

Risk Factors Comparison 2025-03-26 to 2024-03-26 Form: 10-K

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Legislative or executive order healthcare interference in the United States renders the U. S. medical device marketplace unpredictable. A fully government- run healthcare system would likely eliminate healthcare consumer choice as well as commercial incentives for innovation. Increasing regulatory burdens, including premarketing approval delays, may result in significant loss of revenue, unpredictable costs and loss of management focus on developing and marketing products that improve the quality of healthcare: Thousands of small focused medical device manufacturers including UTMD that do not have the overhead structure that the few large medical device companies can afford are increasingly burdened with bureaucratic and underqualified regulator demands that are not reasonably related to assuring the safety or effectiveness of the devices that they provide. **In Europe, recent regulatory changes requiring clinically well- accepted devices used safely for decades to be rigorously reapproved every few years ignores the obvious outcome that millions in dollars in additional regulatory cost may cause devices with specialized applications with only thousands of dollars in revenues to no longer be available to patients who need them.** Premarketing submission administrative burdens, and substantial “ user fees ” or notified body review fees, represent a significant non- clinical and / or non- scientific barrier to new product introduction, resulting in lack of investment or delays to revenues from new or improved devices. The risks associated with such circumstances relate not only to substantial out- of- pocket costs, including potential litigation in millions of dollars, but also loss of business and a diversion of attention of key employees for an extended period of time from managing normal responsibilities, particularly in new product development and routine quality assurance activities. Group Purchasing Organizations (GPOs) in the U. S. add non- productive costs, weaken the Company’ s marketing and sales efforts and cause lower revenues by restricting access: GPOs, theoretically acting as bargaining agents for member hospitals, but actually collecting revenues from the companies that they are negotiating with, have made a concerted effort to turn medical devices that convey special patient safety advantages and better health outcomes, like UTMD’ s, into undifferentiated commodities. GPOs have been granted an antitrust exemption by the U. S. Congress. In other industries their business model based on “ kickbacks ” would be a violation of law. Despite rhetoric otherwise, these bureaucratic entities do not recognize or understand the overall cost of care as it relates to safety and effectiveness of devices, and they create a substantial administrative burden that is primarily driven by collection of administrative fees. The Company’ s business strategy may not be successful in the future: As the level of complexity and uncertainty in the medical device industry increases, evidenced, for example, by the unpredictable and overly cumbersome regulatory environment, the Company’ s views of the future and product / market strategy may not yield financial results consistent with the past. As the healthcare industry becomes increasingly bureaucratic it puts smaller companies like UTMD at a competitive disadvantage: An aging population and **previously** uncontrolled immigration **is are** placing greater burdens on healthcare systems, particularly hospitals. The length of time and number of administrative steps required in adopting new products for use in hospitals has grown substantially in recent years. Smaller companies like UTMD typically do not have the administrative resources to deal with broad new administrative requirements, resulting in either loss of revenue or increased costs. As UTMD introduces new products it believes are safer and more effective, it may find itself excluded from certain clinical users because of the existence of long- term supply agreements for preexisting products, particularly from competitors which offer hospitals a broader range of products and services. Restrictions used by hospital administrators to limit clinician involvement in device purchasing decisions makes communicating UTMD’ s clinical advantages more difficult. A product liability lawsuit could result in significant legal expenses and a large award against the Company: UTMD’ s devices are frequently used in inherently risky situations to help physicians achieve a more positive outcome than what might otherwise be the case. In any lawsuit where an individual plaintiff suffered permanent physical injury, the possibility of a large award for damages exists whether or not a causal relationship exists. The Company’ s reliance on third party distributors in some markets may result in less predictable revenues: UTMD’ s distributors have varying expertise in marketing and selling specialty medical devices. They also sell other devices that may result in less focus on the Company’ s products. In some countries, notably China, Pakistan and India not subject to similarly rigorous standards, a distributor of UTMD’ s products may eventually become a competitor with a cheaper but lower quality version of UTMD’ s devices. The loss of one or more key employees could negatively affect UTMD performance: In a small company with limited resources, the distraction or loss of key personnel at any point in time may be disruptive to performance. The Company’ s benefits programs are key to recruiting and retaining talented employees. An increase in UTMD’ s employee healthcare plan costs, for example, may cause the Company to have to reduce coverages which in turn represents a risk to retaining key employees. Fluctuations in foreign currencies relative to the USD can result in significant differences in period- to- period financial results: Since a significant portion of UTMD’ s sales are invoiced in foreign currencies and consolidated financial results are reported in USD terms, a stronger USD can have negative revenue effects. Conversely, a weaker USD would increase foreign subsidiary operating costs in USD terms. For the portion of sales to foreign entities made in fixed USD terms, a stronger USD makes the devices more expensive and weakens demand. For the portion invoiced in a foreign currency, not only USD- denominated sales are reduced, but also gross profits may be reduced because finished distributed devices and / or U. S. made raw materials and components are likely being purchased in fixed USD. Trade restrictions and / or tariffs resulting from changing government geopolitical trade policies have the potential to disrupt UTMD’ s supply chain **and / or affect costs**. ~~Current lack of predictability of demand from a major OEM customer representing 17 % of total consolidated sales in 2023.~~ 16