UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): December 29, 2023

CQENS Technologies Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-55470**	**27-1521407**
(State or other jurisdiction of incorporation or organization)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

5550 Nicollet Avenue, Minneapolis, MN 55419
(Address of principal executive offices)(Zip Code)

Registrant's telephone number, including area code: **(612) 812-2037**

(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© under the Exchange Act (17 CFR 240.13e-4(c))

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None	Not applicable	Not applicable

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 checkmark 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 3(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On December 29, 2023, CQENS Technologies Inc. distributed a letter to its shareholders of record as of December 28, 2023 providing a review of the company's recent developments and overview and update on the company's plan of operations. A copy of this letter is furnished as Exhibit 99.1 to this report.

Pursuant to General Instruction B.2 of Form 8-K, the information in this Item 7.01 of Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise be subject to the liabilities of that section, nor is it incorporated by reference into any filing of the company under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

		Incorporated by Reference			
No.	**Exhibit Description**	**Form**	**Date Filed**	**Number**	**Filed or Furnished Herewith**
99.1	Letter to Shareholders dated December 28, 2023				Filed
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

SIGNATURES

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.

CQENS TECHNOLOGIES INC.

Date: December 29, 2023

By: */s/ William P. Bartkowski*
William P. Bartkowski, President

Exhibit 99.1

Disclaimer

This letter to our shareholders includes forward-looking statements that relate to future events and involve known and unknown risks, uncertainties and other factors that may cause these actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “targets,” “likely,” “aim,” “will,” “would,” “could,” and similar expressions or phrases identify forward-looking statements. The Company has based these forward-looking statements largely on our current expectations. There can be no assurance that the agreements and joint ventures described in this letter will be formally organized or will operate as successfully as the parties intend. There can be no assurance that our patents and/or prototypes, will receive regulatory approval or be commercially viable. Our technology is subject to compliance with multiple regulations of various states and countries in which our future products, if developed may be sold. There are no assurances that our company will successfully launch the products described above. Furthermore; there can be no assurance that our company will receive any financing or any financing on commercially reasonable terms and conditions in order to complete the development of our products. These forward-looking statements speak only as of the date of this letter. Except for the Company’s ongoing disclosure obligations under US Federal securities laws, the Company undertakes no obligation to release publicly any updates to any forward-looking statements, to report events or to report the occurrence of unanticipated events. You are urged to carefully review and consider any cautionary statements and other disclosures, including the statements made under the heading “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission (the “SEC”) on April 14, 2023, and our other filings with the SEC. All forward-looking statements involve significant risks and uncertainties that could cause actual results to differ materially from those in the forward-looking statements, many of which are generally outside the control of CQENS. and are difficult to predict. CQENS does not undertake any duty to update any forward-looking statements except as may be required by law.

December 28, 2023

To Our Shareholders:

This is both an exciting and challenging time for our company, CQENS Technologies Inc. It’s exciting because we find ourselves having accomplished significant goals and objectives and anticipating greater accomplishments over the next six to twelve months. It’s challenging because it took us longer to get here than originally planned, given the unprecedented events the past 36 months—not the least of which has been the worldwide pandemic. The pandemic problems included supply chain disruptions that delayed device and tobacco consumable development being prepared for FDA submission, and travel difficulties that caused the cancellation or lengthy postponement of critical meetings and product development collaborations in Asia and Europe. We urge you to review our periodic, quarterly and annual reports filed with the U.S. Securities and Exchange Commission for a review of our historical operations and plan of operations. I am pleased to report that 2023 saw us get things back on track and we expect that 2024 will see the progress that will result in our meeting significant milestones.

We describe the CQENS mission as *Inventive Inhalation Solutions.* In the center of what we are about is *Inhalation.* Inhalation is central to everything we do. We are about the power of inhaled drugs and remedies able to reach the brain in less than 10 seconds, increase energy, suppress appetite, manage pain, and correct sleep disorders. We can harness that power with proprietary technologies unlike any on the market today.

In the last 24 months we have had nine new patents granted and we have filed another 21 applications. Today our IP includes 75 worldwide patents and pending patents for technologies and formulas that are designed to address energy, sleep, appetite, erectile dysfunction, pain, and eliminate the constituents of combustion when it comes to tobacco. We refer to our tobacco-related IP as a Heat-not-Burn ("HnB") system.

When it comes to tobacco, consider the damage caused by smoking. Tobacco was inhaled by more than 1.1 billion people around the world every day in 2022 according to the World Health Organization ("WHO"). In the case of tobacco, the WHO further notes that it's not the inhalation of nicotine that causes the damage that prematurely ends the lives of 8 million people annually—it's the combustion, the smoke, the tar and the chemicals that are the byproducts of burning. Today, we have proprietary technology that heats tobacco at high temperatures without causing combustion and provides smokers the satisfying taste and feel of conventional cigarettes without the damaging and dangerous constituents of combustion. Our HnB system, including its device and consumables, as tested by a respected independent lab, has demonstrated that it's 99% less harmful than conventional cigarettes.

As a result, the first product we expect to launch will be an FDA modified risk tobacco product ("MRTP"). An FDA MRTP is defined as a tobacco product that poses lower health risks to individual users and the population as a whole when compared to existing products on the market such as conventional, combustible cigarettes. Our reasons for focusing on completing and launching such a product include, but are not limited to the following: 1) tobacco represents the largest part of the international, inhalable market; it is 85% of the $1.1 trillion USD annual market as estimated by industry analysts; 2) the process to getting an HnB tobacco product authorized for sale in the US via a US FDA Premarket Tobacco Authorization ("PMTA") is now well established, as is the MRTP process; 3) as noted above, our prototypes have tested superior to products that have already been authorized by the FDA; and 4) the PMTA is the de facto gold standard, respected in all countries. We believe that securing the US FDA PMTA and MRTP opens the door for the worldwide manufacturing, marketing and distribution of our product. We believe securing the US PMTA and MRTP will have a significant impact on our valuation and will assist in the potential listing of our shares on a trading exchange when we apply for the listing or quotation of our securities.

We have established strong relationships with independent laboratories, consultants, and law firms that have successfully assisted companies in FDA submissions and authorizations. PMTA application requirements include:

1. *The FDA will require a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing and installation of the product.*

This requirement is why we formed a joint venture ("JV") with the Barker Group of Companies, a US Virginia-based company that manufactures and distributes tobacco products to nearly 150,000 retailers in the US. Barker's history of manufacturing in compliance with FDA standards, and its facilities, controls, experience and expertise in processing and manufacturing tobacco products is our rationale for forming the JV.

It's also the reason we formed a joint venture with a Hong Kong-domiciled electronics manufacturer to manufacture devices that will be utilized all over the world and for consumables ranging from tobacco to other legal substances. This agreement requires that our electronics manufacturing partner bring capital, facilities, tooling, engineering, and staffing to the JV. CQENS will bring our proprietary IP to the JV in the form of an exclusive license, a commitment to protect it, and to keep it current and properly representative of the technology and the products being manufactured and marketed.

2. *The FDA will require a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation.*

This requirement explains why we commissioned an Italian automation manufacturer to build the automated consumable manufacturing module. Under this arrangement we are deeply involved in the development of the module and we retain control of the IP and any IP that results from the development process. We anticipate the first module will be completed and installed in Barker facilities in the second quarter of 2024 just in time for the PMTA submission.

Additionally, our team in Europe is blending the tobacco that will be used in the consumable, keeping the blend as natural as possible. These resources have over 100 years of cumulative experience with the world's largest tobacco companies.

3. *The FDA will require full reports concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products:*

This requirement explains the nature of the testing and trials that we have designed and initiated now that the components of our device and the full ingredients of the consumable have been finalized. We completed our device and consumable design by arriving at device manufacturing solutions and by initiating the important testing protocols.

The PMTA submission also requires the following in the list below and the list represents much of what we have been working on. Our experienced team of tobacco experts are working on these matters, prepping the items for the FDA review that follows our submission. The experience of these experts includes numerous successful launches of next generation tobacco products throughout the world.

- Actual product samples
- Labeling and description of marketing plans
- Product formulation
- Detailed manufacturing plans
- Health risk investigations

Our V5 device is the version that will be in our PMTA submission and its completion this year was challenging in the aftermath of covid. A device redesign was required due to an import/export ban on several of the microprocessor chips that we had selected to use. We had to redesign around new chip sets and completed new firmware to work around these bans. Now completed, we are working on streamlining the device manufacturing process.

Despite the challenges of the past 36 months, we are now fully prepared to enter the most important phase of commercializing our IP portfolio. We are ready to move now due in large part to our JV strategy. This strategy is driven by our vision and willingness to partner with companies which we believe have the resources to commercialize and deploy our technology and products in partnership with us. This allows us to keep control of our IP, limit our capital investments, and maximize our returns on investment by leveraging the "know-how" and the strength of our partners, whether that be tobacco expertise, manufacturing expertise, market knowledge or regulatory experience.

Looking ahead, we expect to raise additional capital in early 2024 to accelerate our plan of operations, including our critical US FDA PMTA and MRTP initiatives.

Currently, we are in discussions with regional tobacco companies in Europe and Asia to form additional JVs to manufacture, distribute, and market our HnB system.

Finally, as we enter the New Year, we'd like to express our gratitude to you, our investors and shareholders. Thank you for your continued interest, support, and patience during the trying times these past 36 months. In 2024 we will provide you regular updates with respect to our progress and look forward to rewarding your patience.

Regards,

/s/ Alexander Chong/

Alexander Chong
Chairman and Chief Executive Officer