

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): **March 31, 2022**

AeroClean Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-41096

(Commission
File Number)

45-3213164

(IRS Employer Identification No.)

10455 Riverside Dr.

Palm Beach Gardens, FL

(Address of principal executive offices)

33410

(Zip Code)

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

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

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

Title of each class	Ticker symbol(s)	Name of each exchange on which registered
Common Stock	AERC	The Nasdaq Stock Market LLC

Item 2.02. Results of Operations and Financial Condition.

On March 31, 2022, AeroClean Technologies, Inc. (the “Company”) issued a press release announcing its financial results for the fourth fiscal quarter and fiscal year ended December 31, 2021.

The press release is included as Exhibit 99.1 hereto. The information furnished under this Item 2.02, including the exhibit related thereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any disclosure document of the Company, except as shall be expressly set forth by specific reference in such document.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release, dated March 31, 2022.</u>
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: March 31, 2022

AEROCLEAN TECHNOLOGIES, INC.

By: /s/ Jason DiBona

Name: Jason DiBona

Title: Chief Executive Officer



AeroClean Reports Fourth Quarter and Full Year 2021 Financial Results

Revenues increased 35.9% to \$355,212 as compared to \$261,299 in the previous quarter

PALM BEACH GARDENS, Fla., March 31, 2022 // -- AeroClean Technologies (“AeroClean” or the “Company”) (Nasdaq: AERC), a pathogen elimination technology company harnessing patented UV-C LED technology with Pürgo™ to significantly reduce and remove harmful pathogens to keep work, play and life going, today reported financial results for the fourth quarter and fiscal year ended December 31, 2021 (“Q4 2021” and “FY 2021”). All financial information is presented in U.S. dollars unless otherwise indicated.

Fourth Quarter 2021 Financial Highlights

- Revenues were \$355,212, an increase of 35.9% as compared with the third quarter of 2021.
- Gross profit and gross profit margin were \$164,049 and 46.2%, respectively, an increase of 270 basis points as compared to the third quarter.
- Net loss for the fourth quarter of 2021 was \$1,741,383. Net loss exclusive of one-time costs associated with the IPO was approximately \$1,600,000 as compared to \$1,528,012 in the third quarter.

Fourth Quarter 2021 Highlights

- Announced closing of Initial Public Offering on November 29, 2021, trading on the Nasdaq Capital Market under the ticker symbol “AERC”
- Completed the submission and filing of the 510(k) application to the U.S. Food and Drug Administration (“FDA”) for the Pürgo continuous air sanitization device
- Installed Pürgo devices at Hospital for Special Surgery (“HSS”) in New York in December 2021
- Completed a large-scale implementation of 100 Pürgo units at Cape Cod Healthcare, a leading provider of healthcare for residents and visitors of Cape Cod with over 450 physicians and 5,700 employees
- Installed Pürgo devices at multiple campuses for Northeastern University

Business Highlights

- Completed the build-out and establishment of our distribution facility and corporate headquarters in Q2 2021
- Launched manufacturing and commercial sales of the Pürgo patented and proprietary continuous air sanitization product for indoor spaces in late Q3 2021
- Debuted the Pürgo Lift air purification solution for elevators and other wall-mount applications in Q1 2022
- Jointly tested and evaluated Pürgo Lift with HSS for future deployment across HSS facilities
- Launched the SAFE AIR TECHNOLOGY program, designed to create awareness and improve identification of areas where pathogen elimination devices have been deployed
- Installed Pürgo devices across our target markets and channels including healthcare, senior living, schools and universities, hospitality and leisure and other commercial spaces

Management Commentary

“After initiating sales in July 2021, we have made progress in our mission to become one of the fastest-growing pathogen elimination companies,” said Jason DiBona, Chief Executive Officer of AeroClean. “Pürgo has been well-received by our customers, and we have witnessed interest from healthcare organizations, schools and universities, and commercial office customers - our target, niche markets – which drove Q4 performance with revenues and gross profit growing 35.9% and 46.2%, respectively, as compared to the third quarter of 2021. Additionally, we continue to see opportunities in the commercial real estate market as owners adopt indoor air quality initiatives. We are currently marketing Pürgo pursuant to the FDA Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. We have applied for 510(k) clearance for Pürgo as a Class II medical device subject to the rigorous standards set by the FDA, which we believe will substantially differentiate Pürgo from the competition and validate performance and efficacy claims for our discriminating healthcare and commercial customers. We expect to receive full FDA 510(k) clearance for Pürgo sometime in the second half of 2022.”

“Our team’s focus and commitment in 2021 has set us on solid footing to pursue our goal of becoming one of the top providers of clean air technology in the industry. The commercial launch of Pürgo allows us to fulfill our founding mission of combating hospital acquired infections, estimated at approximately two million annually and causing approximately 100,000 deaths, and protecting the estimated 10 million immunocompromised-patient population in the United States alone in 2021 from potentially fatal infections. Additionally, the last two years of the COVID-19 pandemic have clearly demonstrated that the threat of known and unknown harmful airborne pathogens is extremely detrimental to both work and social life. As vaccination rates increase and local masking regulations ease, people are cautiously re-entering ‘normal’ life, and we pride ourselves on being able to facilitate safe, healthy indoor environments for all. Further, our customers now recognize the importance of indoor air quality not only to combat airborne pathogens but also to improve health security and productivity. Indoor air pollution contributes to four million premature deaths per year according to the World Health Organization. We look forward to continuing our sustained partnerships and relationships and to forging new connections as the world begins to re-emerge.”

Q4 and FY 2021 Financial Overview

The following is a tabular summary and commentary of revenues, gross profit and net loss for the three-month periods ended December 31, 2021 and September 30, 2021.

	Quarter Ended 12/31/2021	Quarter Ended 9/30/2021	% Change
Product revenues	\$ 355,212	\$ 261,299	35.9%
Gross profit	\$ 164,049	\$ 113,566	44.5%
Net loss	\$ 1,741,383	\$ 1,528,012	14.0%

Revenues for Q4 2021 were \$355,212, compared to \$261,299 during Q3 2021, bringing total revenues for FY 2021 to \$616,511. The Company did not report revenues in the prior year. Total annual product revenues for 2021 were approximately \$617,000, marking our first year of product revenues.

Gross profit of \$164,049, or 46.2% of revenues, increased by \$50,483, or 270 basis points, as compared to \$113,566, or 43.5% in the third quarter of 2021. Total gross profit for the year was approximately \$278,000, representing an annual gross margin of 45.0%.

General and administrative expenses for Q4 2021 were \$1,649,309, compared to \$685,079 in Q3 2021. The increase of \$964,230 was driven primarily by approximately \$150,000 of costs required to become a public company and approximately \$325,000 of increased personnel costs.

Research and development expenses for Q4 2021 were \$576,261, compared to \$956,499 in Q3 2021. Research and development expenses primarily consisted of engineering, product development and manufacturing design costs and decreased by \$380,238 as product development and testing activities related to Pürgo decreased in Q4 as compared to Q3 following its launch in July 2021.

Full Year total operating expenses, including the approximately \$150,000 associated with our IPO, were approximately \$8.5 million, compared with \$3.3 million for the previous year. The increase was driven primarily by the hiring of additional personnel, increased consulting fees for outsourced functions, rent expense for the lease that commenced in 2021, increased professional fees and insurance. Approximately \$3.5 million of fees paid to our underwriters, legal and professional fees, and other offering costs were deferred and offset against the net proceeds of our public offering.

Net loss for Q4 2021 was \$1,741,383, or \$0.14 per share, compared to a net loss of \$1,528,012, or \$0.13 per share, in Q3 2021. Total net loss for the year was \$7.9 million compared to a net loss of \$3.3 million in 2020.

Balance Sheet and Liquidity

Cash was \$19,629,649 as of December 31, 2021, compared to \$2,333,117 as of December 31, 2020, and total current assets were \$21,577,653 and total current liabilities were \$1,511,079 as of December 31, 2021. Net working capital (current assets less current liabilities) at the end of December 31, 2021 was \$20,066,574, and the Company has no debt.

On November 29, 2021, the Company completed a public offering of 2,514,000 shares of its common stock for net proceeds of approximately \$22,000,000 after deducting underwriting fees and closing costs. As a result of the offering, the Company's common stock was listed on The Nasdaq Capital Market under the symbol "AERC". The \$22 million of net proceeds from the IPO strengthens our balance sheet and further positions us for scaled organic and inorganic growth.

Outlook

Commenting on the Company's outlook, Mr. DiBona stated, "With 2022 in full swing, we expect to remain acutely focused on growing our Pürgo customer base by onboarding additional sales team members and developing sales channels through distribution networks and strategic partnerships supported by the continued ramp-up in manufacturing capabilities at our leading medical device contract manufacturer. While we have achieved improvements in manufacturing output since the commercial launch of Pürgo 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."

"Further, we expect to complete the development and launch of Pürgo Lift in 2022. We believe Pürgo Lift is a break-through technology we expect will assist many companies' safe return to work where elevators remain an acute point of vulnerability. We are pleased to have completed our recent public offering as we are now well-positioned with sufficient operating liquidity to support the working capital requirements of growing Pürgo inventories and sales and the completion of the Pürgo Lift product launch. We are also pursuing inorganic growth opportunities and are in various stages of discussion with potential acquisition and/or merger targets."

"The Company has a solid balance sheet and public currency to pursue growth through synergistic, strategic acquisitions that contribute to our goal of becoming a leading provider of indoor air quality products and services. As our customers look for comprehensive indoor air quality solutions, our short and long-term growth strategy includes evaluating opportunities to expand our product and service portfolio with complementary, differentiated technologies while maintaining a strong level of liquidity," concluded Mr. DiBona.

Financial results and analyses are available on the Company's investor relations website (<https://aeroclean.com/investors/>).

The financial results presented in this press release are unaudited and are therefore preliminary. They should not be viewed as a substitute for financial statements prepared in accordance with GAAP. There is a possibility that AeroClean's fourth quarter and 2021 fiscal year financial results could change prior to the completion of the 2021 fiscal year audit.

Conference Call Information:

AeroClean will host a live webcast to discuss its financial results for the fourth quarter and full year 2021 at 8:30 a.m. Eastern time today, March 31, 2022.

Event: Fourth Quarter and Full Year 2021 Financial Results Conference Call
Date: Thursday, March 31, 2022
Time: 8:30 a.m. Eastern Time
Webcast: <https://edge.media-server.com/mmc/p/oxx4jj3k>

Non-GAAP Financial Measures

In addition to disclosing financial measures prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), this press release and the accompanying tables contain certain non-GAAP financial measures, including net loss exclusive of one-time costs associated with the IPO. We believe this non-GAAP measure is useful for management's evaluation of our performance and management reviews and uses this measure for business planning and other purposes. Non-GAAP financial measures are used in conjunction with GAAP measures as part of our management's overall assessment of performance and liquidity, including the preparation of AeroClean's annual operating budget and quarterly forecasts, to evaluate the effectiveness of business strategies, and to communicate with the board of directors concerning financial performance and liquidity. AeroClean's definitions of non-GAAP financial measures may differ from those used by other companies for similarly-titled measures, and therefore comparability may be limited. In addition, other companies may not publish these or similar metrics. Thus, AeroClean's non-GAAP financial measures should be considered in addition to, not as substitutes for, or in isolation from, AeroClean's GAAP results.

We encourage investors and others to review AeroClean's financial information in its entirety, not to rely on any single financial measure, and to view non-GAAP measures in conjunction with GAAP financial measures. In addition, AeroClean compensates for the limitations of non-GAAP financial measures by providing a reconciliation of each non-GAAP measure to the most directly comparable GAAP financial measure. These reconciliations are included in the tables attached to this release.

Forward-Looking Statements

This press release includes forward-looking statements relating to our management's expectations, beliefs and intentions and AeroClean's prospects. Forward-looking statements are statements that are not historical facts, including the statements of our management and statements under the heading "Outlook." Such forward-looking statements are based on our management's current expectations and projections about future events and trends, which are inherently subject to risks, assumptions and uncertainties that could cause actual results to differ materially from those explicitly or implicitly projected, including (without limitation): macroeconomic uncertainties driven by the war between Ukraine and Russia; rising inflation and the COVID-19 pandemic; a failure by our products to perform as expected; our inability to develop adequate distribution, customer service, and technical support networks; our failure to implement our business strategy; any delay in or failure to achieve clearance from the U.S. Food and Drug Administration to market our products or our failure to comply with applicable laws and regulations; our inability to develop and maintain reliable manufacturing, consulting and other vendor relationships important to the commercialization of our products; our inability to protect our intellectual property or our infringement upon the proprietary rights of others; and our inability to efficiently manage research and development spending.

These and other risks and uncertainties that could affect AeroClean's future results are included under the caption "Risk Factors" in AeroClean's offering circular filed with the Securities and Exchange Commission ("SEC") on November 24, 2021, which is available on the SEC's website at www.sec.gov. Further information regarding potential risks or uncertainties that could affect actual results will be included in other periodic filings AeroClean makes with the SEC.

The forward-looking statements in this release reflect management's expectations as of the date hereof and AeroClean expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based. Investors should realize that if our underlying assumptions for the projections contained herein prove inaccurate or that known or unknown risks or uncertainties materialize, actual results could vary materially from our expectations and projections.

About AeroClean Technologies

AeroClean is a pathogen elimination technology company on a mission to keep work, play and life going—with continuous air sanitization products called Pürgo™ (pure-go). We create solutions for hospitals, offices, and many shared spaces as well as elevators and more. Pürgo™ products feature SteriDuct™, a proprietary technology developed by our best-in-class aerospace engineers, medical scientists and innovators. Powered by SteriDuct™, our solutions are medical grade, eradicating viral, fungal and bacterial airborne pathogens. Our purpose is simple: to never stop innovating solutions that keep people healthy and safe, so life never stops. Learn more at aeroclean.com.

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Financial Statements

AEROCLEAN TECHNOLOGIES, INC.
Balance Sheets (Unaudited)

	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	<u>21,577,653</u>	<u>2,738,496</u>
Property and equipment, net	2,123,428	454,679
Other assets	21,667	-
Total assets	<u>\$ 23,722,748</u>	<u>\$ 3,193,175</u>
LIABILITIES AND MEMBERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 927,194	\$ 332,072
Accrued expenses and other current liabilities	583,885	333,236
Total current liabilities	<u>1,511,079</u>	<u>665,308</u>
Long-term liabilities:		
Deferred tax liability	501,254	-
Commitments and contingencies		
Members' equity	-	2,527,867
Stockholders' equity:		
Common stock, \$.01 par value per share; 110,000,000 shares authorized; 13,877,636 issued as of December 31, 2021	145,039	-
Additional paid-in capital	37,712,390	-
Accumulated deficit	(16,147,014)	-
Total members'/stockholders' equity	<u>21,710,415</u>	<u>2,527,867</u>
Total liabilities and members' equity	<u>\$ 23,722,748</u>	<u>\$ 3,193,175</u>

AEROCLEAN TECHNOLOGIES, INC.
Statements of Operations (Unaudited)

	Three Months Ended		Year Ended December 31,	
	December 31,		December 31,	
	2021	2020	2021	2020
Product revenues	\$ 355,212	\$ -	\$ 616,511	\$ -
Cost of sales	191,163	-	338,896	-
Gross profit	<u>164,049</u>	<u>-</u>	<u>277,615</u>	<u>-</u>
Operating expenses:				
Selling, general and administrative	1,649,309	505,573	4,327,998	1,131,385
Research and development	576,261	1,134,430	4,193,362	2,191,696
Total operating expenses	<u>2,225,570</u>	<u>1,640,003</u>	<u>8,521,360</u>	<u>3,323,081</u>
Loss before income tax benefit	(2,061,521)	(1,640,003)	(8,243,745)	(3,323,081)
Income tax benefit	320,138	-	320,138	-
Net loss	<u>\$ (1,741,383)</u>	<u>\$ (1,640,003)</u>	<u>\$ (7,923,607)</u>	<u>\$ (3,323,081)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.30)</u>	<u>\$ (0.74)</u>	<u>\$ (1.02)</u>
Weighted-average common shares outstanding:				
Basic and diluted	<u>12,238,115</u>	<u>5,458,957</u>	<u>10,675,765</u>	<u>3,250,980</u>

AEROCLEAN TECHNOLOGIES, INC.
Statements of Cash Flows (Unaudited)

	Year Ended December 31,	
	2021	2020
Net cash flows used in operating activities	\$ (6,973,688)	\$ (3,069,976)
Net cash flows used in investing activities	(1,748,392)	(454,679)
Net cash flows provided by financing activities	26,018,612	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

AEROCLEAN TECHNOLOGIES, INC.
Reconciliation of GAAP to Non-GAAP Financial Measures
(Unaudited)

	Three Months Ended	
	December 31, 2021	
Net loss	\$	(1,741,383)
One-time IPO costs		150,000
Adjusted net loss	\$	(1,591,383)
