

**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): **August 16, 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 August 16, 2022, AeroClean Technologies, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 2022.

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>
99.1	Press Release, dated August 16, 2022
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: August 16, 2022

AEROCLEAN TECHNOLOGIES, INC.

By: /s/ Jason DiBona

Name: Jason DiBona

Title: Chief Executive Officer



AeroClean Reports Second Quarter 2022 Financial Results

Company Validates Pürgo Effectiveness Against Omicron Variant

PALM BEACH GARDENS, Fla., August 16, 2022 // -- AeroClean Technologies ("AeroClean" or the "Company") (Nasdaq: AERC), a leading pathogen elimination technology company, today reported financial results for the three and six months ended June 30, 2022 ("Q2 2022"). All financial information is presented in U.S. dollars unless otherwise indicated.

Second Quarter 2022 Highlights

- Granted U.S. Food and Drug Administration ("FDA") 510(k) clearance for Pürgo™ medical grade air hygiene technology intended for medical use and the elimination of harmful airborne microorganisms.
- Completed \$15.0 million private placement in June 2022, positioning the company to evaluate a wide range of strategic opportunities including acquisitions.
- Jimmy Thompson, healthcare technology expert, appointed as Vice President of Strategic Sales in June 2022.
- Timothy Scannell, former President and Chief Operating Officer of Stryker, appointed to Board of Directors in May 2022.
- Signed letter of intent to acquire GSI Technology ("GSI"), focused on deploying an analytics-based approach to indoor air quality ("IAQ") by monitoring real-time air quality and work safety conditions in an innovative, integrated dashboard offering air quality, human capital and security. GSI also focuses on public procurement opportunities to utilize the billions of dollars of funding committed by the government to address COVID preparedness as well as enhancing ventilation and IAQ. The Company makes no assurance that the transaction with GSI will be consummated.
- Participated in numerous industry conferences and tradeshow, including for the Association for Professionals in Infection Control and Epidemiology, ASHRAE, American Society for Healthcare Engineering, and National Facilities Management and Technology, further growing a distributor base in target markets.

Recent Developments

- Independent laboratory testing has proven that the Company's Pürgo™ air purifier is effective at reducing 99.99% of indoor viral concentrations of the Omicron variant of SARS-CoV-2, the virus that causes COVID-19, which the CDC identifies as the current dominant variant in the United States.
 - Preparations continue for the launch of Pürgo Lift, the unique, mission-critical application of our patented and proprietary technology engineered for elevators and other wall/ceiling-mounted applications, targeted for the fourth quarter of 2022.
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- Joe Lesters, with a proven track record in building and deploying healthcare technology software, systems, and databases, hired as Chief Technology Officer in July 2022.
- Announced partnership with the Florida chapter of the Club Management Association of America (FLCMAA), securing multiple deployments of safe air technology at notable hospitality and club spaces, as official health and safety sponsor for the organization.
- Launched new Investor Relations website to enhance communications with investors, analysts, media and other stakeholders, offering intuitive access to essential information.

Management Commentary

“In the second quarter, we were pleased to receive FDA 510(k) clearance for our Pürgo™ device, and I again thank the administration for their thorough review of our patented air hygiene technology,” said Jason DiBona, Chief Executive Officer of AeroClean. “Our Pürgo™ system, which is powered by our patented SteriDuct™ technology, has been rigorously tested in a wide variety of laboratory and real-world indoor spaces. The designation of our Pürgo™ technology as a Class II Medical Device represents a major milestone for our business, and further differentiates us from competitors in both performance and efficacy. In fact, we are already seeing increased interest from new potential clients as a result of this development.”

“Following the receipt of FDA clearance, in order to accelerate our go-to-market strategy we were proud to announce the addition of Jimmy Thompson as Vice President of Strategic Sales in June,” said Mr. DiBona. “In this new role, Jimmy is utilizing his deep experience in the healthcare industry to build and grow our sales teams and develop market channels that strengthen the AeroClean brand and drive revenue growth. We believe our investments in talent and scientifically-proven technology, evidenced by our recent testing on Pürgo’s effectiveness at eliminating the Omicron variant of SARS-CoV-2 in real-world scenarios, will continue to differentiate us from the competition.”

“In addition to our focus on organic growth, the completion of the \$15.0 million private placement at the end of June supports the Company’s strategy to continuously evaluate a wide range of strategic opportunities including acquisitions. As part of that strategy, the Company is in discussions with several acquisition candidates and may use the proceeds, together with other sources of capital, to effect transactions that the Company believes would substantially increase revenues, distribution and selling capability, and expand product lines, and, most importantly, add sensor and monitoring technology to enable the Company to effect its recurring revenue “Safe Air-as-a-Service” model. The Company’s goal is to provide actionable data to clients through the internet of things (IOT) to enable clients to provide Indoor Air Quality (IAQ) as part of their Indoor Environmental Quality (IEQ) initiatives.” The company makes no assurance that these acquisitions, or any others, will be consummated.

Mr. DiBona continued, “We are well-positioned with sufficient operating liquidity to complete the development, testing and expected launch of Pürgo Lift in Q4 of 2022. Elevators are a confined space that people are still reluctant to share with others and remain an acute point of vulnerability. We believe Pürgo Lift is a break-through technology to assist companies and hospitals with safe ‘return-to-work’ initiatives as many employees, customers, and patients are still reluctant to fully re-immense themselves in society.

“During the second quarter, we were able to overcome some of the negative impacts caused by the global supply chain issues that peaked earlier this year,” Mr. DiBona continued. “We continue to identify and implement further improvements to our own manufacturing processes, with a particular focus on pre-empting any future electronic component bottlenecks to create lasting strength as our business expands. After the brief pause in production during the first quarter and the FDA 510(k) clearance in the second quarter, we are pleased to report that our sales team has been diligently engaged in numerous discussions for direct sales and distribution opportunities, sales began to rebound from the first quarter pause, and we see positive momentum continuing into the third quarter.”

“Last month, we were proud to announce new partnerships with several organizations including as the official Health & Safety Sponsor of the Florida Chapter of the Club Management Association of America (“FLCMAA”),” DiBona added. “The largest chapter worldwide, FLCMAA has more than 700 members representing more than 300 country, golf, city and yacht clubs. We have enjoyed early success in this channel, and we expect our relationships within this target market to continue to grow over time, expanding into new sales opportunities in Florida and beyond. Meanwhile, we remain focused on securing and developing distribution and channel partner relationships for hospitals, non-hospital/ambulatory/surgery center markets, and both public and private commercial sectors, and we are in active discussions within each of these target markets. We look forward to sharing our continued progress during the rest of 2022, as we expect our sales teams to ramp up steadily through the end of the year.”

Q2 2022 Financial Overview

Revenues for the second quarter of 2022 were \$70,918, a \$64,185 increase as compared to \$6,733 during the first quarter of 2022. The Company did not report revenues in the second quarter of fiscal year 2021. Gross profit of \$34,792, or 49.1% of revenues, increased by \$31,823 as compared to gross profit of \$2,969 in the first quarter of 2022.

Selling, general and administrative (“SG&A”) expenses, including offering costs of \$1,326,212, for the second quarter of 2022 were \$4,105,066 compared to \$2,142,224 in the first quarter of 2022. In the second quarter of 2022, SG&A was \$2,778,854, excluding offering costs.

Research and development expenses for the second quarter of 2022 were relatively flat at \$579,061 compared to \$531,483 in the first quarter of 2022. Research and development expenses primarily consisted of quality and regulatory, testing, engineering, and manufacturing design costs.

Net loss for the second quarter of 2022 was \$5,172,277, or \$0.37 per share, compared to a net loss of \$2,577,964, or \$0.19 per share, in the first quarter of 2022. The Company also incurred a non-cash loss of \$650,000 related to the change in fair value of the warrants issued in connection with the private placement. Excluding the offering costs of \$1,326,212 and non-cash loss of \$650,000, net loss for the second quarter of 2022 was \$3,196,065.

Cash was \$29,163,429 as of June 30, 2022, compared to \$17,774,097 as of March 31, 2022, and total current assets were \$30,724,789 and total current liabilities were \$1,776,165 as of June 30, 2022. Net working capital (current assets less current liabilities) as of June 30, 2022 was \$28,948,624, and the Company has no debt.

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

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 "Management Commentary." 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; the effects of any acquisitions of other companies or technologies, including the possible diversion of the attention of our management or any challenges faced while integrating such into our business; 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; our inability to efficiently manage research and development spending; potential dilution of existing stockholders if we issue additional equity securities (including in connection with acquisitions); and risks related to maintaining our listing on Nasdaq.

These and other risks and uncertainties that could affect AeroClean's future results are included under the caption "Risk Factors" in AeroClean's annual report on Form 10-K for the fiscal year ended December 31, 2021 and our quarterly report on Form 10-Q for the fiscal quarter ended March 31, 2022 filed with the Securities and Exchange Commission ("SEC") on April 1, 2022 and May 12, 2022, respectively, which are 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 expectations contained herein prove inaccurate or that known or unknown risks or uncertainties materialize, actual results could vary materially from our expectations.

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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AEROCLEAN TECHNOLOGIES, INC.
Balance Sheets

	<u>June 30, 2022</u> (Unaudited)	<u>December 31, 2021</u>
ASSETS		
Cash	\$ 29,163,429	\$ 19,629,649
Other current assets	1,561,360	1,948,004
Total current assets	<u>30,724,789</u>	<u>21,577,653</u>
Non-current assets	2,227,120	2,145,095
Total assets	<u>\$ 32,951,909</u>	<u>\$ 23,722,748</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	\$ 1,776,165	\$ 1,511,079
Non-current liabilities	14,926,422	501,254
Total liabilities	<u>16,702,587</u>	<u>2,012,333</u>
Total equity	<u>16,249,322</u>	<u>21,710,415</u>
Total liabilities and stockholders' equity	<u>\$ 32,951,909</u>	<u>\$ 23,722,748</u>

AEROCLEAN TECHNOLOGIES, INC.
Statements of Operations (Unaudited)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Product revenues	\$ 70,918	\$ -	\$ 77,652	\$ -
Cost of sales	36,126	-	39,891	-
Gross profit	<u>34,792</u>	<u>-</u>	<u>37,761</u>	<u>-</u>
Operating expenses:				
Selling, general and administrative	4,105,066	1,613,608	6,247,290	1,993,610
Research and development	579,061	1,070,912	1,110,544	2,660,602
Total operating expenses	<u>4,684,127</u>	<u>2,684,520</u>	<u>7,357,834</u>	<u>4,654,212</u>
Loss from operations	(4,649,335)	(2,684,520)	(7,320,073)	(4,654,212)
Change in Fair value of warrant liability	650,000	-	650,000	-
Loss before income tax benefit	(5,299,335)	(2,684,520)	(7,970,073)	(4,654,212)
Income tax benefit	(127,058)	-	(219,832)	-
Net loss	<u>\$ (5,172,277)</u>	<u>\$ (2,684,520)</u>	<u>\$ (7,750,241)</u>	<u>\$ (4,654,212)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.24)</u>	<u>\$ (0.56)</u>	<u>\$ (0.49)</u>
Weighted-average common shares outstanding:				
Basic and diluted	<u>13,894,119</u>	<u>11,361,025</u>	<u>13,885,923</u>	<u>9,491,797</u>

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

	Six Months Ended June 30,	
	2022	2021
Net cash flows used in operating activities	(4,312,706)	(3,950,684)
Net cash flows used in investing activities	(154,065)	(1,785,517)
Net cash flows provided by financing activities	14,000,551	5,173,599
Net increase in cash	9,533,780	(562,602)
Cash, beginning of period	19,629,649	2,333,117
Cash, end of period	<u>\$ 29,163,429</u>	<u>\$ 1,770,515</u>
Supplemental schedule of non-cash activities:		
Purchases of property and equipment in accounts payable	\$ -	\$ 46,716
Offering costs in private placement	<u>\$ 422,000</u>	<u>\$ -</u>
