UNITED STATES
SECURITIES AND EXCHANGE COMISSION
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, 2021

☐ **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. 001-41096

AeroClean Technologies, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**45-3213164**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

10455 Riverside Dr.
Palm Beach Gardens, FL 33410
(Address, including zip code, of principal executive offices)

Registrant's telephone number, including area code: **833-652-5326**

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, $0.01 Par Value	AERC	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933. 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 Securities Exchange Act of 1934. 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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The Registrant did not have a public float on the last business day of its most recently completed second fiscal quarter because there was no public market for the Registrant's common equity as of such date.

The Registrant has one class of common stock, $0.01 par value per share, of which 13,877,636 shares were outstanding as of March 28, 2022.

DOCUMENTS INCORPORATED BY REFERENCE

Information required by Part III (Items 10, 11, 12, 13 and 14) of this Form 10-K is incorporated by reference to portions of the Registrant's definitive proxy statement for the 2022 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission no later than 120 days after the end of the Registrant's fiscal year covered by this report.

AEROLEAN TECHNOLOGIES, INC.
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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements to encourage companies to provide prospective information to investors. This Annual Report on Form 10-K (this "Annual Report") includes forward-looking statements that reflect our current expectations and projections about our future results, performance and prospects. Forward-looking statements include all statements that are not historical in nature or are not current facts. When used in this Annual Report, the words "believe," "expect," "plan," "project," "intend," "anticipate," "estimate," "predict," "potential," "continue," "may," "might," "likely," "should," "could," "will", "target" or the negative of these terms or similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain such identifying words. These forward-looking statements are based on our current expectations and assumptions about future events and are based on currently available information as to the outcome and timing of future events.

These forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause our actual results, performance and prospects to differ materially from those expressed in, or implied by, these forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed under the heading "Risk Factors" in this Annual Report, including the following factors:

- general economic conditions in the markets where we operate;
- the impact of the COVID-19 pandemic and related prophylactic measures;
- expected timing of regulatory approvals and product launches;
- non-performance of third-party vendors and contractors;
- risks related to our ability to successfully sell our products and the market reception to and performance of our products;
- compliance with, and changes to, applicable laws and regulations;
- our limited operating history;
- ability to manage growth;
- ability to obtain additional financing when and if needed;
- ability to expand product offerings;
- ability to compete with others in our industry;
- ability to protect our intellectual property;
- the ability of certain existing stockholders to determine the outcome of matters which require stockholder approval;
- ability to defend against legal proceedings; and
- success in retaining or recruiting, or changes required in, our officers, key employees or directors.

In light of these risks, uncertainties and assumptions, you are cautioned not to put undue reliance on any forward-looking statements in this Annual Report. These statements should be considered only after carefully reading this entire Annual Report. Except as required under the federal securities laws and rules and regulations of the SEC, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Additional risks that we may currently deem immaterial or that are not presently known to us could also cause the forward-looking events discussed in this Annual Report not to occur.

PART I

Item 1. Business

Overview

AeroClean Technologies, Inc. (the "Company," "AeroClean Technologies," "we," "us" or "our"), is an interior space air purification technology company. Our immediate objective is to continue implementing the full-scale commercialization of our high-performance interior air sterilization and disinfection products for the eradication of harmful airborne pathogens, including COVID-19 (a respiratory disease stemming from a novel coronavirus, the outbreak of which was declared a global pandemic by the World Health Organization in March 2020).

We incorporate our proprietary, patented UV-C LED technology in equipment and devices to protect the occupants of interior spaces. These spaces include hospital and non-hospital healthcare facilities (such as outpatient chemotherapy and other infusion facilities and senior living centers and nursing homes), schools and universities, commercial properties and other indoor spaces.

Our products are being designed and engineered to exceed the rigorous standards set by the U.S. Food and Drug Administration (the "FDA") for interior air sterilization and disinfection products. Our units can be marketed for use pursuant to the FDA Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (the "Policy").

We are currently seeking premarket approval from the FDA ("510(k) clearance") for the use of our products in healthcare and other markets for which product performance is required to be validated by certified independent labs. Regulatory clearances and independent certifications serve as important product imprimaturs that also influence decision-making by non-healthcare market equipment purchasers. We expect to receive FDA 510(k) clearance for Pūrgo in the second half of 2022.

In July 2021, we completed the development stage of our first device, the Pūrgo room air purification unit, including design and independent testing and certification, as well as the scale-up of manufacturing, and began commercial production and sales. Pūrgo's launch also marks the debut of our go-to-market strategy for SteriDuct, the Company's patented air purification technology. We intend to incorporate SteriDuct into a broad line of autonomous air treatment devices. In February 2022, we debuted a prototype of Pūrgo Lift, our air purification solution for elevators and other wall-mount applications, and since then certain of our customers are testing and evaluating Pūrgo Lift for future deployment in their facilities.

To support the transition to commercial operations, in July 2021, we also completed the build out of our corporate headquarters in Palm Beach Gardens, Florida, which includes our warehouse and distribution facility, as well as the site for our future service operations.

As part of our business strategy we continually evaluate a wide array of strategic opportunities, including the acquisition, disposition or licensing of intellectual property, mergers and acquisitions, joint ventures and other strategic transactions. We may seek to acquire technologies, product lines and companies which operate in businesses similar to our own or which are ancillary, complementary or adjacent to our own or in which we do not currently operate. Such businesses could operate in the air purification space or more generally in the health and wellness space or in other industries. We could also seek to merge with or into another company or sell all or substantially all of our assets to another company. We could also seek to merge with or into another company or sell all or substantially all of our assets to another company. In connection with these activities we may enter into non-binding letters of intent as we assess the commercial appeal of potential strategic transactions. Any transactions that we enter into could be material to our business, financial condition and operating results. Please see related risks described under the captions "We may acquire other companies or technologies, which could divert our management's attention, result in additional dilution to stockholders and otherwise disrupt our operations and adversely affect our business, financial condition and results of operations" and "Our executive officers, directors and principal stockholders have the ability to control all matters submitted to stockholders for approval" in the "Risk Factors" section of this Annual Report.

Background and Purpose

We were established by our co-founders, Amin J. Khoury, PhD (Hon), our Chairman; David Helfet, M.D., our Chief Medical Officer; and Mark Krosney, our Chief Scientific Officer, to fulfill their determination to provide solutions for the critical challenges posed by harmful airborne pathogens and resultant hospital acquired infections ("HAIs").

HAIs and other infections acquired in outpatient treatment facilities present an extreme risk to the immunocompromised patient population. In the U.S. alone, it is estimated that 10 million people are immunocompromised. Whether in hospitals or infusion treatment locations, patients with cancer, and a multitude of other disease and disease related treatments, are at an elevated risk of infection. Constant air purification is of extreme benefit in these settings in order to minimize the presence of dangerous airborne pathogens due to the often catastrophic risk that infection poses to the immunocompromised patient population. It is estimated that there are approximately 2 million HAIs annually in the United States, causing approximately 100,000 deaths and costing over $30 billion. These numbers are in-hospital only and do not include the likely much larger number of patients infected in outpatient infusion and treatment centers. For one example, there are more than 650,000 cancer patients that receive outpatient chemotherapy, and they are at risk for acquiring infections in these treatment facilities, despite advanced filtration and ventilation systems. 60,000 cancer patients are hospitalized annually for chemotherapy-induced neutropenia and infections — one patient dies every two hours from this complication.

The onset of COVID-19 has increased our urgency to create innovative and more effective air purification solutions for the risks posed by harmful airborne pathogens, including coronavirus and other viruses, bacteria, molds, particles, fungi and allergens. Studies have shown 85% of COVID-19 transmission to be airborne person-to-person in the form of aerosolized droplets and in enclosed spaces. The Journal of Science estimates the annual U.S. cost of flu and respiratory infections at $50 billion and the World Health Organization estimates that 4 million premature deaths annually are caused by air pollution.

The genesis of our proprietary air purification technology traces back to efforts to address commercial aircraft cabin air quality. Mr. Krosney is a highly-accomplished scientist who is primarily responsible for numerous patents, several of which are important components of our IP portfolio. Mr. Krosney is a former senior scientist and engineer at B/E Aerospace. Dr. Khoury, the founder and long-time Chairman and Chief Executive Officer of B/E Aerospace, envisioned the significant potential to apply such proprietary technology for revolutionary, medical-grade air purification solutions for hospital and other critical healthcare settings. Dr. Khoury consulted with Dr. David Helfet, a leading orthopedic surgeon at both the Hospital for Special Surgery and New York-Presbyterian Hospital, regarding possible solutions for the critical challenges to patients and hospitals posed by harmful airborne pathogens and HAIs.

This collaboration has served as the foundation for our Company and the implementation of our business plan. Dr. Khoury made a substantial investment in the Company, leading an investment group providing the necessary capital to develop the Company's substantial intellectual property portfolio and products.

Dr. Khoury is a renowned industrialist recognized for bringing to market game-changing solutions for diverse challenges and for building market-leading global businesses. Dr. Khoury was Chairman and Chief Executive Officer of B/E Aerospace, a Nasdaq-listed S&P 400 diversified industrial company, sold in April 2017 to Rockwell Collins (now, part of Raytheon) for $8.6 billion. Previously, in December 2014, B/E Aerospace completed the spin-off of KLX Inc. as an independent Nasdaq-listed public company, itself sold in May 2018 to Boeing for $4.25 billion. Drs. Khoury and Helfet were long-time colleagues who served together for many years on the board of directors of Synthes, Inc., which, led by Dr. Khoury's efforts, completed a $21 billion merger in 2012, creating DePuy Synthes, Johnson & Johnson's global orthopaedics business.

Several other members of our leadership team have long-standing working relationships with Dr. Khoury, including in senior-level roles at B/E Aerospace and KLX Inc.

The Global Air Purification Market and our Patented SteriDuct Technology

The COVID-19 pandemic has inspired intensive analysis of how pathogens are transmitted among humans and has isolated the role of airborne transmission as being among the most significant risks. While

each pathogen is unique, deadly viruses proliferate and are transmitted between humans principally through the air, and then can also settle on surfaces and may remain contagious for extended periods of time depending upon the pathology. The application of ultraviolet ("UV") light to both the air and to surfaces has emerged as the most efficacious way to thoroughly eradicate pathogens without the use of chemicals, drugs or solvents, which may leave residues or have other deleterious implications for humans who come in contact after treatment. Most importantly, the UV-LED light embedded in our patented SteriDuct technology treats air continuously, to contain the spread of pathogens in any enclosed space where they are being continuously transmitted by an infected person. A sanitized room is no longer free from cross infection the moment an infected person enters it; and that person will continue to spread pathogens through the air for the duration of their presence, only mitigated by the ability of an in-room air purification system to destroy pathogens while they are being emitted.

The global air purification market for 2021 was estimated by industry sources at over $13.0 billion. We believe the emerging realization that pathogens introduced locally to a room will likely infect other occupants before the central building conditioning and filtering system can treat the air has led to a focus on continuous air treatment at the room level rather than at the building level. In addition, while historically air filtration has been predominantly focused on removing dust, spores, allergens and pathogens from air streams to maintain the efficiency (both energy and air quality) of large HVAC systems, we believe there is increasing focus on the ability to drive continuous, real-time pathogen elimination as part of the air filtration process. This includes the elimination of minute particles, including organic compounds, molds, bio-aerosols, bacteria and viruses.

We believe the large majority of air purification products are built for the consumer market and only use air filtration as a way to filter — not eradicate — airborne pollutants. Many feature high-efficiency particulate air ("HEPA") and "HEPA like" filter material, which is designed to trap 99.97% of particles down to 0.3 microns. Viruses are much smaller than 0.3 microns, and studies show that viruses and drug-resistant bacteria can penetrate HEPA filters. As particle load builds-up and filters become "dirty," tunneling can occur allowing previously captured particulate and pathogens to break through filter material — increasing the probability of recontamination and infection in indoor spaces. We believe our patented UV-C LED SteriDuct technology augments HEPA filtration to not only filter pathogens but to kill them, and to do so continuously and effectively.

We expect that our patented UV-C LED SteriDuct technology, which has been developed over the past seven years, is adaptable to applications addressing major points of potential contamination in interior spaces. While originally developed principally to reduce the number of HAIs and to protect immunocompromised patients, we have completed the development phase of the first commercial application of our technology just at the moment in history where we believe we can have a seminal impact on people's lives across society. We believe AeroClean Technologies can capture an expansive market opportunity by installing our patented devices in hospitals, outpatient treatment facilities, commercial offices, residential buildings, universities and schools, senior living and nursing homes, non-hospital healthcare facilities and human transport and travel industries, providing the Company with both initial sales revenue at attractive margins and a steady stream of aftermarket services revenues related to sales of replacement filters and recurring maintenance at attractive levels of profitability.

Through application and implementation of our UV-C LED technology, the Pūrgo and Pūrgo Lift devices have the potential to create comprehensive solutions for at-risk enclosed spaces.

In the year ended December 31, 2021, we launched the first commercial application of our technology with a lightweight (approximately 42 pounds) portable device, Pūrgo, that continuously purifies the air, and we have begun the manufacturing process to support this rollout. We have additional air purification applications also in development.

Our History

The genesis of our SteriDuct and Pūrgo technology traces back to technology developed by Mark Krosney, Co-Founder and Chief Scientific Officer, a highly-accomplished scientist and formerly one of the lead engineers of B/E Aerospace. The technology was originally intended to address commercial aircraft cabin air quality applications. However, Amin J. Khoury, the Founder and formerly the Chairman and Chief

Executive Officer of B/E Aerospace, recognized the commercial potential of this technology for the healthcare market, after discussions with Dr. David Helfet, Co-Founder and the Director Emeritus of the Orthopedic Trauma Service at both the Hospital for Special Surgery and the New York-Presbyterian Hospital, regarding the critical challenge to patients and hospitals posed by HAIs. Dr. Khoury subsequently led an "angel" investment group in funding the Company to-date, in particular to provide for rigorous design and development of Pūrgo in a manner conforming to demanding regulatory requirements and the development of substantial intellectual property.

Dr. Khoury and Dr. Helfet are long-time colleagues who developed a strong business relationship during their respective 26- and 10-year service on the board of directors of Synthes, Inc., a $4 billion annual revenue company and the world's leading manufacturer and marketer of orthopedic trauma implants. In 2011, Dr. Khoury, at the request of Hansjörg Wyss, Chief Executive Officer of Synthes, led an effort to sell Synthes. In 2012, Synthes successfully merged with Johnson & Johnson's DePuy franchise in a $21 billion transaction.

To date, our team has been formed through the utilization of highly qualified independent contractors and executives, including scientists, engineers, sales and marketing resources and others with expertise in electrical, mechanical and software engineering, computer science and regulatory matters, as well as experience in the healthcare and medical device industries. We have used consultants and other contract personnel for product development and engineering projects as well as for outsourced manufacturing to leverage industry and subject matter experts as well as to manage the Company's fixed cost structure.

We believe the team AeroClean Technologies has assembled, in addition to its differentiated technology and product offering, positions the Company to establish itself as the category leader and industry consolidator in premium air purification solutions for rooms, elevators and transportation systems.

Dr. Khoury and his team, with an established track record and experience from B/E Aerospace in penetrating and ultimately becoming the industry leader for a comprehensive array of commercial aircraft cabin interior components in the face of multiple incumbent competitors, informs AeroClean Technologies' approach to the air purification market, which we believe is currently populated by a number of small companies with technology that relies predominantly on traditional filtration devices.

Leveraging Engineering, Manufacturing and Regulatory Expertise

In developing our patents and related intellectual property into commercial devices that will meet the exacting standards of medical device regulators, while at the same time creating a competitive advantage in our target markets, AeroClean Technologies has chosen to partner with leading companies with both engineering and FDA regulatory expertise as well as FDA regulated contract manufacturers. Utilization of the leading companies in their fields has allowed AeroClean Technologies to dramatically shorten the time-to-market of our Pūrgo device (our first marketable device), while also taking advantage of best-in-class engineering, regulatory expertise and assembly of our first commercial units without having to invest the substantial sums that would be required to establish all these capabilities in-house. The exacting standards embedded in our Pūrgo device are expected to deliver market leading performance in air purification with true competitive differentiation and which we expect will support anticipated final FDA 510(k) clearance for utilization in healthcare and other target markets where performance must be validated by certified independent laboratories.

Our in-house team, leveraging these organizations, has developed what we believe to be the lightest weight, most compact, powerful and cost-effective pathogen elimination device for our target markets.

AeroClean Technologies contracted with IPS, a leading medical and technology device engineering group, in developing the device configuration, which would optimize the performance and reliability of our patented UV-LED and SteriDuct technology. With over 100 designers and engineers who specialize in commercializing highly exacting applications of new technology, a dedicated IPS team has worked continuously with us to design, develop, test and source the components for the commercial production of the Pūrgo device. This is particularly true of electronics design and software engineering as well as product industrial design. To manufacture our first Pūrgo device, AeroClean Technologies has engaged Mack Molding, a leading contract manufacturer of medical devices, which also has experience manufacturing devices for the transportation,

energy/environment, defense/aerospace and consumer markets. AeroClean Technologies has also engaged MethodSense to reduce time to market and move our Pūrgo device successfully through the FDA regulatory process. MethodSense is a global medical device consultancy and software developer with over 21 years of deep industry experience, proven processes and modern technology focused on the commercial success of medical device companies.

Our Value Proposition

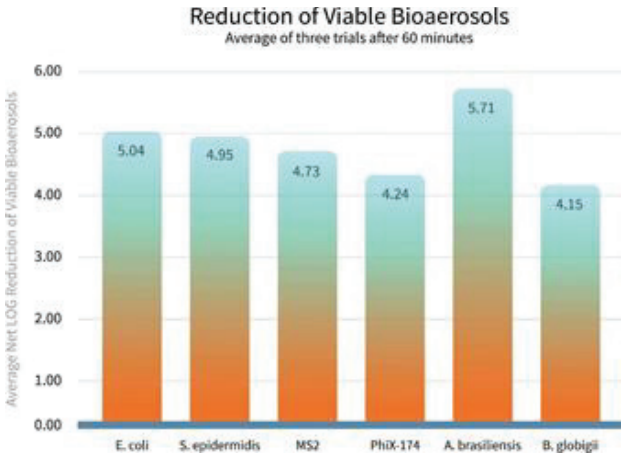
While there are numerous air filtration devices currently on the market, in addition to traditional filters fitted on HVAC systems primarily in hospitals, we believe the Pūrgo devices promise a step-change improvement in air treatment. By employing our patented UV-C LED and SteriDuct technology combined with three-stage filtration, our devices not only remove dust, spores, allergens and pathogens from the air but also eradicate essentially all types of airborne pathogens in occupied room airspaces and do so continuously. The cost of upgrading HVAC systems in hospitals, schools, office buildings, commercial spaces and others looking for air quality solutions can not only be costly, but it can also be disruptive as the core system is retrofitted or construction takes place to address high-risk areas throughout the building.

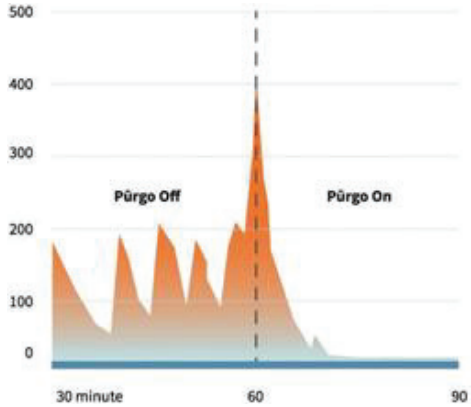
Further, HVAC systems do not always run continuously and cannot, in any event, continuously protect a room's occupants as compared to Pūrgo, which is continuously running and placed closely to potential sources of cross-infection. Larger plug-and-play solutions are generally more costly and, we believe, less effective because they cannot always be placed closest to the occupants we are protecting. Our first Pūrgo device is of a size and price point that allows customers to strategically place units for optimal protection of occupants. We believe the combination of technology, performance and price of the Pūrgo devices will deliver a singular value proposition that will make AeroClean Technologies a disruptor and consolidator in the professional air treatment market.

Our Technological Advantage

The foundation of our patented pathogen-killing technology is the utilization of solid-state light-emitting diodes ("LEDs") and the unique way we have deployed this LED technology through the development of our patented SteriDuct technology, which incorporates a proprietary geometry and reflective coating air induction and treatment process to safely deliver superior pathogen killing capability, while operating at lower power levels and with minimal air flow disruption. Our technology uses UV-emitting LEDs, which replaces conventional vacuum tube UV sources used in other competing UV devices — which are harmful to human beings and the environment and emit poisonous mercury gas when broken.

Studies of COVID-19 transmission have highlighted that, similar to seasonal flu viruses and other pathogens (such as severe acute respiratory syndrome, or "SARS," and Middle East respiratory syndrome, or "MERS"), COVID-19 is transmitted predominantly through contact between an infected person and others. To effectively limit this exposure, the air in the room that the infected person occupies must be continuously treated to remove the pathogens being transmitted into the air in the room. There currently are a number of commercial devices that reduce air pathogen levels, but they do not do so continuously while the room is occupied. The Pūrgo device operates continuously, and the devices are able to be placed strategically within occupied rooms to treat the infected air closer to the source of the infectious material, rather than have the air pulled from the room through traditional filtering systems. Testing results confirmed that our device, powered by SteriDuct, was able to eradicate 99.99% ("4 Log") of airborne pathogens in less than 60 minutes, including a surrogate pathogen for COVID-19.





The Pūrgo air filtration machine is a compact, lightweight, powerful, energy efficient device that we believe delivers best-in-class performance. The LEDs used in Pūrgo produce UV output at precisely the wavelength to maximize pathogen killing, 265 nanometers. Our utilization of LEDs reflects the advances in LED technology that have made LEDs superior to UV vacuum tube bulbs in terms of energy efficiency, superior air flow dynamics and safety. The cost of LEDs has come down by a factor of ten on a per watt basis over the past decade, while the effective operational life has also grown by ten, and output power has increased by a factor of seven. By contrast, UV vacuum tubes are an old technology, which cannot be operated in the presence of human beings and for which we believe significant performance improvements have been infrequent and have had less impact. LEDs also meet current environmental best practices, as they have no toxic materials such as mercury, which are prevalent in conventional UV lamps.

We developed our patented SteriDuct operating system to optimize the application of state-of-the-art UV-C LEDs in several pathogen killing configurations. Optical analysis tools such as ray tracing, combined with mathematical modeling, allows us to geometrically locate the LEDs in the exact spot in SteriDuct to maximize light intensity. Further, material scientific developments have enabled us to utilize alenod material in the coating of SteriDuct, which triples the pathogen killing irradiance of SteriDuct, and computational fluid dynamics were applied in the positioning of the LEDs to optimize air flow and minimize air pressure loss, thereby reducing fan and motor requirements to circulate air, which reduces size, weight and cost while achieving 4 Log average kill rates (99.99%) against viral, bacterial and fungal pathogens. To validate and prove the pathogen killing power of SteriDuct, we have completed extensive microbial testing in Good Laboratory Practice ("GLP") compliant, independent laboratories.

Since the design architecture of the pathogen killing SteriDuct has an efficient high air flow and a low pressure loss profile, the design is flexible and can be incorporated into many applications. Implementation of our SteriDuct technology into the Pūrgo devices incorporates both a sophisticated filtration system that reduces particles, odors, organic solvents, bacteria, viruses, allergen and mold, as well as our patented UV-C LED based pathogen killing system. SteriDuct may also be used in large spaces such as lecture halls and auditoriums. SteriDuct purification devices can be deployed at the HVAC discharge grille or at the central air handler. This implementation would not require additional fans in the air handler due to the low-pressure characteristics of SteriDuct. We expect that similar configurations can be developed for airplanes and buses.

Our Target Markets

We believe our technology is adaptable and superior in the treatment of air and destruction of pathogens in any interior space. The market for our technology, therefore, is both large and global in nature — we estimate the total addressable market opportunity just within the U.S. healthcare market to be approximately $12 billion. Our proprietary patents and the validation of our first device, the compact, lightweight, powerful and cost-effective Pūrgo air purification device, will be important in establishing our brand and commercial footprint.

The markets we intend to focus on initially will be predominantly in the healthcare industry, as the inspiration for our technology was to address the high rate of HAIs acquired throughout hospitals, but particularly in surgeries and outpatient treatment areas with the highest population of immunocompromised patients. Moreover, the healthcare industry in the U.S. represents an approximately $12 billion market opportunity that will continue to be on the front lines of dealing with pathogens and, therefore, we expect will be receptive to technological advances that address the issue. We are acutely focused on the breadth of healthcare facilities that would benefit from utilization of the Pūrgo and Pūrgo Lift devices, as well as our SteriDuct technology. In the U.S. alone, there are 6,090 hospitals, which have 208,500 on-site surgical facilities. In addition, these hospitals have 106,000 intensive care beds, predominantly each in their own room, and 825,000 non-ICU beds, usually configured with three beds per room. We have also assumed each hospital has 15 waiting rooms across both the general admittance and specialty practices within the facility and that each hospital has a minimum of seven elevators. As a result, in total, we estimate the approximate total market opportunity for the Pūrgo device within the U.S. hospital system to be $2.4 billion. For example, our largest customer in 2021, which made up 45% of revenues, was a hospital with a broad deployment of 100 units to address a variety of clinical and non-clinical spaces. While these individual customers may be significant, and customers may purchase units over time to satisfy their needs, the transactional nature of the opportunities and the size of the addressable market mitigate a risk of concentration on an ongoing basis.

We believe the non-hospital medical market presents an equally compelling opportunity. There are approximately 209,000 medical offices in the U.S., as well as 9,280 non-hospital surgery centers containing 16,000 procedure rooms. We believe that most rooms could utilize a minimum of two Pūrgo devices to optimize room sanitization and disinfection, representing a market opportunity of approximately $4.3 billion.

Our third expected healthcare market opportunity is serving the long-term care and assisted living industry. We view this market as a natural extension of the first two areas, hospital and medical offices, which we will address in the first phase of our commercial launch. There are currently 60,000 long-term care and assisted living facilities in the U.S., and we believe, from a safety and fiduciary position, each facility should consider coverage of the common facilities, including dining rooms, activity rooms, therapy rooms and, importantly, reception areas and elevators, representing a market opportunity of approximately $5.1 billion, exclusive of elevators.

We believe adoption of the Pūrgo device in the healthcare environment will create substantial credibility and momentum that will provide us an opportunity to enter the university and K-12 school market. On March 11, 2021, President Biden signed the $1.9 trillion coronavirus relief package, the American Rescue Plan, which included $130 billion to help schools reopen safely by reducing the probability of cross-infection — including for personal protective equipment, reducing class sizes and, importantly, improving ventilation. In a 2021 report on K-12 public school infrastructure, the American Society of Civil Engineers found that more than 40% of schools had HVAC systems in need of repair. Therefore, we believe that the K-12 school market represents a market opportunity of approximately $1 billion. We are engaging in activities with a goal of accessing the K-12 school market, including direct marketing to school administrators online and working with third-parties that specialize in marketing to K-12 schools. While our primary focus in 2021 has been establishing our commercial footprint within the healthcare markets as previously noted, we expect to see word-of-mouth driven demand from universities and schools as the year progresses. We estimate the total addressable market opportunity within the U.S. education and childcare markets (public and private K-12 schools, universities and colleges, preschool and daycare) to be approximately $9.7 billion.

Similarly, we believe emerging public awareness of the realities of airborne infections are focusing both tenants and landlords on the inadequacies of centralized HVAC systems for protecting occupants in individual rooms, in the instance when an infected person is also in the room and contagious. Only localized, continuous sanitizing of the air can reduce the risk of infection in these circumstances. We believe prophylactic placement of the Pūrgo devices in conference rooms, open work environments, cafeterias, lobbies and other communal spaces will substantially improve the air quality of these areas well beyond what is provided by central HVAC systems and thereby make it safe to return to and remain at work in multi-story office buildings. We estimate the total addressable market opportunity within the U.S. for elevator air purification to be approximately $5.0 billion.

Commercialization Plan

As mentioned above, we launched the first commercial application of our technology with the Pūrgo air purification device in July 2021 and have begun the manufacturing start up process to support this rollout. Our founding investors have invested approximately $15 million to date to support our technology conceptualization, product design, prototyping, testing and pre-product launch expenses. We have engaged Mack Molding, an FDA-regulated subsidiary of the privately held Mack Group, to manufacture our first Pūrgo device. Mack Molding is a leading contract manufacturer of medical devices, with a focused team of product development, program management, quality, regulatory, document control and purchasing staff that are skilled in medical device manufacturing.

We have sold the Pūrgo air purification device principally to hospitals, outpatient facilities and medical offices in multi-unit transactions to optimize both our sales productivity and our ability to provide efficient aftermarket service to our proprietary devices. We have begun the process of hiring a dedicated sales team to support our targeted sales efforts. We are also exploring exclusive distribution arrangements with several potential distribution and service partners, both domestically and internationally, which could help accelerate the market penetration of our devices more rapidly than on a purely organic basis.

We launched the Pūrgo device into the multi-billion dollar Florida healthcare market initially, focusing principally on protection of immunocompromised patients in chemotherapy and other outpatient infusion centers, general, specialty and eye surgery-centers and medical offices. We believe the Florida medical market is both extensive and representative of the larger healthcare opportunity across the U.S. and that penetrating this market will allow us to scale up our operations at the same time from our corporate offices in Palm Beach Gardens, Florida. We intend to grow our sales organization ahead of demand to take advantage of the learning curve afforded by our sales in Florida.

At the same time as we are marketing our room air purification device, we intend to accelerate our development of complementary devices that will address other points of pathogen vulnerability within the work and travel markets. Our highest priority in this regard is our elevator air purification device, Pūrgo Lift. We believe the tight enclosure of elevators is a "hot spot" for pathogen transmission that will be crucial for every high rise building to address in re-opening safely. This is particularly true in hospitals, where sick, vulnerable patients and visitors are regularly together on lifts. We developed working prototypes of the Pūrgo Lift device for beta testing and market feedback by the end of 2021, and we expect one of our customers to begin trialing the device in one of its public elevators during the first half of 2022 to evaluate for future deployment across the customer's facilities.

The commercial aviation market is also at a critical stage, with safe travel contingent on the ability to move passengers safely through airport waiting and boarding areas and to treat cabin air in-flight and to disinfect aircraft cabins between flights. Our SteriDuct technology was first developed by one of the former lead engineers of B/E Aerospace, a world leader in cabin interiors, including oxygen systems, and in its current form is adaptable to this application.

Similar to the commercial aviation market, we believe the large building HVAC market will provide substantial retrofit opportunities, as the current large systems generally rely on filtration systems that do not effectively remove and destroy pathogens flowing through the system. We intend to enter into discussions with the leading global HVAC suppliers, as well as directly with building owners, to develop retrofit applications for our SteriDuct technology that will complement existing installed systems in these large buildings.

Intellectual Property

The proprietary nature of, and protection for, our technology, processes and know-how are important to our business. Our commercial success will depend in part on obtaining and maintaining patent protection, protecting our know-how and trade secrets, successfully defending any patents against third-party challenges and, where relevant, collaborating with third party licensors to obtain licenses to use relevant technology.

Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We have been issued four patents in the U.S. We also have a number of other patent

applications pending in the U.S. and other jurisdictions, including Europe and Japan. Our patent portfolio includes patents relating to our UV-C LED SteriDuct technology, which is incorporated into our Pūrgo and Pūrgo Lift products.

We cannot be sure that patents will be granted with respect to any of pending patent applications or with respect to any patent applications we file in the future, nor can we be sure that any existing patents or any patents that may be granted in the future upon which we rely will be commercially useful in protecting our products or processes. See the risks described under the captions "Our success may depend on our ability to protect our intellectual property" and "We may need to initiate lawsuits to protect or enforce our patents or other proprietary rights, which would be expensive, and if unsuccessful, may cause us to lose some of our intellectual property rights" in the section of this Annual Report titled "Risk Factors."

Competition

We believe that the COVID-19 pandemic has increased, and will continue to increase, the global focus on clean air. We experience competition from organizations such as large, diverse companies with extensive product development and manufacturing, as well as smaller specialized companies, that have developed and are attempting to develop air filtration and purification systems. We believe that we have significant competitive advantages over other organizations. For example, we believe that competitive products to the Pūrgo device in the "medical grade" niche are expensive, cumbersome and have a limited effective life.

Additionally, many of our competitors are promoting technologies that are not proven, do not have enough scientific data and are potentially harmful. Importantly, our Pūrgo technology meets or exceeds each of the air purifiers guidelines and recommendations by the Centers for Disease Control and Prevention, Environmental Protection Agency and the American Society of Heating, Refrigerating and Air-Conditioning Engineers.

Our competitors may develop and commercialize products and technologies that compete with our products and technologies. Organizations that compete with us may have substantially greater financial resources than we do and may be able to: (i) provide broader services and product lines; (ii) make greater investments in research and development; (iii) carry on larger research and development initiatives; (iv) undertake more extensive marketing campaigns; and (v) adopt more aggressive pricing policies than we can. They also may have greater name recognition and better access to customers than we do. We also expect to continue to face competition from alternative technologies. Our technology and products may be rendered obsolete or uneconomical by advances in existing technological approaches or products or the development of different approaches or products by one or more of our competitors. See the risk described under the caption "We face intense competition" in the section of this Annual Report titled "Risk Factors."

Governmental Regulations

Our products are being designed and engineered to exceed the rigorous standards set by the FDA for Class II medical devices used for interior air sterilization and disinfection products. During the year ended December 31, 2021 and as of the date of the filing of this Annual Report, our devices are permitted to be marketed for use pursuant to and for the duration of the FDA Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, referred to as the "Policy" throughout this Annual Report. The Policy is only intended to remain in effect for the duration of the public health emergency related to COVID-19. In December 2021, the FDA issued the draft Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (the "draft Transition Plan," and the related transition plan once finalized, the "final Transition Plan") for public comment which, among other things, proposes a 180-day transition period beginning on an undetermined implementation date and ending on the date that the Policy is withdrawn, at which time we will need to be in compliance with applicable statutory and regulatory requirements. The draft Transition Plan provides that companies relying on the Policy, among other COVID-related FDA guidance, must submit and obtain acceptance of their 510(k) submissions prior to the expiration of the transition period in order to continue marketing and distributing devices following withdrawal of the Policy. The final Transition Plan ultimately published by the FDA may deviate, potentially significantly, from the draft Transition Plan and it is therefore impossible to know exactly how the final Transition Plan will impact our business and regulatory compliance requirements.

See the risk described under the caption "We do not yet have full FDA clearance to market our products in the United States" in the section of this Annual Report titled "Risk Factors."

We submitted our 510(k) application for Pūrgo in November 2021. We will be subject to continuing FDA regulation if and when we receive 510(k) clearance for Pūrgo, which is expected to be obtained in the second half of 2022, as well as by other federal and state authorities.

The FDA regulates the development, design, manufacturing, safety, effectiveness, labeling, packaging, storage, installation, servicing, recordkeeping, clearance, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the Federal Food, Drug, and Cosmetic Act ("FDCA").

After an air purification product is cleared for marketing as a medical device, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- requirements that manufacturers, including third-party manufacturers, follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated;
- clearance of a new 510(k) premarket notification for modifications to 510(k) cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of the device;
- medical device reporting regulations, which require that a manufacturer report to the FDA information that reasonably suggests a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- complying with the federal law and regulations requiring Unique Device Identifiers on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations if the FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The manufacturing processes related to our devices are required to comply with applicable regulations covering the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distributions, installation and servicing of finished devices intended for human use. Regulations also require, among other things, maintenance of a device master record, device history file and complaint files. As a manufacturer, Mack Molding's facilities, records and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA. Mack Molding's failure to maintain compliance with applicable regulatory requirements could result in the shutdown of, or restrictions on, its manufacturing operations and the recall or seizure of our products. The discovery of previously unknown problems with our devices could result in restrictions on the device, including the inability to market the device for its intended use or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals or administrative detention or seizure of our devices;
- operating restrictions or partial suspension or total shutdown of production;
- refusal to grant export or import approvals for our products; or
- criminal prosecution.

Employees

We utilize the services of 7 direct employees. The Company also utilizes full-time independent contractors and full-time equivalent consultants as well as consulting firms for product development, engineering, quality and regulatory matters, investor relations, marketing and advertising, public relations and social media. The services of our Chief Scientific Officer, Director of Engineering & Product Development, Director of Regulatory Affairs & Quality and Director of Operations are provided to us under service arrangements. We also utilize many consultants in the ordinary course of our business and hire additional personnel on a project-by-project basis. We believe that our employee and labor relations are good.

Item 1A. Risk Factors

A description of the risks and uncertainties associated with our business is set forth below. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," particularly before deciding whether to invest in our securities. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. The risks described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and adversely affect our results of operations and financial condition.

Risks associated with our business and industry

If Pūrgo fails to perform as expected, our ability to develop, market and sell our products could be harmed.

In the year ended December 31, 2021, we launched our first commercial air purification unit, Pūrgo, for in-room applications and in February 2022 we debuted a Pūrgo Lift prototype, an air purification device for elevators and other wall-mount applications. The successful commercialization of these products is highly uncertain and subject to a number of risks. These risks include, but are not limited to: (i) the possibility that our products will be found to be less effective than anticipated or fail to receive necessary regulatory clearances; (ii) that the products, even if effective, will be difficult to scale up or manufacture at commercial levels or uneconomical to market; (iii) that proprietary rights of third parties will preclude us from using such technologies or marketing such products; and (iv) that third parties will use or market superior or equivalent technologies or products.

Our products may contain defects in design and manufacture that may cause them to not perform as expected or that may require repairs, recalls and design changes. We have a limited frame of reference from which to evaluate the long-term performance of Pūrgo and Pūrgo Lift. If these devices, or additional devices or applications of our technology that we may develop in the future, fail to perform as expected, customers may delay deliveries or terminate further orders and we may need to initiate product recalls, each of which could adversely affect our sales and brand and could adversely affect our business, financial condition and results of operations.

Our future success will depend on our ability to implement our business strategy and to develop and introduce, on a timely basis, products that address the evolving needs of our customers. If we are unable to develop, validate and scale the technology necessary to compete successfully with existing or newly emerging technologies, or if we are unable to develop products based on these technologies, our business, financial condition and results of operations could be seriously harmed.

If we cannot develop adequate distribution, customer service and technical support networks, or navigate applicable global logistics and supply chain bottlenecks, then we may not be able to market and distribute our products effectively or customers may decide not to order our products. In either case, our sales and revenues will suffer.

Our strategy requires us to distribute our products and provide a significant amount of customer service and maintenance. To provide these services, we have begun, and will need to continue, to develop a network of distribution and a staff of employees and independent contractors in each of the areas in which we intend to operate. We cannot assure that we will be able to organize and manage this network on a cost-effective basis, if at all. If we cannot effectively organize and manage this network, then it may be difficult for us to provide competitive service and support to our customers, in which case customers may be unable, or decide not, to order our products, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, governmental mandates related to the COVID-19 pandemic — among other dynamics — have negatively impacted, and may continue to impact, personnel and operations at third party manufacturing and component part supplier facilities in the United States and around the world, creating logistics and supply chain bottlenecks across many industries. These disruptions have adversely impacted the availability and cost of raw materials and component parts. For example, various electronic components and semi-conductor chips have become increasingly difficult to source, and when available, may be subject to substantially longer lead times and higher costs than historically applicable. While we have achieved improvements in our third-party manufacturing output since our commercial launch of Pūrgo at the end of the third quarter in 2021, we expect these ongoing global logistics and supply chain bottlenecks and component shortages may adversely impact our ability to source component parts at favorable prices (if at all) and may result in delays in, or reduced output from, our third-party manufacturing activities. Higher component costs and/or delays in our ability to manufacture and distribute Pūrgo and Pūrgo Lift could have a material adverse effect on our sales, revenues, and results of operations in 2022.

We expect to incur future losses through the year ending December 31, 2022 and cannot be certain that our Company will become profitable.

We have incurred operating losses each year since our inception and have only begun to recognize revenue starting in July 2021. These losses are expected to continue through the year ending December 31, 2022, notwithstanding that we have begun to generate revenue, because we plan to continue to make significant investments to develop and market our products and to establish our consumables and service business. We cannot be certain that we will ever achieve or sustain profitability. If we continue to incur operating losses for a period longer than expected, or in an amount greater than expected, we may be unable to continue our operations.

We may not be successful in implementing our proposed business strategy to achieve our expected revenue growth or effectively manage growth.

The Company began recognizing revenues as of July 2021. In the future, even if our revenues increase, our rate of growth may decline. In any event, we will not be able to grow as rapidly or at all if we do not:

- successfully establish our technology and brand;
- establish a commercial footprint;
- accelerate development of prototypes and market introduction of our devices and other novel applications of our proprietary SteriDuct technology;
- capitalize on our collaboration with experts in aerospace;

- explore opportunities for collaboration; or
- identify opportunities to establish industry leadership domestically and internationally.

We cannot assure you that we will be able to meet these objectives. As we grow, we expect to invest substantial financial and other resources to:

- expand into non-medical markets such as schools, long-term care facilities and the aviation and HVAC industries;
- support the development of a team of senior sales associates;
- accelerate our development of complementary devices; and
- incur general administration, including legal, accounting and other compliance, expenses related to being a public company.

Our planned growth will place significant demands on our management and on our operational and financial resources. We have hired and expect to continue hiring additional personnel to support our planned growth. Our organizational structure will become more complex as we add staff, and we will need to improve our operational, legal, financial and management controls as well as our reporting systems and procedures. We will require significant capital expenditures and the investment of valuable management resources to grow and develop in these areas. A failure to manage our growth effectively could materially and adversely affect our ability to market our products, which could have a material adverse effect on our business, financial condition and results of operations.

We depend on sales of a single product for our future growth.

We are currently in the commercialization phase of our principal product, the Pūrgo device. We will depend for our growth on the success of this product. We cannot guarantee that our rollout of this product will be successful or that we will be able to increase sales of our Pūrgo device. In 2021, we generated sales of approximately $0.6 million of the Pūrgo device and, while we intend to promote sales of this product during 2022 and beyond, we cannot guarantee that we will succeed in these efforts. In addition, we may not be successful in developing or acquiring additional products. Any failure to expand sales of our Pūrgo device, or any failure to obtain market acceptance of our product, would have a material adverse effect on our financial condition, results of operations and business.

We do not yet have full FDA clearance to market our products in the United States.

The FDA's Policy provides that we can market and sell the Pūrgo and Pūrgo Lift devices for intended use for the duration of the Policy, which is intended to remain in effect only for the duration of the public health emergency related to COVID-19. In December 2021, the FDA issued the draft Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (the "draft Transition Plan," and the related transition plan once finalized, the "final Transition Plan") for public comment which, among other things, proposes a 180-day transition period beginning on an undetermined implementation date and ending on the date that the Policy is withdrawn, at which time we will need to be in compliance with applicable statutory and regulatory requirements. The draft Transition Plan provides that companies relying on the Policy, among other COVID-related FDA guidance, must submit and obtain acceptance of 510(k) submissions prior to the expiration of the transition period in order to continue marketing and distributing devices following withdrawal of the Policy. The final Transition Plan ultimately published by the FDA may deviate, potentially significantly, from the draft Transition Plan and it is therefore impossible to know exactly how the final Transition Plan will impact our business and results of operations.

We are pursuing full FDA 510(k) clearance for the Pūrgo, which we believe will provide differentiated, superior performance and efficacy standards to prospective customers. The process of obtaining regulatory clearance to market our products can be costly and time-consuming, a dynamic that could be exacerbated by a possible influx of new submissions in response to the current draft and anticipated final Transition Policy, and we may not receive such clearances on a timely basis, if at all. Failure to obtain regulatory clearance prior to the withdrawal of the Policy may hinder our ability to continue marketing and distribution of our

devices and would therefore have a significant adverse impact on our business, results of operations and financial condition. The regulatory process may delay the marketing of new products for lengthy periods and impose substantial additional costs, or it may prevent the introduction of new products altogether. Further, if we were to sell our products outside of the United States, our products may be subject to similar regulatory schemes in such other jurisdictions.

We are subject to continuing regulation by the FDA, and if we fail to comply with regulations, including FDA and other state regulations, our business could suffer.

We are subject to regulation by the FDA in marketing the Pūrgo device under the Policy and will be subject to continuing FDA regulation if and when we receive full FDA 510(k) clearance for this device. We are subject to Medical Device Reporting regulations, which require us to report to the FDA if we become aware of information that reasonably suggests the Pūrgo device may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device we market would likely cause or contribute to a death or serious injury if the malfunction were to recur. We must report corrections and removals to the FDA where the correction or removal was initiated to reduce a risk to health posed by the Pūrgo device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act, or FDCA, caused by the device that may present a risk to health, and maintain records of other corrections or removals.

The FDA regulates promotion, advertising and claims made with respect to FDA-regulated medical devices, including Pūrgo. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement actions by the FDA or state agencies, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- recall, termination of distribution, administrative detention, injunction or seizure of our Pūrgo device;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for modifications to the Pūrgo device;
- withdrawing or suspending clearance that has already been granted;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any corrective action, whether voluntary or involuntary, as well as potentially defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Our products have not been proven to reduce the risk of COVID-19 transmission.

We expect that much of the demand for our products will be based not only on their ability to protect immunocompromised patients from HAIs, but also reduce the risk of COVID-19 transmission. Since the beginning of the COVID-19 pandemic, we have learned that the original COVID-19 virus strain can mutate rapidly, and these mutant strains, such as the Delta and Omicron variants, continue to spread throughout the global population. Accordingly, much is still unknown about the manner in which bacteria and viruses, including the novel coronavirus underlying COVID-19, and any mutation or variation thereof, are transmitted among human beings. Current studies have highlighted that COVID-19, like seasonal flu viruses and other pathogens (such as SARS and MERS), is transmitted by air predominantly through contact between an infected person and others. While we have proven that our devices can eliminate 99.99% (“4 Log”) of airborne pathogens in controlled laboratory environments, including a pathogen that is a surrogate for COVID-19, we have not conducted any tests or studies regarding the ability of such devices to reduce the

spread of COVID-19 and any mutation or variation thereof, and our devices may ultimately not succeed in reducing the spread of COVID-19 or any mutation or variation thereof. Further, additional research may determine that COVID-19 is transmitted among human beings in other ways not known or fully understood. We expect demand for our products would be significantly less than anticipated if our products are not perceived as being effective at reducing the risk of COVID-19 transmission or if COVID-19 is determined to spread in ways other than through airborne transmission.

We may face significant challenges in obtaining market acceptance of our products, which could adversely affect our potential sales and revenues.

We do not yet have an established market or customer base for our products. Acceptance of our products in the marketplace by both potential users and potential purchasers, including hospitals, schools, universities, commercial facilities, transportation systems and other healthcare and non-healthcare providers, is uncertain, and our failure to achieve sufficient market acceptance will significantly limit our ability to generate revenue and be profitable. Market acceptance will require substantial marketing efforts and the expenditure of significant funds by us to inform hospitals, schools, universities, commercial facilities, transportation systems, residential spaces and other health care and non-healthcare providers of the benefits of using our products. We may encounter significant clinical and market resistance to our products, and our products may never achieve market acceptance. We may not be able to build key relationships with physicians, education administrators and government agencies. Product orders may be cancelled or customers that are beginning to use our products may cease to do so and customers expected to begin using our products may not. Factors that may affect our ability to achieve acceptance of our products in the marketplace include, but are not limited, to whether:

- such products will be effective;
- such products will be cost-effective; and
- we will be able to demonstrate product safety, efficacy and cost-effectiveness.

Acceptance of our products in the marketplace is also uncertain, and our failure to achieve sufficient market acceptance and any inability to sell such products at competitive prices will limit our ability to generate revenue and be profitable. Our products and technologies may not achieve expected reliability, performance and endurance standards. Our products and technologies may also not achieve market acceptance, including among hospitals, or may not be deemed suitable for other commercial applications.

We lack manufacturing experience and capabilities.

We do not have our own manufacturing facilities or capabilities. We have engaged Mack Molding, an FDA-regulated subsidiary of the privately held Mack Group, to manufacture the Pūrgo device. Although Mack Molding is an experienced contract manufacturer of medical devices, there can be no assurance that Mack Molding will be able to continue to manufacture our products successfully, including in a manner that complies with regulatory requirements, or at a scale to meet customer demand. There also can be no assurance that we would be able to secure another manufacturer for our products or do so on terms similar to those with Mack Molding. The inability to have our products manufactured in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

We receive a significant portion of our revenues from a small number of customers and the loss of, or nonperformance by, one or more of our significant customers could adversely affect our business.

During the year ended December 31, 2021, our largest and second largest customers accounted for approximately 45% and 12% of the Company's revenues, respectively. Our largest customer in the 2021 fiscal year was a hospital deploying 100 units to address a variety of clinical and non-clinical spaces. As we roll out the Pūrgo device to a wider group of potential customers, we expect our largest customers may vary from period to period. However, as we continue to market our products and seek to develop and grow our customer base, our revenues and operating results in any given period going forward may materially rely on one or a few significant customers. The failure of such customer or customers to fulfill their obligations under purchase commitments could result in a material reduction in our reported revenues and operating results.

Our success may depend on our ability to protect our intellectual property.

Our success may depend on our ability to obtain and maintain patent and trade secret protection. We rely on patents and scientific know-how to protect a significant part of our intellectual property and competitive position. Our patents may not afford meaningful protection for our technologies and products. Some of our patent filings are in an early phase and may not be issued. Further, with respect to our existing patents and any future patents that may be issued, there can be no assurance that the issued claims will provide any significant protection against competitive products or otherwise be valuable commercially. Our competitors may develop technologies and products similar to our technologies and products that do not infringe upon our patents. Legal standards relating to the validity of patents and the proper scope of their claims, including in the medical device field, are still evolving, including that there is uncertainty regarding the breadth of claims in medical device patents or the effect of prior art on them.

We also rely on trade secrets to protect our technologies. However, trade secrets are difficult to protect. We require all of our employees to sign agreements that prohibit the improper use of our trade secrets or the disclosure of such to others, but we may be unable to determine if our employees have complied or will comply with their legal obligations under these agreements. We also require collaborators and consultants to enter into confidentiality agreements, but we may not be able to adequately protect our trade secrets or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of this information. Many of our employees and consultants were, and many of our consultants may currently be, parties to confidentiality agreements with other companies, and the use of our technologies could violate these agreements. In addition, third parties may independently discover our trade secrets or proprietary information.

To date, we have primarily used consultants and other contract personnel for product development and engineering, as well as for outsourced manufacturing expertise. While we believe the contracts underlying these relationships adequately provide for the protection of our patents and trade secrets, the use of such third-party contracts heightens the risk of unauthorized use or theft of our intellectual property.

If we are not able to obtain adequate patent protection, enforce our intellectual property rights and/or protect our trade secrets, our ability to prevent competitors from making, using and selling competing products will be limited, which could have a material adverse effect on our business, financial condition or results of operations.

Our ability to expand our product offerings and introduce additional products and services may be limited, which could have a material adverse effect on our business, financial condition and results of operations.

In July 2021, we completed the development stage of our first commercial air purification unit, Pūrgo, for in-room applications and began commercial production and sales, and in February 2022 we debuted a prototype of Pūrgo Lift, an air purification device for elevators and other wall-mount applications. There can be no assurance that we will be successful in commercializing the Pūrgo or Pūrgo Lift devices or developing any other products or applications of our proprietary technology, or that demand will develop for such in the future. Entry into new markets may require us to compete with new companies, cater to customer expectations and comply with new complex regulations, which may be unfamiliar. Accordingly, we could need to invest significant resources in market research, legal counsel and our organizational infrastructure, and a return on such investments may not be achieved for several years, if at all. Additionally, failure to comply with applicable regulations or to obtain required licenses could result in penalties or fines. Further, we may fail in demonstrating the value of any new value-added product to customers, which would compromise our ability to successfully create new revenue streams or receive returns in excess of investments. Any of these risks, if realized, could materially and adversely affect our business, financial condition and results of operations.

Quality problems with, and product liability claims in connection with, our products could lead to recalls or safety alerts, harm to our reputation, or adverse verdicts or costly settlements, and could have a material adverse effect on our business, financial condition and results of operations.

Quality is extremely important to us and our customers due to the serious and costly consequences of product failure, and our business exposes us to potential product liability risks that are inherent in the design,

manufacture and marketing of medical devices and services. In addition, our products may be used in intensive care settings with immunocompromised and seriously ill patients. Component failures, manufacturing defects or design flaws could result in an unsafe condition or injury to, or death of, a patient or other user of our products. These problems could lead to the recall of, or issuance of a safety alert relating to, our products and could result in unfavorable judicial decisions or settlements arising out of product liability claims and lawsuits, including class actions, which could negatively affect our business, financial condition and results of operations. In particular, a material adverse event involving one of our products could result in reduced market acceptance and demand for all products offered under our brand and could harm our reputation and ability to market products in the future.

High quality products are critical to the success of our business. If we fail to meet the high standards we set for ourselves and that our customers expect, and if our products are the subject of recalls, safety alerts or other material adverse events, our reputation could be damaged, we could lose customers and our revenue could decline.

Any product liability claim brought against us, with or without merit, could be costly to defend and resolve. Any of the foregoing problems, including product liability claims or product recalls in the future, regardless of their ultimate outcome, could harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

We have limited experience selling our products to healthcare facilities, and we might be unsuccessful in increasing our sales.

Our business strategy depends largely on our ability to sell our products to hospitals and other healthcare facilities. We have limited experience with respect to sales and marketing, and in particular marketing to hospitals and healthcare facilities. If we are unsuccessful at manufacturing, marketing and selling our products, our business, financial condition and results of operations will be materially adversely affected.

Our operating results could be negatively impacted if we are unable to capitalize on research and development spending.

We have and intend to continue to spend a significant amount of time and resources on research and development projects in order to develop and validate new and innovative products. We believe these projects will result in the commercialization of new products and will create additional future sales. However, factors including regulatory delays, safety concerns or patent disputes could delay the introduction or marketing of new products. We may experience an unfavorable impact on our financial condition and business operations if we are unable to capitalize on those efforts to successfully market new products.

Our success will depend partly on our ability to operate without infringing or misappropriating the proprietary rights of others.

We may be sued for infringing or misappropriating the proprietary rights of others. We may have to pay substantial damages, including treble damages, for past infringement if it is ultimately determined that our products or technology infringe a third party's proprietary rights. Other companies may have filed patent applications on concepts similar to the concepts underlying our technologies and products. In addition, patents may be issued covering UV-C LED technology or other technologies or methods of air purification that could prevent us from developing our technologies or products, or that relate to certain other aspects of technology that we utilize or expect to utilize. From time to time, we may receive invitations from third parties to license patents owned or controlled by such parties. We will evaluate these requests and may consider obtaining licenses that are compatible with our business objectives. However, we may not be able to obtain licenses on acceptable terms, if at all. Our inability to operate without infringing upon the proprietary rights of others or a failure to obtain or maintain any necessary licenses could have a material adverse effect on our business, financial condition or results of operations.

We may collaborate with third parties to help develop certain technologies.

We may seek out collaboration opportunities to extend our UV-C LED air purification technology to the integrated air handling systems of large buildings, elevators and commercial aircraft. During the year

ended December 31, 2021, we accelerated our development of air purification equipment utilizing our proprietary, patented SteriDuct technology for elevators in the Pūrgo Lift unit, and we have engaged a veteran of the elevator industry to continue to develop that product. We also may create strategic alliances with aviation industry suppliers to provide both ground-based and in-flight air purification systems. There can be no assurances that we will enter into any such collaborations or that they will be successful. If our collaborations are not successful, it may impact our ability to develop new technologies and products, which could adversely impact our business, financial condition and results of operations. Further, such collaborations may introduce additional risk with respect to possible unauthorized use or infringement upon our intellectual property rights by the third-parties with whom, if any, we ultimately engage in strategic collaborations.

Significant additional governmental regulation could subject us to unanticipated delays, which would adversely affect our sales and revenues.

Our business strategy depends in part on our ability to get our products into the market as quickly as possible. Additional laws and regulations, or changes to existing laws and regulations that are applicable to our business, may be enacted or promulgated, and the interpretation, application or enforcement of existing laws and regulations may change. We cannot predict the nature of any future laws, regulations, interpretations, applications or enforcement or the specific effects any of these might have on our business.

Any future laws, regulations, interpretations, applications or enforcement could delay or prevent regulatory clearance of our products and our ability to market our products. Moreover, changes that result in our failure to comply with the requirements of applicable laws and regulations could result in the types of enforcement actions by the FDA or other agencies as described above, all of which could impair our ability to have manufactured and to sell the affected products.

Risks associated with our common stock

Our executive officers, directors and principal stockholders have the ability to control all matters submitted to stockholders for approval.

The Company's executive officers, directors and stockholders who own 5% or more of our currently outstanding shares of common stock beneficially own shares, in the aggregate, representing approximately 73.7% of the shares of our outstanding common stock as of December 31, 2021. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act collectively, would control the election of directors and approval of any charter amendment, merger, consolidation or sale of all or substantially all of our assets. These stockholders could cause the Company to take actions which these stockholders believe to be in their best interests but with which the remainder of our stockholders disagree. For example, they could cause the Company to enter into mergers with companies which operate in different businesses, or they could elect to cause the Company to sell all or substantially all of its assets. This concentration of voting power could delay or prevent an acquisition of the Company on terms that other stockholders may desire.

While our common stock is listed on The Nasdaq Capital Market, if we do not meet Nasdaq's continuing listing requirements we could be delisted and there can be no assurance that an active and liquid public market will fully develop or be sustained.

Our common stock is listed on The Nasdaq Capital Market ("Nasdaq"). Notwithstanding such listing, there can be no assurance that an active or liquid public market will fully develop or be sustained. In addition, if we do not meet Nasdaq's continuing listing requirements, including Nasdaq requirements related to maintenance of a minimum stock price, the aggregate market value of our common stock, and the number of public holders of our common stock, we could be delisted by Nasdaq. In the absence of an active or liquid public market, investors may have difficulty buying and selling or obtaining market quotations; market visibility for our securities may be limited; and a lack of visibility for our securities may have a depressive effect on any market price for our securities. Moreover, there can be no assurance that securities analysts of brokerage firms will provide coverage of the Company, if at all. In the event there is no active or liquid public

market for our common stock or coverage of the Company by securities analysts of brokerage firms, you may be unable to dispose of your common stock at desirable prices or at all. Moreover, there is a risk that our common stock could be delisted from Nasdaq or any other trading market on which it may be listed or quoted.

The lack of an active or liquid public market may impair our ability to raise capital to continue to fund operations by selling securities and may impair our ability to use our securities as consideration for future acquisitions.

The price of our shares of common stock in the future may be volatile.

If a market develops for our common stock, of which no assurances can be given, the market price of our common stock will likely be volatile and could fluctuate widely in price in response to various factors, many of which are beyond our control, including, but not limited to:

- technological innovations or new products and services by us or our competitors;
- additions or departures of key personnel;
- sales of shares of our common stock;
- our ability to integrate operations, technology, products and services;
- our ability to execute our business plan;
- operating results below expectations;
- loss of any strategic relationship (including, in particular, our relationship with the third-party manufacturer we use to produce the Pūrgo device);
- industry developments;
- regulatory developments, including with respect to FDA rules and regulations and/or changes in COVID-related accommodations afforded by the FDA, such as adoption of the final Transition Plan and ultimate withdrawal of the Policy;
- economic and other external factors; and
- period-to-period fluctuations in our financial results.

Any of these factors could have a significant and adverse impact on the market price of our common stock. Because we have a limited operating history and a very limited history of generating revenue, you may consider any one of these factors to be material. Our stock price may fluctuate widely as a result of any of the above factors. In addition, the securities markets have from time to time experienced significant price and volume fluctuations, extreme volatility or rapid declines that are unrelated or disproportionate to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock, regardless of our actual operating performance.

If our shares become subject to the SEC's penny stock rules, broker-dealers may experience difficulty in completing customer transactions, and trading activity in our shares may be adversely affected.

If we fail to meet certain criteria specified in the federal securities laws, including with respect to our reported net tangible assets, transactions in our shares may become subject to the "penny stock" rules promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Under these rules, broker-dealers who recommend such shares to persons other than institutional accredited investors must:

- make a special written suitability determination for the purchaser;
- receive the purchaser's written agreement to the transaction prior to sale;
- provide the purchaser with risk disclosure documents that identify certain risks associated with investing in "penny stocks" and that describe the market for these "penny stocks" as well as a purchaser's legal remedies; and

- obtain a signed and dated acknowledgment from the purchaser demonstrating that the purchaser has actually received the required risk disclosure document before a transaction in a "penny stock" can be completed.

If our shares become subject to these rules, broker-dealers may find it difficult to effectuate customer transactions, and trading activity in our shares may be adversely affected. As a result, the market price of our shares may be depressed, and you may find it more difficult to sell our shares. We believe that we are currently not subject to the "penny stock" rules, but that could change in the future.

We have never declared dividends and do not intend to.

We have never declared or paid dividends on our equity securities and do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will be dependent upon our financial condition, operating results, capital requirements, applicable contractual restrictions and other such factors as we may deem relevant.

We are an "emerging growth company" under the JOBS Act and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (the "Securities Act"), for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to take advantage of the extended transition period for complying with new or revised accounting standards.

We will remain an "emerging growth company" for up to five years, although we will lose that status sooner if our revenue exceeds $1.07 billion, if we issue more than $1.0 billion in non-convertible debt in a three- year period or if the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30 of any year.

Our status as an "emerging growth company" under the JOBS Act may make it more difficult to raise capital as and when we need it.

Because of the exemptions from various reporting requirements provided to us as an "emerging growth company" and because we will have an extended transition period for complying with new or revised financial accounting standards, we may be less attractive to investors, and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. Any inability to raise additional capital as and when we need it could have a material adverse effect on our business, financial condition, operating results, liquidity and prospects.

All of the Company's stockholders who acquired their shares of common stock prior to our IPO are subject to a 12-month lock, and the expiration of the lock-up and those shares becoming eligible for future sale may have an adverse effect on the market price of our shares.

There are 11,363,636 shares of common stock held by the Company's pre-IPO stockholders. All of such outstanding shares are subject to restrictions on sale and are "restricted securities" as defined in

accordance with Nasdaq's initial listing requirements. Any sale, or the prospect of any such sale, in the future of such shares could have an adverse effect on the future market price for our shares or on our ability to obtain future financing. Any of the foregoing may have a depressive effect on the price of our shares. Additionally, while the shares held by our pre-IPO stockholders are subject to 12-month lock-up agreements with the underwriters of our IPO, any release of these lock-up agreements or lock-up arrangements, or the prospect of any such release, may also place downward pressure on the price of our shares.

We have and expect to continue to incur significant increased costs as a result of operating as a public company, and our management is now required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to reporting requirements under the Exchange Act, the other rules and regulations of the SEC, and the rules and regulations of Nasdaq and any other trading market on which our securities may be quoted or traded.

The expenses required to adequately report as a public company are material, and compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges impose various requirements on public companies, including requiring the establishment and maintenance of effective disclosure and internal controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. These rules and regulations have and will continue to increase our legal and financial compliance costs and have and will continue to make some activities more time consuming and costly. For example, we expect these rules and regulations will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits on coverage or incur substantial costs to maintain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers.

If we fail to implement and maintain an effective system of internal control to remediate our material weakness over financial reporting, we may be unable to accurately report our results of operations, meet our reporting obligations as a public company or prevent fraud, and investor confidence and the trading prices of our securities may be materially and adversely affected.

Prior to the completion of this offering, the Company has had limited accounting personnel and other resources to address internal controls over financial reporting. In connection with the audits of our financial statements as of December 31, 2021, 2020 and 2019 and for the two years ended December 31, 2021and 2020, we identified a material weakness in our internal control over financial reporting. As defined in the standards established by the Public Company Accounting Oversight Board (the "PCAOB"), a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Management identified the following deficiencies, which in the aggregate are material weaknesses, in its assessment of the effectiveness of internal control over financial reporting as of December 31, 2021. Management noted we do not have sufficient segregation of duties within the accounting function, a lack of timely reconciliation of accounts and review of the Company's financial statements at each reporting period, a lack of appropriate contemporaneous documentation and/or valuation for certain equity transactions and execution of significant agreements containing inaccurate terms and errors.

We are in the process of implementing a number of measures to address this material weakness. See "Controls and Procedures". However, we cannot assure you that these measures will fully address the material weakness and deficiencies in our internal control over financial reporting or that we may conclude that they have been fully remediated.

We are subject to the Sarbanes-Oxley Act of 2002, and specifically to Section 404 thereof, which will require that we include a certification from management on the effectiveness of our internal controls in our annual reports on Form 10-K, beginning with the Form 10-K filed for the year ending December 31, 2022. In addition, once we cease to be either an "emerging growth company" as such term is defined in the

JOBS Act or a non-accelerated filer in accordance with Rule 12b-2 under the Exchange Act, our independent registered public accounting firm must attest to and report on the effectiveness of our internal control over financial reporting. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue a report that is qualified if it is not satisfied with our internal controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, our continuing reporting obligations have and may continue to place a significant strain on our management, operational and financial resources and systems. We may be unable to complete our evaluation testing and any required remediation on a timely basis or at all.

During the course of documenting and testing our internal control procedures, in order to satisfy the requirements of Section 404, we may identify other weaknesses and deficiencies in our internal control over financial reporting. If we fail to maintain the adequacy of our internal control over financial reporting, as these standards are modified, supplemented or audited from time to time, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. Generally speaking, if we fail to achieve and maintain an effective internal control environment, it could result in material misstatements in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis. As a result, our reputation, business, financial condition and results of operations may be materially and adversely affected. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from Nasdaq, regulatory investigations and civil or criminal sanctions. We may also be required to restate our financial statements from prior periods.

Financial Industry Regulatory Authority sales practice requirements may also limit your ability to buy and sell our common stock, which could depress the price of our shares.

Financial Industry Regulatory Authority ("FINRA") rules require broker-dealers to have reasonable grounds for believing that an investment is suitable for a customer before recommending that investment to the customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status and investment objectives, among other things. Under interpretations of these rules, FINRA believes that there is a high probability such speculative low-priced securities will not be suitable for at least some customers. Thus, FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our shares once publicly traded, have an adverse effect on the market for our common stock and thereby depress our share price.

General Risk Factors

Business or economic disruptions could seriously harm our business.

Broad-based business or economic disruptions could adversely affect our business. For example, Russia's recent invasion of Ukraine has prompted the U.S. and other countries to announce sanctions against Russia. The full effect of this military conflict and related sanctions on the global economy and our existing and prospective customers, and as a result, our business, remains uncertain. While the onset of the COVID-19 global pandemic underscored the urgency of bringing to market air purification solutions to protect front-line healthcare workers, patients and the general population, associated business shutdowns or disruptions could impair our ability to manufacture or sell our products, which would adversely affect our business, financial condition and results of operations.

If we lose key personnel or are unable to attract and retain qualified personnel, our business could be harmed, and our ability to compete could be impaired.

Our success depends, to a significant degree, upon the continued contributions of the members of our senior management and highly credentialed scientists. If we lose the services of one or more of these people, we may be unable to achieve our business objectives. We may be unable to attract and retain personnel

with the advanced technical qualifications or managerial experience necessary for the development of our business and products or commercialization of our products. In addition, our current employees are at-will employees, which means that either we or the employee may terminate the employment relationship at any time, and our agreements with our independent contractors generally extend only on a monthly basis after an initial term, with the ability of either party to terminate the agreement upon prior notice to the other party.

We face intense competition.

We face, and will continue to face, intense competition from organizations such as large, diverse companies with extensive product development and manufacturing capabilities, as well as smaller specialized companies, that have developed and are attempting to develop air filtration and purification systems. We believe that the COVID-19 pandemic and recently discovered new more virulent and infectious strains of the coronavirus have increased, and will continue to increase, this competition. Further, the Policy and other temporary accommodations implemented by the FDA as a result of the COVID-19 pandemic to enable disinfectant devices, sterilizers, air purifiers, and other medical equipment to be brought to market in an expedited manner has made it easier for new entrants into our market.

Although we believe that we have significant competitive advantages over other organizations, our competitors may develop and commercialize products and technologies that compete with our products and technologies. Organizations that compete with us may have substantially greater financial resources than we do and may be able to: (i) provide broader services and product lines; (ii) make greater investments in research and development; (iii) carry on larger research and development initiatives; (iv) undertake more extensive marketing campaigns; and (v) adopt more aggressive pricing policies than we can. Our competitors may also have greater name recognition and better access to customers than we do. We also expect to continue to face competition from alternative technologies. Our technology and products may be rendered obsolete or uneconomical by advances in existing technological approaches or products or the development of different approaches or products by one or more of our competitors.

We may not be able to achieve or maintain satisfactory pricing and margins for our products, which could harm our business and results of operations.

We can give no assurance that we will be able to maintain satisfactory prices for our Pūrgo and Pūrgo Lift devices and other products we develop in the future. If we are forced to lower the price we charge for our Pūrgo and Pūrgo Lift devices, our gross margins will decrease, which will harm our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode, which could harm our business, financial condition and results of operations.

We may acquire other companies or technologies, which could divert our management's attention, result in additional dilution to stockholders and otherwise disrupt our operations and adversely affect our business, financial condition and results of operations.

Our success will depend, in part, on our ability to grow our business, which can include acquisitions.

We may identify opportunities to establish industry leadership domestically and internationally through selective joint ventures and acquisitions that further capitalize on our differentiated technology. In some circumstances, we may determine to do so through the acquisition of complementary businesses and technologies rather than through internal development. We may also seek to acquire businesses in industries in which we do not currently operate. Some of these acquisitions or other transactions may be material. The identification of suitable acquisition candidates can be difficult, time-consuming and costly, and we may not be able to successfully complete identified acquisitions. The risks we face in connection with acquisitions include:

- diversion of management's time and focus from operating our business to addressing acquisition integration challenges;
- coordination of technology, research and development and sales and marketing functions;
- retention of employees from the acquired company;

- cultural challenges associated with integrating employees from the acquired company into our organization;
- integration of the acquired company's accounting, management information, human resources and other administrative systems;
- the need to implement or improve controls, policies and procedures at a business that prior to the acquisition may have lacked effective controls, policies and procedures;
- potential write-offs of intangibles or other assets acquired in such transactions that may have an adverse effect on our operating results;
- liability for activities of the acquired company before the acquisition, including patent and trademark infringement claims, violations of laws, commercial disputes, tax liabilities and other known and unknown liabilities; and
- litigation or other claims in connection with the acquired company, including claims from terminated employees, consumers, former stockholders or other third parties.

Our failure to address these risks or other problems encountered in connection with acquisitions and investments could result in our failure to realize the anticipated benefits of these acquisitions or investments, cause us to incur unanticipated liabilities and otherwise harm our business. Future acquisitions could also result in dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities, amortization expenses or the write-off of goodwill, any of which could harm our financial condition. Also, the anticipated benefits of any acquisitions may not materialize. Any of these risks, if realized, could materially and adversely affect our business, financial condition and results of operations.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation.

We utilize information technology systems and networks to process, transmit and store electronic information in connection with our business activities. As the use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data, all of which are vital to our operations and business strategy. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects.

Despite the implementation of security measures, our computer systems and those of our current and future third-party service providers are vulnerable to damage or disruption from hacking, computer viruses, software bugs, unauthorized access or disclosure, natural disasters, terrorism, war and telecommunication, equipment and electrical failures. In addition, there can be no assurance that we will promptly detect any such disruption or security breach, if at all. Unauthorized access, loss or dissemination could disrupt our operations, including our ability to conduct research and development activities, process and prepare company financial information and manage various general and administrative aspects of our business. To the extent that any such disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure or theft of confidential, proprietary or personal information, we could incur liability, suffer reputational damage or poor financial performance or become the subject of regulatory actions by federal, state or non-U.S. authorities, any of which could adversely affect our business.

We may need to initiate lawsuits to protect or enforce our patents or other proprietary rights, which would be expensive and, if unsuccessful, may cause us to lose some of our intellectual property rights.

In order to protect or enforce our patent and other intellectual property rights, it may be necessary for us to initiate patent or other intellectual property litigation proceedings against third parties, such as infringement suits or interference proceedings. These lawsuits could be expensive, take significant time and could divert management's attention from other business concerns. These lawsuits could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at a risk of not being issued.

Further, these lawsuits may also provoke the defendants to assert claims against us. The patent position of medical device firms is highly uncertain, involves complex legal and factual questions and has recently been the subject of much litigation. There can be no assurance that we will prevail in any such suits or proceedings or that the damages or other remedies awarded to us, if any, will be commercially valuable.

We may be subject to legal proceedings in the ordinary course of our business. If the outcomes of these proceedings are adverse to us, it could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to various litigation matters from time to time, which could have a material adverse effect on our business, financial condition and results of operations. Claims arising out of actual or alleged violations of law could be asserted against us by individuals, either individually or through class actions, by governmental entities in civil or criminal investigations and proceedings or by other entities. These claims could be asserted under a variety of laws, including but not limited to consumer finance laws, consumer protection laws, intellectual property laws, privacy laws, labor and employment laws, securities laws and employee benefit laws. These actions could expose us to adverse publicity and to substantial monetary damages and legal defense costs, injunctive relief and criminal and civil fines and penalties, including but not limited to suspension or revocation of licenses to conduct business.

Insurance policies may be expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not know if we will be able to obtain and maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which may adversely affect our business, financial position and results of operations.

Our operating results may fluctuate significantly, which will make our future results difficult to predict and could cause our results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly, which will make it difficult for us to predict our future results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including, but not limited to:

- the timing and cost of, and level of investment in, research, development and commercialization activities, which may change from time to time;
- the timing and cost of, and level of investment in, research and development relating to our technologies and our current or future facilities;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- the level of demand for any future products, which may vary significantly over time;
- customer mix and varying length of sales cycles for different customer segments;
- developments involving our competitors;
- the cost of servicing and maintaining our products;
- the cost of manufacturing, as well as building out our supply chain, which may vary depending on the quantity of productions, and the terms of any agreements we enter into with third-party suppliers; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or operating guidance we may provide.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive offices are located at 10455 Riverside Drive, Palm Beach Gardens, FL 33410. We lease approximately 20,000 square feet at this location from a related party, which includes our warehouse and distribution facilities. We consider these facilities adequate for our current operations.

Item 3. Legal Proceedings

We are not currently party to any legal proceedings, the adverse outcome of which, individually or in the aggregate, we believe will have a material adverse effect on our business, financial condition or results of operations.

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 traded on The Nasdaq Capital Market under the symbol "AERC."

Holders

As of March 28, 2022, there were approximately 20 record holders of shares of our common stock. This does not reflect persons or entities that hold our common stock in nominee or "street" name through various brokerage firms.

Dividends

We have not paid any cash dividends on our shares of common stock to date. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition and will be declared at the discretion of our board of directors. It is the current intention of our board of directors to retain all earnings, if any, for use in our business operations and, accordingly, our board of directors does not anticipate declaring any dividends in the foreseeable future.

Equity Compensation Plans

This information related to our equity compensation plans is incorporated by reference to the applicable information in our Proxy Statement for the 2022 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

Unregistered Sales of Securities

Between January 1, 2021 and the IPO, AeroClean Technologies, LLC sold 5,073,056 Class A units to existing members resulting in gross cash proceeds of $5,073,056. The proceeds from this sale were used to fund our operations. In connection with our IPO, we reorganized our corporate structure to become a Delaware corporation by converting the Class A units of AeroClean Technologies, LLC into shares of AeroClean Technologies, Inc. common stock at a conversion ratio of 0.8462 shares of common stock for each Class A unit. We did not use a placement agent for this offering. These Class A units were issued in privately negotiated transactions not involving any public offering or solicitation in reliance upon the exemption from registration under Section 4(a)(2) of the Securities Act.

Effective April 1, 2021, AeroClean Technologies, LLC's board of directors approved issuance of an aggregate of 274,314 Class A units, of which 140,085 Class A units were issued to independent contractors as compensation for services relating to various activities including legal services, operations and supply chain, and regulatory matters, and 134,229 Class A units were issued to members of our board of directors as compensation for services provided. These Class A units were issued in reliance upon the exemption from registration under Rule 701 under the Securities Act as transactions pursuant to compensatory benefit plans or written compensation contracts.

Use of Proceeds from Registered Offerings

On November 29, 2021, we completed our IPO of 2,514,000 shares of common stock at a public offering price of $10.00 per share, resulting in aggregate gross proceeds of $25,140,000 and net proceeds of approximately $21,640,000 (after deducting underwriting fees and closing costs of approximately $3,500,000). Shares of our common stock began trading on The Nasdaq Capital Market on November 24, 2021. The offer and sale of these shares was registered under the Securities Act on an offering statement on Form 1-A (File No. 024-11650), for which notice of qualification was received from the SEC on November 23, 2021. In connection with our IPO, the underwriters were issued a purchase option exercisable for 5.0% of the shares

of our common stock issued in our IPO at an exercise price of $12.50 and a term of five years starting from the date of commencement of sales in our IPO.

Except as described below, no payments were made by us to directors, officers, persons owning 10% or more of any class of our equity securities, or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors pursuant to our director compensation policy. The Benchmark Company, LLC, HCFP/Capital Markets LLC and Valuable Capital Limited acted as joint bookrunning managers for our IPO. On December 1, 2021, the Company paid approximately $1,000,000 out of the net proceeds from our IPO in connection with the satisfaction and discharge of two bridge loans extended to us by the chair of our board of directors (see "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources" for more information).

There has been no material change in the planned use of proceeds from our IPO as described in the related prospectus filed with the SEC pursuant to Rule 253(g)(1) under the Securities Act. Pending the uses described in the aforementioned prospectus, we have invested or intend to invest the funds received and not yet allocated in cash equivalents and other marketable securities.

Purchase of Equity Securities by the Registrant and Affiliated Purchasers

None.

Item 6. Reserved

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

The following discussion and analysis should be read in conjunction with the historical consolidated financial statements and related notes included elsewhere in this Annual Report. This discussion contains forward-looking statements reflecting our current expectations and estimates and assumptions concerning events and financial trends that may affect our future operating results or financial position. Actual results and the timing of events may differ materially from those contained in these forward-looking statements due to a number of factors, including those discussed in the sections entitled "Risk Factors" and "Cautionary Statement Concerning Forward-Looking Statements" appearing elsewhere in this Annual Report.

Overview

AeroClean Technologies is an interior space air purification technology company. Our immediate objective is to initiate full-scale commercialization of our high-performance interior air sterilization and disinfection products for the eradication of harmful airborne pathogens, including COVID-19. We were established to develop unmatched, technology-driven medical-grade air purification solutions for hospitals and other healthcare settings. The onset of the COVID-19 global pandemic underscores the urgency of bringing to market air purification solutions to protect front-line healthcare workers, patients and the general population.

We incorporate our proprietary, patented UV-C LED technology in equipment and devices to protect the occupants of interior spaces. These spaces include hospital and non-hospital healthcare facilities (such as outpatient chemotherapy and other infusion facilities and senior living centers and nursing homes), schools and universities, commercial properties and other indoor spaces.

Our products are being designed and engineered to exceed the rigorous standards set by the FDA for interior air sterilization and disinfection products. Our units can be currently marketed for use pursuant to the FDA Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, referred to as the "Policy" elsewhere in this Annual Report.

We are currently seeking FDA 510(k) clearance for the use of our products in healthcare and other markets for which product performance is required to be validated by certified independent labs. Regulatory clearances and independent certifications serve as important product imprimaturs that also influence

decision-making by non-healthcare market equipment purchasers. We expect to receive FDA 510(k) clearance for Pūrgo in the second half of 2022.

We initiated the full-scale launch of our first product, Pūrgo, in the year ended December 31, 2021. Pūrgo is our proprietary, continuous air sanitization product for indoor spaces. Pūrgo's launch also marks the debut of our go-to-market strategy for SteriDuct, the Company's patented air purification technology. We intend to incorporate SteriDuct into a broad line of autonomous air treatment devices. For example, we debuted a prototype of Pūrgo Lift, our air purification solution for elevators and other wall-mount applications, in February 2022.

In July 2021, we completed the development stage of our first device, the Pūrgo room air purification unit, including design and independent testing and certification, as well as the scale-up of manufacturing, and began commercial production and sales. Pūrgo has been well-received by our customers. Our success depends to a large extent on our ability to increase sales of our Pūrgo device during 2022 and beyond.

To support the transition to commercial operations, in July 2021, we also completed the build out of our corporate headquarters in Palm Beach Gardens, Florida, which includes our warehouse and distribution facility, as well as the site for our future service operations.

As part of our business strategy we continually evaluate a wide array of strategic opportunities, including the acquisition, disposition or licensing of intellectual property, mergers and acquisitions, joint ventures and other strategic transactions. In connection with these activities we may enter into non-binding letters of intent as we assess the commercial appeal of potential strategic transactions. We may seek to acquire technologies, product lines and companies which operate in businesses similar to our own or which are ancillary, complementary or adjacent to our own or in which we do not currently operate. Such businesses could operate in the air purification space or more generally in the health and wellness space or in other industries. We could also seek to merge with or into another company or sell all or substantially all of our assets to another company. Any transactions that we enter into could be material to our business, financial condition and operating results. Please see related risks described under the captions "We may acquire other companies or technologies, which could divert our management's attention, result in additional dilution to stockholders and otherwise disrupt our operations, and adversely affect our business, financial condition and results of operations" and "Our executive officers, directors and principal stockholders have the ability to control all matters submitted to stockholders for approval" in the "Risk Factors" section of this Annual Report.

COVID-19 Pandemic

We continue to monitor the outbreak of COVID-19 and its variants, including the most recent Omicron variant, which continue to spread throughout the world and adversely impact global commercial activity and contribute to significant declines and volatility in financial markets. Our on-going research and development activities, including development of product prototypes and manufacturing activities, are all conducted in the United States, and as a result, we have been able to mitigate the adverse impact of the COVID-19 pandemic on our global supply chain. During the year ended December 31, 2021, we have not experienced any significant adverse impact on our operations as a result of the COVID-19 pandemic. However, across many industries, including our own, COVID-19 — among other factors — has negatively impacted personnel and operations at third-party manufacturing and component part supplier facilities in the United States and around the word. These disruptions have adversely impacted the availability and cost of raw materials and component parts. For example, various electronic components and semi-conductor chips have become increasingly difficult to source, and when available, may be subject to substantially longer lead times and higher costs than historically applicable. While we have achieved improvements in manufacturing output since the commercial launch of Pūrgo in late Q3 2021, the ongoing global logistics and supply chain bottlenecks and shortages have increased lead times for electronics, semi-conductors, chips, and even recently-in-stock and short lead time items. The team has taken action to minimize the impact of these supply chain and logistics disruptions to ongoing production, and we expect these challenges will resolve towards the end of the first half of 2022.

We continue to actively monitor the situation and may take further actions that impact operations as may be required by federal, state or local authorities or that we determine is in the best interests of our

employees, customers, suppliers and stockholders. As of the date of this Annual Report, the pandemic presents uncertainty and risk as we cannot reasonably determine or predict the nature, duration or scope of the overall impact the COVID-19 pandemic will have on our business, results of operations, liquidity or capital resources.

Results of Operations

The following table summarizes our results of operations for the periods indicated:

	Year Ended December 31,		
	2021	2020	Change
Product revenues	$ 616,511	$ —	$ 616,511
Cost of sales	338,896	—	338,896
Gross profit	277,615	—	277,615
Operating expenses:			
Selling, general and administrative	4,327,998	1,131,385	3,196,613
Research and development	4,193,362	2,191,696	2,001,666
Total operating expenses	8,521,360	3,323,081	5,198,279
Loss before income tax benefit	(8,243,745)	—	(8,243,745)
Income tax benefit	320,138	—	320,138
Net loss	$(7,923,607)	$(3,323,081)	$(4,600,526)

Revenue and Cost of Sales

The Company began the production and sale of its first commercial product, Pūrgo, in July 2021, generating $616,511 in product revenues for the year ended December 31, 2021 (of which amount $80,000 was generated from sales to certain of the Company's directors and shareholders). The Company did not have any revenue in the year ended December 31, 2020. Cost of sales increased in conjunction with the increase in revenues.

Operating Expenses

Selling General and Administrative Expenses

Selling, general and administrative expenses consist primarily of costs related to our employees, independent contractors and consultants. Other significant selling, general and administrative expenses include accounting and legal services and expenses associated with obtaining and maintaining patents as well as marketing and advertising services and expenses associated with establishing our brand and developing our website, marketing materials and call center.

For the years ended December 31, 2021 and 2020, we incurred $4,327,998 and $1,131,385, respectively, of selling, general and administrative expenses. We attribute the increase of $3,196,613 primarily to a greater level of business activities being conducted in the year ended December 31, 2021 as compared to the same period in 2020, including costs related to the hiring of additional personnel (an increase of approximately $800,000), increased fees for outside consultants (an increase of approximately $1,000,000), stock-based compensation of approximately $260,000, rent expense (an increase of approximately $400,000) and professional fees and insurance (an increase of approximately $400,000).

Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities. We expense research and development costs as they are incurred. Our research and development expenses primarily consist of outsourced engineering, product development and manufacturing design costs.

For the years ended December 31, 2021 and 2020, we incurred $4,193,362 and $2,191,696, respectively, in research and development costs. We attribute the increase of $2,001,666 primarily to additional costs in

the year ended December 31, 2021 as incremental outsourced engineering, testing, and regulatory costs associated with our 510(k) submission were incurred to launch Pūrgo in July 2021 as compared to the year ended December 31, 2020 where significant spending on research and development costs did not commence until approximately May 2020.

Net Losses

Our net losses were $7,923,607 and $3,323,081 for the years ended December 31, 2021 and 2020, respectively. Losses increased in fiscal 2021 as compared to fiscal 2020 for the reasons set forth above.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2021, we had cash of $19,629,649 compared to cash of $2,333,117 as of December 31, 2020. During the year ended December 31, 2021, our predecessor, AeroClean Technologies, LLC, raised approximately $5,100,000 in gross proceeds from the sale of our Class A units and issued approximately $900,000 of our Class A units to our independent contractors and members of our board of directors for services rendered. On September 30, 2021, we borrowed $500,000, and on November 5, 2021, we borrowed an additional $500,000 pursuant to bridge loans (collectively, the "Bridge Loans") from the chair of our board of directors at an interest rate equal to the prime rate plus 3.0% per annum, 6.25% for the life of the Bridge Loans, with the principal and accrued interest due upon demand. On November 29, 2021, we completed our IPO of 2,514,000 shares of our common stock, which included the partial exercise of the underwriters' overallotment option, at a public offering price of $10.00 per share for aggregate gross proceeds of $25,140,000 and net proceeds of approximately $21,640,000, after deducting underwriting fees and closing costs of approximately $3,500,000. We repaid the Bridge Loans and accrued interest on December 1, 2021 with a portion of the net proceeds from our IPO.

Prior to our IPO, AeroClean Technologies, LLC, our predecessor, funded its operations principally with approximately $15,000,000 in gross proceeds from the sale of Class A units. As of December 31, 2021, we had an accumulated deficit of $1,747,860. The Company's net cash used in operating activities was $7,795,087 for the year ended December 31, 2021 as compared to $3,069,976 used in operating activities for the prior year period.

We have incurred operating losses since our inception. While the Company began producing and selling its Pūrgo device in July 2021, these losses are expected to continue through the end of 2022 as we continue to make significant investments to develop and market our products and to establish our consumables and service business.

We believe that our cash balances as of December 31, 2021 will be sufficient to meet our cash needs for at least 12 months.

Future Funding Requirements and Outlook

We have incurred operating losses each year since our inception. These losses are expected to continue through at least the end of 2022 because we plan to continue to make significant investments to develop and market our products and to establish our consumables and service business. We also expect to continue to incur increased costs to comply with corporate governance, internal controls and similar requirements applicable to public companies.

On February 1, 2021, we entered into a lease with Garden Bio Science Partners, LLC, an entity controlled by the chair of our board of directors, with a term of ten years at an annual base rent of $260,000, subject to escalation of 2.5% on an annual basis. As of December 31, 2021, the future minimum lease payments under this arrangement approximated $2,675,000.

Based on our current financial resources, our expected revenues and our expected level of operating expenditures, we believe that we will be able to fund our projected operating requirements for at least the next 12 months.

Over the long-term, the Company will continue to have significant capital requirements, and expects to devote substantial resources to grow its operations. Moreover, if the Company pursues an acquisition strategy, it may need to raise incremental capital in order to finance the purchase price to be paid to target stockholders. As a result of these funding requirements, we will likely need to obtain additional financing by engaging in debt and/or equity offerings or seeking additional borrowings. To the extent that we raise additional capital through the sale of convertible debt or equity securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. The availability of debt financing or equity capital will depend upon the Company's financial condition and results of operations as well as prevailing market conditions.

Inflation

We do not believe that inflation or changes in prices will have a material effect on our business.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of the financial statements in accordance with GAAP requires us to make estimates and assumptions that affect the reported amounts and related disclosures. We evaluate these estimates, judgments and methodologies on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe are reasonable. Our actual results could differ from those estimates.

Our significant accounting policies are more fully described in Note 2, Summary of Significant Accounting Policies to our audited financial statements included elsewhere in this Annual Report. We believe that the accounting policies are critical for fully understanding and evaluating our financial condition and results of operations.

JOBS Act

On April 5, 2012, the JOBS Act, was enacted. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will not be subject to the same new or revised accounting standards as public companies that are not emerging growth companies. As a result of this election, our financial statements may not be comparable to companies that are not emerging growth companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) the exemption from providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) the exemption from complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of the Public Offering; (iii) the date on which we have issued more than $1 billion in non-convertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

As a smaller reporting company, we are not required to provide the information required by Item 305 of Regulation S-K.

Item 8. Financial Statements and Supplementary Data

The information called for by Item 8 is found in a separate section of this Annual Report starting on page F-1. See the "Index to Financial Statements" on page F-1.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that the information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers (who are our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), respectively), or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met.

In connection with the preparation of this Annual Report for the year ended December 31, 2021, an evaluation was performed under the supervision of and with the participation of management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the Company's disclosure controls and procedures. Based on that evaluation, our CEO and CFO have concluded that our disclosure controls and procedures were not effective as of December 31, 2021 due to the existence of a material weakness in internal control over financial reporting that was identified in connection with the audits of our financial statements as of December 31, 2021 and 2020 and for each of the years in the two-year period ended December 31, 2021 and 2020, and which is still being remediated.

Notwithstanding the existence of the material weaknesses discussed below, our management, including our CEO and CFO, has concluded that the financial statements included in this Annual Report fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in this Annual Report in conformity with GAAP.

Prior to the completion of our IPO, the Company has had limited accounting personnel and other resources to address internal controls over financial reporting. In connection with the audits of our financial statements as of December 31, 2021 and 2020 and for each of the years in the two-year period ended December 31, 2021 and 2020, we identified a material weakness in our internal control over financial reporting. As defined in the standards established by the PCAOB, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented on a timely basis.

The material weakness identified related to a lack of sufficient segregation of duties within the accounting function, a lack of timely reconciliation of accounts and review of the Company's financial statements at each reporting period, a lack of appropriate contemporaneous documentation and/or valuation for certain equity transactions and execution of significant agreements containing inaccurate terms and errors.

Due to the size and nature of the accounting function, segregation of all conflicting duties may not always be possible and has also limited its ability to perform timely reconciliations of accounts and reviews of the Company's financial statements as well as other documentation required to timely and accurately account for significant transactions. In order to remediate the material weaknesses described above, we will need to hire additional accounting qualified personnel with appropriate knowledge and expertise in accounting and U.S. GAAP to assist us in timely maintaining support for our financial statements as well as to allow for appropriate segregation of duties. Management plans to increase the number of personnel dedicated to the accounting and reporting function and may, on an as needed basis, utilize experts in technical accounting matters to assist in the review and analysis of complex transactions. In light of the material weaknesses, management also performed additional procedures in connection with the preparation of our financial statements.

Management's Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Inherent Limitations on Effectiveness of Controls

The design of any system of control is based upon certain assumptions about the likelihood of future events, and as a result all internal control systems, no matter how well designed, have inherent limitations. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. There can be no assurance that any design will succeed in achieving its stated objectives under all future events, no matter how remote, or that the degree of compliance with the policies or procedures may not deteriorate. Due to these inherent limitations, our disclosure controls and procedures and our internal control over financial reporting may not prevent or detect all misstatements. Accordingly, even effective controls and procedures can provide only reasonable assurance of achieving their control objectives. In addition, the design of such controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Changes in Internal Control over Financial Reporting

Except as disclosed above, there were no changes in our internal control over financial reporting during the three months ended December 31, 2021 that have materially affected or, are reasonably likely to materially affect, our internal control over financial reporting; however, we expect to make changes to our internal control over financial reporting in the future to remediate the material weaknesses identified above.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 is incorporated by reference to the applicable information in our Proxy Statement for the 2022 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

Item 11. Executive Compensation

The information required by this Item 11 is incorporated by reference to the applicable information in our Proxy Statement for the 2022 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

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

The information required by this Item 12 is incorporated by reference to the applicable information in our Proxy Statement for the 2022 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

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

The information required by this Item 13 is incorporated by reference to the applicable information in our Proxy Statement for the 2022 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 is incorporated by reference to the applicable information in our Proxy Statement for the 2022 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: April 1, 2022

AEROCLEAN TECHNOLOGIES, INC.

By: /*s*/ Jason DiBona

Name: Jason DiBona

Title: Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of AeroClean Technologies, Inc. and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Jason DiBona Jason DiBona	Chief Executive Officer (Principal Executive Officer)	April 1, 2022
/s/ Ryan Tyler Ryan Tyler	Chief Financial Officer (Principal Financial Officer)	April 1, 2022
/s/ Amin J. Khoury Amin J. Khoury, PhD (Hon)	Chairman of the Board	April 1, 2022
/s/ David Helfet David Helfet, M.D.	Director	April 1, 2022
/s/ Michael Senft Michael Senft	Director	April 1, 2022
/s/ Thomas P. McCaffrey Thomas P. McCaffrey	Director	April 1, 2022
/s/ Heather Floyd Heather Floyd	Director	April 1, 2022

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INDEX TO FINANCIAL STATEMENTS

Audited Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of AeroClean Technologies, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of AeroClean Technologies, Inc. (the "Company") as of December 31, 2021 and 2020, and the related statements of operations, changes in members' equity/ stockholders' equity and cash flows for each of the years in the two-year period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ CITRIN COOPERMAN & COMPANY, LLP

We have served as the Company's auditor since 2020.

New York, New York
April 1, 2022

AEROCLEAN TECHNOLOGIES, INC.
BALANCE SHEETS

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash	$19,629,649	$2,333,117
Accounts receivable	177,064	—
Prepaid expenses and other current assets	1,124,998	304,836
Subscription receivable	—	100,543
Inventories	645,942	—
Total current assets	21,577,653	2,738,496
Property and equipment, net	2,123,428	454,679
Other assets	21,667	—
Total assets	$23,722,748	$3,193,175
LIABILITIES AND MEMBERS'/STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 927,194	$ 332,072
Accrued expenses and other current liabilities	583,885	333,236
Total current liabilities	1,511,079	665,308
Long-term liabilities:		
Deferred tax liability	501,254	—
Total Liabilities	2,012,333	665,308
Commitments and contingencies (Note 8)		
Members' equity	—	2,527,867
Stockholders' equity:		
Preference Shares, $0.01 par value; 11,000,000 shares authorized; none issued and outstanding	—	—
Common stock, $0.01 par value per share; 110,000,000 shares authorized; 13,877,636 issued and outstanding as of December 31, 2021	138,776	—
Additional paid-in capital	23,319,499	—
Accumulated deficit	(1,747,860)	—
Total members'/stockholders' equity	21,710,415	2,527,867
Total liabilities and members'/stockholders equity	$23,722,748	$3,193,175

See accompanying notes to the financial statements.

AEROCLEAN TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2021	**2020**
Product revenues	$ 616,511	$ —
Cost of sales	338,896	—
Gross profit	277,615	—
Operating expenses:		
Selling, general and administrative	4,327,998	1,131,385
Research and development	4,193,362	2,191,696
Total operating expenses	8,521,360	3,323,081
Loss before income tax benefit	(8,243,745)	(3,323,081)
Income tax benefit	320,138	—
Net loss	$ (7,923,607)	$(3,323,081)
Net loss per share:		
Basic and diluted	$ (0.74)	$ (1.02)
Weighted-average common shares outstanding:		
Basic and diluted	10,675,765	3,250,980

See accompanying notes to the financial statements.

AEROCLEAN TECHNOLOGIES, INC.
STATEMENTS OF CHANGES IN MEMBERS'/STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020:

	Class A		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Members'/ Stockholders' Equity
	Units	Amount	Shares	Amount			
Balance, January 1, 2020	2,000,000	$ 4,669,696	—	$ —	$ —	$(4,900,326)	$ (230,630)
Issuance of equity units	6,081,578	6,081,578	—	—	—	—	6,081,578
Net loss	—	—	—	—	—	(3,323,081)	(3,323,081)
Balance, December 31, 2020	8,081,578	$10,751,274	—	$ —	$ —	$(8,223,407)	$ 2,527,867
Reclassification of accumulated deficit	—	$ (8,223,407)	—	—	—	$ 8,223,407	—
Issuance of equity units	5,073,056	5,073,056	—	—	—	—	5,073,056
Initial public offering of common stock, net of underwriting discounts, commissions and issuance costs	—	—	2,514,000	25,140	21,641,265	—	21,666,404
Corporate conversion	(13,428,948)	(1,528,222)	11,363,636	113,636	1,414,586	—	—
Stock compensation expense	274,314	924,438	—	—	263,648	—	1,188,087
Net loss	—	(6,997,139)	—	—	—	(926,468)	(7,923,607)
Corporate conversion tax-effect	—	—	—	—	—	(821,392)	(821,392)
Balance, December 31, 2021	—	—	13,877,636	138,776	$23,319,499	$(1,747,860)	$21,710,415

See accompanying notes to the financial statements.

AEROCLEAN TECHNOLOGIES, INC.
STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,923,607)	$(3,323,081)
Adjustments to reconcile net loss to net cash flows used in operating activities		
Deferred tax benefit	(320,138)	—
Depreciation and amortization	79,646	—
Equity-based compensation	1,188,086	62,359
Changes in operating assets and liabilities:		
Accounts receivable	(177,064)	—
Inventories	(645,942)	—
Other current and non-current assets	(841,836)	(304,836)
Accounts payable	595,119	187,346
Accrued expenses and other current liabilities	250,649	333,236
Due to related parties	—	(25,000)
Net cash flows used in operating activities	(7,795,087)	(3,069,976)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(1,748,392)	(454,679)
Net cash flows used in investing activities	(1,748,392)	(454,679)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of equity units	5,173,599	5,856,976
Proceeds from issuance of common stock from initial public offering	25,140,000	—
Payment of issuance costs	(3,473,588)	—
Proceeds from loan from related party	1,000,000	—
Repayment of loan from related party	(1,000,000)	—
Net cash flows provided by financing activities	26,840,011	5,856,976
Net increase in cash	17,296,532	2,332,321
Cash, beginning of period	2,333,117	796
Cash, end of period	$19,629,649	$ 2,333,117
Supplemental Disclosure of cash flow information:		
Cash paid for interest	$ 7,465	$ —
Supplemental schedule of non-cash activities:		
Subscription receivable	$ —	$ 100,543
Equity units issued to related party	—	$ 61,700

See accompanying notes to the financial statements.

1. Description of Business

Description of Business

AeroClean Technologies, Inc. ("AeroClean" or the "Company") was initially formed as CleanCo Bioscience Group LLC ("CBG") in the State of Florida on September 2, 2011. Subsequent to its formation, CBG established a team of scientists, engineers and medical experts to provide solutions for the challenges posed by harmful airborne pathogens and resultant hospital acquired infections. On September 15, 2020, CBG converted into AeroClean Technologies, LLC as a Delaware limited liability company and is headquartered in Palm Beach Gardens, Florida. On November 23, 2021, AeroClean Technologies, LLC incorporated in the state of Delaware as AeroClean Technologies, Inc. See Note 3, Public Offering for a discussion of the Company's recent initial public offering (the "Public Offering"). AeroClean is an interior space air purification technology company with an immediate objective of initiating full-scale commercialization of its high-performance interior air sterilization and disinfection products for the eradication of coronavirus and other harmful airborne pathogens. AeroClean was established to develop technology-driven, medical-grade air purification solutions for hospitals and other healthcare settings.

Liquidity and Capital Resources

The provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements — Going Concern* (ASC 205-40) require management to assess an entity's ability to continue as a going concern within one year of the date the financial statements are issued. In each reporting period (including interim periods), an entity is required to assess conditions known and reasonably knowable as of the financial statement issuance date to determine whether it is probable an entity will not meet its financial obligations within one year from the financial statement issuance date. Substantial doubt about an entity's ability to continue as a going concern exists when conditions and events, considered in the aggregate, indicate it is probable the entity will be unable to meet its financial obligations as they become due within one year after the date the financial statements are issued.

The Company incurred a net loss of $7,923,607 during the year ended December 31, 2021 and had working capital of $20,066,574 and an accumulated deficit of $1,747,860 at December 31, 2021. The Company's net cash used in operating activities was $7,795,087 for the year ended December 31, 2021. For the year ended December 31, 2020, the Company incurred a net loss of $3,323,081 and had an accumulated deficit of $8,223,407, and net cash used in operating activities was $3,069,976 at December 31, 2020. The Company is an early-stage company and has begun generating revenues through the commercial production and sale of its Pūrgo air purification device. The Company first shipped units to customers in July 2021 and generated revenues of $616,511 through December 31, 2021.

The Company's ability to fund its operations is dependent upon management's plans, which include generating sufficient revenues and controlling the Company's expenses. A failure to generate sufficient revenues or control expenses, among other factors, will adversely impact the Company's ability to meet its financial obligations as they become due and payable and to achieve its intended business objectives. On November 29, 2021, the Company completed the Public Offering resulting in aggregate gross proceeds of $25,140,000 and net proceeds of $21,640,000 after deducting underwriting fees and closing costs of approximately $3,500,000. See Note 3, Public Offering. The accumulated deficit from the inception of the Company through December 31, 2021 is substantially less than the amount raised through the Public Offering. Further, the Company's investment into research and development, engineering and other product development costs has been decreasing following the product launch, and as discussed, the Company is now generating revenues and margins from the sale of its Pūrgo device. Operating costs associated with revenue generation can also be managed as the Company increases revenues.

Based on the available cash balance and management's plan as described above, management believes that it has the ability to fund the Company's operation for one year after the financial statements are issued.

COVID-19 Pandemic

The Company continues to monitor the outbreak of COVID-19 and its variants, including the most recent Omicron variant, which continue to spread throughout the world and adversely impact global commercial activity and contribute to significant declines and volatility in financial markets. The Company's on-going research and development activities, including development of product prototypes and manufacturing activities, are all conducted in the United States, and as a result, the Company has been able to mitigate some of the adverse impact of the COVID-19 pandemic on its global supply chain.

The Company continues to actively monitor the situation and may take further actions that impact operations as may be required by federal, state or local authorities or that the Company determines is in the best interests of its employees, customers, suppliers and stockholders. As of the date of issuance of these financial statements, the pandemic presents uncertainty and risk as the Company cannot reasonably determine or predict the nature, duration or scope of the overall impact the COVID-19 pandemic will have on its business, results of operations, liquidity or capital resources.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the accounting and disclosure rules and regulations of the U.S. Securities and Exchange Commission (the "SEC").

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to avail itself of this exemption from new or revised accounting standards and, therefore, the financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of the public company effective dates.

Use of Estimates

The preparation of the Company's financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. Significant estimates in these financial statements include those related to the fair value of equity-based compensation and revenue recognition. On an ongoing basis, the Company evaluates its estimates, judgments and methodologies. The Company bases its estimates on historical experience and on various other assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Due to the inherent uncertainty involved in making estimates, actual results could differ materially from those estimates.

Cash and Cash Equivalents

The Company considers all short-term investments with an original maturity of three months or less when purchased to be cash and cash equivalents. The Company did not have any cash equivalents as of December 31, 2021.

Revenue Recognition

The Company recognizes revenues related to sales of products upon the customer obtaining control of promised goods, in an amount that reflects the consideration that is expected to be received in exchange for those goods. To determine revenue recognition for arrangements within the scope of ASC Topic 606, *Revenue from Contracts with Customers (*"ASC 606"), the following five steps are performed: (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 Company satisfies a performance obligation. Revenue is recognized

in the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Revenues from product sales are recognized at a point in time, and revenue is recognized when title, and risk and rewards of ownership have transferred to the customer, which is generally upon shipment. In instances where title does not pass to the customer upon shipment, the Company recognizes revenue upon delivery or customer acceptance, depending on the terms of the arrangement.

Warranty Costs

The Company provides a three-year warranty on its Pūrgo device from the date of sale to its customers. The Company's policy is to record a provision for estimated future costs related to warranty expense when they are probable and reasonably estimable, which is when revenue is recognized. There was no warranty accrual as of December 31, 2021 and 2020, respectively.

Research & Development Expenses

Research and development expenses are expensed as incurred and consist principally of contract labor and third-party engineering, product development and testing costs related to the development of medical grade air purification devices and related components as well as concepts for future product development.

Income Taxes

Prior to the Public Offering, the Company was a limited liability company and was treated as a partnership for federal and state income tax purposes. Therefore, no provision for income taxes had been included in the financial statements since taxable income or loss was allocated to members, who were responsible for any taxes thereon, in accordance with the provisions of the operating agreement.

On November 23, 2021 in conjunction with the Public Offering, the Company incorporated in the State of Delaware. The Company recognizes and measures its unrecognized tax benefit in accordance with FASB ASC 740, Income Taxes. The Company provides deferred income taxes for temporary differences between the amounts of assets and liabilities recognized for financial reporting purposes and such amounts recognized for income tax purposes. Deferred income taxes are computed using enacted tax rates that are expected to be in effect when the temporary differences reverse. Under that guidance, management assesses the likelihood that tax positions will be sustained upon examination based on the facts, circumstances and information available at the end of each period, including the technical merits of those positions. The measurement of unrecognized tax benefits is adjusted when new information is available or when an event occurs that requires a change. For the years ended December 31, 2021, and 2020, the Company did not identify any uncertain tax positions taken or expected to be taken in an income tax return that would require adjustment to, or disclosure in, its financial statements.

Accounts Receivable

Trade accounts receivable are stated net of an allowance for doubtful accounts. We estimate the allowance for doubtful accounts based on review and analysis of specific customer balances that may not be collectible and how recently payments have been received. Accounts are considered for write-off when they become past due and when it is determined that the probability of collection is remote. As of December 31, 2021, there was no allowance for doubtful accounts.

Inventories

The Company values inventories at the lower of cost or net realizable value using the first-in, first-out or weighted average cost method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonable predictable costs of completion, disposal and transportation. Inventories on hand at December 31, 2021 consisted primarily of spare parts and finished goods.

Property and Equipment

Property and equipment are stated at cost and depreciated generally under the straight-line method over their estimated useful lives (or the lesser of the term of the lease for leasehold improvements, as

appropriate), except for tooling, which is depreciated utilizing the units-of-production method. The Company periodically reviews long-lived assets for impairment whenever events or changes in business circumstance indicate that the carrying value of the assets may not be recoverable. Under those circumstances, if the fair value were less than the carrying amount of the asset, the Company would recognize a loss for the difference. The Company has determined that long-lived assets were not impaired during the years ended December 31, 2021 and 2020.

Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees directly associated with in-process equity financing as deferred offering costs. Deferred offering costs were offset against the proceeds from the Public Offering.

Common Stock Equivalents

The Company has potential common stock equivalents related to its outstanding restricted stock units. These potential common stock equivalents are not included in diluted loss per share for any period presented in which there is a net loss because the effect would have been anti-dilutive.

Share-based Payments

The Company accounts for share-based payments to employees and non-employees in accordance with the provisions of FASB ASC 718, Compensation — Stock Compensation ("ASC 718"). Under ASC 718, the Company measures the share-based compensation cost on the date of grant, based on the fair value of the award, and expense is recognized over the requisite service period. Compensation cost recognized during the year ended December 31, 2021 related to the issuance of Class A Units and grants of restricted stock units.

Fair Value Measurements

Certain assets and liabilities are carried at fair value in accordance with U.S. GAAP. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants at the measurement date. A three-tier fair value hierarchy that prioritizes the inputs used in the valuation methodologies, is as follows:

Level 1 Valuations based on quoted prices for identical assets and liabilities in active markets.

Level 2 Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs observable or that can be corroborated by observable market data.

Level 3 Valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

At December 31, 2021 and 2020, the carrying amounts of the Company's financial instruments, including cash, prepaid expenses and other current assets, accounts payable and accrued liabilities approximated their respective fair value due to the short-term nature of these instruments.

Operating Segment

The Company operates in one segment. All of the Company's assets are in the United States of America.

Concentrations of Credit Risk

The Company maintains its cash at a major financial institution with high credit quality, and at times, the balance in its cash deposits may exceed the Federal Deposit Insurance Corporation limits of $250,000.

The Company has not experienced and does not anticipate any losses on deposits with commercial banks and financial institutions that exceed federally insured limits.

The Company's suppliers and vendors include engineering firms and consultants, research and development companies, testing laboratories, contract manufacturers and other suppliers required to design, test and manufacture its products. The Company obtains some of its services from a limited group of vendors; however, the Company has neither experienced any significant disruptions nor expects any significant disruptions to its operations due to supplier concentration. The Company's largest supplier accounted for 13% and 12% of total expenditures for the years ended December 31, 2021 and 2020, respectively, while its second largest supplier accounted for 11% and 33% of total expenditures for the years ended December 31, 2021 and 2020, respectively.

Significant customers may change from year to year depending on the overall level of activity and the sales of the Company's products to each customer. During the year ended December 31, 2021, the Company's largest and second largest customers accounted for approximately 45% and 12% of the Company's revenues, respectively.

JOBS Act Accounting Election

The Company is an "emerging growth company," as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to avail itself of this exemption from new or revised accounting standards and, therefore, the financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of the public company effective dates.

Recent Accounting Standards

The Company has reviewed recent accounting pronouncements and, with the exception of the below, concluded they are either not applicable to the business or no material effect is expected on the financial statements as a result of future adoption.

In June 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments — Credit Losses, which was subsequently amended by ASU No. 2018-19 and ASU No. 2019-10, and which requires the measurement of expected credit losses for financial instruments carried at amortized cost held at the reporting date based on historical experience, current conditions and reasonable forecasts. The updated guidance also amends the current other-than-temporary impairment model for available-for-sale debt securities by requiring the recognition of impairments relating to credit losses through an allowance account and limits the amount of credit loss to the difference between a security's amortized cost basis and its fair value. In addition, the length of time a security has been in an unrealized loss position will no longer impact the determination of whether a credit loss exists. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The standard is effective for the fiscal year beginning after December 15, 2022. The Company will continue to assess the possible impact of this standard, but it currently does not expect that the adoption of this standard will have a significant impact on its financial statements and its limited history of bad debt expense relating to trade accounts receivable.

In February 2016, the FASB issued ASU 2016-02, Leases ("Topic 842"), which supersedes ASC Topic 840, Leases. Topic 842 requires lessees to recognize a lease liability and a lease asset for all leases, including operating leases, with a term greater than 12 months on its balance sheet. The update also expands the required quantitative and qualitative disclosures surrounding leases. Topic 842 will be applied using a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. In November 2019, FASB deferred the effective date for implementation of Topic 842 by one year and, in June 2020, FASB deferred the effective date by an additional year. The guidance under Topic 842 is effective for fiscal years beginning after December 15, 2021 and interim periods within fiscal years beginning after December 15, 2022. Earlier adoption is permitted. The Company only has one operating lease in place as of December 31, 2021 related

to its warehouse, distribution facility and corporate headquarters for a 10-year term. The Company's remaining lease payments of approximately $2,675,000 will be discounted to record its lease liability using its incremental borrowing rate and to record the corresponding right of use asset.

3. Public Offering

On November 29, 2021, the Company completed the Public Offering of 2,514,000 shares of its common stock, which included the partial exercise of the underwriters' overallotment option, at a public offering price of $10.00 per share for aggregate gross proceeds of $25,140,000 and net proceeds of approximately $21,640,000 after deducting underwriting fees of approximately $2,200,000 and other offering costs of approximately $1,300,000.The Company issued a purchase option to the underwriters ("UPO") exercisable within five years of the Public Offering for 5.0% of the shares of common stock issued, or 125,700 shares of common stock, at an exercise price of $12.50 per share. The Company's common stock is listed on The Nasdaq Capital Market under the symbol "AERC." In connection with the Public Offering, on November 23, 2021, the Company converted from a Delaware limited liability company into a Delaware corporation (the "Corporate Conversion") and changed its name to AeroClean Technologies, Inc. In connection with the Corporate Conversion, the outstanding member units of 13,428,948 were converted into 11,363,636 shares of common stock at a conversion ratio of 0.8462. The Corporate Conversion has been adjusted retroactively for the purposes of calculating basis and diluted earnings per share. The Company's certificate of incorporation authorizes 110,000,000 shares of common stock and 11,000,000 of shares preferred stock.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist primarily of prepaid insurance premiums and amounts paid to suppliers and vendors for inventories and retainers for engineering, product development, testing and other services to be performed. Prepaid expenses and other current assets were $1,124,988 and $304,836 at December 31, 2021 and December 31, 2020, respectively.

5. Inventories

Inventory consists of the following:

	December 31,	
	2021	2020
Raw materials	$475,767	$—
Finished goods	170,175	—
Total inventories	$645,942	$—

6. Property and Equipment

Property and equipment consisted of the following:

	Useful Life (Years)	December 31,	
		2021	2020
Leasehold improvements	Lesser of useful life or lease term	$ 847,217	$ —
Machinery and tooling	7	1,123,391	454,679
Furniture and equipment	3 — 10	232,466	—
		2,203,074	454,679
Less accumulated depreciation		79,646	—
		$2,123,428	$454,679

Property and equipment are stated at cost and depreciated generally under the straight-line method over their estimated useful lives (or the lesser of the term of the lease for leasehold improvements, as

appropriate), except for tooling, which is depreciated utilizing the units-of-production method. Depreciation expense was $79,646 for the year ended December 31, 2021. There was no depreciation expense for the year ended December 31, 2020.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of:

	December 31,	
	2021	2020
Accrued wages and bonus	$408,418	$ —
Research and development	35,708	271,800
Professional and consulting fees	13,120	33,345
Legal fees	29,512	10,000
Customer advance deposits	—	6,000
Other accrued liabilities	97,127	12,091
Total accrued expenses and other current liabilities	$583,885	$333,236

8. Commitments and Contingencies

Lease Commitments — On February 1, 2021, the Company entered into a lease with Gardens Bio Science Partners, LLC, an entity under common control of the Company's co-founder and Chairman of the Board. The leased premises consist of 20,000 square feet of office and warehouse space and has a lease term of 10 years at an annual base rent of $260,000 subject to escalation of 2.5% on an annual basis. The approximate future minimum lease payments under our noncancelable operating lease are as follows:

Years ending December 31,	
2022	$ 266,500
2023	273,163
2024	279,992
2025	286,991
2026	294,166
Thereafter	1,273,734
Total	$2,674,546

Legal Proceedings — The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

Indemnities, Commitments and Guarantees — Effective November 1, 2020, the Company executed employment agreements with two key members of management that will continue until terminated by either party. In the event of termination without cause, the Company is obligated to pay the executive their base salary for a period of six months. Further, in the event of termination without cause or resignation for good reason, or a change of control, each as defined in the agreements, within twelve months of such termination or resignation, each of the executives is entitled to accelerated vesting of any outstanding time-based equity awards. The employment agreements provide for a base salary and a discretionary annual bonus to be determined at the sole discretion of the Company's Board of Managers, for periods prior to the Corporate Conversion, and the Company's Board of Directors (in either case, the "Board"), for periods following the Corporate Conversion. The Company's employment agreements generally provide for certain protections in the event of a change of control. These protections generally include the payment of severance under certain circumstances in the event of a change of control. On May 1, 2021, the employment agreements were amended to provide for the eligibility of each executive to receive restricted stock units upon the conversion of the Company to a Delaware corporation. See Note 3, Public Offering. Accordingly, the executives were granted an aggregate of 443,269 restricted stock units contemporaneously with the Public Offering. The

Company also had agreements in place with independent contractors whereby the Company was required to compensate the independent contractors fifty percent in cash and fifty percent in equity. The equity consideration was contingent upon future events, including the conversion to a Delaware corporation and a new round of equity financing from third party sources, which were not deemed to be probable at December 31, 2020. Subsequent to December 31, 2020, these agreements were amended so that the compensation will be in cash only for services provided subsequent to March 31, 2021. Effective April 1, 2021, the contractors were issued Class A Units to compensate them for the fifty percent equity portion of their consideration earned. See Note 9, Stockholders' Equity.

Registration Rights Agreement — In connection with the Public Offering we entered into a registration rights agreement with the chair of our board of directors and each of our other stockholders that held 10% or more of our outstanding common stock immediately upon completion of the Public Offering, providing (x) our chair with "demand" registration and customary "piggyback" registration rights, and (y) the other stockholders party to the registration rights agreement with customary "piggyback" registration rights. The registration rights agreement provides that we will pay certain expenses relating to such registrations and indemnify the registration rights holders against certain liabilities that may arise under the Securities Act of 1933, as amended.

9. Related Party Transactions

The Company recorded an aggregate of $80,000 of revenues for units sold to related parties of which $63,290 was included in accounts receivable as of December 31, 2021.

Bridge Loans — On each of September 30, 2021 and November 5, 2021, the Company borrowed $500,000 pursuant to bridge loan agreements (the "Bridge Loans") from a related party at an interest rate of the prime rate plus 3.0% per annum, which was 6.25% for the life of the Bridge Loans, with the principal and accrued interest due upon demand. The Company used the proceeds from the Bridge Loans to fund operations, including working capital requirements, continued product launch costs and other overhead costs until the proceeds from the Public Offering became available. On December 1, 2021, the Company repaid the Bridge Loans in full, including unpaid accrued interest, with a portion of the net proceeds of the Public Offering. See Note 3, Public Offering.

10. Stockholders' Equity

Common Stock

The Company is authorized to issue up to 110,000,000 shares of common stock with a par value of $0.01. In November 2021, the Company completed its Public Offering and sold 2,514,000 shares of common stock for net proceeds of approximately $21,640,000. See Note 3, Public Offering.

Dividend Rights — Subject to the rights, if any, of the holders of any outstanding series of the Company's preferred stock, holders of the Company's common stock will be entitled to receive dividends out of any of its funds legally available when, as and if declared by the Board.

Voting Rights — Each holder of the Company's common stock is entitled to one vote per share on all matters on which stockholders are generally entitled to vote. The Company's certificate of incorporation does not provide for cumulative voting in the election of directors.

Liquidation — If the Company liquidates, dissolves or winds up its affairs, holders of its common stock are entitled to share proportionately in the Company's assets available for distributions to stockholders, subject to the rights, if any, of the holders of any outstanding series of the Company's preferred stock.

Other Rights — Holders of the Company's common stock have no preemptive, subscription, redemption or conversion rights.

Preference Shares

The Company is authorized to issue up to 11,000,000 shares of preferred stock with a par value of $0.01. Under the Company's certificate of incorporation and subject to the limitations prescribed by law,

our Board of Directors may issue the Company's preferred stock in one or more series and may establish from time to time the number of shares to be included in such series and may fix the designation, the voting powers, if any, and preferences and relative participating, optional or other rights, if any, of the shares of each such series and any qualifications, limitations or restrictions thereof. When and if the Company issues any shares of preferred stock, the Board of Directors will establish the number of shares and designation of such series and the voting powers, if any, and preferences and relative participating, optional or other special rights, and the qualifications, limitations and restrictions thereof, for the particular preferred stock series.

Long-term Incentive Plan

In conjunction with the Public Offering, on November 23, 2021, the Company adopted the Employee Stock Purchase Plan, the 2021 Incentive Award Plan ("Long-Term Incentive Plan" or "LTIP") and the Non-Employee Directors Stock and Deferred Compensation Plan (collectively, the "Plans"). Accordingly, the Company reserved 1,802,273 shares, collectively, for issuance or sale under the Plans. On November 29, 2021, at the closing of the Public Offering, the Company granted 443,269 restricted stock units to members of management (See Note 7, Commitments and Contingencies) and 182,999 restricted stock units to members of the Board under the Incentive Award Plan.

The Company maintains an LTIP under which the Company's Compensation Committee has the authority to grant stock options; stock appreciation rights; restricted stock; restricted stock units; performance stock, performance units; and other forms of equity-based or equity-related awards.

During the year ended December 31, 2021, the Company granted restricted stock to members of the Company's Board of Directors and certain members of management. Restricted stock grants vest over periods ranging from two to three years and are granted at the discretion of the Compensation Committee of the Company's Board of Directors. Compensation cost is generally recorded on a straight-line basis over the vesting term of the shares based on the grant date value using the closing trading price.

Stock-based compensation expense of $263,648 was recorded in selling, general and administrative expense for the year ended December 31, 2021. Unrecognized compensation cost related to restricted stock awards made by the Company was $5,999,032 at December 31, 2021, which is expected to be recognized over the weighted average remaining life of 2.35 years at the grant date fair value of $10.00 per share.

The following is the restricted stock unit activity for the year ended December 31, 2021:

Outstanding January 1, 2021	—
Granted	626,268
Vested	—
Forfeited	—
Outstanding January 1, 2021	626,268

Members' Units

Prior to the completion of the Public Offering (See Note 3, Public Offering), the Board was authorized to issue Class A Units ("Units"), which entitled unitholders to allocations of profits and losses and other items and distributions of cash and other property as was set forth in the Company's operating agreement, as amended. The Board had the right at any time and from time to time to authorize and cause the Company to create and/or issue equity securities to any person, in which event, all units of a class, group or series would have been diluted in an equal manner as to the other units of such class, group or series, and the Board had the power to amend the operating agreement to allow for such additional issuances and dilution and to make any such other amendments necessary or desirable to reflect such issuances. The holder of each Unit had the right to one vote per Unit on all matters to be voted on by the Members.

At December 31, 2020, the Company recorded a subscription receivable for $100,543 relating to the purchase of Units in December 2020 for which cash was received in February of 2021.

In May 2020, the Board approved an action to effectuate a reverse stock split of the Units, which reduced each unit holder's number of Units on a pro-rata basis. Each unit holder's proportional voting power remained unchanged, and the rights and privileges of the holders of Units were substantially unaffected by the reverse stock split. The number of Units outstanding and footnotes have been adjusted to reflect the aforementioned reverse stock split.

Between January 1, 2021 and the Public Offering, the Company sold an additional 5,073,056 Units to existing members resulting in gross proceeds of $5,073,056.

Effective April 1, 2021, the Board approved the issuance of an aggregate of 274,314 Units, of which 140,085 Units were issued to independent contractors and 134,229 Units were issued to Board members as compensation for services provided. Certain of the Units were issued to independent contractors as consideration for services pursuant to existing agreements, which provided for payment of fifty percent in cash and fifty percent in equity (See Note 7, Commitments and Contingencies). The subscription agreements issued to the contractors included a provision that no payments for services rendered after March 31, 2021 will be in the form of equity.

Equity-based compensation expense of $924,438 related to these issuances was recognized and is included in selling, general and administrative expenses in the Company's statement of operations for the year ended December 31, 2021. The fair value of $3.37 for each Unit was determined utilizing the income-based approach, which relies on the discounted cash flow method and considers future cash flows discounted at an appropriate discount rate, or weighted average cost of capital. The discounted cash flow method is affected by assumptions regarding complex and subjective variables, including future levels of revenue growth, operating margins and working capital needs as well as the weighted average cost of capital, which was determined by evaluating the rates of return required for other companies of a similar size and stage of development.

11. Loss Per Common Share

Basic net loss per common share is computed using the weighted average common shares outstanding during the year. Diluted net loss per common share reflects the potential dilution from assumed conversion of all dilutive securities such as unvested restricted stock units and UPO using the treasury stock method. When the effects of the outstanding restricted stock units and UPO are anti-dilutive, they are not included in the calculation of diluted net loss per common share.

The following table sets forth the computation of basic and diluted net loss per share for the years ended December 31, 2021 and 2020:

	Year Ended December 31,	
	2021	2020
Net (loss) earnings	$ (7,923,607)	$(3,323,081)
Basic weighted average common shares	10,675,765	3,250,980
Diluted weighted average common shares	10,675,765	3,250,980
Basic net (loss) earnings per common share	$ (0.74)	$ (1.02)
Diluted net (loss) earnings per common share	$ (0.74)	$ (1.02)

12. Income Taxes

Income tax benefit consisted of the following:

	December 31, 2021
Current Expense:	
Federal	$ —
State	—
	—
Deferred Benefit:	
Federal	266,278
State	53,860
	320,138
Total Income Tax Benefit	$320,138

The significant components of the Company's deferred tax assets and liabilities at December 31, 2021 are as follows:

	December 31, 2021
Federal Net Operating Loss	$ 205,018
State Net Operating Loss	42,419
Capitalized Costs	(536,567)
Tax credits	5,968
Stock Compensation	66,822
Accrued Expenses and Other	(284,914)
Total gross deferred tax assets/(liabilities)	(501,254)
Less valuation allowance	—
Net deferred tax assets/(liabilities)	(501,254)

The income tax benefit for the years ended December 31, 2021 differed from the amounts computed by applying the U.S. federal income tax rate of 21% to loss before tax benefit as a result of non-deductible expenses, tax credits generated, and utilization of net operating loss carryforwards. Since the Company is in a deferred tax liability position, a valuation allowance is not required.

	December 31, 2021
Federal Statutory Rate	$(261,788)
Permanent Differences	1,253
Research and Development	(5,968)
State Income Tax	(53,860)
Change in tax status	—
Effective Tax	(320,363)

At December 31, 2021, the Company had available operating loss carryforwards of approximately $976,277 for federal income tax purposes, all of which was generated after 2017 and can be carried forward indefinitely under the Tax Cuts and Jobs Act. At December 31, 2021, the Company had approximately $5,968 of federal Research and Development (R&D) tax credit carry-forwards. If not utilized, the federal R&D credits will begin to expire in 2041.

At December 31, 2021, the Company had available operating loss carryforwards for state tax purposes of approximately $976,277 which were generated during 2021 that do not expire.

Sections 382 and 383 of the Internal Revenue Code, and similar state regulations, contain provisions that may limit the NOL carryforwards available to be used to offset income in any given year upon the

occurrence of certain events, including changes in the ownership interests of significant stockholders. In the event of a cumulative change in ownership in excess of 50% over a three-year period, the amount of the NOL carryforwards that the Company may utilize in any one year may be limited. Although the Company has not undertaken a formal analysis, it is unlikely that such an ownership change occurred during 2021.

13. Subsequent Events

The Company has evaluated subsequent events through the date the financial statements were available to be issued and, except as otherwise noted herein, has concluded there were no material subsequent events that required recognition or disclosure in the financial statements.