one one-hundredth of a share (a "Unit") of Series A Junior Participating Preferred Stock, par value $0.01 per share at a Purchase Price of $21.00 per Unit, subject to adjustment. While our Rights Agreement was scheduled to expire in late 2022, we have extended it for a short period of time and expect to again extend it for a longer period of time.

Risks associated with Stockholder activism.

Our business, financial condition and operating results could be negatively affected as a result of actions by activist investors.

An activist stockholder (the "Activist") submitted a notice to our Board, purporting to nominate two nominees to our three-member Board at the 2022 Annual Meeting of Stockholders. We informed the Activist that our Board determined its purported notice of nomination was invalid, as it did not comply with our Amended and Restated Bylaws. We initiated a lawsuit against the Activist, the Activist's two nominees, and four additional individuals–all of whom we believe to be acting as a group, orchestrated and funded by two convicted securities law felons, to attempt to effectuate a takeover of our Board without registering as a group pursuant to U.S. securities laws and some of whom we believe have committed other unlawful actions. The Activist subsequently sued AIM and each of our board members in the Court of Chancery of the State of Delaware, seeking a declaratory judgment that the purported notice of nominations was valid and certain injunctive relief. The Delaware Chancery Court denied the Activist's motion on October 28, 2022, and the Activist announced on November 2, 2022, that it did not intend to appeal the decision. Had the Activist prevailed in its lawsuit, we most likely would have been involved in a proxy contest for control of our Board, despite the deficiencies in the Activist's purported notice of nominations. Certain members of this group also persistently disparaged the stock using alias names on message boards. Even though we prevailed in the Delaware litigation, the litigation and the campaign by the Activist and those with whom the Activist is acting in concert against us (which includes two convicted securities law felons) has, and will have, likely diverted the time and energies of management and required us to incur substantial expense, possibly causing a decrease in stockholder value.

A proxy contest and related litigation, along the lines discussed above, could have a material adverse effect on us for the following reasons:

- Activist investors may attempt to effect changes in our governance and strategic direction or to acquire control over the Board or AIM. In particular, if the Activist is successful in its litigation and subsequent proxy contest, it may gain control of the Board.

- While we welcome the opinions of all stockholders, responding to proxy contests and related litigation by activist investors is likely to be costly and time-consuming, disrupt our operations, and potentially divert the attention of our Board, management team and other employees away from their regular duties and the pursuit of business opportunities to enhance stockholder value.

- Perceived uncertainties as to our future direction as a result of potential changes to the composition of the Board may lead to the perception of a change in the strategic direction of the business, instability or lack of continuity, which may cause concern to our existing or potential strategic partners, customers, employees and stockholders; may be exploited by our competitors; may result in the loss of potential business opportunities or limit our ability to timely initiate or advance clinical trials; and may make it more difficult to attract and retain qualified personnel and business partners.

- Proxy contests and related litigation by activist investors could cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

ITEM 1B. Unresolved Staff Comments.

None.

ITEM 2. Properties.

Our principal executive office and finance is located at 2117 SW Highway 484, Ocala FL 34473 and our human resource office is located at 604 Main Street, Riverton, NJ 08077. We currently lease our principal executive office for $2,700 per month and our accounting and human resource office for about $2,500 per month.

In March 2018, we sold our property located at 783 Jersey Ave., New Brunswick, NJ. This property houses our development and production facilities. The purchase price was $4,080,000 gross and purchaser received 3,225,806 warrants to purchase common stock.

In May 2021, we exercised the option to re-purchase the New Brunswick manufacturing facility, pursuant to the terms of the March 2018 sale and lease-back agreement. We thereafter sold certain equipment and machinery that it determined to be obsolete and no longer needed for current or future manufacturing. On March 3, 2022, we entered into an Agreement of Sale and Purchase with Acellories, Inc. to purchase the property for an estimated $3.9 million, and maintained some space specifically for its Alferon activity. The sale closed on November 1, 2022 for $3.7 million net of normal closing cost.

ITEM 3. Legal Proceedings.

We commenced an action against BioLife in December of 2017 for Breach of Contract. The amount of damages we are seeking in this matter have yet to be determined. Damages are not covered by insurance. BioLife, the defendant, has filed its Answer, Affirmative Defenses and a Counterclaim in the amount of $96,676 representing the invoices withheld after BioLife indicated that they were not intending to fulfill the balance of the contract. We have denied the allegations of the counterclaim. We have conducted two mediation sessions, but have been unable to resolve the matter. The parties are still currently engaged in discovery, which we believe will now lead to a trial date in the later part of 2023. The scheduled dates for these events to transpire were extended several times as they were dependent on the safe and full reopening of the Courts. Although it cannot be reasonably determined at this time, we believe the likelihood of an unfavorable outcome on the defendant's counterclaim is remote.

On July 8, 2022, we received a notice from Jonathan Jorgl (the "Jorgl Notice"), an AIM stockholder who first purchased 1,000 AIM shares on June 27, 2022, seeking to nominate a control slate of two individuals for election to the three-member AIM Board of Directors (the "Board") at the 2022 Annual Meeting of Stockholders. The Board unanimously determined the Jorgl Notice to be invalid due to numerous deficiencies, including failure to comply with the Company's bylaws. The rejection of the Jorgl Notice was announced on July 18, 2022.

Also on July 18, 2022, we filed a complaint in the U.S. District Court for the Middle District of Florida, Ocala Division, against individuals we believe failed to register as a group pursuant to U.S. securities laws and committed other unlawful actions in the context of their attempt to effectuate a takeover of the Company's Board. The court granted the defendants' motion to dismiss, but allowed the filing of an amended complaint. Defendants' renewed motion to dismiss is pending, and AIM is in the process of obtaining discovery from the defendants.

On August 12, 2022, a hearing was held in the Delaware Court of Chancery concerning a motion for a temporary restraining order sought by Jorgl to require the AIM Board of Directors to accept his director nominations and include his nominees on a universal proxy card for the upcoming Annual Meeting of Stockholders. The court denied the motion several days later and scheduled a hearing on Jorgl's motion for a preliminary injunction to be held on October 5, 2022. Extensive discovery was conducted in advance of the hearing, which was then held as scheduled.

On October 5, 2022, the Delaware Court of Chancery held a hearing regarding a motion to require the AIM Board of Directors to accept the Jorgl Group's director nominations and include the group's nominees on a universal proxy card for the 2022 Annual Meeting of Stockholders. On October 28, 2022, the court denied Jorgl's motion, citing that he failed to meet the burden of proof in light of the evidence showing that he was part of efforts by convicted securities law felons working toward taking control of the AIM Board. The Jorgl Group announced on November 2, 2022, that it did not intend to appeal the decision.

ITEM 4. Mine Safety Disclosures.

Not Applicable.

PART II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is listed and traded on the NYSE American under the symbol AIM.

Holders of Common Stock

As of March 25, 2023, there were approximately 150 holders of record of our Common Stock. This number was determined from records maintained by our transfer agent and does not include beneficial owners of our securities whose securities are held in the names of various dealers and/or clearing agencies.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Dividends

We have not paid any cash dividends on our Common Stock in recent years. It is management's intention not to declare or pay dividends on our Common Stock, but to retain earnings, if any, for the operation and expansion of our business.

Recent Sales of Unregistered Securities

During the year ended December 31, 2022, we issued and sold the following unregistered securities under the 2018 Equity Incentive Plan, effective September 12, 2018, which will continue in effect for a period of 10 years from its effective date:

On July 7, 2020, the board of directors approved a plan pursuant to which all directors, officers, and employees could purchase from us up to an aggregate of $500,000 worth of shares at the market price. Pursuant to NYSE American rules, this plan was effective for a sixty-day period commencing upon the date that the NYSE American approved the our Supplemental Listing Application. We issued 10,730 shares of our common stock at a price of $2.33 for a total of $25,000 under this plan. When this plan expired, the board of directors approved subsequent similar $500,000 plans for all directors, officers and employees to buy shares from us at the market price. Subsequent plans were approved by the board of directors upon the expiration of prior plans. The last plan approved by the board of directors for the fiscal year ending December 31, 2022, was on November 16, 2022.

During the fiscal year ended December 31, 2020, we issued a total of 27,501 shares of our common stock at prices ranging from $1.72 to $2.03 for a total of $50,000.

During the fiscal year ended December 31, 2021, we issued a total of 132,238 shares of our common stock at prices ranging from $1.16 to $2.35 for a total of $205,000.

During the fiscal year ended December 31, 2022, we issued a total of 86,817 shares of our common stock at prices ranging from $0.76 to $1.02 for a total of $80,000.

The offers, sales and issuances of securities described above was deemed to be exempt from registration under the Securities Act in reliance on either Section 4(a)(2) in that the issuance of securities to the accredited investors did not involve a public offering, or Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701.

ITEM 6. [Reserved]

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

The following discussion and analysis is related to our financial condition and results of operations for the two years ended December 31, 2022 This information should be read in conjunction with our consolidated financial statements and related notes thereto beginning on F-1 of this Form 10-K. Please also see "Special Note Regarding Forward Looking Statements and Summary Risk Factors" in ITEM 1. Business.

Fair Value

We have issued warrants (the "Warrants") in February 2017, June 2017, August 2017, April 2018, and March 2019 that are single compound derivatives containing both an embedded right to obtain stock upon exercise (a "Call") and a series of embedded rights to settle the Warrants for cash upon the occurrence of certain events (each, a "Put"). Generally, the Put provisions allow the Warrant Holders liquidity protection; the right to receive cash in certain situations where the Holders would not have a means of readily selling the shares issuable upon exercise of the Warrants (e.g., where there would no longer be a significant public market for our common stock). However, because the contractual formula used to determine the cash settlement value of the embedded Put requires use of certain assumptions, the cash settlement value of the embedded Put can differ from the fair value of the unexercised embedded Call option at the time the embedded Put option is exercised.

We recompute the fair value of the Warrants at the end of each quarterly reporting period. Such value computation includes subjective input assumptions that are consistently applied each period. If we were to alter our assumptions or the numbers input based on such assumptions, the resulting fair value could be materially different.

RESULTS OF OPERATIONS

Year ended December 31, 2022 versus year ended December 31, 2021

Our net loss was approximately $19,445,000 and $19,127,000 for the years ended December 31, 2022 and 2021, respectively, representing an increase in net loss of approximately $318,000 when compared to the same period in 2021. This increase in net loss for the year ended December 31, 2022, was primarily due to the following:

- an increase in general and administrative expenses of $4,402,000;
- an increase in loss on investments of $1,478,000; offset by
- an increase in interest/other income of $629,000;
- a decrease in interest expense and finance costs $2,768,000; and
- a decrease in impairment losses of $1,779,000;
- a decrease in research and development expenses of $682,000;
- a decrease in production costs of $850,000;
- a decrease in gain from sale of Income tax operating losses of $829,000;
- a decrease in gain of sale of fixed assets of $213,000
- a decrease of the quarterly revaluation of certain redeemable warrants of $110,000;

Net loss per share was $ (0.40) and $(0.40) for the years ended December 31, 2022, and 2021, respectively. The weighted average number of shares of our common stock outstanding as of December 31, 2022, was 48,047,288 as compared to 47,339,975 as of December 31, 2021.

Revenues

Revenues from our Ampligen® Cost Recovery Program were $141,000 and $135,000 for the years ended December 31, 2022, and 2021, representing an increase of $6,000 which is primarily related to the timing of orders.

For the years ended December 31, 2022 and 2021, we had no Alferon N Injection® Finished Good product to commercially sell and all revenue was generated from the EAP and our FDA approved open-label treatment protocol, ("AMP 511"), that allows patient access to Ampligen® for treatment in an open-label safety study.

Production Costs

Production costs were approximately $0 and $850,000, respectively, for the years ended December 31, 2022, and 2021, representing a decrease of $850,000 in production costs in the current period. The decrease was due primarily to the sale of the facility and no production for 2022 compared to 2021.

Research and Development Costs

Overall Research and Development ("R&D") costs for the year ended December 31, 2022, were approximately $6,990,000 as compared to $7,672,000 for the same period a year ago, reflecting a decrease of approximately $682,000. The primary reason for the decrease in research and development costs was due to decreases in Company sponsored clinical trials expenses of $1,728,000, offset by increases in salaries and outside consultant costs of $607,00, $66,000 in rent and $304,000 in patents & trademarks.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the years ended December 31, 2022, and 2021, were approximately $13,074,000 and $8,672,000, respectively, reflecting an increase of approximately $4,402,000. The increase in G&A expenses during the current period was mainly due to increases in legal fees of $4,582,000, public relations expenses of $348,000, insurance expenses of $439,000 and general expense of $51,000 net of decreases in stock compensation of $613,000, salary expenses of $243,000 and depreciation of $12,000.

Gain (loss) on Investments

Gain (loss) on investments for the years ended December 31, 2022, and 2021 were approximately ($1,679,000) and ($201,000), respectively, reflecting an increase in the loss on investments of approximately ($1,478,000). The loss was due to the change in the fair value of equity investments.

Impairment of plant property and equipment and other assets

During the year ended December 31, 2022, there was a loss of $0 related to the impairment of plant property and equipment (see Note 2 Summary of Significant Accounting Policies).

During the year ended December 31, 2021, there was a loss of $1,779,000 related to the impairment of plant property and equipment (see Note 2 Summary of Significant Accounting Policies).

Interest expense and finance costs for the year ended December 31, 2022, was $0 compared to $2,768,000 in the prior year, a decrease of $2,768,000 primarily due to the extinguishment of debt of $2,768,000 in 2021.

Redeemable Warrants

The quarterly revaluation of certain redeemable warrants resulted in a non-cash adjustment to the redeemable warrants liability amounted to a gain of $35,000 for the year ended December 31, 2022, compared to a gain of approximately $145,000 in December 31, 2021 (see "Financial Statements: Note 15: Fair Value" for the various factors considered in the valuation of redeemable warrants).

Gain from sale of income tax operating losses

We effectively sold $20,500,000 New Jersey state operating losses from 2021 for approximately $1,676,000. Additionally, we recorded a deferred tax asset in the amount of $1,118,000 for the current year 2022 operating losses to be sold in 2023. (see Note 12 Income Taxes (FASB ASC 740 Income Taxes).

Liquidity and Capital Resources

Cash used in operating activities for the year ended December 31, 2022, was approximately $16,108,000 compared to approximately $13,965,000 for the same period in 2021, an increase of $2,143,000. The primary reasons for this increase in cash used in operations in 2022 was related to the loss on marketable securities of $1,679,000, as well as in increase in the prepaid expenses of $151,000 and an increase in accounts payable of $179,000.

Cash provided by investing activities for the year ended December 31, 2022, was approximately $10,988,000 compared to cash used in 2021 was approximately $631,000, representing a change of $11,619,000. The primary reason for the change during the current period is the net purchase and sale of marketable securities activity of $7,359,000 compared to the $243,000 for the same period in 2021, and by the proceeds from the sale of the asset held for sale of $3,900,000 in 2022.

Cash provided by financing activities for the year ended December 31, 2022, was approximately $80,000 compared to approximately $8,188,000 for the same period in 2021, a decrease of $8,108,000. The primary reason for this decrease was our receipt of $13,042,000 in net proceeds from the sale of shares in 2021compared to $80,000 from the proceeds from sale of stock, net of issuance costs in 2022. As of December 31, 2022, we had approximately $34,190,000 in cash, cash equivalents and marketable securities, inclusive of approximately $7,137,000 in Marketable Securities, representing a decrease of approximately $14,078,000 from December 31, 2021.

We are committed to a focused business plan oriented toward finding senior co-development partners with the capital and expertise needed to commercialize the many potential therapeutic aspects of our experimental drugs and our FDA approved drug Alferon N Injection.

Today, some two years after COVID-19 first appeared, the world has a number of vaccines and some promising therapeutics. Our quest to prove the antiviral activities of Ampligen continues. If Ampligen has the broad-spectrum antiviral properties that we believe that it has, it could be a very valuable tool in treating variants of existing viral diseases, including COVID-19, or novel ones that arise in the future. Unlike most developing therapeutics which attack the virus, Ampligen works differently. We believe that it activates antiviral immune system pathways that fight not just a particular virus or viral variant, but other similar viruses as well.

The development of our products requires the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. We believe, based on our current financial condition, that we have adequate funds to meet our anticipated operational cash needs and fund current clinical trials over approximately the next sixteen months. In February 2022, the SEC declared our universal shelf registration statement on Form S-3 effective. Pursuant to that registration statement, we can sell up to $100 million of our securities and raise additional capital as needed in the future. No assurance can be given as to the amount of funds that could be raised pursuant to this registration statement or the potential dilution to current stockholders.

At present we do not generate any material revenues from operations and we do not anticipate doing so in the near future. We may need to obtain additional funding in the future for new studies and/or if current studies do not yield positive results, require unanticipated changes and/or additional studies. If we are unable to commercialize and sell Ampligen and/or recommence material sales of Alferon N Injection, our operations, financial position and liquidity may be adversely impacted, and additional financing may be required. There can be no assurances that, if needed, we will be able to raise adequate funds or enter into licensing, partnering or other arrangements to advance our business goals. We may seek to access the public equity market whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. See Part I, Item 1A - “Risk Factors; *We may require additional financing which may not be available*”.

Certain Relationships and Related Transactions

Refer to PART III, ITEM 13 - “Certain Relationships and Related Transactions, and Director Independence.”

New Accounting Pronouncements

Refer to “Note 2(h) – Recent Accounting Standards and Pronouncements” under Notes to Consolidated Financial Statements.

Critical Accounting Estimates

Our significant accounting estimates are described in the Notes to Consolidated Financial Statements. The significant accounting estimates that we believe are most critical to aid in fully understanding our reported financial results are the following:

Long-Lived Assets

We assess long-lived assets for impairment when events or changes in circumstances indicate that the carrying value of the assets or the asset grouping may not be recoverable. Factors that we consider in deciding when to perform an impairment review include significant under-performance of a business or product line in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. We measure the recoverability of assets that we will continue to use in our operations by comparing the carrying value of the asset grouping to our estimate of the related total future undiscounted net cash flows. If an asset grouping’s carrying value is not recoverable through the related undiscounted cash flows, the asset grouping is considered to be impaired.

In the event if the carrying value exceeds the future undiscounted net cash flows, we would estimate the fair values using a combination of market and income approaches. Under the market approach, fair values would be estimated using published market multiples for comparable companies. Under the income approach, a discounted cash flow methodology would be used, considering: (i) management estimates, such as projections of revenue, operating costs and cash flows, taking into consideration historical and anticipated financial results; (ii) general economic and market conditions; and (iii) the impact of planned business and operational strategies.

We measure the impairment by comparing the difference between the asset grouping's carrying value and its fair value. We measure our long-lived assets, in accordance to ASC 360 impairment (patents, trademarks, intangibles, fixed assets) Long-lived assets are considered a non-financial asset and are recorded at fair value only if an impairment charge is recognized. Impairments are determined for groups of assets related to the lowest level of identifiable independent cash flows. We make subjective judgments in determining the independent cash flows that can be related to specific asset groupings. In addition, as we review our manufacturing process and other manufacturing planning decisions, we must make subjective judgments regarding the remaining useful lives of assets. When we determine that the useful lives of assets are shorter than originally estimated, we accelerate the rate of depreciation over the assets' new, shorter useful lives. At the end of fiscal year December 31, 2022, we engaged an outside third party to provide a valuation for the impairment of our patents and trademarks. The determination was, from a qualitative standpoint, it would appear highly unlikely that there would be any impairment to the patnets. (see Note 2 Summary of Significant Accounting Policies)

Redeemable Warrants

We utilize the guidance contained in ASC 480 Distinguishing Liabilities from Equity in the determination of whether to record warrants and options as Equity and/or Liability. If the guidance of ASC 480 is deemed inconclusive, we continue our analysis utilizing ASC 815 Derivatives and Hedging.

Our method of recording the related value is consistent with the standards as defined by the Financial Accounting Standards Board utilizing the concept of "Fair Value" from ASC 820-10-55-1 that states that any fair value measurement requires that the reporting entity, to determine the valuation technique(s) appropriate for the measurement, consider the availability of data with which to develop inputs that represent the assumptions that market participants would use in pricing the asset or liability and the level in the fair value hierarchy within which the inputs fall.

We recomputed the value of the redeemable warrants at the end of each quarterly period. We use the Monte Carlo Simulation approach which includes subjective input assumptions that are consistently applied each quarter. If we were to alter our assumptions or the numbers input based on such assumptions, the resulting fair value could be materially different. As discussed in greater detail in "Fair Value" at the beginning of this ITEM 7, the significant assumptions using this model are: (i) Risk-Free Interest Rate; (ii) Expected Holding Period; (iii) Expected Volatility; (iv) Expected Dividend Yield; (v) Expected Probability of a Fundamental Transaction; (vi) Expected Timing of Announcement of a Fundamental Transaction; (vii) Expected 100 Day Volatility at Announcement of a Fundamental Transaction; (viii) Expected Risk-Free Interest Rate at Announcement of a Fundamental Transaction; and (ix) Expected Time Between Announcement and Consummation of a Fundamental Transaction. The derivative is values using Level 3 inputs which are highly subjective and require a high degree of judgment.

Concentration of Credit Risk

Our policy is to limit the amount of credit exposure to any one financial institution and place investments with financial institutions evaluated as being credit worthy, or in short-term money markets, which are exposed to minimal interest rate and credit risks. We have bank deposits and overnight repurchase agreements that exceed federally insured limits.

Concentration of credit risk, with respect to receivables, is limited through our credit evaluation process. We do not require collateral on our receivables. Our receivables historically consisted principally of amounts due from wholesale drug companies.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not Applicable.

ITEM 8. Financial Statements and Supplementary Data.

Please see the "Index to Financial Statements and Financial Statement Schedule" on page F-1.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures.

None.

ITEM 9A. Controls and Procedures.

Effectiveness of Control Procedures

As of December 31, 2022, the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our Management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Exchange Act. Our disclosure controls and procedures are intended to ensure that the information we are required to disclose in the reports that we file or submit under the Securities Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the Securities Exchange Commission's rules and forms and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as the principal executive and financial officers, respectively, to allow final decisions regarding required disclosures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the controls and procedures were effective as of December 31, 2022, to ensure that material information was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our management has concluded that the financial statements included in this Form 10-K present fairly, in all material respects our financial position, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States of America.

Changes in Internal Control over Financial Reporting

We made no changes in our internal control over financial reporting during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act).

Management's Report on Internal Control over Financial Reporting

Our Management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rules 13a-15(f) or 15d-15(f), under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers and affected by our Board of Directors, Management and other personnel, and 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, Management used the criteria set forth in the framework in 2013 established by the Committee of Sponsoring Organizations of the Treadway Commission Internal Control—Integrated Framework, (COSO). Based on this assessment, Management has not identified any material weaknesses as of December 31, 2021. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

Management has concluded that we did maintain effective internal control over financial reporting as of December 31, 2022, based on the criteria set forth in "Internal Control—Integrated Framework" issued by the COSO.

ITEM 9B. Other Information.

On March 28, 2023, our Board approved an amendment and restatement of the our bylaws (as amended and restated, the "Restated and Amended Bylaws"), effective as of such date.

The amendments set forth in the Restated and Amended Bylaws, among other things: (a) revise procedures and disclosure requirements for stockholders to provide notice of nominations of directors and the submission of proposals for consideration at meetings of our stockholders including, among other things, disclosure of specified information about the noticing stockholder(s), any nominees, and persons acting in concert with them, and information about agreements, arrangements, and understandings between the noticing stockholder(s) and others (including any nominees) relating to AIM or the proposal or nominations; (b) clarify the powers of the Board and the chair of a stockholder meeting to establish rules for the conduct of any meeting of stockholders, as well as the chair's power to convene, recess, or adjourn the meeting; (c) revise procedures related to stockholder and Board actions taken by written consent to more closely reflect delivery mechanisms contemplated by the General Corporation Law of the State of Delaware (the "DGCL"); (d) adopt a forum selection bylaw to provide that the state and federal courts of the State of Delaware shall be the exclusive forum for litigating derivative actions, claims arising under the DGCL, the certificate of incorporation, or the bylaws, breach of fiduciary duty claims against AIM, its directors or officers, or claims relating to AIM's internal affairs, and that the federal

courts shall be the exclusive forum for the resolution of claims under the Securities Act of 1933, as amended; and (e) make certain administrative, modernizing, clarifying, and conforming changes, including making updates to reflect recent amendments to the DGCL.

The foregoing summary of the Restated and Amended Bylaws does not purport to be complete and is qualified in its entirety by reference to the full text of the Restated and Amended Bylaws, which is attached hereto as Exhibit 3.7(ii) and incorporated herein by reference.

In addition, the Board increased its size to four and appointed Nancy Bryan to fill the new slot, appointed her to a number of Board committees and reduced compensation to directors. Please see "*Item 10. Directors and Executive Officers and Corporate Governance"* and "*Item 11. Executive Compensation*."

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

ITEM 10. Directors and Executive Officers and Corporate Governance.

The following sets forth biographical information about each of our Directors and Executive Officers as of the date of this report:

Name	Age	Position
Thomas K. Equels, Esq	70	Chief Executive Officer, President, and Director
Peter W. Rodino III	71	Chief Operating Officer, General Counsel & Secretary
William M. Mitchell, M.D., Ph.D.	88	Chairman of the Board and Director
Stewart L. Appelrouth	69	Director
Nancy Bryan	65	Director
Robert Dickey IV	66	Chief Financial Officer

Each Director has been elected to serve until the next annual meeting of stockholders, or until their earlier resignation, removal from office, death or incapacity. Each Executive Officer serves at the discretion of the Board of Directors, subject to rights, if any, under contracts of employment.

We believe our Board Members represent a desirable diversity of backgrounds, skills, education and experiences, and they all share the personal attributes of dedication to be effective directors. In recommending Board candidates, Corporate Governance and Nomination Committee considers a candidate's: (1) general understanding of elements relevant to the success of a publicly traded company in the current business environment; (2) understanding of our business; and (3) diversity in educational and professional background. The Committee also gives consideration to a candidate's judgment, competence, dedication and anticipated participation in Board activities along with experience, geographic location and special talents or personal attributes. The following are qualifications, experience and skills for Board members which are important to our business and its future:

Leadership Experience: We seek directors who have demonstrated strong leadership qualities. Such leaders bring diverse perspectives and broad business insight to our Company. The relevant leadership experience that we seek includes a past or current leadership role in a large or entrepreneurial company, a senior faculty position at a prominent educational institution or a past elected or appointed senior government position.

Industry or Academic Experience: We seek directors who have relevant industry experience, both with respect to the disease areas where we are developing new therapies as well as with the economic and competitive dynamics of pharmaceutical markets, including those in which our drugs will be prescribed.

Scientific, Legal or Regulatory Experience: Given the highly technical and specialized nature of biotechnology, we desire that certain of our directors have advanced degrees, as well as drug development experience. Since we are subject to substantial regulatory oversight, both here and abroad by the FDA and other agencies, we also desire directors who have legal or regulatory experience.

Finance Experience: We believe that our directors should possess an understanding of finance and related reporting processes, particularly given the complex budgets and long timelines associated with drug development programs.

THOMAS K. EQUELS, has been a Director and serves as our Executive Vice Chairman (since 2008), Chief Executive Officer (since 2016) and President (since 2015). Mr. Equels was the owner of and former President and Managing Director of the Equels Law Firm headquartered in Miami, Florida that focused on litigation. For over a quarter century, Mr. Equels represented national and state governments as well as companies in the banking, insurance, aviation, pharmaceutical and construction industries. Mr. Equels received his Juris Doctor degree with high honors from Florida State University. He received his Bachelor of Science, summa cum laude, from Troy University and also obtained his Master of Science Degree from Troy University. Mr. Equels began his professional career as a military pilot. Equels is a member of the Board of Directors of BioFlorida Inc., an life science industry organization representing 6,700 establishments and research organizations in the biopharmaceutical, medical technology, and bioagriculture sectors that collectively employ 94,000 Floridians. He served in Vietnam and was awarded two Distinguished Flying Crosses, the Bronze Star, the Purple Heart, and fifteen Air Medals. In 2012, he was Knighted by Pope Benedict.

THOMAS K. EQUELS – Director Qualifications:

- Leadership Experience – Military; Owner and former President; Managing Director of Equels Law Firm, Court-appointed receiver in numerous industries;

- Industry Experience –legal counsel, General Counsel, CFO and CEO of the company; and

- Scientific, Legal or Regulatory Experience – Law degree with over 25 years as a practicing attorney specializing in litigation, development of clinical trials, creating intellectual property concepts, and established plan to finance drug development.

WILLIAM M. MITCHELL, M.D., Ph.D., has been a Director since July 1998 and Chairman of the Board since February 2016. Dr. Mitchell is a Professor of Pathology at Vanderbilt University School of Medicine and is a board-certified physician. Dr. Mitchell earned a M.D. from Vanderbilt and a Ph.D. from Johns Hopkins University, where he served as House Officer in Internal Medicine, followed by a Fellowship at its School of Medicine. Dr. Mitchell has published over 200 papers, reviews and abstracts that relate to viruses, anti-viral drugs, immune responses to HIV infection, and other biomedical topics. Dr. Mitchell has worked for and with many professional societies that have included the American Society of Investigative Pathology, the International Society for Antiviral Research, the American Society of Clinical Oncology, the American Society of Biochemistry and Molecular Biology, the American Chemical Society, and the American Society of Microbiology. Dr. Mitchell is a member of the American Medical Association. He has served on numerous government review committees, among them the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health, including the initial AIDS and Related Research Review Group. Dr. Mitchell previously served as one of our Directors from 1987 to 1989. The Board has determined Dr. Mitchell to be an Independent Director as required under Section 803(2) of the NYSE: American Company Guide and Rule 10A-3 under the Exchange Act.

WILLIAM M. MITCHELL, M.D., Ph.D. – Director Qualifications:

- Leadership Experience – Professor at Vanderbilt University School of Medicine. He was a member of the Board of Directors of Chronix Biomedical, a company involved in next generation DNA sequencing for medical diagnostics, until its recent acquisition/merger by the public company, Oncocyte, and was the former Chairman of its Medical Advisory Board. Additionally, he has served on multiple governmental review committees of the National Institutes of Health, Centers for Disease Control and Prevention and for the European Union, including key roles as Chairman;

- Academic Experience – Well published medical researcher with extensive investigative experience on virus and immunology issues relevant to our scientific business; and

- Scientific, Legal or Regulatory Experience – M.D., Ph.D. and professor at a top ranked school of medicine, and inventor of record on numerous U.S. and international patents who is experienced in regulatory affairs through filings with the FDA.

STEWART L. APPELROUTH, CPA was appointed as a director and head of the Audit Committee in August 2016 and is a certified public accountant and partner at Appelrouth Farah & Co., P.A. and, since March 2022, a partner at Citrin Cooperman Advisors, LLP, both Certified Public Accountants. Mr. Appelrouth is also a certified forensic accountant and possesses 40 years of experience in Accounting and Consulting. He is a member of or has affiliations with the AICPA, American College of Forensic Examiners, FINRA Arbitrator, Association of Certified Fraud Examiners, past member of the Florida Bar Grievance Committee, Florida Institute of Certified Public Accountants and InfraGard Member, a national information sharing program between the Federal Bureau of Investigation and the private sector.

Mr. Appelrouth graduated from Florida State University in 1975 and received his Master's Degree in Finance from Florida International University in 1980. The Board has determined Mr. Appelrouth to be an Independent Director as required under Section 803(2) of the NYSE: American Company Guide and Rule 10A-3 under the Exchange Act.

STEWART L. APPELROUTH – Director Qualifications:

- Leadership Experience –has served in leadership positions on numerous Boards and other organizations;

- Industry Experience – Partner at certified public accounting and advisory firm; Certified Public Accountant and Certified Fraud Examiner;

- Regulatory Experience – FINRA Arbitrator.

- Financial Expert – over 40 years of accounting and audit experience.

NANCY K. BRYAN was appointed as a director in March 2023. Ms. Bryan is the President and CEO of BioFlorida. In this role, she leads the development and execution of strategies to strengthen Florida's life sciences industry and advance innovative products and technologies that improve lives. She has 25 years of experience in the life sciences in commercial positions of increasing responsibility involving primary care, biologics and specialty markets. Her experience began with major pharmaceutical companies (MERCK, GlaxoSmithKline) and progressed to executive leadership positions in specialty pharmaceuticals and smaller, start-up biotech companies (Indevus Pharmaceuticals, NPS Pharmaceuticals). She has served on executive leadership teams and played a key role in companies' successes including marketing, sales, business development, financing initiatives and investor and PR communications. Throughout her career, Ms. Bryan has developed, launched and commercialized many products including: blockbusters (Zantac, Levitra), major biologics (Tysabri) and orphan drugs for rare diseases (Valstar for bladder cancer, Supprelin LA for central precocious puberty) and has established franchises in a wide variety of therapeutic areas including: Oncology, Anti-infectives, GI and Autoimmune (MS,CD).

Ms. Bryan earned a BA in Economics from the University of Virginia and an MBA from Columbia University. Academic honors include Phi Beta Kappa and Beta Gamma Sigma.

The Board has determined Ms. Bryan to be an Independent Director as required under Section 803(2) of the NYSE: American Company Guide and Rule 10A-3 under the Exchange Act.

NANCY K. BRYAN – Director Qualifications:

- Leadership Experience – President and CEO of BioFlorida; served on executive leadership teams and played a key role in companies' successes including marketing, sales, business development, financing initiatives and investor and PR communications; and

- Scientific, Legal or Regulatory Experience – 25 years of experience in the life sciences in commercial positions of increasing responsibility involving primary care, biologics and specialty markets; throughout her career, she has developed, launched and commercialized many products, major biologics and orphan drugs for rare diseases and has established franchises in a wide variety of therapeutic areas including: Oncology, Anti-infectives, GI and Autoimmune (MS,CD).

Information about our Executive Officers

In addition to Mr. Equels (discussed above), the following are (or were) our Executive Officers during fiscal 2022:

PETER W. RODINO III was a Director from July 2013 until September 30, 2016, at which time he resigned as a member of our Board to permit him to serve us in a new capacity. Effective October 1, 2016, we retained Mr. Rodino as our Executive Director for Governmental Relations, and as our General Counsel and, as of October 16, 2019, Mr. Rodino assumed the role of Chief Operating Officer. Mr. Rodino has been our Secretary since November 2016. Mr. Rodino has broad legal, financial, and executive experience. In addition to being President of Rodino Consulting LLC and managing partner at several law firms during his many years as a practicing attorney, he served as Chairman and CEO of Crossroads Health Plan, the first major Health Maintenance Organization in New Jersey. He also has had experience as an investment executive in the securities industry and acted as trustee in numerous Chapter 11 complex corporate reorganizations. Previously, as founder and president of Rodino Consulting, Mr. Rodino provided business and government relations consulting services to smaller companies with a focus on helping them develop business plans, implement marketing strategies and acquire investment capital. Mr. Rodino holds a B.S. in Business Administration from Georgetown University and a J.D. degree from Seton Hall University.

ROBERT DICKEY IV, has been our Chief Financial Officer since April 4, 2022. Mr. Dickey has more than 25 years of experience of C-suite financial leadership for life science and medical device companies, both private and public, ranging from preclinical development to commercial operations and across a variety of disease areas and medical technologies. Earlier in his career, Mr. Dickey spent 18 years in investment banking, primarily at Lehman Brothers, with a background split between mergers and acquisitions and capital markets transactions. Mr. Dickey was a senior vice president of the Company from 2008 until 2013. Throughout his career he has demonstrated C-level (CFO, COO and CEO) and Board level experience in public, private, revenue stage and development stage life sciences and medical device companies, and has played a leading role in two start-ups. His prior career as an investment banker included 14 years at Lehman Brothers. Mr. Dickey is experienced in all stages of the business lifecycle, including start-up, high-growth and turnarounds, and in building businesses and achieving an exit. He also has international experience and has expertise in public and private financings, M&A, partnering/licensing transactions, project management and Chapter 11 reorganizations, as well as interacting with Boards, VCs, shareholders and Wall Street. Mr. Dickey has an MBA from The Wharton School and an AB from Princeton University.

DAVID R. STRAYER, M.D., has acted as our Medical Director and Chief Scientific Officer since 1986. He has served as Professor of Medicine at the Medical College of Pennsylvania and Hahnemann University. Dr. Strayer is Board Certified in Medical Oncology and Internal Medicine with research interests in the fields of cancer and immune system disorders. He has served as principal investigator in studies funded by the Leukemia Society of America, the American Cancer Society, and the National Institutes of Health. Dr. Strayer attended the School of Medicine at the University of California at Los Angeles where he received his M.D. in 1972.

Audit Committee and Audit Committee Expert

The Audit Committee of our Board consists of Stewart L. Appelrouth (Chair) and Dr. Mitchell, both determined by the Board to be Independent Directors as required under Section 803(2) of the NYSE: American Company Guide and Rule 10A-3 under the Exchange Act. The Board has determined that Mr. Appelrouth qualifies as an "audit committee financial expert" as that term is defined by Section 803B(2) of the NYSE: American Company Guide and the rules and regulations of the SEC. On March 28, 2023, Ms. Bryan was appointed as an additional member of the Audit Committee.

We believe Dr. Mitchell and Mr. Appelrouth to be independent of management and free of any relationship that would interfere with their exercise of independent judgment as members of this Committee. The principal functions of the Audit Committee are to (1) assist the Board in fulfilling its oversight responsibility relating to the annual independent audit of our consolidated financial statements and management's assessment of internal control over financial reporting, the engagement of the independent registered public accounting firm and the evaluation of the independent registered public accounting firm's qualifications, independence and performance; (2) select the independent registered public accounting firm, oversee the work of the independent registered public accounting firm, pre-approve all auditing services of the independent registered public accounting firm and evaluate the independent registered public accounting firm's qualifications, independence and performance; (3) prepare the reports or statements as may be required by NYSE American or the securities laws; (4) assist the Board in fulfilling its oversight responsibility relating to the integrity of our financial statements and financial reporting process and our system of internal accounting and financial controls; (5) discuss the financial statements and reports with management and the independent registered public accounting firm, including critical accounting policies and practices, our disclosures in our Annual Report and any significant financial reporting that arose in the preparation of the audited financial statements; and (6) oversee the Disclosure Control Committee. The Audit Committee is authorized to engage independent counsel and other advisors as it deems necessary.

This Audit Committee formally met six times in 2022 with all committee members in attendance. Our General Counsel and Chief Financial Officer support the Audit Committee in its work. The full text of the Audit Committee's Charter, as approved by the Board, is available on our website: http://www.aimimmuno.com in the "Investor Relations" tab under "Corporate Governance".

Scientific Advisory Board ("SAB")

The SAB was established to leverage its member's scientific and pharmaceutical expertise and advice to advance our drug development programs by providing guidance on steering us forward and capitalizing on business opportunities as well as interactions with the FDA. It is responsible for: (i) reviewing all submissions made by us to the FDA and other regulators to ensure that the submissions fully, accurately, and timely describe the status of any clinical trials, tests, or other studies or analyses of drug safety and efficacy undertaken by us, and any agreements, protocols, or guidance provided by relevant regulatory agencies; and (ii) monitoring and supervising our relationship with the FDA. The SAB shall have free and open access to our scientific and executive personnel, including the Chief Scientific Officer and the members of our Board of Directors. The SAB is comprised of William Mitchell, M.D., Chairman, and Ronald Brus, M.D., W. Neal Burnette, M.D., Christopher Nicodemus, M.D., and Philip Ransom Roane, Ph.D. all of whom are members. The SAB did not meet in 2022,

Disclosure Controls Committee

The Disclosure Controls Committee ("DCC") reports to the Audit Committee and is responsible for procedures and guidelines on managing disclosure information. The purpose of the DCC is to make certain that information required to be publicly disclosed is properly accumulated, recorded, summarized and communicated to the Board and management. This process is intended to allow for timely decisions regarding communications and disclosures and to help ensure that we comply with related SEC rules and regulations. The DCC is responsible for (1) implementing, monitoring and evaluating our disclosure controls and procedures; (2) reviewing and evaluating our interactions with the FDA and other similar regulatory bodies; and (3) reviewing with the Audit Committee our earnings and other press releases and periodic reports and proxy statements that are to be filed with the SEC. Robert Dickey, our CFO, is the DCC's Investor Relations Coordinator and Chair. The other members of the DCC are Peter Rodino, our COO and General Counsel, William Mitchell, one of our Independent Directors, Dr. David Strayer, Chief Scientific Officer, Diane Young, our Clinical Project Manager, Jodie Pelz, our Director of Finance, and Ann Marie Coverly, Director of HR and Administration serving as the Deputy Investor Relations Coordinator. The full text of the DCC's Charter, as approved by the Board, is available on our website: www.aimimmuno.com in the "Investor Relations" tab under "Corporate Governance." The DCC actively met on numerous occasions in 2021.

The DCC actively met on numerous occasions in 2022.

Executive Committee

In February 2016, our Board formed the Executive Committee. The Executive Committee reports to the Board, and its purpose is to aid the Board in handling matters which, in the opinion of the Chairman of the Board, should not be postponed until the next scheduled meeting of the Board. Mr. Equels, our Chief Executive Officer is the chair of the Committee, and is a member of the Committee along with two of our independent directors, Mr. Appelrouth and Dr. Mitchell. The full text of the Executive Committee Charter, as approved by the Board, is available on our website: www.aimimmuno.com in the "Investor Relations" tab under "Corporate Governance". The Committee did not meet in 2022. On March 28, 2023, Ms. Bryan was appointed as an additional member of this committee.

Corporate Governance and Nomination Committee

The Corporate Governance and Nomination Committee consists of Dr. William M. Mitchell (Chair) and Director, and Mr. Stewart L. Appelrouth, Director. In 2022, the Corporate Governance and Nomination Committee met three times. All committee members were in attendance for the meetings. On March 28, 2023, Ms. Bryan was appointed as an additional member of this committee.

All of the members of the Committee meet the independence standards contained within the NYSE American Company Guide and AIM's Corporate Governance Guidelines. The full text of the Corporate Governance and Nomination Committee Charter as well as the Corporate Governance Guidelines, are available on our website: https://aimimmuno.com/corporate-governance/.

The Corporate Governance and Nomination Committee is responsible for (1) assisting the Board in identifying, recommending, assessing, recruiting and selecting candidates to serve as members of the Board, including in connection with filling vacancies; (2) assisting the Board in developing criteria for identifying and selecting individuals for nomination to the Board; (3) advising the Board with respect to the Board's composition, procedures and committees; (4) reviewing, assessing and recommending appropriate Corporate Governance Guidelines; (5) reviewing the charter of each committee of the Board and recommending to the Board the number, identity and responsibilities of each committee; (6) reviewing our business practices as they relate to preserving our good reputation; (7) developing and recommending to the Board procedures for succession planning for our executives and continuity of the Board; and (8) assessing the effectiveness of the Board in meeting the long-terms interest of the stockholders. The Committee is authorized to retain search firms and other consultants to assist it in identifying candidates and fulfilling its other duties.

Stockholders who wish to suggest qualified candidates should write to the Corporate Secretary, AIM ImmunoTech Inc., 2117 SW Highway 484, Ocala, Florida 34473, stating in detail the qualifications of such persons for consideration by the Committee. Director candidates should demonstrate the qualifications, experience and skills for Board members which are important to AIM's business and its future, as outlined in Proposal 1 below.

We aspire to the highest standards of ethical conduct; reporting results with accuracy and transparency; and maintaining full compliance with the laws, rules and regulations that govern our business. AIM's Corporate Governance Guidelines embody many of our policies and procedures which are at the foundation of our commitment to best practices. The guidelines are reviewed annually and revised if deemed necessary, to continue to reflect best practices.

Code of Ethics

Our Board of Directors adopted a revision to the 2003 Code of Ethics and business conduct for officers, directors, employees, agents and consultants. The principal amendments included broadening the Code's application to our agents and consultants, adoption of a regulatory compliance policy and adoption of a policy for protection and use of Company computer technology for business purposes only. On an annual basis, this Code is reviewed and signed by each Officer, Director, employee and strategic consultant with none of the amendments constituting a waiver of provision of the Code of Ethics on behalf of our Chief Executive Officer, Chief Financial Officer, or persons performing similar functions.

You may obtain a copy of this Code by visiting our website at www.aimimmuno.com (Investor Relations / Corporate Governance) or by written request to our office at 2117 SW Highway 484, Ocala, FL 34473.

ITEM 11. Executive Compensation.

COMPENSATION DISCUSSION AND ANALYSIS

This discussion and analysis describes our executive compensation philosophy, process, plans and practices as they relate to our "Named Executive Officers" ("NEO") listed below and gives the context for understanding and evaluating the more specific compensation information contained in the narratives, tables and related disclosures that follow. For the purposes of discussion and analysis, the following NEOs are included in the narratives, tables and related disclosures that follow:

- Thomas K. Equels, Chief Executive Officer ("CEO") and President;
- Robert Dickey IV, Chief Financial Officer ("CFO"); and
- Peter Rodino, Chief Operating Officer ("COO"), General Counsel and Company Secretary ("CS").

In November 2020, we entered into an employment agreement with Thomas Equels, the agreement runs for five years with a base salary of $850,000. Mr. Equels will be awarded a year end target bonus of $350,000. In March 2021, subsequent to the fiscal year ended December 31, 2020, we entered into employment agreements with Peter Rodino. The agreement runs for three years, respectively. Compensation is divided into both short- and long-term compensation. Short term (cash) compensation will consist of a base salary of $425,000. Mr. Rodino will be awarded a year-end target bonus based on performance and goals established by the Compensation Committee. Long term compensation will be provided by 100,000 non-qualified yearly stock options with one-year vesting commencing on November 30, 2021. In addition, Mr. Equels and Mr. Rodino will be be entitled to awards ("Event Awards") equal to 3% for Mr. Equels and 1% for Mr. Rodino of the "Gross Proceeds" from specific events such as Acquisitions, licensing agreements or "therapeutic indication" (each, an "Event"). Gross Proceeds means those cash amounts paid to us by the other parties for licensing agreements, therapeutic acquisitions or any other one time cash generating event. Therapeutic indications are for example target organ specific pathologically defined cancer indications, vaccine enhancers, broad spectrum antiviral indications, or medical entities associated with persistent severe fatigue. Mr. Equels and Mr. Rodino also will each be entitled to an award (an "Acquisition Award") equal to 3% for Mr. Equels and 1% for Mr. Rodino of the Gross Proceeds, upon the sale of our Company or substantially all of its assets (an "Acquisition"). An Event Award or Acquisition Award shall be paid in cash within 90 days of our receipt of the Gross Proceeds. On March 2022, the Company entered into a consulting agreement with Foresite Advisors, LLC, a company wholly-owned by Robert Dickey IV, for $375 an hour pursuant to which Mr. Dickey will serve as our new Chief Financial Officer effective April 4, 2022.

Governance of Compensation Committee

The Compensation Committee consists of the following two directors, each of whom is "independent" under applicable NYSE American rules, a "Non-Employee Director" as defined in Rule 16b-3 under the Exchange Act, and an "Outside Director" as defined under the U.S. Treasury regulations promulgated under Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"): William Mitchell, M.D., Ph.D. (Chair) and Stewart L. Appelrouth. On March 28, 2023, Ms. Bryan was appointed as an additional member of this committee.

The Compensation Committee oversees implementation and administration of our compensation and employee benefits programs with the goal of attracting, retaining and motivating executives and officers, as well as other employees, to improve their performance and our financial performance. In that regard, the Compensation Committee (1) reviews and approves corporate goals and objectives relevant to compensation; (2) evaluates the performance and compensation of our officers and executives and reviews the compensation of all other non-officer executives that are considered highly paid; (3) reviews and approves employment agreements, severance agreements, change of control agreements, deferred compensation agreements, perquisites and similar compensation arrangements of our executive officers; (4) makes recommendations to the Board on the compensation of non-employee members of the Board; (5) administers our incentive and equity-based compensation plans, including, approving the grant of equity awards under such plans, reviewing such plans and making recommendations to the Board regarding the adoption, amendment or termination of such plans; (6) selects and determines the fees and scope of work of its compensation consultants; and (7) reviews our compensation strategy to assure that it continues to advance our objectives and promote stockholder value. The full text of the Compensation Committee's Charter, as approved by the Board, is available on our website: www.aimimmuno.com in the "Investor Relations" tab under "Corporate Governance".

This Committee formally met four times in 2022 and all committee members were in attendance for the meetings. Our General Counsel, Chief Financial Officer and Director of Human Resources support the Compensation Committee in its work.

Results of Stockholder Advisory Vote on Executive Compensation

At the November 2022 Annual Meeting of Stockholders, the Stockholders did not approve the annual, non-binding advisory vote on Executive Compensation.

Objectives and Philosophy of Executive Compensation

The primary objectives of the Compensation Committee of our Board of Directors with respect to Executive compensation are to attract and retain the most talented and dedicated Executives possible, to tie annual and long-term cash and stock incentives to achievement of measurable performance objectives, and to align Executives' incentives with stockholder value creation. To achieve these objectives, the Compensation Committee expects to implement and maintain compensation plans that tie a substantial portion of Executives' overall compensation to key strategic financial and operational goals such as the establishment and maintenance of key strategic relationships, the development of our products, the identification and advancement of additional products and the performance of our common stock price. The Compensation Committee evaluates individual Executive performance with the goal of setting compensation at levels the Committee believes are comparable with Executives in other companies of similar size and stage of development operating in the biotechnology industry while taking into account our relative performance, our own strategic goals, governmental regulations and the results of Stockholder Advisory Votes regarding executive compensation.

EXECUTIVE COMPENSATION

The following table provides information on the compensation during the fiscal years ended December 31, 2022 and 2021 of Thomas Equels, our Chief Executive Officer, Peter Rodino our Chief Operating Officer, General Counsel and Secretary, Robert Dickey IV our Chief Financial Officer and Ellen Lintal, our former Chief Financial Officer.

Summary Compensation Table

Name & Principal Position	Year	Salary / Fees $ (2)	Bonus $	Stock Awards $	Option Awards $ (1)	Non-Equity Incentive Plan Compensation $	Change in Pension Valued and NQDC Earnings $	All Other Compensation $	Total $ (1)
Thomas K Equels	2022	850,000	300,000	—	111,556	—	—	90,472	1,352,028
CEO & President (2)3	2021	850,000	352,500	—	473,038	—	—	86,106	1,761,644
Ellen Lintal	2022	90,417	—	—	32,110	—	—	18,699	141,226
Former CFO (4)(7)	2021	350,000	102,500	—	132,346	—	—	49,893	634,739
Robert Dickey IV	2022	37,815	$ 10,000	—	—	—	—	—	47,815
CFO (5)	2021	—	—	—	—	—	—	—	—
Peter Rodino									
COO, General Counsel	2022	425,000	150,000	—	69,295	—	—	55,003	699,298
& Secretary (6)	2021	425,000	102,500	—	132,346	—	—	57,949	717,795

Notes:

(1) All option awards were valued using the Black-Scholes method.

(2) For Named Executive Officers, who are also Directors that receive compensation for their services as a Director, the Salary/Fees and Option Awards columns include compensation that was received by them for their role as a member of the Board of Directors. As is required by Regulation S-K, Item 402(c), compensation for services as a Director have been reported within the "Summary Compensation Table" (above) for fiscal years of 2022 and 2021 as well as reported separately in the "Compensation of Directors" section (see below) for calendar year 2022.

Pursuant to his current employment agreement, Mr. Equels is entitled to 3% of the "Gross Proceeds" (as defined in the employment agreement) for "significant events" (as described in the employment agreement) There were no payments during 2022 and 2021.

(3) Mr. Equels' All Other Compensations consists of:

	2022	2021
Life & Disability Insurance	$ 31,375	$ 22,037
Healthcare Insurance	26,764	26,479
Car Expenses/Allowance	18,000	18,000
401(k) Matching Funds	14,333	19,500
Total	$ 90,472	$ 86,016

(4) Ms. Lintal's All Other Compensations consists of:

	2022	2021
Life & Disability Insurance	$ 803	$ 3,014
Healthcare Insurance	12,146	12,978
Car Expenses/Allowance	3,600	14,400
401(k) Matching Funds	2,150	19,500
Total	$ 18,699	$ 49,892

(5) Mr. Dickey's All Other Compensations consists of:

	2022	2021
Life & Disability Insurance	$ —	$ —
Healthcare Insurance	—	—
Car Expenses/Allowance	—	—
401(k) Matching Funds	—	—
Total	$ —	$ —

(6) Mr. Rodino's All Other Compensations consists of:

	2022	2021
Life & Disability Insurance	$ 2,450	$ 2,521
Healthcare Insurance	23,820	21,528
Car Expenses/Allowance	14,400	14,400
401(k) Matching Funds	14,333	19,500
Total	$ 55,003	$ 57,949

(7) On April 4, 2022, the Company entered into a consulting agreement with Ms. Lintal, who stepped down as the Company's Chief Financial Officer on April 4, 2022.

Outstanding Equity Awards at Fiscal Year End	**Option Awards**					**Stock Awards**			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Options Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested (#)	Market Value of Shares or Units of Stock that Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights that Have Not Vested ($)
Thomas K Equels	568	—	—	163.68	6/6/2023	—	—	—	—
President and Chief	284	—	—	132.00	8/2/2023	—	—	—	—
Executive Officer	568	—	—	190.08	6/6/2024	—	—	—	—
	568	—	—	132.00	6/8/2025	—	—	—	—
	568	—	—	73.92	6/8/2026	—	—	—	—
	6,818	—	—	24.64	6/8/2027	—	—	—	—
	323	—	—	21.56	6/15/2027	—	—	—	—
	323	—	—	21.56	6/30/2027	—	—	—	—
	412	—	—	21.12	7/15/2027	—	—	—	—
	472	—	—	18.48	7/31/2027	—	—	—	—
	485	—	—	18.04	8/15/2027	—	—	—	—
	556	—	—	15.84	8/31/2027	—	—	—	—
	8,446	—	—	16.28	2/13/2028	—	—	—	—
	2,841	—	—	16.72	4/12/2028	—	—	—	—
	6,818	—	—	13.20	5/16/2028	—	—	—	—
	5,682	—	—	13.20	5/16/2028	—	—	—	—
	3,666	—	—	13.64	7/18/2028	—	—	—	—
	6,457	—	—	9.68	10/17/2028	—	—	—	—
	23	—	—	9.68	11/14/2028	—	—	—	—
	9,685	—	—	9.68	1/28/2029	—	—	—	—
	300,000	—	—	3.05	8/12/2030	—	—	—	—
	300,000	—	—	1.96	11/11/2030	—	—	—	—
	—	300,000		1.71	11/11/2031	—	—	—	—
Total	955,563	300,000	—			—	—	—	—
Ellen Lintal	23	—	—	9.68	11/14/2029	—	—	—	—
Former Chief Financial Officer	75,000	75,000	—	1.85	12/9/2030	—	—	—	—
	100,000	—		1.44	11/30/2031	—	—	—	—
	50,000	—	—	0.70	3/3/2023	—	—	—	—
	—	50,000	—			—	—	—	—
Total	225,023	50,000	—			—	—	—	—
Robert Dickey IV	50,000	—	—	0.70	03/03/2032	—	—	—	—

Chief financial Officer									
Total	50,000	—	—			—	—	—	—
Peter Rodino	285	—	—	132.00	8/2/2023	—	—	—	—
COO, General Counsel and Secretary	285	—	—	68.65	6/21/2026	—	—	—	—
	151	—	—	21.56	6/15/2027	—	—	—	—
	151	—	—	21.56	6/30/2027	—	—	—	—
	192	—	—	21.12	7/15/2027	—	—	—	—
	220	—	—	18.48	7/31/2027	—	—	—	—
	226	—	—	18.04	8/15/2027	—	—	—	—
	259	—	—	15.84	8/31/2027	—	—	—	—
	3,941	—	—	16.28	2/13/2028	—	—	—	—
	2,273	—	—	16.72	4/12/2028	—	—	—	—
	2,652	—	—	13.20	5/16/2028	—	—	—	—
	1,711	—	—	13.64	7/18/2028	—	—	—	—
	3,013	—	—	9.68	10/17/2028	—	—	—	—
	23	—	—	9.68	11/14/2028	—	—	—	—
	4,520	—	—	9.68	1/28/2029	—	—	—	—
	75,000	—	—	1.85	12/9/2030	—	—	—	—
	100,000	—	—	1.44	11/30/2031	—	—	—	—
	50,000	—	—	0.70	03/03/2032	—	—	—	—
	—	100,000		0.41	11/30/2032	—	—	—	—
Total	244,902	100,000	—			—	—	—	—

Payments on Disability

As of December 31, 2020, we had an employment agreement with Mr. Equels which entitled him to his base salary, applicable benefits otherwise due and payable through the last day of the month in which disability occurs and for an additional two year period. All of his unvested options vest too. On March 24, 2021, we entered into employment agreements with Mr. Rodino and Ms. Lintal which entitled them to their base salary, applicable benefits otherwise due and payable through the last day of the month in which disability occurs and for an additional two year period. All of each NEO's unvested options vest too. In addition, each NEO has the same short and long-term disability coverage which is available to all eligible employees. The coverage for short-term disability provides up to six months of full salary continuation up to 60% of weekly pay, less other income, with a $1,500 weekly maximum limit. The coverage for group long-term disability provides coverage at the exhaustion of short-term disability benefits of full salary continuation up to 60% of monthly pay, less other income, with a $10,000 monthly maximum limit. The maximum benefit period for the group long-term disability coverage is 60 months for those age 60 and younger at the time of the claim with the coverage period proportionately reduced with the advanced age of the eligible employee to a minimum coverage period of 12 months for those of 69 years old and older as of the date of the claim. For the period June 2010 through December 2022, Mr. Equels was entitled to receive total disability coverage of $400,000 pursuant to his employment agreement and payable by us.

Payments on Death

Pursuant to their employment agreements, the NEOS are entitled to their base salary and applicable benefits otherwise due and payable through the last day of the month in which death occurs and for an additional two year period. In addition, all of their unvested options vest. Each NEO, has coverage of group life insurance, along with accidental death and dismemberment benefits, consistent to the dollar value available to all eligible employees. The benefit is equal to two times current salary or wage with a maximum limit of $300,000, plus any supplemental life insurance elected and paid for by the NEO. For the period June 2010 and through December 2022, Mr. Equels is entitled to receive total death benefit coverage of $3,000,000 pursuant to his employment agreement and payable by us.

Estimated Payments Following Severance — Named Executive Officers (NEO)

Pursuant to his employment agreement, Mr. Equels is entitled to severance benefits on certain types of employment terminations not related to a change in control or termination not for cause. Mr. Rodino and Mr. Dickey are not covered by an employment severance agreement and therefore would only receive severance as determined by the Compensation Committee in its discretion.

The dollar amounts below assume that the termination occurred on January 1, 2023. The actual dollar amounts to be paid can only be determined at the time of the NEO's separation from us based on their prevailing compensation and employment agreements along with any determination by the Compensation Committee in its discretion.

Name	Event	Cash Severance ($)	Value of Stock Awards That Will Become Vested (1) ($)	Continuation of Medical Benefits ($)	Additional Life Insurance ($)	Total ($)
Thomas K. Equels,	Involuntary (no cause)	$ 3,654,000	$ 111,556	—	—	$ 3,765,556
CEO & President	Termination (for cause)	—	—	—	—	—
	Death or disability	$ 868,000	$ 111,556	—	—	$ 979,556
	Termination by employee or retirement	—	$ 111,556	—	—	$ 111,556
Robert Dickey IV	Involuntary (no cause)	—	—	—	—	—
CFO	Termination (for cause)	—	—	—	—	—
	Death or disability	—	—	—	—	—
	Termination by employee or retirement	—	—	—	—	—
Peter Rodino	Involuntary (no cause)	$ 647,280	$ 69,295	—	—	$ 716,575
COO, General Counsel and	Termination (for cause)	—	—	—	—	—
Secretary	Death or disability	$ 439,400	$ 69,295	—	—	$ 508,695
	Termination by employee or retirement	—	$ 69,295	—	—	$ 69,295

Notes:

(1) Consists of stock options contractually required per the employee's respective employment agreement or arrangement to be granted during each calendar year of the term under our 2018 Equity Incentive Plan. The stock options have a ten-year term and an exercise price equal to the closing market price of our common stock on the date of grant. The value was obtained using the Black-Scholes-Merton pricing model for stock-based compensation in accordance with FASB ASC 718.

Payments on Termination in Connection with a Change in Control of Named Executive Officers

Pursuant to their employment agreements, each NEO is entitled to severance benefits on certain types of employment terminations related to a change in control. In such event, the term of their employment agreements would automatically be extended for three additional years, except where such change in control occurs as a result of certain "significant events" (as described in his or her employment agreement).

The dollar amounts in the chart below assume that change in control termination occurred on January 1, 2023, based on the employment agreements that existed at that time. The actual dollar amounts to be paid can only be determined at the time of the NEO's separation from us based on their prevailing compensation and employment agreements along with any determination by the Compensation Committee in its discretion.

Estimated Benefits on Termination Following a Change in Control — December 31, 2022

The following table shows potential payments to the NEO if employment terminates following a change in control under contracts, agreements, plans or arrangements at December 31, 2022. The amounts assume a January 3, 2023, termination date regarding base pay and use of the opening price of $0.32 on the NYSE American for our common stock at that date.

Name	Aggregate Severance Pay ($)	PVSU Acceleration (2) ($)	Early Vesting of Restricted Stock (4) (5) ($)	Early Vesting of Stock Options and SARs (3) ($)	Acceleration and Vesting of Supplemental Award (5) ($)	Welfare Benefits Continuation ($)	Outplacement Assistance ($)	Parachute Tax Gross-up Payment ($)	Total ($)
Thomas K. Equels	$5,208,000(1)	—	—	—	$ 576,000(4)	—	—	—	$5,784,000
Robert Dickey IV	—	—	—	—	—	—	—	—	—
Peter Rodino	—	—	—	—	—	—	—	—	—

Notes:

(1) This amount represents the Base Salary and benefits for the remaining current term of the NEO's employment agreement plus a three-year extension in the term upon the occurrence of a termination from a change in control. The employment agreement with Mr. Equels has a term through December 31, 2025. This amount excludes the following payments as they cannot be calculated unless and until certain events occur: Mr. Equels is entitled to 3% of the "Gross Proceeds" (as defined in the employment agreement) for "significant events" (as described in his employment agreement) and 3% of the Gross Proceeds from any sale of our Company or substantially all of our assets.

(2) This amount represents the payout of all outstanding performance-vesting share units ("PVSU") awarded on a change in control at the target payout level with each award then pro-rated based on the time elapsed for the applicable three-year performance period.

(3) This amount is the intrinsic value [fair market value] on January 3, 2023 ($0.32 per share) minus the weighted average per share exercise price of $0.43 of all unvested stock options for each NEO, including Stock Appreciation Rights ("SAR"). Any option with an exercise price of greater than fair market value was assumed to be cancelled for no consideration and, therefore, had no intrinsic value.

(4) This amount represents the options to be issued annually for the remaining term of the NEO's employment agreement plus a three-year extension in the occurrence of termination from a change in control. For the purpose of this schedule, a NYSE American closing price at January 3, 2023 of $0.32 was used with an estimated exercise price of $0.32 for Mr. Equels. The value was obtained using the Black-Scholes-Merton pricing model for stock-based compensation in accordance with FASB ASC 718.

(5) Any purchase rights represented by the Option not then vested shall, upon a change in control, shall become vested.

Post-Employment Compensation

The following is a description of post-employment compensation payable to the respective NEO. If a NEO does not have a specific benefit, they will not be mentioned in the subsection. In such event, the NEO does not have any such benefits upon termination unless otherwise required by law.

Termination for Cause

All of our NEOs can be terminated for cause. For each NEO "Cause" means willful engaging by any NEO in illegal conduct, gross misconduct or gross violation of our Code of Ethics and Business Conduct for Officers, which is demonstrably and materially injurious to our Company. Mr. Equels' agreement provides that he shall not be deemed to have been terminated for Cause unless and until we initiate a process by delivery to him a copy of a resolution duly adopted by the affirmative vote of not less than a majority of the directors of the Board specifying the grounds for termination. After reasonable notice to Mr. Equels and an opportunity for him to be heard, the issues shall be adjudicated by a retired Florida judge or a Florida certified mediator mutually acceptable to the Board of Directors and Mr. Equels. Termination requires a finding that Mr. Equels was guilty of intentional and material misconduct according to the standards set forth above, and specifying the particulars thereof in detail supported by legally admissible evidence and utilizing the legal standard of beyond reasonable doubt. In the event that an NEO's employment is terminated for Cause, we shall pay such NEO, at the time of such termination, only the compensation and benefits otherwise due and payable to him or her through the last day of his actual employment by us.

Termination without Cause

In the event that an NEO is terminated at any time without "Cause", we shall pay to him or her, at the time of such termination, the compensation and benefits otherwise due and payable through the last day of the then current term of his or her Agreement. However, benefit distributions that are made due to a "separation from service" occurring while he or she is a Named Executive Officer shall not be made during the first six months following separation from service. Rather, any distribution which would otherwise be paid to him or her during such period shall be accumulated and paid to him or her in a lump sum on the first day of the seventh month following the "separation from service". All subsequent distributions shall be paid in the manner specified.

Death or Disability

An NEO can be terminated for death or disability. "Disability" means the NEO's inability effectively to carry out substantially all of his or her duties by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months. In the event his or her employment is terminated due to his or her death or disability, we will pay him or her (or their estate as the case may be), at the time of such termination, his or her base salary, applicable benefits, and immediate vesting of unvested stock options. In the event of permanent disability, we will provide an additional two years of base salary.

Compensation of Directors

Our Compensation, Audit and Corporate Governance and Nomination Committees, consist of Dr. William M. Mitchell, Compensation and Corporate Governance and Nomination Committee Chair, and Stewart L. Appelrouth, Audit Committee Chair, both of whom are independent Board of Director members.

We reimburse Directors for travel expenses incurred in connection with attending board, committee, stockholder and special meetings along with other Company business-related expenses. We do not provide retirement benefits or other perquisites to non-employee Directors under any current program.

There was no cost of living increase granted in 2021 or 2022.

All Directors have been granted options to purchase common stock under our Stock Option Plans and/or Warrants to purchase common stock. We believe such compensation and payments are necessary in order for us to attract and retain qualified outside directors. Options shares for stock compensation were issued under the 2009 and 2018 Equity Incentive Plans.

Director Compensation – 2022 & 2021

Name and Title of Director	Year	Fees Earned or Paid in Cash $	Stock Award $	Option Award $	Non-Equity Incentive Plan Compensation $	Change in Pension Value & Nonqualified Deferred Compensation Earnings $	All Other Compensation As Director $	Total $
T. Equels	2022	—	—	—	—	—	—	—
Executive Vice Chairman	2021	—	—	—	—	—	—	—
W. Mitchell	2022	182,462	—	50,703	—	—	—	233,165
Chairman of the Board	2021	182,462	—	78,673	—	—	—	261,135
S. Appelrouth	2022	182,462	—	50,703	—	—	—	233,165
Director	2021	182,462	—	78,673	—	—	—	261,135

In March 2023, the Board reduced annual cash compensation from $182,462 to $125,000 to make room for more Board members.

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

The following table sets forth as of March 25, 2023, the number and percentage of outstanding shares of Common Stock beneficially owned by:

- Each person, individually or as a group, known to us to be deemed the beneficial owners of five percent or more of our issued and outstanding Common Stock;
- Each of our Directors and the Named Executives Officers; and
- All of our officers and directors as a group.
- Total number of shares of Common Stock at March 24, 2023 was ~48,407,326.

Name and Address of Beneficial Owner	Shares Beneficially Owned	% Of Shares Beneficially Owned
Thomas K. Equels, Executive Vice Chairman, Chief Executive Officer, President*	1,499,558(1)	**0.03%
Peter W. Rodino III, Chief Operating Officer, General Counsel, Secretary*	388,741(2)	**%
William M. Mitchell, M.D., Chairman of the Board of Directors*	256,286(3)	**%
Stewart L. Appelrouth, Director*	238,454(4)	**%
Robert Dickey IV, Chief Financial Officer*	50,000(5)	**%
All directors and executive officers as a group (5 persons)	2,433,039	0. 05%

** Less than 1%

(1) For Mr. Equels, shares beneficially owned include 955,563 shares issuable upon exercise of options and excludes 300,000 shares issuable upon exercise of options not vested or not exercisable within the next 60 days.

(2) For Mr. Rodino, shares beneficially owned include 244,902 shares issuable upon exercise of options and excludes 100,000 shares issuable upon exercise of options not vested or not exercisable within the next 60 days.

(3) For Dr. Mitchell, shares beneficially owned include 179,874 shares issuable upon exercise of options and excludes 50,000 shares issuable upon exercise of options not vested or not exercisable within the next 60 days. Also includes 190 shares of common stock owned by his spouse and 190 shares owned by family trusts.

(4) For Mr. Appelrouth, shares beneficially owned include 89,599 shares issuable upon exercise of options and excludes 50,000 shares issuable upon exercise of options not vested or not exercisable within the next 60 days.

(5) For Mr. Dickey IV, shares beneficially owned include 50,000 shares issuable upon exercise of options.

The following table gives information about our Common Stock that may be issued upon the exercise of options, warrants and rights under all of our equity compensation plans as of December 31, 2021:

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted Average Exercise Price Per Share	Number of securities Remaining available for future issuance under equity compensation plans (excluding securities reflected in column) (a) (c)
Equity compensation plans approved by security holders:	2,599,370	$ 4.03	466,120
Equity compensation plans not approved by security holders:	288,077	$ 9.10	—
Total	2,887,447	$ 4.54	466,120

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

Review, Approval or Ratification of Transactions with Related Persons

Our policy is to require that any transaction with a related party required to be reported under applicable SEC rules, other than compensation related matters and waivers of our code of business conduct and ethics, be reviewed and approved or ratified by a majority of independent, disinterested Directors. We have adopted procedures in which the Audit Committee shall conduct an appropriate review of all related party transactions for potential conflict of interest situations on an annual and case-by-case basis with the approval of this Committee required for all such transactions.

We have employment agreements with certain of our executive officers and have granted such Officers and Directors options and warrants to purchase our Common Stock, as discussed under the headings, Item 11. "Executive Compensation", and Item 12. "Security Ownership of Certain Beneficial Owners and Management", as noted above.

ITEM 14. Principal Accountant Fees and Services.

All audit and professional services are approved in advance by the Audit Committee to assure such services do not impair the auditor's independence from us. The total fees by BDO USA, LLP ("BDO") for 2022 were $517,000 and total 2021 were $485,000.

	Amount ($)	
	2022	2021
Description of Fees:		
Audit Fees	$ 503,000	$ 370,000
Audit-Related Fees	-	42,000
Tax Fees	14,000	73,000
Total	$ 517,000	$ 485,000

Audit Fees

Audit fees include the audit of our annual financial statements and the review of our financial statements included in our quarterly reports and services in connection with statutory and regulatory filings.

Audit-Related Fees

Represents the fees for assurance and related services that were reasonably related to the performance of the audit or review of our financial statements. Audit-related fees include professional services related to the Company's filing of SEC Form S-3 and S-8 (i.e., stock shelf offering procedures).

The Audit Committee has determined that BDO's rendering of these audit-related services and all other fees were compatible with maintaining auditor's independence. The Board of Directors considered BDO to be well qualified to serve as our independent public accountants. The Committee also pre-approved the charges for services performed in 2022 and 2021.

The Audit Committee pre-approves all auditing and accounting services and the terms thereof (which may include providing comfort letters in connection with securities underwriting) and non-audit services (other than non-audit services prohibited under Section 10A(g) of the Exchange Act or the applicable rules of the SEC or the Public Company Accounting Oversight Board) to be provided to us by the independent auditor; provided, however, the pre-approval requirement is waived with respect to the provisions of non-audit services for us if the "de minimus" provisions of Section 10A (i)(1)(B) of the Exchange Act are satisfied. This authority to pre-approve non-audit services may be delegated to one or more members of the Audit Committee, who shall present all decisions to pre-approve an activity to the full Audit Committee at its first meeting following such decision.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules.

Financial Statements and Schedules - See index to financial statements on page F-1 of this Annual Report. All other schedules called for under regulation S-X are not submitted because they are not applicable or not required, or because the required information is included in the financial statements or notes thereto.

(i) Exhibits - See exhibit index below.

Exhibit No.	Description
3.1(i)	Amended and Restated Certificate of Incorporation of the Company, as amended, along with Certificates of Designations (incorporated by reference to exhibits of the Company's Registration Statement on Form S-1 (No. 33-93314) filed November 2, 1995).
3.2(i)	Amendment to Certificate of Incorporation (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A (No. 001-13441) filed September 16, 2011).
3.3(i)	Amendment to Certificate of Incorporation(incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A (No. 000-27072) filed June 27, 2016).
3.4(i)	Amendment to Certificate of Incorporation(incorporated by reference to exhibit 3.11 to the Company's Current report on Form 8-K (No. 001-27072) filed June 5, 2019).
3.5(i)	Amendment to Certificate of Incorporation (incorporated by reference to exhibit 3.11 to the Company's Current report on Form 8-K (No. 001-27072) filed August 23, 2019).
3.6(i)	Certificate of Designation of Preference, Rights and Limitations of Series B Convertible Preferred Stock (incorporated by reference to exhibit 3.5 to the Amendment to the Company's Registration Statement on Form S-1/A (No. 333-229051) filed February 6, 2019).
3.7(ii)	Amended and Restated By-Laws of Registrant.*
4.1	Specimen certificate representing our Common Stock (incorporated by reference to exhibits of the Company's Registration Statement on Form S-1 (No. 33-93314) filed November 2, 1995).
4.2	Amended and Restated Rights Agreement, dated as of November 14, 2017, between the Company and American Stock Transfer & Trust Company LLC. The Amended and Restated Right Agreement includes the Form of Certificate of Designation, Preferences and Rights of the Series A Junior Participating Preferred Stock, the Form of Rights Certificate and the Summary of the Right to Purchase Preferred Stock (incorporated by reference to exhibit 1 to the Company's Registration Statement on Form 8-A12B (No. 001-27072) filed November 14, 2017).
4.3	Amended and Restated Rights Agreement, dated as of November 9, 2022, between the Company and American Stock Transfer & Trust Company LLC. (incorporated by reference to exhibit 4.4 to the Company's Registration Statement on Form 8-A12B (No. 001-27072) filed November 14 2022)
4.4	Amended and Restated Rights Agreement, dated as of February 9, 2023, between the Company and American Stock Transfer & Trust Company LLC. (incorporated by reference to exhibit 1 to the Company's Registration Statement on Form 8-A12B (No. 001-27072) filed February 10, 2023)
4.5	Form of Indenture filed with Form S-3 Universal Shelf Registration Statement (incorporated by reference to exhibit 4.4 to the Company's Form S-3 Registration Statement (No. 333- 262280) filed January 21, 2022).
4.6	Form of Warrant pursuant to August 30, 2016 Securities Purchase Agreement (incorporated by reference to exhibit 4.1 to the Company's Current report on Form 8-K (No. 000-270720 filed September 1, 2016).

4.7	Form of Warrant pursuant to February 1, 2017 Securities Purchase Agreement (incorporated by reference to exhibit 4.1 to the Company's Current report on Form 8-K (No. 000-27072) filed February 3, 2017).
4.8	Form of Series A Warrant-June 2017 (incorporated by reference to exhibit 4.1 to the Company's Current report on Form 8-K (No. 000-27072) filed June 1, 2017).
4.9	Form of Series B Warrant-June 2017(incorporated by reference to exhibit 4.2 to the Company's Current report on Form 8-K (No. 000-27072) filed June 1, 2017).
4.10	Form of New Series A Warrant-August 2017 (incorporated by reference to exhibit 4.1 the Company's Current report on Form 8-K (No. 000-27072) filed August 23, 2017).
4.11	Form of New Series B Warrant-August 2017 (incorporated by reference to exhibit 4.2 the Company's Current report on Form 8-K (No. 000-27072) filed August 23, 2017).
4.12	Form of Warrant issued to Purchaser of facility (incorporated by reference to exhibit 4.8 to the Company's Annual report on Form 10-K (No. 000-27072) for the year ended December 31, 2017).
4.13	Form of Class A Warrant- April 2018 (incorporated by reference to exhibit 4.1 to the Company's Current report on Form 8-K (No. 001-27072) filed April 20, 2018).
4.14	Form of Class B Warrant- April 2018 (incorporated by reference to exhibit 4.2 to the Company's Current report on Form 8-K (No. 001-27072) filed April 20, 2018).
4.15	September 28, 2018 Secured Convertible Promissory Note from the Company to Iliad Research and Trading, L.P. (incorporated by reference to exhibit 10.2 to the Company's Current report on Form 8-K (No. 001-27072) filed October 4, 2018).
4.16	Rights Offering Form of Non-Transferable Subscription Rights Certificate (incorporated by reference to exhibit 4.14 to the Company's Registration Statement on Form S-1/A (No. 333-229051) filed February 6, 2019).
4.17	Rights Offering Form of Warrant Agreement (incorporated by reference to exhibit 4.1 to the Company's Current report on Form 8-K filed February 27, 2019 and is hereby incorporated by reference).
4.18	Rights Offering Form of Warrant Certificate (incorporated by reference to exhibit 4.15 to the Company's Registration Statement on Form S-1/A (No. 333-229051) filed February 6, 2019).
4.19	Rights Offering Warrant Agency Agreement with American Stock Transfer & Trust (incorporated by reference to exhibit 4.1 to the Company's Current report on Form 8-K (No.001-27072) filed March 8, 2019).
4.20	AGP Offering-Form of Pre-Funded Warrant (incorporated by reference to exhibit 4.1 to the Company's Current report on Form 8-K (No. 001-27072) filed September 27, 2019).
4.21	AGP Offering-Form of Warrant (incorporated by reference to exhibit 4.2 to the Company's Current report on Form 8-K (No. 001-27072) filed September 27, 2019).
4.22	AGP Offering-Form of Representative's Warrant (incorporated by reference to exhibit 4.20 to the Company's Registration Statement on Form S-1/A (No. 333-233657) filed September 24, 2019).
4.23	March 2019 Amendment to September 28, 2018 Secured Convertible Promissory Note from the Company to Iliad Research and Trading, L.P. (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No. 001-27072) filed March 15, 2019).
4.24	December 5, 2019 Secured Promissory Note with Atlas Sciences, LLC (incorporated by reference to exhibit 10.2 to the Company's Current report on Form 8-K (No.001-27072) filed December 11, 2019).
4.25	Description of Common Stock.*
10.1	Form of Confidentiality, Invention and Non-Compete Agreement (incorporated by reference to exhibits of the Company's Registration Statement on Form S-1 (No. 33-93314) filed November 2, 1995).

10.2	Form of Clinical Research Agreement (incorporated by reference to exhibits of the Company's Registration Statement on Form S-1 (No. 33-93314) filed November 2, 1995.
10.3	Supply Agreement with HollisterStier Laboratories LLC dated December 5, 2005 (incorporated by reference to exhibit 10.46 to the Company's Annual report on Form 10-K (No. 001-13441) for the year ended December 31, 2005).
10.4	Amendment to Supply Agreement with HollisterStier Laboratories LLC dated February 25, 2010 (incorporated by reference to exhibit 10.68 to the Company's Annual report on Form 10-K (No. 001-13441) for the year ended December 31, 2009).
10.5	Vendor Agreement with Armada Healthcare, LLC dated August 15, 2011 (incorporated by reference exhibit 10.2 to the Company's Quarterly report on Form 10-Q (No. 001-131) for the period ended September 30, 2011).
10.6	Amendment to Supply Agreement with HollisterStier Laboratories LLC executed September 9, 2011 (incorporated by reference to exhibit 10.22 to the Company's Annual report on Form 10-K (No. 001-13441) for the year ended December 31, 2011).
10.7	Vendor Agreement extension with Armada Healthcare, LLC dated August 14, 2012 (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No. 000-27072) filed August 15, 2012).
10.8	Vendor Agreement extension with Armada Healthcare, LLC dated July 19, 2013 (incorporated by reference to exhibit 10.22 to the Company's Annual report on Form 10-K (No. 000-27072) for the year ended December 31, 2013).
10.9	Vendor Agreement extension with Bio Ridge Pharma, LLC and Armada Healthcare, LLC dated August 8, 2014. (incorporated by reference to exhibit 10.24 to the Company's Annual report on Form 10-K (No. 000-27072) for the year ended December 31, 2014).
10.10	Sales, Marketing, Distribution, and Supply Agreement with Emerge Health Pty Ltd. dated March 9, 2015. (Confidential Treatment granted with respect to portions of the Agreement) (incorporated by reference to exhibit 10.25 to the Company's Annual report on Form 10-K (No. 000-27072) for the year ended December 31, 2014).
10.11	Vendor Agreement extension with Armada Healthcare, LLC dated July 29, 2015 (incorporated by reference to exhibit 10.1 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended June 30, 2015).
10.12	Early Access Agreement with Impatients N.V. dated August 3, 2015.(Confidential Treatment granted with respect to portions of the Agreement) (incorporated by reference to exhibit 10.1 to the Company's Quarterly report on Form 10-Q (No. 001-13441) for the period ended September 30, 2015).
10.13	Sales, Marketing, Distribution, and Supply Agreement with Emerge Health Pty Ltd. dated August 6, 2015. (Confidential Treatment granted with respect to portions of the Agreement) (incorporated by reference to exhibit 10.4 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended June 30, 2015).
10.14	Addendum to Early Access Agreement with Impatients N.V. dated October 16, 2015. (Confidential Treatment granted with respect to portions of the Agreement) (incorporated by reference to exhibit 10.2 to the Company's Quarterly report on Form 10-Q (No. 001-13441) for the period ended September 30, 2015).
10.15	2016 Senior Executive Deferred Cash Performance Award Plan (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No. 000-27072) filed February 4, 2016).
10.16	2016 Voluntary Incentive Stock Award Plan (incorporated by reference to exhibit 10.2 to the Company's Current report on Form 8-K (No. 000-27072) filed February 4, 2016).
10.17	Amended and Restated 2016 Senior Executive Deferred Cash Performance Award Plan (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No. 000-27072) filed March 1, 2016).
10.18	Sales, Marketing, Distribution and Supply Agreement (the "Agreement") with Scientific Products Pharmaceutical Co. LTD dated March 3, 2016 (Confidential Treatment granted with respect to portions of the Agreement) (incorporated by reference to exhibit 10.1 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended March 31, 2016).

10.19	Agreement between Avrio Biopharmaceuticals ("Avrio") and the Company dated July 20, 2016 (Confidential Treatment granted with respect to portions of the Agreement) (incorporated by reference to exhibit 10.1 to the Company's Quarterly report on Form 10-Q (No.000-27072) for the period ended June 30, 2016).
10.20	Licensing Agreement dated April 13, 2016 with Lonza Sales AG (Confidential Treatment granted with respect to portions of the Agreement) (incorporated by reference to exhibit 10.2 to the Company's report Form 10-Q/A (No. 000-27072) for the period ended March 31, 2016).
10.21	Form of Securities Purchase Agreement entered into on August 30, 2016 (incorporated by reference to exhibit 10.1 to the Company's Current report Form 8-K (No. 000-27072) filed September 1, 2016).
10.22	Amended and Restated Early Access Agreement with Impatients N.V. dated May 20, 2016. (Confidential Treatment granted with respect to portions of the Agreement) (incorporated by reference to exhibit 10.1 to the Company's report Form 8-K/A (No. 000-27072) filed May 8, 2017).
10.23	December 13, 2016 Amendment No. 1 to Amended and Restated Early Access Agreement with Impatients N.V. (incorporated by reference to exhibit 10.45 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2017).
10.24	June 28, 2017 Amendment No. 2 to Amended and Restated Early Access Agreement with Impatients N.V. (incorporated by reference to exhibit 10.46 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2017).
10.25	February 14, 2018 Amendment No. 3 to Amended and Restated Early Access Agreement with Impatients N.V. (incorporated by reference to exhibit 10.47 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2017).
10.26	March 26, 2018 Amendment No. 4 to Amended and Restated Early Access Agreement with Impatients N.V. (incorporated by reference to exhibit 10.48 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2017).
10.27	Form of Securities Purchase Agreement entered into on February 1, 2017 (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No. 000-27072) filed February 3, 2017).
10.28	August 2017 Form of Employee Pay Reduction Plan (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No. 000-27072) filed August 29, 2017).
10.29	August 2017 Form of Executive Compensation Deferral Plan (incorporated by reference to exhibit 10.2 to the Company's Current report on Form 8-K (No. 000-27072) filed August 29, 2017).
10.30	August 2017 Form of Directors' Compensation Deferral Plan (incorporated by reference to exhibit 10.3 to the Company's Current report on Form 8-K (No. 000-27072) filed August 29, 2017).
10.31	Form of August 2017 Agreement between the Company and the Warrant holders . (incorporated by reference to exhibit 10.1 the Company's Current report on Form 8-K (No. 000-27072) filed August 23, 2017).
10.32	Form of June 2017 Agreement between the Company and the Warrant holders (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No. 000-27072) filed June 1, 2017).
10.33	Mortgage and Security Agreement with SW Partners LLC dated May 12, 2017 (incorporated by reference to exhibit 10.1 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended March 31, 2017).
10.34	Promissory Note with SW Partners LLC dated May 12, 2017 (incorporated by reference to exhibit 10.2 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended March 31, 2017).
10.35	September 11, 2017 Purchase and Sale Agreement- 5 Jules Lane (incorporated by reference to exhibit 10.57 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2017).
10.36	January 8, 2018 Purchase and Sale Agreement- 783 Jersey Lane (incorporated by reference to exhibit 10.58 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2017).

10.37	Lease Agreement for 783 Jersey Lane (incorporated by reference to exhibit 10.59 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2017).
10.38	Form of Stock Purchase Agreement entered into on March 21, 2018 (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No. 001-27072) filed March 22, 2018).
10.39	Form of Securities Purchase Agreement entered into on May 24, 2018 (incorporated by reference to exhibit 10.55 to the Company's Registration Statement on Form S-1 (No. 333-226057) filed July 2, 2018).
10.40	2018 Equity Incentive Plan (filed with the Securities and Exchange Commission as Appendix A to the Company's Definitive Proxy Statement on Schedule 14A (No. 001-27072) filed on August 3, 2018).
10.41	September 28, 2018 Securities Purchase Agreement with Iliad Research and Trading, L.P. (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No. 001-27072) filed October 4, 2018).
10.42	September 28, 2018 Security Agreement with Iliad Research and Trading, L.P. (incorporated by reference to exhibit 10.3 to the Company's Current report on Form 8-K (No. 001-27072) filed October 4, 2018).
10.43	October 9, 2018, Clinical Trial Agreement with Roswell Park Comprehensive Cancer Center (incorporated by reference to exhibit 10.1 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended September 30, 2018).
10.44	October 8, 2018, Restated First Amendment to Purchase and Sale Agreement (incorporated by reference to exhibit 10.2 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended September 30, 2018).
10.45	October 9, 2018, Restated Bill of Sale for the Restated First Amendment and Sale Agreement (incorporated by reference to exhibit 10.3 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended September 30, 2018).
10.46	Form of Agreement between the Company and the Warrantholders.- May 2, 2019 (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No. 001-27072) filed May 2, 2019).
10.47	Note Purchase Agreement dated August 5, 2019 with Chicago Venture Partners, L.P. (incorporated by reference to exhibit 10.1 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended June 30, 2019).
10.48	Secured Promissory Note dated August 5, 2019 issued to Chicago Venture Partners, L.P. (incorporated by reference to exhibit 10.2 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended June 30, 2019).
10.49	Security Agreement dated August 5, 2019 with Chicago Venture Partners, L.P. (incorporated by reference to exhibit 10.3 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended June 30, 2019).
10.50	Salary Reduction and Restricted Stock Award Memo (August 2019) (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No. 001-27072) filed August 26, 2019).
10.51	Form of Restricted Stock Award (incorporated by reference to exhibit 10.2 to the Company's Current report on Form 8-K (No. 001-27072) filed August 26, 2019).
10.52	December 5, 2019 Note Purchase Agreement with Atlas Sciences, LLC (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No.001-27072) filed December 11, 2019).
10.53	December 5, 2019 Security Agreement with Atlas Sciences, LLC (incorporated by reference to exhibit 10.2 to the Company's Current report on Form 8-K (No.001-27072) filed December 11, 2019).

10.54	March 20, 2020 Amendment to 2017 Material Transfer and Research Agreement with Roswell Park Cancer Institute (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No. 001-27072) filed March 26, 2020).
10.55	April 1, 2020 Material Transfer and Research Agreement with Shenzhen Smoore Technology Limited (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No.)001-27072) filed April 6, 2020).
10.56	April 21, 2020 Mutual Confidentiality Agreement with UMN Pharma Inc., National Institute of Infectious Diseases, and Shionogi & Co., Ltd (incorporated by reference to exhibit 10.1 to the Company's Current report on Form 8-K (No. 001-27072) filed April 27, 2020).
10.57	June 1, 2020, Material Transfer and Research Agreement with the University of Rochester. (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.1 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended June 30, 2020).
10.58	June 23, 2020, Specialized Services Agreement with Utah State University. (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.2 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended June 30, 2020).
10.59	July 1, 2020, Material Transfer and Research Agreement with the Japanese National Institute of Infectious Diseases and Shionogi & Co., Ltd. (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.3 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended June 30, 2020).
10.60	July 6, 2020, Clinical Trial Agreement with Roswell Park Comprehensive Cancer Center. (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.5 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended June 30, 2020).
10.61	August 6, 2020, Project Work Order with Amarex Clinical Research LLC. (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.5 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended June 30, 2020).
10.62	November 10, 2020 employment agreement with Thomas K. Equels. (incorporated by reference to exhibit 10.1 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended September 30, 2020).
10.63	December 22, 2020 Master Service Agreement with Pharmaceutics International Inc. as a Fill & Finish provider for Ampligen (incorporated by reference to exhibit 10.75 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2020).
10.64	January 11, 2021 Sponsor Agreement with Centre for Human Drug Research. (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.76 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2020).
10.65	November 29, 2020, Material Transfer and Research Agreement with Leyden Laboratories, B.V. (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.77 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2020).
10.66	December 30, 2020 Amendment to Project Work Order with Amarex Clinical Research LLC. (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.78 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2020).

10.67	December 23, 2020 Amendment to Master Service Agreement with Pharmaceutics International Inc. as a Fill & Finish provider for Ampligen (incorporated by reference to exhibit 10.79 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2020).
10.68	March 24, 2021 employment agreement with Peter Rodino (incorporated by reference to exhibit 10.80 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2020).
10.69	March 24, 2021 employment agreement with Ellen Lintal (incorporated by reference to exhibit 10.81 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2020).
10.70	April 1, 2021 extension of April 1, 2020 Material Transfer and Research Agreement with Shenzhen Smoore Technology Limited. (incorporated by reference to exhibit 10.3 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended March 31, 2021).
10.71	Material Transfer And Research Agreement with the University of Cagliari Dipartimento di Scienze della Vita e dell'Ambiente executed on April 5, 2021 (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.4 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended March 31, 2021).
10.72	Material Transfer and Research agreement with Roswell Park Comprehensive Cancer Center executed on April 14, 2021 (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.2 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended March 31, 2021).
10.73	April 19, 2021 Purchase and Sale Agreement with Phoenix Equipment Corporation, Branford Auctions, LLC and Perry Videx LLC (incorporated by reference to exhibit 10.1 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended March 31, 2021).
10.74	May 12, 2021 Amendment to the Renewed Sales, Marketing, Distribution and Supply Agreement with GP Pharm. (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.5 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended March 31, 2021).
10.75	May 21, 2021 extension of April 1, 2020 Material Transfer and Research Agreement with Shenzhen Smoore Technology Limited (incorporated by reference to exhibit 10.2 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended June 30, 2021).
10.76	July 8, 2021 Reservation and Start-Up Agreement with hVIVO Services Limited (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (No. 000-27072) for the period ended June 30, 2021 filed August 16, 2021)
10.77	September 27, 2021 Clinical Trial Agreement with hVIVO Services Limited (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.2 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended September 30, 2021)
10.78	March 1, 2022 Consulting Agreement with Foresite Advisors, LLC pursuant to which Robert Dickey IV will serve as the Company's Chief Financial Officer (Portions of this agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.78 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2021).

10.79	March 24, 2022 Consulting Agreement with Ellen Lintal (Portions of this agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)).
10.80	March 1, 2022 Amendment to Clinical Trial Agreement with hVIVO Services Ltd dated September 27, 2021. (incorporated by reference to exhibit 10.80 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2021).
10.81	March 3, 2022 Agreement of Sale and Purchase with Acellories, Inc for sale of 783 Jersey Avenue, New Brunswick, NJ building. (incorporated by reference to exhibit 10.81 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2021).
10.82	March 8, 2022 Change order to Master Service Agreement with Pharmaceutics International Inc. as a Fill & Finish provider for Ampligen. (incorporated by reference to exhibit 10.82 to the Company's Annual report on Form 10-K (No. 001-27072) for the year ended December 31, 2021).
10.83	April 7, 2022 Project Work Order with Amarex Clinical Research LLC.to manage Phase 2 clinical trial in advanced pancreatic cancer patients (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.1 to the Company's Current Report on Form 8-K (No. 001-27072) filed April 12, 2022).
10.84	June 13, 2022 Project Work Order with Amarex Clinical Research LLC. for a Randomized Double Blind, Placebo Controlled study to Evaluate the Efficacy and Safety of Ampligen in Patients with Post Covid Conditions (Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to exhibit 10.1 to the Company's Current Report on Form 8-K (No. 001-27072) filed June 17, 2022).
10.85	June 16, 2022 Lease agreement entered into with New Jersey Economic Development Authority for 5,210 square-foot R&D facility at the New Jersey Bioscience Center (incorporated by reference 10.1 to the Company's Current Report on Form 8-K (No.001-27072) filed June 21, 2022).
10.86	June 27, 2022 First Amendment to Agreement of Sale and Purchase with Acellories, Inc. (incorporated by reference 10.86 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended June 30, 2022 filed August 15, 2022).
10.87	August 2, 2022 Second Amendment to Agreement of Sale and Purchase with Acellories, Inc. (incorporated by reference 10.87 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended June 30, 2022 filed August 15, 2022).
10.88	August 10, 2022 Termination agreement with Shenzhen Smoore Technology Limited (incorporated by reference 10.88 to the Company's Quarterly report on Form 10-Q (No. 000-27072) for the period ended June 30, 2022 filed August 15, 2022).
10.89	October 5, 2022 Lease extension for Riverton office (incorporated by reference 10.4 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended September 30, 2022 filed November 14, 2022).
10.90	October 11, 2022 Material Transfer and Research Agreement with University of Pittsburgh (portions of this agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference 10.5 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended September 30, 2022 filed November 14, 2022).
10.91	October 21, 2022 Material Transfer and Research Agreement with University of Pittsburgh (portions of this agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference 10.6 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended September 30, 2022 filed November 14, 2022).

10.92	October 21, 2022 Fourth Amendment to Agreement of Sale and Purchase with Acellories, Inc)) (incorporated by reference 10.7 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended September 30, 2022 filed November 14, 2022).
10.93	December 5, 2022 Master Service Agreement between Sterling Pharma Solutions Limited and AIM ImmunoTech Inc*.
10.94	January 13, 2023 Study Support Agreement with Erasmus University Medical Center Rotterdam (portions of this agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) *
10.95	January 13, 2023 Co-ordination Agreement with Erasmus University Medical Center Rotterdam and AstraZeneca BV (portions of this agreement have been redacted in compliance with Regulation S-K Item 601(b)(10))*
10.96	March 1, 2023 Extension Agreement with Foresite Advisors LLC*
21.1	List of Subsidiaries*
23.1	Consent of BDO USA, LLP.*
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer. *
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer. *
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer. *
32.2	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer. *
101	The following materials from AIM' Annual Report on Form 10-K for the year ended December 31, 2019, formatted in eXtensible Business Reporting Language ("XBRL"): (i) the Condensed Consolidated Statements of Income; (ii) the Condensed Consolidated Balance Sheets; (iii) the Condensed Consolidated Statements of Cash Flows; and (iv) Notes to Condensed Consolidated Financial Statements.

* Filed herewith.

(b) Financial Statement Schedules

All schedules have been omitted because either they are not required, are not applicable or the information is otherwise set forth in the financial statements and related notes thereto.

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.

AIM IMMUNOTECH INC.

By: */s/ Thomas K. Equels*
Thomas K. Equels
Chief Executive Officer

March 31, 2023

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange of 1934, as amended, this report has been signed below by the following persons on behalf of this Registrant and in the capacities and on the dates indicated.

/s/ Thomas K Equels Thomas K. Equels	Chief Executive Officer & President, Director of the Board	March 31, 2023
/s/ William Mitchell William Mitchell, M.D., Ph.D.	Chairman of the Board and Director	March 31, 2023
/s/ Stewart L Appelrouth Stewart L. Appelrouth	Director	March 31, 2023
/s/ Robert Dickey IV Robert Dickey IV	Chief Financial Officer	March 31, 2023

AIM IMMUNOTECH INC. AND SUBSIDIARIES
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
AIM ImmunoTech Inc.
Ocala, Florida

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of AIM ImmunoTech Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2022, 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 at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matter

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

Redeemable Warrants

As discussed in Note 15 to the consolidated financial statements, the Company has certain redeemable warrants issued in conjunction with offerings that contain a cash settlement feature upon the occurrence of a Fundamental Transaction. The Company calculates the fair value of the redeemable warrants at the end of each quarterly reporting period using a Monte Carlo Simulation, which includes subjective assumptions. Subsequent changes in the fair value of the redeemable warrants are recorded in the consolidated statement of comprehensive loss. The estimated fair value of the redeemable warrants was approximately $0 as of December 31, 2022.

We identified the calculation of the fair value of the redeemable warrants as a critical audit matter. Specifically, there was a high degree of management subjectivity and judgment in selecting the assumptions used in the Monte Carlo Simulation, including the expected probability of a Fundamental Transaction and the expected stock price volatility. Auditing these elements involved especially subjective auditor judgment due to the nature and extent of audit effort required to address these matters, including the use of personnel with specialized skill and knowledge to evaluate the Company's Monte Carlo Simulation.

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

- Evaluating management's process for developing the fair value estimate by analyzing significant assumptions used in the calculation, including the probability of a Fundamental Transaction.
- Testing the accuracy and completeness of data used by management to estimate the fair value of the redeemable warrants, including considering evidence obtained in other areas of the audit to determine if contradictory evidence existed.
- Utilizing personnel with specialized skills and knowledge in valuation to assist in evaluating (i) the appropriateness of the Monte Carlo Simulation model, and (ii) the expected stock price volatility range, including independent development of the equity volatilities, considering the daily historical stock price volatility information.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2021.
Miami, Florida
March 31, 2023

AIM IMMUNOTECH INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2022 and 2021
(in thousands, except for share and per share amounts)

	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,053	$ 32,093
Marketable securities	7,137	16,175
Funds receivable from New Jersey net operating loss	1,676	1,641
Prepaid expenses and other current assets	455	304
Total current assets	36,321	50,213
Property and equipment, net	195	4,047
Right of use asset, net	829	149
Patent and trademark rights, net	1,941	1,974
Other assets	1,202	1,316
Total assets	$ 40,488	$ 57,699
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 377	$ 198
Accrued expenses	806	438
Current portion of operating lease liability	178	37
Total current liabilities	1,361	673
Long-term liabilities:		
Operating lease liability	659	112
Redeemable warrants	—	35
Commitments and contingencies (Notes 8, 10, 11, and 16)		
Stockholders' equity:		
Series B Convertible Preferred Stock, stated value $1,000 per share, issued and outstanding 696 and 715, respectively	696	715
Common Stock, par value $0.001 per share, authorized 350,000,000 shares; issued and outstanding 48,084,287 and 47,994,672, respectively	48	48
Additional paid-in capital	418,270	417,217
Accumulated deficit	(380,546)	(361,101)
Total stockholders' equity	38,468	56,879
Total liabilities and stockholders' equity	$ 40,488	$ 57,699

See accompanying notes to consolidated financial statements.

AIM IMMUNOTECH INC. AND SUBSIDIARIES
Consolidated Statements of Comprehensive Loss
(in thousands, except share and per share data)

	Years ended December 31,	
	2022	2021
Revenues:		
Clinical treatment programs – US	$ 141	$ 135
Total Revenues	141	135
Costs and Expenses:		
Production costs	—	850
Research and development	6,990	7,672
General and administrative	13,074	8,672
Impairment of assets	—	1,779
Total Costs and Expenses	20,064	18,973
Operating loss	(19,923)	(18,838)
Loss on investments	(1,679)	(201)
Interest expense and other finance costs	—	(67)
Interest and other income	629	—
Extinguishment of financing obligation	—	(2,701)
Gain on sale of fixed assets	3	216
Redeemable warrants valuation adjustment	35	145
Gain from sale of income tax operating losses	1,490	2,319
Net Loss	(19,445)	(19,127)
Other comprehensive loss		
Reclassification adjustment for realized investment loss	—	376
Change in unrealized loss on marketable securities available for sale	—	(329)
Net comprehensive loss	$ (19,445)	$ (19,080)
Basic and diluted loss per share	$ (0.40)	$ (0.40)
Weighted average shares outstanding basic and diluted	48,047,288	47,339,975

See accompanying notes to consolidated financial statements.

AIM IMMUNOTECH INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity
(in thousands except share data)

	Series B Preferred Shares	Common Stock Shares	Common Stock .001 Par Value	Additional Paid-in Capital	Accumulated other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance December 31, 2020	732	42,154,371	$ 42	$ 402,541	$ (47)	$ (341,974)	$ 61,294
Shares issued for:							
Common Stock issuance, net of costs	—	5,790,301	6	13,036	—	—	13,042
Shares issued to pay accounts payable	—	50,000	—	55	—	—	55
Series B preferred shares converted to Common shares	(17)	—	—	17	—	—	—
Net comprehensive loss	—	—	—	—	47	(19,127)	(19,080)
Balance December 31, 2021	715	47,994,672	48	417,217	—	(361,101)	56,879
Shares issued for:							
Common Stock issuance, net of costs	—	88,977	—	80	—	—	80
Warrant modification	—	638	—	—	—	—	—
Equity-based compensation	—	—	—	954	—	—	954
Series B preferred shares converted to Common shares	(19)	—	—	19	—	—	—
Net comprehensive loss	—	—	—	—	—	(19,445)	(19,445)
Balance December 31, 2022	696	48,084,287	$ 48	$ 418,270	$ —	$ (380,546)	$ 38,468

See accompanying notes to consolidated financial statements.

AIM IMMUNOTECH INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
(in thousands)

	Years ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (19,445)	$ (19,127)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	38	659
Redeemable warrants valuation adjustment	(35)	(145)
Gain on sale of fixed assets	—	(216)
Extinguishment of financing obligation	—	2,701
Amortization of patent, trademark rights	218	116
Changes in ROU assets	(680)	30
Impairment of plant property equipment and other assets	—	1,779
Loss (gain) from sale of income tax operating losses	197	(2,319)
Equity-based compensation	954	1,568
Loss on sale of marketable securities	1,679	47
Amortization of finance and debt issuance costs	—	47
Change in assets and liabilities:		
Accounts receivable	—	34
Funds receivable from New Jersey operating loss sales	(35)	(551)
Prepaid expenses and other current assets and other non current assets	(151)	1,631
Lease liability	688	(30)
Other Assets	(83)	—
Accounts payable	179	(185)
Accrued expenses	368	(4)
Net cash used in operating activities	(16,108)	(13,965)
Cash flows from investing activities:		
Proceeds from sale of marketable securities	10,083	22,292
Purchase of marketable securities	(2,724)	(22,535)
Purchase of property and equipment	(86)	(41)
Proceeds from sales of property and equipment	3,900	245
Purchase of patent and trademark rights	(185)	(592)
Net cash provided by (used in) investing activities	10,988	(631)
Cash flows from financing activities:		
Financing obligation payments	—	(122)
Payoff of financing obligation	—	(4,732)
Proceeds from sale of stock, net of issuance costs	80	13,042
Net cash provided by financing activities	80	8,188
Net decrease in cash and cash equivalents	(5,040)	(6,408)
Cash and cash equivalents at beginning of period	32,093	38,501
Cash and cash equivalents at end of period	$ 27,053	$ 32,093
Supplemental disclosures of non-cash investing and financing cash flow information:		
Stock issued to settle accounts payable	$ —	$ 55
Unrealized loss on marketable securities	$ (928)	$ (88)
Conversion of Series B preferred	$ 19	17
Operating Lease - Right of Use Assets	$ 680	$ 18

See accompanying notes to consolidated financial statements.

(1) Business

AIM ImmunoTech Inc. and its subsidiaries (collectively, "AIM", "Company", "we" or "us") are an immuno-pharma company headquartered in Ocala, Florida, and focused on the research and development of therapeutics to treat multiple types of cancers, viral diseases and immune-deficiency disorders. We have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of nucleic acids and natural interferon to enhance the natural antiviral defense system of the human body, and to aid the development of therapeutic products for the treatment of certain cancers and chronic diseases.

AIM's flagship products are Ampligen (rintatolimod), a first-in-class drug of large macromolecular RNA (ribonucleic acid) molecules, and Alferon N Injection (Interferon Alfa-N3). Ampligen has not been approved by the FDA or marketed in the United States. Ampligen is approved for commercial sale in the Argentine Republic for the treatment of severe Chronic Fatigue Syndrome ("CFS").

The Company's primary present business focus involves Ampligen. Ampligen is a double-stranded RNA ("dsRNA") molecule being developed for globally important cancers, viral diseases and disorders of the immune system.

AIM currently is proceeding primarily in three areas:

- Ampligen plus Standard of Care ("SOC") to treat pancreatic cancer patients, and in other cancers, as a potential therapeutic that modifies the tumor microenvironment with the goal of increasing anti-tumor responses to check point inhibitors and with SOC.
- Exploring Ampligen's antiviral activities and potential use as a prophylactic or treatment for existing viruses, mutations thereof or new viruses.
- Ampligen as a treatment for myalgic encephalomyelitis/chronic fatigue syndrome ("ME/CFS") and what we refer to as Post-COVID-19 chronic fatigue-like conditions.

Alferon N Injection is approved in Argentina for a category of sexually transmitted disease infections and patients that are not responsive or are intolerant to recombinant interferon. Alferon N Injection is the only natural-source, multi-species alpha interferon currently approved for sale in the United States for the intralesional treatment of refractory (i.e., resistant to other treatment) or recurring external condylomata acuminata/genital warts in patients 18 years of age or older. Certain types of human papilloma viruses cause genital warts. AIM also has approval from ANMAT for the treatment of refractory patients that failed or were intolerant to treatment with recombinant interferon in Argentina.

The Company recently sold its 30,000 sq. ft. facility at 783 Jersey Ave, New Brunswick, N.J., where it conducted testing and had produced limited quantities of active pharmaceutical ingredients ("API") for its products. While the Company believes it has sufficient API to meet its current needs, it is also continually exploring new opportunities to maximize its ability to fulfill future needs. AIM's current and active production plan is to shift to the utilization of Contract Manufacturing Organizations ("CMO"), while maintaining on-site teams for Quality Control (QC), Quality Assurance (QA), Research & Development (R&D), bench and small-batch manufacturing. (See Note 2c Property and Equipment, net)

(2) Summary of Significant Accounting Policies

(a) Cash, Cash Equivalents and Marketable Securities

Cash, Cash Equivalents and marketable securities total $34,190,000 and $48,268,000 at December 31, 2022 and 2021, respectively. Marketable securities consist of mutual funds. The Company's securities are stated at fair value.

(b) Property and Equipment, net

	(in thousands) December 31,	
	2022	2021
Land, buildings and improvements	$ —	$ 3,900
Furniture, fixtures, and equipment	2,233	2,353
Total property and equipment	2,233	6,253
Less: accumulated depreciation and amortization	(2,038)	(2,206)
Property and equipment, net	$ 195	$ 4,047

Property and equipment are recorded at cost. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the respective assets, ranging from three to ten years. Depreciation expense for the years ending December 31, 2022 and December 31, 2021 was $38,000 and $659,000, respectively.

The Company made a strategic shift on in-house manufacturing and recorded an impairment of the facility in the amount of $1,800,000 during the year ended December 31, 2021. During the period ending March 31, 2022, the Company reported assets held for sale related to the pending sale of the manufacturing facility located at 783 Jersey Avenue (See Note 15 Fair Value). The Company sold the manufacturing facility on November 1, 2022.

(c) Patent and Trademark Rights, net

Patents and trademarks are stated at cost (primarily legal fees) and are amortized using the straight-line method over the established useful life of 17 years. The Company reviews its patents and trademark rights periodically to determine whether they have continuing value, or their value has become impaired. Such review includes an analysis of the patent and trademark's ultimate revenue and profitability potential. Management's review addresses whether each patent continues to fit into the Company's strategic business plans.

(d) Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure ("GAAP") of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates, and those differences may be material. Accounts requiring the use of significant estimates include determination of other-than-temporary impairment on securities, valuation of deferred taxes, patent and trademark valuations, stock-based compensation calculations, building valuation, fair value of warrants, and contingency accruals.

(e) Revenue

The Company accounts for revenue in accordance with Accounting Standards Codification (ASC) Topic 606, Revenue from Contracts with Customers ("Topic 606"), Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Revenue from the sale of Ampligen under cost recovery clinical treatment protocols approved by the FDA is recognized when the product is shipped. The Company has no other obligation associated with its products once shipment has been accepted by the customer.

Revenue from the sale Ampligen under the EAP is recognized as the product is distributed and administered to patients involved in the cost recovery program.

(f) Accounting for Income Taxes

Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws in effect when the differences are expected to reverse. The measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The Company applies the provisions of FASB ASC 740-10 Uncertainty in Income Taxes. As a result of the implementation, there has been no material change to the Company's tax positions as they have not paid any corporate income taxes due to operating losses. With the exception of net operating losses generated in New Jersey, all tax benefits will likely not be recognized due to the substantial net operating loss carryforwards which will most likely not be realized prior to expiration. With no tax due for the foreseeable future, the Company has determined that a policy to determine the accounting for interest or penalties related to the payment of tax is not necessary at this time.

(g) Recent Accounting Standards and Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Measurement of Credit Losses on Financial Instruments,* and subsequent amendments to the guidance, ASU 2018-19 in November 2018 and ASU 2020-02 in February 2020. The standard significantly changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. The standard will replace today's "incurred loss" approach with an "expected loss" model for instruments measured at amortized cost. For available-for-sale debt securities, entities will be required to record allowances rather than reduce the carrying amount, as they do today under the other-than-temporary impairment model. It also simplifies the accounting model for purchased credit-impaired debt securities and loans. The amendment will affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. ASU 2018-19 clarifies that receivables arising from operating leases are accounted for using lease guidance and not as financial instruments. The amendments should be applied on either a prospective transition or modified-retrospective approach depending on the subtopic. This ASU will be effective for us beginning the first day of our 2023 fiscal year. Early adoption is permitted. We have evaluated the impact of adoption of this ASU on our financial condition, results of operations and cash flows, and, as such, have determined that the adoption of the new standard is not applicable and has no impact on our financial statements.

Other recent accounting pronouncements issued by the FASB did not or are not believed by management to have a material impact on the Company's present or future financial statements.

(h) Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, "Compensation – Stock Compensation", which requires recognition of compensation expense related to stock-based compensation awards over the period during which an employee is required to provide service for the award. Compensation expense is equal to the fair value of the award at the date of grant, net of estimated forfeitures.

(i) Common Stock Per Share Calculation

Basic and diluted net loss per share is computed using the weighted average number of shares of Common Stock outstanding during the period. Equivalent Common shares, consisting of 2,966,538 and 2,150,163 of stock options and warrants, are excluded from the calculation of diluted net loss per share for the years ended December 31, 2022 and 2021, respectively, since their effect is antidilutive due to the net loss of the Company.

(j) Long-Lived Assets

The Company assesses long-lived assets for impairment when events or changes in circumstances indicate that the carrying value of the assets or the asset grouping may not be recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant under-performance of a business or product line in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in its use of the assets. The Company measures the recoverability of assets that it will continue to use in its operations by comparing the carrying value of the asset grouping to our estimate of the related total future undiscounted net cash flows. If an asset grouping's carrying value is not recoverable through the related undiscounted cash flows, the asset grouping is considered to be impaired.

The Company measures the impairment by comparing the difference between the asset grouping's carrying value and its fair value. Long-lived assets are considered a non-financial asset and are recorded at fair value only if an impairment charge is recognized. Impairments are determined for groups of assets related to the lowest level of identifiable independent cash flows. The Company makes subjective judgments in determining the independent cash flows that can be related to specific asset groupings. In addition, as the Company reviews its manufacturing process and other manufacturing planning decisions, the useful lives of assets are shorter than the Company had originally estimated, it accelerates the rate of depreciation over the assets' new, shorter useful lives.

(3) Marketable Securities

Marketable securities consist of mutual funds and debt securities. At December 31, 2022 and 2021, it was determined that none of the marketable securities had an other-than-temporary impairment. At December 31, 2022 and December 31, 2021, all securities were measured as Level 1 instruments of the fair value measurements standard (See Note 15: Fair Value). As of December 31, 2022, and December 31, 2021, the Company held $7,137,000 and $16,175,000 in mutual funds.

Mutual Funds classified as available for sale consisted of:

	December 31, 2022 (in thousands)	
Securities	Fair Value	Short-Term Investments
Mutual Funds	$ 7,137	$ 7,137
Totals	$ 7,137	$ 7,137

Securities	December 31, 2022 (in thousands)
Net losses recognized during the period on equity securities	$ (1,679)
Less: Net gains and losses recognized during the period on equity securities sold during the period	(751)
Unrealized gains and losses recognized during the reporting period on equity securities still held at the reporting date	$ (928)

Mutual Funds classified as available for sale consisted of:

	December 31, 2021 (in thousands)	
Securities	Fair Value	Short-Term Investments
Mutual Funds	$ 16,175	$ 16,175
Totals	$ 16,175	$ 16,175

Securities	December 31, 2021 (in thousands)
Net losses recognized during the period on equity securities	$ (88)
Less: Net gains and losses recognized during the period on equity securities sold during the period	—
Unrealized gains and losses recognized during the reporting period on equity securities still held at the reporting date	$ (88)

(4) Patents, and Trademark Rights, Net

December 31, 2020	$	1,498
Acquisitions		592
Amortization		(116)
December 31, 2021	$	1,974
Acquisitions		375
Abandonments		(190)
Amortization		(218)
December 31, 2022	$	1,941

Patents and trademarks are stated at cost (primarily legal fees) and are amortized using the straight-line method of the estimated useful life of 17 years.

As described in Note 2, the Company reviews its patents and trademark rights periodically to determine whether they have continuing value, or their value has become impaired. Since the Company is a pre-revenue entity that is currently undergoing clinical trial for its products, it has current and historical operating and cash flow losses. The Company requires, and will continue to require, the commitment of substantial resources to develop its products, and, as of December 31, 2022, the Company's accumulated deficit is approximately $380.6 million.

ASC 360, Property, Plant and Equipment, specifies that a long-lived asset (or asset group) shall be tested for recoverability whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. A current period operating, or cash flow loss combined with a history of operating or cash flow losses associated with the use of a long-lived asset was identified by the Company as the triggering event to assess whether impairment indicators are present for the Company's long-lived assets, including the patents and trademark rights. In connection therewith, the Company engaged an outside third party to provide a valuation for the impairment of the Company's long-lived assets, including the patents and trademark rights. Based upon the analysis performed, there is no impairment to the Company's long-lived assets as of December 31, 2022.

Amortization of patents and trademarks for each of the next five years is as follows:

Year Ending December 31,		
2023	$	177
2024		166
2025		161
2026		159
2027		149
Thereafter		1,129
Total	$	1,941

(5) Accrued Expenses

Accrued expenses at December 31, 2022 and 2021 consist of the following:

	(in thousands) December 31,	
	2022	2021
Compensation	$ 1	$ 1
Professional fees	492	169
Clinical trial expenses	110	61
Other expenses	203	207
	$ 806	$ 438

(6) Stockholders' Equity

(a) Preferred Stock

The Company is authorized to issue 5,000,000 shares of $0.01 par value preferred stock with such designations, rights and preferences as may be determined by the Board of Directors. Of our authorized preferred stock, 250,000 shares have been designated as Series A Junior Participating Preferred Stock and 8,000 shares have been designated as Series B Convertible Preferred Stock. The Series B Convertible Preferred Stock has a stated value $1,000 per share.

The Company is authorized to issue 8,000 Series B Convertible Preferred Stock, no par value, stated value $1,000 per share. As of December 31, 2022, and December 31, 2021, the Company had 696 and 715 shares of Series B Convertible Preferred Stock outstanding, respectively. Holders shall be entitled to receive, and the Company shall pay, dividends on shares of Series B Preferred Stock equal (on an as-if-converted-to-Common-Stock basis) to and in the same form as dividend actually paid on shares of Common Stock when as and if such dividends are paid on shares of the Common Stock. Each such Preferred Share is convertible into 114 shares of common stock. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the Holders shall be entitled to receive out of the assets, whether capital or surplus of the Company the same amount that a holder of Common Stock would receive if the Preferred Stock was fully converted. The Series B Convertible Preferred Stock have no voting Rights.

Pursuant to a registration statement relating to a rights offering declared effective by the SEC on February 14, 2019, AIM distributed to its holders of common stock and to holders of certain options and warrants as of February 14, 2019, at no charge, one non-transferable subscription right for each share of common stock held or deemed held on the record date. Each right entitled the holder to purchase one unit, at a subscription price of $1,000 per unit, consisting of one share of Series B Convertible Preferred Stock with a face value of $1,000 (and immediately convertible into common stock at an assumed conversion price of $8.80) and 114 warrants with an assumed exercise price of $8.80. The warrants are exercisable for five years after the date of issuance. The net proceeds realized from the rights offering were approximately $4,700,000. During the twelve months ending December 31, 2022, 19 shares of Series B Convertible Preferred Stock were converted into common stock.

(b) Common Stock and Equity Finances

The Company has authorized shares of 350,000,000 with specific limitations and restrictions on the usage of 8,000,000 of the 350,000,000 authorized shares.

On July 7, 2020, the board of directors approved a plan pursuant to which all directors, officers, and employees could purchase from the Company up to an aggregate of $500,000 worth of shares at the market price. Pursuant to NYSE American rules, this plan was effective for a sixty-day period commencing upon the date that the NYSE American approved the Company's Supplemental Listing Application. The Company created successive new plans following the expiration of the plan. From July 2020 through December 31, 2022 and during the fiscal years ended December 31, 2021 and 2022, the Company issued 132,238 and 86,817 shares of its common stock at prices ranging from $1.16 to $2.35; from $0.76 to $1.02 /per share under these plans. The latest plan was approved by the board of directors in January 2023.

On September 27, 2019, the Company closed a public offering underwritten by A.G.P./Alliance Global Partners, LLC (the "Offering") of (i) 1,740,550 shares of Common Stock; (ii) pre-funded warrants exercisable for 7,148,310 shares of Common Stock (the "Pre-funded Warrants"), and (iii) warrants to purchase up to an aggregate of 8,888,860 shares of Common Stock (the "Warrants"). In conjunction with the Offering, a Representative's Warrant to purchase up to an aggregate of 266,665 shares of common stock (the "Representative's Warrant"). The shares of Common Stock and Warrants were sold at a combined Offering price of $0.90, less underwriting discounts and commissions. Each Warrant sold with the shares of Common Stock represents the right to purchase one share of Common Stock at an exercise price of $0.99 per share. The Pre-Funded Warrants and Warrants were sold at a combined Offering price of $0.899, less underwriting discounts and commissions. The Pre-Funded Warrants were sold to purchasers whose purchase of shares of Common Stock in the Offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of the Company's outstanding Common Stock immediately following the consummation of the Offering, in lieu of shares of Common Stock. Each Pre-Funded Warrant represents the right to purchase one share of Common Stock at an exercise price of $0.001 per share. The Pre-Funded Warrants are exercisable immediately and may be exercised at any time until the Pre-Funded Warrants are exercised in full. A registration statement on Form S-1, relating to the Offering was filed with the SEC and was declared effective on September 25, 2019, the net proceeds were approximately $7,200,000. During the year ending December 31, 2020, 1,870,000 of the Pre-funded Warrants were exercised and 8,873,960 Warrants were exercised. In addition, on March 25, 2020, the Representative's Warrant was amended to permit exercise of such warrant to commence on March 30, 2020. These warrants were exercised on March 31, 2020 and an aggregate of 266,665 shares were issued upon exercise of this warrant for gross proceeds of approximately $264,000 and a $46,000 expense for the warrant modification. As of December 31, 2022, there are 15,000 Warrants outstanding.

On July 19, 2019, the Company entered into a new Equity Distribution Agreement (the "2019 EDA") with Maxim Group LLC ("Maxim"), pursuant to which it could sell, from time to time, shares of its Common Stock through Maxim, as agent (the "Offering"). The 2019 EDA replaced a prior EDA with Maxim. For the year ended December 31, 2020, the Company sold 20,444,807 shares under the 2019 EDA for total gross proceeds of $53,936,615, which includes a 3.5% fee to Maxim of $1,888,727. During the period ended December 31, 2021, the Company sold 5,665,731 shares under the 2019 EDA for total gross proceeds of $13,301,526, which includes a 3.5% fee to Maxim of $465,533. The 2019 EDA was terminated in early February 2021.

The 2018 Equity Incentive Plan, effective September 12, 2018, authorizes the grant of (i) Incentive Stock Options, (ii) Nonstatutory Stock Options, (iii) Stock Appreciation Rights, (iv) Restricted Stock Awards, (v) Restricted Stock Unit Awards, (vi) Performance Stock Awards, (vii) Performance Cash Awards, and (viii) Other Stock Awards. Initially, a maximum of 7,000,000 shares of Common Stock is reserved for potential issuance pursuant to awards under the 2018 Equity Incentive Plan. Unless sooner terminated, the 2018 Equity Incentive Plan will continue in effect for a period of 10 years from its effective date. On October 17, 2018, the Board of Directors issued 26,324 options to the officers and directors at the exercise price of $9.68 expiring in 10 years, and on November 14, 2018, the Board of Directors issued 23 options to each employee, officer and director at the exercise price of $9.68 expiring in ten years. On January 28, 2019, 27,570 options were issued to each of these officers with an exercise price of $9.68 for a period of ten years with a vesting period of one year. In August 2020, 400,000 options were issued to each of these officers with an exercise price range of $2.77 to $3.07 for a period of ten years with a vesting period of one year. During the fiscal year ending December 31, 2022, 850,000 options were issued to employees with an exercise price range of $0.31 to $1.71 for a period of ten years with a vesting period of one year. During fourth quarter of 2021, 613,512 options were issued to employees with an exercise price range of $1.11 to $1.71 for a period of ten years with a vesting period of one year.

As of December 31, 2022, and 2021, there were 48,084,287 and 47,994,672 shares outstanding, respectively.

(c) Common Stock Options and Warrants

(i) Stock Options

The 2018 Equity Incentive Plan, effective September 12, 2018, authorizes the grant of (i) Incentive Stock Options, (ii) Nonstatutory Stock Options, (iii) Stock Appreciation Rights, (iv) Restricted Stock Awards, (v) Restricted Stock Unit Awards, (vi) Performance Stock Awards, (vii) Performance Cash Awards, and (viii) Other Stock Awards. Initially, a maximum of 7,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the 2018 Equity Incentive Plan. Unless sooner terminated, the 2018 Equity Incentive Plan will continue in effect for a period of 10 years from its effective date.

The Equity Incentive Plans of 2018 are administered by the Board of Directors. The Plans provide for awards to be made to such Officers, other key employees, non-employee Directors, consultants and advisors of the Company and its subsidiaries as the Board may select.

Stock options awarded under the Plans may be exercisable at such times (not later than 10 years after the date of grant) and at such exercise prices (not less than fair market value at the date of grant) as the Board may determine. The Board may provide for options to become immediately exercisable upon a “change in control”, which is defined in the Plans to occur upon any of the following events: (a) the acquisition by any person or group, as beneficial owner, of 20% or more of the outstanding shares or the voting power of the outstanding securities of the Company; (b) either a majority of the Directors of the Company at the annual stockholders meeting has been nominated other than by or at the direction of the incumbent Directors of the Board, or the incumbent Directors cease to constitute a majority of the Company’s Board; (c) the Company’s stockholders approve a merger or other business combination pursuant to which the outstanding common stock of the Company no longer represents more than 50% of the combined entity after the transaction; (d) the Company’s stockholders approve a plan of complete liquidation or an agreement for the sale or disposition of all or substantially all of the Company’s assets; or (e) any other event or circumstance determined by the Company’s Board to affect control of the Company and designated by resolution of the Board as a change in control.

The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton pricing option valuation model. Expected volatility is based on the historical volatility of the price of the Company’s stock. The risk-free interest rate is based on U.S. Treasury issues with a term equal to the expected life of the option and equity warrant. The Company uses historical data to estimate expected dividend yield, life and forfeiture rates. The expected life of the options and equity warrants was estimated based on historical option and equity warrant holders’ behavior and represents the period of time that options and equity warrants are expected to be outstanding. The fair values of the options granted were estimated based on the following weighted average assumptions:

	Year Ended December 31,	
	2022	2021
Risk-free interest rate	1.74% - 3.88%	0.66% - 1.23%
Expected dividend yield	—	—
Expected life	10 years	5 years
Expected volatility	98.43% - 107.18%	108.08% - 108.46%
Weighted average grant date fair value for options issued	$ 0.51 per option for 850,000 options	$ 1.61 per option for 613,512 options

The exercise price of all stock options and equity warrants granted was equal to or greater than the fair market value of the underlying common stock on the date of the grant.

Information regarding the options approved by the Board of Directors under Equity Plan of 2009 is summarized below. The plan expired June 24, 2019:

	2022			2021		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
Outstanding, beginning of year	128,504	$ 13.20 – 2,127.84	$ 25.58	129,680	$ 13.20 – 2,127.84	$ 23.05
Granted	—		—	—		—
Forfeited	(4,105)	16.76-2,127.84	129.88	(1,176)	16.76-1056.00	289.62
Exercised	—	—	—	—	—	—
Outstanding, end of year	124.399	$13.20-1,003.20	$ 22.23	128,504	$13.20-2,127.84	$ 25.58
Exercisable, end of year	124,399	$13.20-1,003.20		126,393	$13.20-2,127.84	
Weighted average remaining contractual life (years)	5.98 years			5.9 years		

Information regarding the options approved by the Board of Directors under the Equity Plan of 2018 is summarized below:

	2022			2021		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
Outstanding, beginning of year	1,650,017	$ 1.11-9.68	$ 2.35	1,086,549	$ 1.85 – 9.68	$ 2.75
Granted	850,000	$ 0.31-1.71	$ 0.51	613,512	$ 1.11 – 1.71	$ 1.67
Forfeited	(25,046)	$ 1.85 – 9.68	$ 1.86	(50,044)	$ 1.85 – 8.50	$ 1.86
Exercised	—	—	—	—	—	—
Outstanding, end of year	2,474,971	$ 0.31-9.68	$ 1.72	1,650,017	$ 1.11 – 9.68	$ 2.35
Exercisable, end of year	1,916,637	$ 0.41-9.68	$ 2.22	1,141,798	$ 1.11 – 9.68	$ 2.35
Weighted average remaining contractual life (years)	9.65 years			9.12 years		
Available for future grants	466,120			344,322		

Stock option activity during the years ended December 31, 2022 and 2021 is as follows:

Vested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2020	1,049,695	$ 5.38	9.28	—
Granted	500,000	1.60	9.11	—
Forfeited	(50,897)	19.50	—	—
Expired	—	348.48	—	—
Outstanding December 31, 2021	1,498,798	$ 4.22	9.11	—
Granted	550,000	0.49	9.71	—
Forfeited	(28,584)	17.71		
Expired	—	—	—	—
Outstanding December 31, 2022	2,020,214	$ 3.01	8.86	—
Vested and expected to vest at December 31, 2022	2,020,214	$ 3.01	8.86	—
Exercisable at December 31, 2022	1,627,888	$ 2.36	6.54	—

The weighted-average grant-date fair value of employee options granted during the year 2022 was $269,000 for 550,000 options at $0.49 per option and during year 2021 was $801,000 for 500,000 options at $1.60 per option.

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Unvested December 31, 2020	728,846	$ 3.71	9.61	—
Granted	449,102	1.60	9.11	—
Vested	(765,448)	2.24	8.36	—
Forfeited	—	—	—	—
Unvested December 31, 2021	412,500	$ 4.15	5.85	—
Granted	550,000	0.49	9.71	—
Vested	(541,590)	1.31	9.73	—
Forfeited	(28,584)	17.71	—	—
Unvested December 31, 2022	392,326	$ 0.80	8.86	—

Vested stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2020	166,533	$ 11.03	6.88	—
Granted	113,512	1.64	—	—
Exercised	—	—	—	—
Forfeited	(322)	965.93	—	—
Outstanding December 31, 2021	279,723	$ 6.12	7.93	—
Granted	300,000	0.54	9.68	—
Exercised	—	—	—	—
Forfeited	(568)	153.12	—	—
Outstanding December 31, 2022	579,155	$ 3.09	8.36	—
Vested and expected to vest at December 31, 2022	579,155	$ 3.09	8.36	—
Exercisable at December 31, 2022	412,487	$ 3.60	9.49	—

The weighted-average grant-date fair value of non-employee options granted during year 2022 was $161,500 for 300,000 options at $0.54 per option and during the year 2021 was $181,161 for 109,154 options at $1.66 per option.

Unvested stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Unvested December 31, 2020	66,202	$ 7.24	6.13	—
Granted	113,512	1.64	9.92	—
Vested	(81,883)	3.48	—	—
Forfeited	—	—	—	—
Unvested December 31, 2021	97,831	$ 3.89	7.82	—
Granted	300,000	0.54	9.68	—
Vested	(229,053)	0.82	—	—
Forfeited	—	—	—	—
Unvested December 31, 2022	168,778	$ 4.05	9.49	—

Stock-based compensation expense was approximately $954,000 and $1,568,000 for the years ended December 31, 2022, and 2021 resulting in an increase in general and administrative expenses and loss per share of $0.02 and $0.03, respectively.

As of December 31, 2022, and 2021, there was $217,000 and $779,000, respectively, of unrecognized stock-based compensation cost related to options granted under the Equity Incentive Plans. Stock-based compensation related to options granted under the Equity Incentive Plans will be recorded over the vesting period which is typically one year or upon reaching agreed upon Company and/or individual performance milestones being met which is indefinite.

(ii) Stock Warrants

Stock warrants are issued as needed by the Board of Directors and have no formal plan.

The fair value of each warrant award is estimated on the date of grant using a Black-Scholes-Merton pricing option valuation model. Expected volatility is based on the historical volatility of the price of the Company's stock. The risk-free interest rate is based on U.S. Treasury issues with a term equal to the expected life of the warrant. The Company uses historical data to estimate expected dividend yield, life and forfeiture rates. The expected life of the warrants was estimated based on historical option holder's behavior and represents the period of time that options are expected to be outstanding. There were 16,907,471 granted in 2019 at $0.99 - $8.80 per warrant. No warrants were granted in 2022, 2021 or 2020.

Information regarding warrants outstanding and exercisable into shares of common stock is summarized below:

	2022			2021		
	Shares	Warrant Price	Weighted Average Exercise Price	Shares	Warrant Price	Weighted Average Exercise Price
Outstanding, beginning of year	294,939	$0.99 – 469.92	$ 15.19	375,100	$0.99 – 469.92	$ 116.38
Granted	—	—	—	—	—	—
Expired	(95)	469.92	469.92	(79,593)	17.16 – 84.48	20.85
Exercised	(114)	8.80	8.80	(568)	8.80	8.80
Outstanding, end of year	288,077	$0.99-132.00	$ 9.10	294,939	$0.99-469.92	$ 15.19
Exercisable	288,077	$0.99-132.00	$ 9.10	294,939	$0.99-469.92	$ 15.19
Weighted average remaining contractual life	.94 years		4.75 years			
Years exercisable	2023-2024		2022-2025			

Stock warrants are issued at the discretion of the Board. In 2022 and 2021 there were no warrants issued and 114 warrants were exercised in 2022 and 568 were exercised in 2021.

(7) Segment and Related Information

The Company operates in one segment, which performs research and development activities related to Ampligen and other drugs under development. The Company's revenues for the two-year period ended December 31, 2022, were earned in the United States. All assets are maintained in the United States of America.

(8) Research, Consulting and Supply Agreements

In 2016, the Company entered into a five-year agreement (the "Impatients Agreement") with Impatients, N.V. ("myTomorrows"), a Netherlands-based company, for the commencement and management of an EAP in Europe and Turkey (the "Territory") related to ME/CFS. Pursuant to the agreement, myTomorrows, as our exclusive service provider and distributor in the Territory, is performing EAP activities. The agreement was automatically extended for a period of 12 months on May 20, 2021; automatically extended again for an additional period of 12 months on May 20, 2022; and will be automatically extended again on May 20, 2023.

Jubilant HollisterStier (Jubilant) is AIM's authorized CMO for Ampligen for the approval in Argentina. In 2017, the Company entered into a purchase order with Jubilant pursuant to which Jubilant will manufacture batches of Ampligen® for the Company. Since the 2017 engagement of Jubilant, four lots of Ampligen consisting of more than 16,000 units have been manufactured and released in year 2018. The first lot was designated for human use in the US in the cost recovery CFS program and for expanded oncology clinical trials. The second lot has been designated for these programs in addition to commercial distribution in Argentina for the treatment of CFS.

The production of additional polymer (Ampligen intermediates) took place in 2019 at the Company's New Brunswick facility. Additionally, two lots of Ampligen were manufactured in December 2019 and January 2020 at Jubilant. The current manufactured lots of Ampligen have been fully tested and released for commercial product launch in Argentina and for clinical trials.

In August 2020, we contracted Amarex Clinical Research LLC ("Amarex") to act as our Clinical Research Organization and provide regulatory support with regard to a possible clinical trial testing Ampligen's potential as a COVID-19 prophylaxis via intranasal delivery, and for the development of Ampligen as a therapy for pancreatic cancer. For the year ended December 31, 2022, and for the year ended December 31, 2021 the Company has incurred an expense and paid Amarex approximately $2,153,000 and $437,000, respectively.

In December 2020, AIM added Pharmaceutics International Inc. (“Pii”) as a “Fill & Finish” provider to enhance the Company’s capacity to produce the drug Ampligen. This addition amplifies AIM’s manufacturing capability by providing redundancy and cost savings. The contracts augment AIM’s existing fill and finish capacity. As agreed to in the Master Services Agreement, the terms of each of AIM’s projects with Pii will be negotiated separately and defined in individual Service Contracts. For the year ended December 31, 2022, the Company has incurred an expense and paid Pii approximately $278,000.

In January 2021, the Company entered into a Sponsor Agreement with the Centre for Human Drug Research (“CHDR”) for a Phase 1 clinical study to assess the safety, tolerability, and biological activity of Ampligen as a potential intranasal therapy. For the year ended December 31, 2022, the Company has incurred an expense and paid CHDR approximately $56,000.

In April 2021, the Company approved a proposal from Polysciences Inc. (“Polysciences”) for the manufacture of our Poly I and Poly C12U polynucleotides and associated test methods at Polysciences’ Warrington, PA location to enhance our capacity to produce the polymer precursors to the drug Ampligen. We are working with Polysciences to negotiate and finalize both a Service Agreement and a Quality Agreement. For the year ended December 31, 2022 the Company has incurred an expense and paid Polysciences approximately $103,000.

In July 2021, the Company executed a Reservation and Start-Up Agreement (the “Agreement”) with hVIVO Services Limited (“hVIVO”), and subsequently signed a clinical trial agreement (“CTA”) in September. For the year ended December 3, 2021, the Company had incurred an expense and paid hVIVO approximately $2,340,000 for services incurred in 2021. In March 2022, the Company announced that it had officially withdrawn its application from the Medicines and Healthcare Regulatory Agency and terminated its agreement with hVIVO and incurred a cancelation fee of $60,000 which was paid in the first quarter 2022.

(9) 401(k) Plan

The Company has a defined contribution plan, entitled the AIM ImmunoTech Employees 401(k) Plan and Trust Agreement (the “401(k) Plan”). Full time employees of the Company are eligible to participate in the 401(k) Plan following one year of employment. Subject to certain limitations imposed by federal tax laws, participants are eligible to contribute up to 15% of their salary (including bonuses and/or commissions) per annum. Participants’ contributions to the 401(k) Plan may be matched by the Company at a rate determined annually by the Board of Directors.

Each participant immediately vests in his or her deferred salary contributions, while Company contributions will vest over one year. A 6% Company matching contribution was reinstated effective January 1, 2021. For the year ending December 31, 2022 the Company made $122,000 in contributions and for the year ending December 31, 2021 $139,000 in contributions were made

(10) Employment Agreements

The Company had contractual agreements with Named Executive Officers (“NEO”) in 2022, and 2021. The aggregate annual base compensation for these NEO under their respective contractual agreements for 2022 and 2021 was $1,275,000 and $1,625,000, respectively. In addition, certain of these Officers were entitled to receive performance bonuses of up to 25% or 20% of their respective annual base salary, at the sole discretion of the Compensation Committee of the Board of Directors. In 2022 and 2021, Officers’ bonuses were $450,000 and $550,000 respectively.

In 2022, equity was granted as a form of compensation to these Officers.

a. The Company granted 300,000 ten-year options to purchase common stock with an exercise price of $0.41 per share to vest in a year to Thomas K. Equels, Chief Executive Officer.

b. The Company granted 150,000 ten-year options to purchase common stock with an exercise price of $0.41 to $0.70 per share which vest in one year to Peter Rodino, Chief Operating Officer and General Counsel.

c. The Company granted 50,000 ten-year options to purchase common stock with an exercise price of $0.70 per share which vest in one year to Ellen Lintal, former Chief Financial Officer.

The Company recorded stock compensation expense of approximately $66,000 during the year ended December 31, 2022. With regard to these issuances to Officers Equels, Rodino, and former Officer Lintal.

In 2021, equity was granted as a form of compensation to these Officers.

d. The Company granted 300,000 ten-year options to purchase common stock with an exercise price of $1.71 per share to vest in a year to Thomas K. Equels, Chief Executive Officer.

e. The Company granted 100,000 ten-year options to purchase common stock with exercise price of $1.44 per share which vest in one year to Peter Rodino, Chief Operating Officer and General Counsel.

f. The Company granted 100,000 ten-year options to purchase common stock with exercise price of $1.44 per share which vest in one year to Ellen Lintal, Chief Financial Officer.

The Company recorded stock compensation expense of approximately $105,000 during the year ended December 31, 2021. with regard to these issuances to Officer Equels, Officer Rodino, and former Officer Lintal.

(11) Leases

The Company leases office and storage space, and other equipment under non-cancellable operating leases with initial terms typically ranging from 1 to 5 years. At contract inception, the Company reviews the facts and circumstances of the arrangement to determine if the contract is or contains a lease. The Company follows the guidance in Topic 842 "*Leases*" to evaluate whether the contract has an identified asset; if the Company has the right to obtain substantially all economic benefits from the asset; and if the Company has the right to direct the use of the underlying asset. When determining if a contract has an identified asset, the Company considers both explicit and implicit assets, and whether the supplier has the right to substitute the asset. When determining if the Company has the right to direct the use of an underlying asset, the Company considers if it has the right to direct how and for what purpose the asset is used throughout the period of use and if it controls the decision-making rights over the asset.

The Company's lease terms may include options to extend or terminate the lease. The Company exercises judgment to determine the term of those leases when extension or termination options are present and include such options in the calculation of the lease term when it is reasonably certain that it will exercise those options.

The Company has elected to include both lease and non-lease components in the determination of lease payments. Payments made to a lessor for items such as taxes, insurance, common area maintenance, or other costs commonly referred to as executory costs, are also included in lease payments if they are fixed. The fixed portion of these payments are included in the calculation of the lease liability, while any variable portion would be recognized as variable lease expenses, when incurred. Variable payments made to third parties for these, or similar costs, such as utilities, are not included in the calculation of lease payments.

At lease commencement, lease-related assets and liabilities are measured at the present value of future lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company exercises judgment in determining the incremental borrowing rate based on the information available when the lease commences to measure the present value of future payments.

Operating leases are included in other assets, current operating lease obligations, and operating lease obligations (less current portion) on the Company's consolidated balance sheet. Short term leases with an initial term of 12 months or less are not presented on the balance sheet with expense recognized as incurred.

The Company entered into a Lease Agreement for a term of five years commencing on September 14, 2020 pursuant to which the Company agreed to lease two Sharp copiers. The base of $1,415 per month.

On June 13, 2018, the Company entered into a Lease Agreement for a term of six years commencing on July 1, 2018 pursuant to which the Company agreed to lease approximately 3,000 rentable square feet. The base rent increases by 3% each year, and ranges from $2,100 per month for the first year to $2,785 per month for the sixth year.

On May 1, 2019, the Company entered into a Lease Agreement for a term of three years commencing on May 1, 2019, pursuant to which the Company agreed to lease approximately 3,000 rentable square feet. The base rent is $1,500 per month for the term of the lease. On October 4, 2021, the Company renewed the lease for a one-year term as defined in the Lease Agreement. On September 30, 2022, the Company renewed the lease for a one-year term as defined in the Lease Agreement.

The expected lease term includes both contractual lease periods and, when applicable, cancelable option periods when it is reasonably certain that the Company would exercise such options. The Company's leases have remaining lease terms between 4 months and 5 years. As of December 31, 2022, and 2021, the weighted-average remaining term is 2.35 and 2.72 years, respectively.

The Company has determined that the incremental borrowing rate is 10% as of December 31, 2022, and 2021, respectively, based upon the recently completed financing transaction in December 2022.

Future minimum payments as of December 31, 2022, are as follows:

Year Ending December 31, (in thousands)		
2023	$	271
2024		243
2025		216
2026		200
2027		133
Thereafter		—
Less imputed interest		(226)
Total	$	837

As of December 31, 2022, and 2021, the balance of the right of use assets was $829,000 and $149,000, respectively, and the corresponding lease liability balance was $837,000 and $149,000, respectively. The total rent expense for the years ended December 31, 2022, and 2021 amounted to approximately $190,000 and $67,000, respectively. Total rent expense for short term leases for the years ended December 31, 2022, and 2021

amounted to approximately $56,000 and 12,000, respectively.

(12) Income Taxes (FASB ASC 740 Income Taxes)

The Company applies the provisions of FASB ASC 740-10 Uncertainty in Income Taxes. As a result of the implementation, there has been no material change to the Company's tax positions as they have not paid any corporate income taxes due to operating losses. With the exception of net operating losses and research and development credits generated in New Jersey, all tax benefits will likely not be recognized due to the substantial net operating loss carryforwards which will most likely not be realized prior to expiration.

As of December 31, 2022, the Company has approximately $250.5 million of Federal net operating loss carryforwards (expiring in the years 2023 through 2038), the use of which has been limited by Internal Revenue Code Section 382 and $53.6 million of Federal net operating loss with no expiration date available to offset future federal taxable income. The Company has approximately $19.6 million of New Jersey state net operating loss carryforwards (expiring in 2042). The Company has approximately $58.4 million of Florida state net operating loss carryforwards with no expiration date to offset future Florida taxable income. The Company has approximately $3.6 million of Belgium net operating loss carryforwards with no expiration date to offset future taxable income. In December 2022, the Company effectively sold $20,500,000 of its New Jersey state net operating loss carryforward and $15,000 in R&D credits for the year 2021 for approximately $1,676,000.

The utilization of certain state net operating loss carryforwards may be subject to annual limitations. With no tax due for the foreseeable future, the Company has determined that a policy to determine the accounting for interest or penalties related to the payment of tax is not necessary at this time.

Under the Tax Reform Act of 1986, the utilization of a corporation's net operating loss carryforward is limited following a greater than 50% change in ownership. As noted above, due to the Company's prior and current equity transactions, some of the Company's net operating loss carryforwards are subject to an annual limitation generally determined by multiplying the value of the Company on the date of the ownership change by the federal long-term tax-exempt rate. Any unused annual limitation may be carried forward to future years for the balance of the net operating loss carryforward period.

Deferred income taxes reflect the net tax effects of temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the carrying amounts used for income tax purposes. In assessing the realizability of deferred tax assets, Management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences representing net future deductible amounts become deductible. With the exception of net operating losses generated in New Jersey which can be surrendered for 80% of their value, due to the uncertainty of the Company's ability to realize the benefit of the deferred tax asset, the remainder of our deferred tax assets are fully offset by a valuation allowance at December 31, 2022 and 2021.

The components of the net deferred tax assets and liabilities as of December 31, 2022 and 2021 consist of the following:

Deferred tax assets:	(in thousands) December 31, 2022	2021
Net operating losses	$ 19,674	$ 15,988
Research and Development costs	7,647	7,077
Amortization & depreciation	2,342	1,107
R&D credits	744	82
Other	77	54
ROU	2	—
Stock compensation	63	708
Total deferred tax assets	30,549	25,016
Less: Valuation allowance	(29,431)	(23,711)
Deferred tax assets, net	$ 1,118	$ 1,305

Deferred tax assets are included within other assets in the accompanying Consolidated Balance Sheets. The benefits of deferred tax assets are included within the gain from sale of income tax operating losses in the accompanying Consolidated Statements of Comprehensive Loss. The Company's deferred tax asset estimates the projected sale of 2022 and 2021 New Jersey state operating losses to be sold in the subsequent year, respectively.

Rate Reconciliation

Reconciliation between the effective tax rate on income from continuing operations and the statutory tax rate is as follows (in thousands):

Pre Tax Book Loss	$ (19,498)	
Federal Rate	(4,095)	21.0%
State Taxes	(1,640)	8.4%
RTP	(1,590)	8.2%
Other	1,606	-8.2%
Valuation Allowance	5,719	-29.4%
Total	—	0.0%

(13) Certain Relationships and Related Transactions

The Company has an employment agreement with its NEOs and has granted its NEOs and directors options to purchase its common stock. Please see details of these Employment Agreements in Note 10 - Employment Agreements.

(14) Concentrations of Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash, cash equivalents, investments and accounts receivable. The Company places its cash with high-quality financial institutions and, at times, such amounts in non-interest-bearing accounts may be in excess of Federal Deposit Insurance Corporation insurance limits. There were no credit-based sales for 2022 and 2021.

There are a limited number of suppliers in the United States and abroad available to provide the raw and packaging materials/reagents for use in manufacturing Ampligen and Alferon N Injection. At present, we do not have any agreements with third parties for the supply of any of these materials or we are relying on a limited source of reagent suppliers necessary for the manufacture of Alferon N Injection. Jubilant HollisterStier LLC has manufactured batches of Ampligen for us pursuant to purchase orders. We anticipate that additional orders will be placed upon approved quotes and purchase orders provided by us to Jubilant. On December 22, 2020, we added Pharmaceutics International Inc. ("Pii") as a "Fill & Finish" provider to enhance our capacity to produce the drug Ampligen. This addition amplifies our manufacturing capability by providing redundancy and cost savings. The contracts augment our existing fill and finish capacity. If we are unable to place adequate acceptable purchase orders with Jubilant or Pii in the future at acceptable prices upon acceptable terms, we will need to find another manufacturer. The costs and availability of products and materials we would need for the production of Ampligen are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, ownership of intellectual property, FDA and other governmental regulations. There can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all.

Currently, the Alferon N Injection manufacturing process is on hold and there is no definitive timetable to restart production. If we are unable to acquire FDA approvals related to the manufacturing process and/or final product of new Alferon N Injection inventory or contract with a CMO, our operations most likely will be materially and/or adversely affected. In light of these contingencies, there can be no assurances that the approved Alferon N Injection product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

(15) Fair Value

The Company is required under U.S. GAAP to disclose information about the fair value of all the Company's financial instruments, whether or not these instruments are measured at fair value on the Company's consolidated balance sheets.

The Company estimates that the fair values of cash and cash equivalents, other assets, accounts payable and accrued expenses approximate their carrying values due to the short-term maturities of these items. The Company also has certain warrants with a cash settlement feature in the occurrence of a Fundamental Transaction, which is defined if the Company, directly or indirectly, in one or more related transactions, consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another person or group of persons, whereby such other person or group acquires more than 50% of the outstanding shares of common stock (not including any shares of common stock held by the other person or group of persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination). The fair value of the redeemable warrants ("Warrants") related to the Company's April 2018, and March 2019 common stock and warrant issuance, are calculated using a Monte Carlo Simulation. While the Monte Carlo Simulation is one of a number of possible pricing models, the Company has determined it to be industry accepted and fairly presented the fair value of the Warrants. As an additional factor to determine the fair value of the Put's liability, the occurrence probability of a Fundamental Transaction event was factored into the valuation.

The Company recomputes the fair value of the Warrants at the issuance date and the end of each quarterly reporting period. Such value computation includes subjective input assumptions that are consistently applied each period. If the Company were to alter its assumptions or the numbers input based on such assumptions, the resulting fair value could be materially different.

The Company utilized the following assumptions to estimate the fair value of the April 2018 Warrants:

	December 31, 2022	December 31, 2021
Underlying price per share	$ 0.31	$ 0.92
Exercise price per share	$ 17.16	$ 17.16
Risk-free interest rate	4.74%	0.67%
Expected holding period	0.81	1.81
Expected volatility	75%	120%
Expected dividend yield	—	—

The Company utilized the following assumptions to estimate the fair value of the March 2019 Warrants:

	December 31, 2022	December 31, 2021
Underlying price per share	$ 0.31	$ 0.92
Exercise price per share	$ 8.80	$ 8.80
Risk-free interest rate	4.67%	0.78%
Expected holding period	1.19	2.19
Expected volatility	70%	125%
Expected dividend yield	—	—

The significant assumptions using the Monte Carlo Simulation approach for valuation of the Warrants are:

(i) *Risk-Free Interest Rate*. The risk-free interest rates for the Warrants are based on U.S. Treasury constant maturities for periods commensurate with the remaining expected holding periods of the warrants.

(ii) *Expected Holding Period*. The expected holding period represents the period of time that the Warrants are expected to be outstanding until they are exercised. The Company utilizes the remaining contractual term of the Warrants at each valuation date as the expected holding period.

(iii) *Expected Volatility*. Expected stock volatility is based on daily observations of the Company's historical stock values for a period commensurate with the remaining expected holding period on the last day of the period for which the computation is made.

(iv) *Expected Dividend Yield*. Expected dividend yield is based on the Company's anticipated dividend payments over the remaining expected holding period. As the Company has never issued dividends, the expected dividend yield is 0% and this assumption will be continued in future calculations unless the Company changes its dividend policy.

(v) *Expected Probability of a Fundamental Transaction.* The possibility of the occurrence of a Fundamental Transaction triggering a Put right is extremely remote. As discussed above, a Put right would only arise if a Fundamental Transaction 1) is an all cash transaction; (2) results in the Company going private; or (3) is a transaction involving a person or entity not traded on a national securities exchange. The Company believes such an occurrence is highly unlikely because:

1. The Company only has one product that is FDA approved but is currently not available for commercial sales.
2. The Company will have to perform additional clinical trials for FDA approval of its flagship product.
3. Industry and market conditions continue to include uncertainty, adding risk to any transaction.
4. Available capital for a potential buyer in a cash transaction continues to be limited.
5. The nature of a life sciences company is heavily dependent on future funding and high fixed costs, including Research & Development.
6. The Company has minimal revenues streams which are insufficient to meet the funding needs for the cost of operations or construction at their manufacturing facility; and
7. The Company's Rights Agreement and Executive Agreements make it less attractive to a potential buyer.

With the above factors utilized in analysis of the likelihood of the Put's potential Liability, the Company estimated the range of probabilities related to a Put right being triggered as:

Range of Probability	Probability
Low	0.5%
Medium	1.0%
High	5.0%

The Monte Carlo Simulation has incorporated a 5.0% probability of a Fundamental Transaction to date for the life of the securities.

(vi) *Expected Timing of Announcement of a Fundamental Transaction.* As the Company has no specific expectation of a Fundamental Transaction, for reasons elucidated above, the Company utilized a discrete uniform probability distribution over the Expected Holding Period to model in the potential announcement of a Fundamental Transaction occurring during the Expected Holding Period.

(vii) *Expected 100 Day Volatility at Announcement of a Fundamental Transaction*. An estimate of future volatility is necessary as there is no mechanism for directly measuring future stock price movements. Daily observations of the Company's historical stock values for the 100 days immediately prior to the Warrants' grant dates, with a floor of 100%, were utilized as a proxy for the future volatility.

(viii) *Expected Risk-Free Interest Rate at Announcement of a Fundamental Transaction*. The Company utilized a risk-free interest rate corresponding to the forward U.S. Treasury rate for the period equal to the time between the date forecast for the public announcement of a Fundamental Transaction and the Warrant expiration date for each simulation.

(ix) *Expected Time Between Announcement and Consummation of a Fundamental Transaction.* The expected time between the announcement and the consummation of a Fundamental Transaction is based on the Company's experience with the due diligence process performed by acquirers and is estimated to be six months. The Monte Carlo Simulation approach incorporates this additional period to reflect the delay Warrant Holders would experience in receiving the proceeds of the Put.

While the assumptions remain consistent from period to period (e.g., utilizing historical stock prices), the numbers input change from period to period (e.g., the actual historical prices input for the relevant period). The carrying amount and estimated fair value of the above Warrants was approximately $0 and $35,000 at December 31, 2022 and 2021, respectively.

The Company applies FASB ASC 820 (formerly Statement No. 157 *Fair Value Measurements*) that defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The guidance does not impose any new requirements around which assets and liabilities are to be measured at fair value, and instead applies to asset and liability balances required or permitted to be measured at fair value under existing accounting pronouncements. The Company measures its warrant liability for those warrants with a cash settlement feature at fair value.

FASB ASC 820-10-35-37 (formerly SFAS No. 157) establishes a valuation hierarchy based on the transparency of inputs used in the valuation of an asset or liability. Classification is based on the lowest level of inputs that is significant to the fair value measurement. The valuation hierarchy contains three levels:

1. Level 1 – Quoted prices are available in active markets for identical assets or liabilities at the reporting date. Generally, this includes debt and equity securities that are traded in an active market.

2. Level 2 – Observable inputs other than Level 1 prices such as quote prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Generally, this includes debt and equity securities that are not traded in an active market.

3. Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or other valuation techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation. As of December 2022, the Company has classified the warrants with cash settlement features as Level 3. Management evaluates a variety of inputs and then estimates fair value based on those inputs. As discussed above, the Company utilized the Monte Carlo Simulation Model in valuing the warrants and the convertible note.

The table below presents the balances of assets and liabilities measured at fair value on a recurring basis by level within the hierarchy as:

	(in thousands) As of December 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets:				
Marketable securities	$ 7,137	$ 7,137	$ —	$ —
Liabilities:				
Redeemable warrants	$ —	$ —	$ —	$ —

	(in thousands) As of December 31, 2021			
	Total	Level 1	Level 2	Level 3
Assets:				
Marketable securities	$ 16,175	$ 16,175	$ —	$ —
Liabilities:				
Redeemable warrant	$ 35	$ —	$ —	$ 35

The changes in Level 3 Liabilities measured at fair value on a recurring basis are summarized as follows (in thousands):

Redeemable warrants:	
Balance at December 31, 2021	$ 35
Fair value adjustments	(35)
Balance at December 31, 2022	$ —

The table below presents the balances of assets and liabilities measured at fair value on a nonrecurring basis by level within the hierarchy as:

	(in thousands) As of December 31, 2021				
	Total	Level 1	Level 2	Level 3	Total Gains (Losses)
Assets:					
Long lived assets held and used[(a)]	$ 3,900	$ —	$ —	$ 3,900	$ 1,800

(a) In accordance with Subtopic 360-10, long-lived assets held and used with a carrying amount of $5,700,000 were written down to their fair value of $3,900,000, resulting in an impairment charge of $1,800,000, which is included in earnings for the period.

(16) Financing Obligation Arising from Sale Leaseback Transaction

On March 16, 2018, the Company sold land and a building for $4,080,000 and concurrently entered into an agreement to lease the property back for ten years at $408,000 per year for two years through March 31, 2020. The lease payments will increase 2.5% per year for the next three years through March 31, 2023, and the lease payments will increase 3% for the remaining five years through March 31, 2028. As part of the sale of this building, warrants were provided to the buyer for the purchase of up to 73,314 shares of Company common stock for a period of five years at an exercise price of $17.05 per share, 125% of the closing price of the common stock on the NYSE American on the date of execution of the letter of intent for the purchase. The sale of the property includes an option to repurchase the property based on a contractual formula which does not permanently transfer all the risks and rewards of ownership to the buyer. Because the sale of the property includes the option to repurchase the property and includes the above attributes, the transaction was accounted for as a financing transaction whereby the Company recorded the cash received and a financing obligation. The warrants cannot be exercised to the extent that any exercise would result in the purchaser owning in excess of 4.99% of our issued and outstanding shares of common stock.

On May 13, 2021, the Company completed its repurchase of the property for cash of $4,732,637. The repurchase resulted in the related liability recorded upon sale being extinguished on the date of the repurchase. A loss on the extinguishment was recorded based on the difference between the carrying value of the financing obligation including unamortized debt discount and the amount exchanged to extinguish the debt.

For the period ended December 31, 2021, the loss on extinguishment was $2,701,460. Interest expense relating to this financing agreement was $19,000 for the period ended December 31, 2021.

(17) Subsequent Events

On March 28, 2023, Nancy K. Bryan was appointed a Director to the Company's Board of Directors. See "PART III ITEM 10. / Directors and Executive Officers and Corporate Governance" for biographical information.