

Risk Factors Comparison 2025-03-13 to 2024-03-21 Form: 10-K

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In addition to risks and uncertainties in the ordinary course of business, important risk factors that may affect us are discussed below. Additional risks not presently known to us, or that we currently believe are immaterial, may also significantly impact or impair our business operations. Risks Relating to Our Business We manufacture the majority of our products at our Clearwater, Florida and Sofia, Bulgaria facilities. Components, labor- intensive assemblies and sub- assemblies, and sterilization services are outsourced to third parties and produced to our specifications. We are also dependent on OEM customers who have no legal obligation to purchase products from us. Should such customers fail to give us purchase orders for products after development, our future business could be negatively affected. Furthermore, no assurance can be given that such customers will give sufficient high priority to our products. Finally, disagreements or disputes may arise between us and our customers, which could adversely affect production and sales of our products. Macroeconomic trends including inflation and higher interest rates may adversely affect our financial condition, results of operations and cash flows. **We are in an inflation-inflationary period** in the United States ~~has recently accelerated~~ and is ~~currently~~ expected to continue at an elevated level in the near- term. Higher inflation and interest rates could have an adverse impact on our operating expenses and our credit facilities. There is no guarantee we will be able to mitigate the impact of inflation. The Federal Reserve has raised interest rates to combat inflation and restore price stability. Increases in interest rates on any of our debt will result in higher debt service costs, which will adversely affect our cash flows. Higher interest rates can also impact our customers' ability to purchase capital. We cannot assure you that our access to capital and other sources of funding will not become constrained, which could adversely affect the availability and terms of future borrowings. Such future constraints could increase our borrowing costs, which would make it more difficult or expensive to obtain additional financing or refinance existing obligations and commitments, which could slow or deter future growth. The health of the economy may affect consumer purchases of discretionary services, such as cosmetic services, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. Our results of operations may be materially affected by conditions in the capital and credit markets and the economy generally. Uncertainty in the economy could adversely impact customer purchases of discretionary services, including cosmetic services. Factors that could affect customers' willingness to make such discretionary purchases include general business conditions, levels of employment, interest rates, tax rates, the availability of consumer credit, consumer confidence in future economic conditions and risks, or the public perception of risks, related to epidemics or pandemics. In the event of a prolonged economic downturn or acute recession, consumer spending habits could be adversely affected, and doctor' s purchasing decisions as it relates to capital goods may be impacted and we could experience lower than expected net sales. Our revenue could decline due to changes in credit markets and decisions made by credit providers. Historically, some doctors have financed their purchase of generators through third-party credit providers some of whom with which we have existing relationships. If we are unable to maintain our relationships with our financing partners, there is no guarantee that we will be able to find replacement partners who will provide our doctor customers with financing on similar terms, and our revenue may be adversely affected. Further, reductions in consumer lending and the availability of consumer credit could limit the number of patients with the financial means to afford the procedures where our products are used. Higher interest rates could increase our costs or the monthly payments for consumer products financed through other sources of consumer financing. In the future, we cannot be assured that third- party financing providers will continue to provide doctor customers or patients with access to credit or that available credit limits will not be reduced. Such restrictions or reductions in the availability of consumer credit, or the loss of our relationship with our current financing partners, could have an adverse effect on our business, financial conditions, and operating results. **APYX MEDICAL CORPORATION** We have had a history of operating losses that have impacted our overall cash flows and may impact our ability to continue as a going concern. We anticipate that we may need to adjust our operating expenditures to be commensurate with our expected levels of revenue and / or raise additional capital to finance operations. ~~APYX MEDICAL CORPORATION~~ Due to our recurring net losses and the continued ~~impact-level~~ of the FDA Safety Communication on demand for the adoption and utilization of our technology, we may need to raise additional capital to fund our future operations. Our cash needs will depend on numerous factors, including our revenues, successful completion of our FDA product clearance activities, our continued ability to commercialize our advanced energy products, and our ability to reduce and control costs. If we are unable to secure such additional financing on terms that are acceptable to us, it will have a material adverse effect on our business, and we may have to limit operations in a manner inconsistent with our growth strategy. If additional funds are raised through the issuance of equity securities, it will be dilutive to our stockholders and could result in a decrease in our stock price. If we are unable to obtain the requisite amount of financing needed to fund our planned operations, it would have a material adverse effect on our business and ability to continue as a going concern. Our indebtedness levels could impact our business. Our ability to make payments on, and to refinance, our indebtedness will depend on our ability to generate cash from operations or other financings. Our ability to generate cash is subject to general economic, financial, competitive, regulatory, and other factors that are beyond our control. We may not generate sufficient funds to service our debt, meet our required debt covenants, or meet our business needs, such as funding working capital or the expansion of our operations. If we are unable to do so, we may be forced to take disadvantageous actions, including issuing additional shares of our stock on acceptable terms, reducing spending on marketing, product development, reducing financing in the future for working capital, capital expenditures and general corporate purposes, or dedicating an unsustainable level of our cash flows from operations to the payment of principal and interest on our indebtedness. The creditors who hold our debt could also accelerate amounts due in the event that we trigger a

default. Any inability to generate sufficient cash flow or to refinance our indebtedness on favorable terms could have a material adverse effect on our financial condition. The aesthetic equipment market is characterized by rapid innovation. To compete effectively, we must develop and / or acquire new products, seek regulatory clearance, ensure adequate product supply, execute successful marketing, and identify new markets for our technology. Our industry is subject to continuous technological development and product innovation. If we do not continue to innovate and develop new products and applications, our competitive position will likely deteriorate as other companies successfully design and commercialize new products and applications or enhancements to our current products. To grow in the future, we must continue to develop and / or acquire new and innovative aesthetic products and applications, identify new markets, and successfully launch the newly acquired or developed product offerings. Our research and development activities are an essential component of our efforts to develop new and innovative products. New and improved products play a critical role in our sales growth. We continue to place emphasis on the development of proprietary products, such as our Renuvion and J- Plasma technology, and product improvements to complement and expand our existing product lines. We maintain close working relationships with physicians and medical personnel in hospitals and universities who assist in product research and areas of development. While we expect to continue making future investments to enable us to develop and market new technologies and products to further our strategic objectives and strengthen our existing business. We cannot guarantee that any of our previous or future investments in both facilities will be successful or that our new products will gain market acceptance. This would have a material adverse effect on our business and results of operations. Even if we are successful in developing new, or enhancing our existing products, there are various circumstances that could prevent their successful commercialization. Our ability to successfully commercialize our products, including AYON, which we expect to launch during 2025, will depend on a number of factors, any of which could delay or prevent commercialization, including:

- our inability to obtain the necessary regulatory clearances or approvals for expanded indications, new products, or product modifications;
- our inability to demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials;
- if our product is determined to be ineffective or unsafe following approval, and is removed from the market or we are required to perform additional research and development to further prove the safety and effectiveness of the product before re- entry into the market;
- if the regulatory approvals / clearances of our new products are delayed or denied, or we are required to conduct further research and development of our products prior to receiving regulatory approval;
- APYX MEDICAL CORPORATION
- our inability to build and maintain a sales and marketing group to successfully launch and sell our new products;
- if we experience sudden or extreme volatility in commodity prices and availability, including supply chain disruptions;
- if we are required to allocate available funds to litigation matters;
- if the needs of our physicians or their patients are not sufficiently met;
- if we are unable to manufacture the quantity of products needed, in accordance with quality manufacturing standards, to meet market demand;
- competition from other products or technologies prevents or reduces market acceptance of our products;
- if we do not have, and cannot obtain, the intellectual property rights needed to manufacture or market our products without infringing on another company' s patents; or
- if we are unsuccessful in defending against patent infringement, or other intellectual property rights claims, that could be brought against us, our products or technologies.

The failure to successfully commercialize our products will have a material and adverse effect on the future growth of our business, financial condition, results of operations and cash flows. The energy- based medical device industry in the aesthetics market is highly competitive and we may be unable to compete effectively. The energy- based medical device industry for the aesthetics market is highly competitive. Many competitors in this industry are well- established, do a substantially greater amount of business, and have greater financial resources and facilities than we do. We have invested and continue to invest, substantial resources to develop and monetize our Renuvion technology into the cosmetic surgery market. We believe we must continue to innovate and develop new applications for our products and obtain new indications for use in order to differentiate ourselves and stay competitive. If we are unable to gain acceptance of our technology in the marketplace, or obtain new indications for use, our business and results of operations and cash flows may be materially and adversely affected. Part of our strategy depends on developing strong working relationships with key plastic surgeons, cosmetic physicians and other healthcare professionals. The guidance we get from these relationships is important from both a commercialization strategy and product development standpoint. Without establishing and maintaining these relationships globally, the development and commercialization of our products could suffer which could have a material adverse impact on our business. If we are unable to protect our patents or other proprietary rights, or if we infringe on the patents or other proprietary rights of others, our competitiveness and business prospects may be materially damaged. We have been issued 39-38 patents in the United States and 46-57 foreign patents. We have 17-14 pending patent applications in the United States and 48-19 pending foreign applications. Our intellectual property portfolio for our Renuvion and J- Plasma products continues to grow on an annual basis. We intend to continue to seek legal protection, primarily through patents, for our proprietary technology. Seeking patent protection is a lengthy and costly process and there can be no assurance that patents will be issued from any pending applications, or that any claims allowed from existing or pending patents will be sufficiently broad or strong to protect our proprietary technology. There is also no guarantee that any patents we hold will not be challenged, invalidated or circumvented, or that the patent rights granted will provide competitive advantages to us. Our competitors have developed, and may continue to develop and obtain, patents for technologies that are similar or superior to our technologies. In addition, the laws of foreign jurisdictions in which we develop, manufacture or sell our products may not protect our intellectual property rights to the same extent as the laws of the United States. Adverse outcomes in current or future legal disputes regarding patent and other intellectual property rights could result in the loss of our intellectual property rights, subject us to significant liabilities to third parties, require us to seek licenses from third parties on terms that may not be reasonable or favorable to us, prevent us from manufacturing, importing or selling our products, or compel us to redesign our products to avoid infringing third parties' intellectual property. As a result, our product offerings may be delayed, and we may be unable to meet customers' requirements in a timely manner. Regardless of the merit of any related legal proceeding, we have incurred in the past, and may be required to

incur in the future, substantial costs to prosecute, enforce or defend our intellectual property rights. Even in the absence of infringement by our products on third parties' intellectual property rights, or litigation related to trade secrets, we have elected in the past, and may in the future, elect to enter into settlements to avoid the costs and risks of protracted litigation and the diversion of resources and management' s attention. If the terms of settlements entered into with certain of our competitors are not observed or enforced, we may suffer further costs and risks. Any of these circumstances could have a material adverse effect on our business, financial condition, results of operations or cash flows. **APYX MEDICAL CORPORATION** In addition to patent, copyright, and trademark protection, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our consultants, vendors, and our former or current employees. Despite these efforts, however, any of these parties may breach those agreements and disclose our trade secrets and other unpatented or unregistered proprietary information, and once disclosed, we are likely to lose trade secret protection. Monitoring unauthorized uses and disclosures of our trade secrets is difficult, and we cannot be certain that the steps we have taken to protect our intellectual property will be effective. In addition, our remedies may not be sufficient to cover our losses. We have been, and may in the future, become subject to litigation proceedings that could materially and adversely affect our business. The medical device industry is characterized by frequent claims and litigation, and we are and may become subject to various claims, lawsuits and proceedings in the ordinary course of our business, including claims by current or former employees, distributors and competitors, and with respect to our products and product liability claims, lawsuits and proceedings. We are involved in a number of legal actions relating to the use of our technology. The outcomes of these legal actions are not within our complete control and may not be known for prolonged periods of time. In the opinion of management, we have meritorious defenses, and such claims are adequately covered by insurance, or are not expected, individually or in the aggregate, to result in a material, adverse effect on our financial condition, results of operations and cash flows. However, in the event that damages exceed the aggregate coverage limits of our policy, or if our insurance carriers disclaim coverage, or if we are unable to continue to obtain coverage on commercially reasonable terms, we believe it is possible that costs associated with these claims could have a material adverse impact on our consolidated financial position, results of operations and cash flows (see below ITEM 3: Legal Proceedings). We rely on certain suppliers, subcontractors, and manufacturers for raw materials and other products and are vulnerable to fluctuations in the availability and price of such products and services. Fluctuations in the price, availability and quality of the raw materials (including plastics and other petroleum- based materials, along with semi- conductors and precious metals) and subcontracting services we use in our manufacturing could have a negative effect on our cost of sales and our ability to meet the demands of our customers. Inability to meet the demands of our customers could result in the loss of future sales. In addition, the costs to manufacture our products depend in part on the market prices of the raw materials used to produce them. We may not be able to pass along to our customers all or a portion of our higher costs of raw materials due to competitive and market pressures, which could decrease our earnings and profitability. We also have collaborative arrangements with three key foreign suppliers under which we request the development of certain items and components, which we purchase pursuant to purchase orders. Our purchase order commitments are never more than one year in duration and are supported by our sales forecasts. The majority of our raw materials are purchased from sole- source suppliers. While we believe we could ultimately procure other sources for these components, should we experience any significant disruptions in this key supply chain, there are no assurances that we could do so in a timely manner which could render us unable to meet the demands of our customers, resulting in a material and adverse effect on our business and results of operations. Our manufacturing facilities are located in Clearwater, Florida and Sofia, Bulgaria and could be affected due to multiple weather risks, including risks to our Florida facility from hurricanes and similar phenomena. Our manufacturing facilities are located in Clearwater, Florida and Sofia, Bulgaria and could be affected by multiple weather risks, most notably hurricanes in Clearwater, Florida. Although we carry property and casualty insurance and business interruption insurance, future possible disruptions of operations or damage to property, plant and equipment due to hurricanes or other weather risks could result in impaired production and affect our ability to meet our commitments to our customers and impair important business relationships, the loss of which could adversely affect our operations and profitability. We do, however, maintain a backup power source at our Clearwater facility, are working to establish deeper redundancies between both facilities, and have a disaster recovery plan in place to help mitigate this risk. **APYX MEDICAL CORPORATION** If there is not sufficient consumer demand for the procedures performed with our products, surgeon demand for our products could be inhibited, resulting in unfavorable operating results and reduced growth potential. Continued expansion of the global market for aesthetic procedures is a material assumption of our business strategy. The procedures performed using our products are elective procedures not reimbursable through government or private health insurance, with the costs borne by the patient. The decision to utilize our products may therefore be influenced by a number of factors, including: • consumer disposable income and access to consumer credit, which as a result of an unstable economy, may be significantly impacted; • the cost, safety and effectiveness of alternative treatments; • the success of our direct to consumer sales and marketing efforts; and • the education of our customers and their patients on the benefits and uses of our products, compared to competitors' products and technologies. If, as a result of these factors, there is not sufficient demand for the procedures performed with our products, customer demand could be reduced, which could have a material adverse effect on our business, financial condition, revenue and result of operations. Quality problems and product liability claims could lead to recalls or safety alerts, reputational harm, adverse verdicts or costly settlements, and could have a material adverse effect on our business, results of operations, financial condition and cash flows. The success of our business depends on the quality of our products, and we have global processes, procedures and programs that are intended to help us maintain the highest possible level of quality. We operate in an industry susceptible to significant product liability claims; these claims may be brought by individuals seeking relief on their own behalf or purporting to represent a class. Quality is extremely important to us and our customers due to the **potential** impact on patients, and the serious and potentially

costly consequences of product failure. Our business exposes us to potential product liability risks that are inherent in the design, manufacture, and marketing of medical devices. If they were to occur, component failures, manufacturing nonconformances, design defects, off-label use, or inadequate disclosure of product-related risks or product related information, could result in an unsafe condition, injury to, or even death of, a patient. These problems could lead to recall or issuance of safety notices relating to our products and could result in product liability claims and lawsuits, including class actions. Even if our product is not found at fault, we may incur significant legal fees as well as potential losses in excess of insurance coverage associated with product liability. Risk Related to Government Regulations Product Approval and Monitoring Most countries where we sell medical devices subject our technologies to their own approval and other regulatory requirements regarding performance, safety, and quality. The global regulatory environment is increasingly challenging and stringent. Countries that did not have regulatory requirements for medical devices have established such requirements in recent years, and other countries have expanded, or plan to expand, their existing regulations. While there are some efforts at some harmonization of global regulations, requirements continue to differ significantly among countries. We expect that as this global regulatory environment continues to evolve, it could impact the cost, the time needed to approve, and ultimately, our ability to maintain existing approvals or obtain future approvals for our products. Regulations of the ~~the~~ FDA and other regulatory agencies in and outside the U. S. impose significant compliance and monitoring obligations on our business. **APYX MEDICAL CORPORATION** We are subject to costly and complex laws and governmental regulations and any adverse regulatory action may materially adversely affect our financial condition and business operations. As a part of the regulatory process for obtaining marketing clearance or approval for new products and new indications for existing products, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations, and trial endpoints. Unfavorable or inconsistent clinical data from existing or future clinical trials, or the market's or the FDA's perception of these clinical data, may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate. We cannot guarantee that we will be able to obtain or maintain marketing clearance for our new products or enhancements or modifications to existing products, and the failure to maintain approvals or obtain approval or clearance could have a material adverse effect on our business, results of operations, financial condition and cash flows. Even if we are able to obtain approval or clearance, it may: • take a significant amount of time; • require the expenditure of considerable resources; • involve rigorous clinical and pre-clinical testing, as well as increased post-market surveillance; • involve modifications, repairs, corrections, or replacements of our products; and • limit the proposed intended uses of our products. ~~On March 14, 2022, the FDA posted a Communication that warned consumers and health care providers against the use of our Advanced Energy products outside of their FDA-cleared indications for general use in cutting, coagulation, and ablation of soft tissue during open and laparoscopic surgical procedures. We worked with the FDA towards securing 510 (k) clearance for specific additional indications for our Advanced Energy productions. On May 26, 2022, we announced that we received 510 (k) clearance from the FDA for the use of the Renuvion Dermal handpiece for specific dermal resurfacing procedures. On July 18, 2022, we announced that we received 510 (k) clearance from the FDA for the use of the Renuvion APR handpiece for use in subcutaneous dermatological and aesthetic procedures. On June 2, 2022, and July 21, 2022, the FDA updated the Medical Device Safety Communication to recognize the new 510 (k) clearances for the Renuvion Dermal handpiece, and the expanded indications for the Renuvion APR handpiece. The 510 (k) clearance for the Renuvion Dermal handpiece allows surgeons to perform dermal resurfacing procedures for the treatment of moderate to severe wrinkles and rhytides, limited to patients with Fitzpatrick Skin Types I, II or III. The 510 (k) clearance for the Renuvion APR handpiece now addresses improving the appearance of lax (loose) skin in the neck and submental region. On February 27, 2023, we announced that we received 510 (k) clearance from the FDA for the use of the Renuvion APR handpiece for the delivery of radiofrequency energy and /or helium plasma where coagulation /contraction of soft tissue is needed. Soft tissue includes subcutaneous tissue. On April 28, 2023, we announced that we received 510 (k) clearance from the FDA for the use of Renuvion APR handpiece for coagulation of subcutaneous soft tissues following liposuction for aesthetic body contouring. This submission was supported by a clinical study and real world evidence. On May 10, 2023, the FDA updated the Safety Communication to inform consumers and healthcare providers about the clearance for the Renuvion APR handpiece for use under the skin in certain procedures intended to improve the appearance of the skin including for coagulation of subcutaneous soft tissues following liposuction for aesthetic body contouring. On June 14, 2023, we announced that we received 510 (k) clearance from the FDA for the Renuvion Micro handpiece, a new addition to the Renuvion production family. The Renuvion Micro handpiece was cleared with an indication for the delivery of radiofrequency energy and /or helium plasma where coagulation /contraction of soft tissue is needed. Soft tissue includes subcutaneous tissue. While we expected that receiving these clearances would materially mitigate the financial effects of the Safety Communication in future periods, we continue to experience reduced demand for the adoption and utilization of our technology and we believe that this may have an adverse effect in future periods. Before and after a product is commercially released, we have ongoing responsibilities under the FDA, Health Canada, Australia, Brazil, EU, and other applicable government agency regulations. For instance, our processes and facilities, as well as those of our suppliers, are subject to periodic audits to determine compliance with applicable regulations. The results of these audits can include major inspectional observations, warning letters, or other forms of enforcement. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical products are ineffective or pose an unreasonable health risk, they could ban such medical products, determine that our products are adulterated or misbranded, order a recall, repair, replacement, correction, or refund of such products ~~7~~. **The FDA may also** refuse to grant pending pre-market clearances or approvals, refuse to issue export certificates for foreign governments, or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA and other foreign and domestic regulators may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis. The FDA may also recommend prosecution to the U. S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may~~

restrict us from effectively marketing and selling our products and limit our ability to obtain future pre-market clearances or approvals, and could result in a substantial modification to our business practices and operations. These potential consequences, as well as any adverse outcome from government investigations, could have a material adverse effect on our business, results of operations, financial condition, and cash flows. In addition, the FDA has taken the position that device manufacturers are prohibited from promoting their products other than for the uses and indications set forth in the cleared product labeling. Any failure to comply could subject us to significant civil or criminal exposure, administrative obligations and costs, other potential penalties from, and / or agreements with, the federal government. Governmental regulations worldwide have, and may continue to become, increasingly stringent and customary. In the EU, **a single regulatory approval process exists, and conformity all medical devices must carry the CE marking before being sold in the EU. The CE mark represents compliance** with the legal requirements is represented by the CE Mark. **To obtain a CE Mark, defined products must meet minimum standards of performance, safety, and quality (i. e., the essential requirements) , and . Based on then the device , according to their classification, comply with one or more of a selection of conformity assessment routes - route is selected. An accredited notified body provides an assessment and issues the certificate.** The competent authorities of the EU countries separately regulate the clinical research for medical devices and the market surveillance of products once they are placed on the market. A new Regulation (EU) 2017 / 745 on medical devices, or **European Union Medical Device Regulation (“ EU MDR ”) , was published came into effect** in May 2017, which imposes significant additional premarket and post- market requirements. The **Essential Requirements have been revised and are now referred to as the General Safety and Performance Requirements. APYX MEDICAL CORPORATION** The EU MDR represents the first major change to the EU medical device regulatory environment **since the 1990s when the Medical Device Directive (“ MDD ”) was put into effect. The EU MDR supersedes the MDD and** has significantly raised the compliance bar for the medical device industry , and will cause significant changes to the regulatory obligations of manufacturers, importers and distributors involved in the medical device distribution chain. Classification has changed for some product categories, and strict new requirements have been imposed on clinical data, risk management, post market surveillance, and supplier management. Penalties for regulatory non- compliance could be severe, including fines and revocation or suspension of a company’ s business license, and criminal sanctions. The regulation initially provided a three- year implementation period to May 2020, but that timeline was delayed to May 2021 due to the global pandemic and its impact on audits and technical file review by Notified Bodies. After that time, medical devices marketed in the EU will require certification according to these new requirements, except for devices with valid CE certificates, issued pursuant to the Medical Device Directives before May 2020, which can be placed in the market until May 2024 . **Additionally, due to the initial delay in the date of application and the reduction in accredited notified bodies, an extension was provided to the validity of MDD certificates. Devices which have a MDD certificate and have met the extension requirements set forth in the EU MDR may be placed on the market until December 31, 2028. High risk devices and implants have a shorter certificate extension period (December 31, 2027).** Outside of the EU, regulations vary significantly from country to country and are becoming increasingly stringent and country specific. Territories and countries around the world continue to develop their own unique regulatory requirements, and these individual governments are passing laws that enforce these new regulations, including imposing fees, to register products in their country. The time and effort required to obtain approval to market products may be longer or shorter than that required in the U. S. or the EU. Certain European countries outside of the EU, and other countries around the world do not recognize the CE mark certification or FDA clearance / approval and have their own regulatory requirements to register and sell products in these territories. Environmental Regulation The medical device industry continues to be the subject of intense scrutiny and stringent regulation and the demand for green, sustainable products is rapidly increasing. There are increasing requirements for efficient and accurate processes for hazardous substance handling, supplier disclosures, and regulatory reporting in order to comply with numerous global health and environmental regulatory requirements and restrictions, including but not limited to: • Restriction on Hazardous Substances (“ RoHS ”) Directive • Packaging and Packing Waste Directive • REACH Regulation • Proposition 65 • Hazardous Air Pollutants: Ethylene Oxide Compliance with existing and future environmental regulations may have an impact on the manufacturing and sterilization of our medical devices. Environmental regulations in the U. S. and EU limit or prohibit the use of certain chemicals, substances and materials in the manufacture of our medical devices such as Prop 65 in California and others in the EU such as REACH, RoHS, and WEEE Directive. With the current global concerns over climate change and the tangible effects human beings are having on the environment, there is no doubt that the amount of environmental legislation is primed to increase still further, with the EU being at the forefront of this movement. Ethylene oxide (“ EtO ”) is used to sterilize approximately 50 % of medical devices in the U. S. While some alternative methods currently exist, potential device incompatibility issues exist with these alternatives. The U. S. Environmental Protection Agency (EPA) classified EtO as a carcinogen after linking it to cases of breast cancer, lymphoma and leukemia. Currently, shortages due to current closures are not expected, but any additional commercial sterilization facility closures could result in shortages for certain devices. Our devices are not currently impacted by these closures, however, it is unknown if the current EtO facilities utilized by Apyx Medical could be impacted in the future. **APYX MEDICAL CORPORATION** The FDA is closely monitoring the supply chain effects of closures and potential closures of certain facilities that use EtO to sterilize medical devices prior to their use, and is concerned about the future availability of sterile medical devices and the potential for medical device shortages that might impact patient care. However, they do not have oversight authority over EtO emissions, which is within the purview of the EPA. Our operations and those of certain third- party suppliers involve the use of substances subject to these laws and regulations, primarily those used in manufacturing and sterilization processes. If we or our suppliers violate these environmental laws and regulations, facilities could be shut down and violators could be fined, criminally charged, or otherwise sanctioned. Furthermore, environmental laws outside of the U. S. are becoming more stringent, resulting in increased costs and compliance burdens. In addition, certain environmental laws assess liability on current or previous owners or operators of real property for

the costs of investigation, removal or remediation of hazardous substances or materials at their properties or at properties which they have disposed of hazardous substances. In addition to cleanup actions brought by governmental authorities, private parties could bring personal injury or other claims due to the presence of, or exposure to, hazardous substances. The ultimate cost of site cleanup and timing of future cash outflows is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations, and alternative cleanup methods. The costs of complying with current or future environmental protection and health and safety laws and regulations, or liabilities arising from past or future releases of, or exposures to, hazardous substances, may exceed our estimates, or have a material adverse effect on our business, results of operations, financial condition, and cash flows. Anti-Corruption Regulation As we grow our international presence and global operations, we will be increasingly exposed to statutes, anti-corruption trade policies, economic sanctions and other restrictions imposed by the United States and other foreign governments and organizations, including the U. S. Foreign Corrupt Practices Act, or the FCPA, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control, or OFAC. In addition, other foreign statutes, such as the U. K. Bribery Act of 2010, or the Bribery Act, prohibits both domestic and international bribery, as well as bribery across both private and public sectors. We have implemented policies and procedures designed to ensure compliance by our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti-corruption, anti-money-laundering and anti-terrorism laws and regulations, and require training of our employees, management team and our global distributors on an annual basis. However, there can be no assurance that our policies and procedures are or will be sufficient to prevent violations from occurring. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti-corruption, anti-money laundering and anti-terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our reputation, financial condition, and results of operations. We are subject to governmental export controls and economic sanctions that could impair our ability to compete in international markets due to licensing requirements and subject us to potential liability if we are not in compliance with applicable laws. Any non-compliance could have a material adverse effect on our business, financial condition, and results of operations **and cash flows**. We are subject to export control laws and regulations, including the Export Administration Regulations (EAR), administered by the U. S. Department of Commerce's Bureau of Industry and Security (BIS) and various economic and trade sanctions regulations overseen by the U. S. Treasury Department's Office of Foreign Assets Control (OFAC). Some of the products we manufacture and provide are controlled for export by BIS. Exports of our products to territories outside of the United States must be made in compliance with these laws and regulations. We take specific measures that are designed to ensure our compliance with U. S. export and economic sanctions laws, including training our employees and maintaining policies for managing employee conduct. We may engage third-party agents, intermediaries, or distributors to act on our behalf in certain countries, and if these third-party agents or intermediaries violate applicable laws, their actions may result in criminal or civil fines or penalties or other sanctions being assessed against us. We cannot provide assurances that our internal controls and procedures will guarantee compliance by our employees or third parties with whom we work. Additionally, it is possible that some of our products have or will be sold to distributors or other parties, without our knowledge or consent, in violation of applicable law and there can be no assurances that we will be in compliance with such rules and regulations in the future. Any such violation could result in significant criminal or civil fines, penalties, or other consequences, including reputational harm, which could have a material adverse effect on our business, financial condition, and results of operations **and cash flows**.

APYX MEDICAL CORPORATION Risks Relating to Our Stock The market price of our stock has been and may continue to be highly volatile. Our common stock is listed on ~~The NASDAQ Stock~~ **the Nasdaq Global Select** Market ~~LLC~~ under the ticker symbol " APYX ". The market price of our stock has been, and may continue to be, highly volatile and announcements by us or by third parties may have a significant impact on our stock price. These announcements may include: • our listing status on the ~~The NASDAQ Stock~~ **Nasdaq Global Select** Market ~~LLC~~; • our operating results falling below the expectations of public market analysts and investors; • developments in our relationships with or developments affecting our major customers; • negative regulatory action or regulatory non-approval with respect to our new products; • government regulation, governmental investigations, or audits related to us or to our products; • developments related to our patents or other proprietary rights or those of our competitors and • changes in the position of securities analysts with respect to our stock. The stock market has from time-to-time experienced extreme price and volume fluctuations, which have particularly affected the market prices for the medical technology sector companies, and which have often been unrelated to their operating performance. These broad market fluctuations may adversely affect the market price of our common stock. In addition, future sales by our security holders may lower the price of our common stock, which could result in losses to our stockholders. We have no present intention to pay dividends on our common stock and, even if we change that policy, we may be unable to pay dividends. We currently do not anticipate paying any dividends on our common stock in the foreseeable future, and we are subject to restrictions on our ability to pay dividends pursuant to our credit agreement executed in November 2023 **and as amended in November 2024**. We currently intend to retain future earnings, if any, to finance operations and invest in our business. Any declaration and payment of future dividends to holders of our common stock will be at the discretion of our board of directors and will depend on many factors, including our financial condition, earnings, capital requirements, level of indebtedness, statutory and contractual restrictions applying to the payment of dividends, and other considerations that our board of directors deems relevant. If we change that policy and commence paying dividends, we will not be obligated to continue paying those dividends, and our stockholders will not be guaranteed, or have contractual or other rights, to receive dividends. If we commence paying dividends in the future, our board of directors may decide, at its discretion, at any time, to decrease the number of dividends, otherwise modify or repeal the dividend policy or discontinue entirely the payment of dividends. Under Delaware law, our board of directors may not authorize the payment of a dividend unless it is paid out of our statutory surplus. Issuance of equity through our shelf registration statement, as well as the exercise of options and warrants issued by us will dilute the ownership interest of

existing stockholders. As of December 31, ~~2023~~ **2024**, our outstanding stock options to our employees, officers, directors and consultants amounted to ~~7,342,638~~, ~~883,458~~ shares of our common stock, representing approximately ~~21.2~~ % of our outstanding common stock. In connection with the execution of the MidCap Credit Agreement and the Perceptive Credit Agreement, we issued warrants to purchase 1,500,000 shares of our common stock, representing approximately 4.30% of our outstanding common stock. **Additionally, in the registered direct offering that we completed in November 2024, we issued 2,934,690 pre-funded warrants which will have a dilutive effect on our common stock outstanding when exercised. As of the date of this annual report on Form 10-K, the dilution is 7.8%.** The issuance of additional equity through our shelf registration or through the exercise of some or all of our stock options and warrants will dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon such conversion or exercise could adversely affect prevailing market prices of our common stock. **APYX MEDICAL CORPORATION** General Risks We may, in the future, identify deficiencies in internal controls over financial reporting. While we have concluded that, as of December 31, ~~2023~~ **2024**, our disclosure and reporting controls were effective as included in Part II, Item 9A of this Form 10-K, there can be no assurance that future control deficiencies or material weaknesses will not be identified. If we do identify material weaknesses in our internal controls over financial reporting in the future, our ability to analyze, record and report financial information free of material misstatements, and to prepare our financial statements within the time periods specified by the rules and forms of the SEC, may likely be adversely affected. We rely on our management team and other key personnel, and we may lose key personnel or fail to attract, train, and retain other talented personnel. We depend on the skills, working relationships, and continued services of key personnel, including our experienced management team. In addition, our ability to achieve our strategic operating objectives depends on our ability to identify, hire, train, and retain qualified individuals throughout the organization. We compete with other companies both within and outside of our industry for talented personnel, and we may lose key personnel or fail to attract, train, develop, and retain other talented personnel. Any such loss or failure could adversely affect our sales, operating results, and financial condition. We are at risk of being the victim of a cyber-attack or a security breach that may expose confidential customer, product and Company data or compromise our internal IT infrastructure. This could lead to liabilities resulting from failure to comply with US and foreign data security and privacy regulations and negative impacts to our business operations. We store in our computer systems and network various elements of data and information related to our customers, products and company that could be compromised as the result of a cyber-attack or security breach. If an individual or group of individuals, including a Company employee, were to compromise confidential information, or if customer confidential information is inappropriately disclosed due to a security breach of our computer systems, system failures or otherwise, we may face substantial liabilities or incur penalties in connection with any violation of applicable privacy laws or regulations. We also rely heavily on our internal systems, network and data. To date, we have not had any breaches against our systems and network, and we obtain cyber security insurance coverage on an annual basis. However, our inability to properly scale IT security levels as our business grows, or any future attacks on our IT infrastructure could have a significant impact on our daily manufacturing and customer service functions which could result in a material adverse impact on our financial results, potentially in excess of our current coverage limits. Our business is dependent on the security of our IT networks and those of our customers. Internal or external attacks on any of those could disrupt the normal operations of our engagements and impede our ability to provide critical services to our customers, thereby subjecting us to liability under our contracts. Additionally, our business involves the use, storage and transmission of information about our employees, our customers and clients of our customers. **We** While we take measures to protect the security of, and unauthorized access to, our systems, as well as the privacy of personal and proprietary information. **However, despite these preventative measures**, it is possible that our security controls over our systems, as well as other security practices we follow or those systems of our customers into which we operate and rely upon, may not prevent the improper access to or disclosure of personally identifiable or proprietary information. Such disclosure could harm our reputation and subject us to liability under our contracts and laws that protect personal data, resulting in increased costs or loss of revenue. Data privacy is subject to frequently changing rules and regulations, which sometimes conflict among the various jurisdictions and countries in which we operate and continue to develop in ways which we cannot predict. We are subject to U. S. federal and state laws regarding data privacy and security including Section 5 of the Federal Trade Commission Act, or FTC Act. We are also subject to foreign data privacy and security laws, including the Global Data Protection Regulation, or GDPR, the European Union- wide legal framework to govern data collection, use and sharing and related consumer privacy rights. The GDPR includes significant penalties for non-compliance. Our failure to adhere to, or successfully implement processes in response to, changing regulatory requirements in this area could result in legal liability or impairment to our reputation in the marketplace, which could have a material adverse effect on our business, financial condition and results of operations. **APYX MEDICAL CORPORATION** Adverse global and regional economic conditions could materially adversely affect the Company's business, results of operations and financial condition. Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs and other barriers to trade, changes to fiscal and monetary policy, tighter credit, higher interest rates, high unemployment and currency fluctuations can adversely impact consumer confidence and spending and materially adversely affect demand for the Company's products and services. In addition, uncertainty about, or a decline in, global or regional economic conditions could have a significant impact on the Company's suppliers, contract manufacturers, freight carriers, and distributors, resulting in delayed or limited availability of components, higher component costs, and higher freight costs. These and other economic factors could materially adversely affect the Company's business, results of operations, financial condition and stock price. The Company's business can be impacted by political events, trade and other international disputes, war, terrorism, natural disasters, public health issues, industrial accidents and other business interruptions. Political events, trade and other international disputes, war, terrorism, natural disasters, public health issues, industrial accidents and other business interruptions can harm or disrupt international commerce and the global economy, and could have a material adverse effect on the Company and its customers, suppliers,

contract manufacturers, freight carriers, and distributors. Changes in U. S. trade policies could significantly increase the cost of imported goods into the United States, which may materially reduce our sales or profitability. Changes in U. S. trade policy could trigger retaliatory actions by affected countries, resulting in "trade wars," in increased costs for goods imported into the United States, which may reduce customer demand for these products if the parties having to pay those tariffs increase their prices, or in trading partners limiting their trade with the United States. If these consequences are realized, the volume of economic activity in the United States, may be materially reduced. Such a reduction may materially and adversely affect our sales volumes. Further, the realization of these matters may increase our cost of goods and, if those costs cannot be passed on to our customers, our business and profits may be materially and adversely affected.