BD Receives FDA 510(k) Clearance for Updated BD Alaris™ Infusion System

- ***BD Alaris™ Infusion System is the only modular and most comprehensive infusion system on the U.S. market that includes large volume pumps, syringe pumps, patient-controlled analgesia (PCA) pumps, respiratory monitoring, auto-identification, dose error reduction software and EMR interoperability***
- ***BD Alaris™ Infusion System's unique "One System" platform securely connects all patient modules to provide care teams with a single, comprehensive patient view***
- ***BD sales and service teams will begin actively engaging customers on next steps for their infusion devices; Operational capacity investments will enable rapid scale-up of BD Alaris™ Infusion System to begin distribution and remediation or replacement of existing devices***
- ***BD does not expect any material incremental revenue contribution from the BD Alaris™ Infusion System for the remainder of FY23; Expects to absorb initial re-launch investments within FY23 guidance range***

FRANKLIN LAKES, N.J., July 21, 2023 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that the updated BD Alaris™ Infusion System has received 510(k) clearance from the U.S. Food and Drug Administration (FDA), which enables both remediation and a return to full commercial operations for the most comprehensive infusion system available in the United States.

This clearance covers updated hardware features for Point-of-Care Unit (PCU), large volume pumps, syringe pumps, patient-controlled analgesia (PCA) pumps, respiratory monitoring and auto-identification modules. It also covers a new BD Alaris™ Infusion System software version with enhanced cybersecurity, along with interoperability features that enable smart, connected care with the most widely used electronic medical record (EMR) systems.

"The 510(k) clearance of the updated BD Alaris™ Infusion System has been the number one priority for our teams who have been steadfast in their efforts to achieve this milestone, consistent with our commitment to quality," said Tom Polen, chairman, CEO and president of BD. "We are deeply committed to ensuring clinicians can continue to rely on our market leading system to meet today's most critical infusion needs. The features and enhancements incorporated into the updated BD Alaris™ Infusion System and subject to this clearance reinforce our advancements in smart, connected care, which deliver greater benefit to clinicians and patients and help improve health care system efficiency through better care coordination and utilization of actionable information."

Extending BD's Decades-Long Legacy of Leadership in Infusion Innovation

Today's clearance further enhances BD leadership in the infusion pump market. The updated BD Alaris™ Infusion System will help empower hospitals and health systems to optimize their workflows and deliver a higher standard of care, which has never been more important than in today's health care environment of staffing shortages and resource constraints.

The BD Alaris™ Infusion System is the only system with a centralized user interface for up to four modules for all major types of infusions, including large volume pumps, syringe pumps, and PCA therapy with optional respiratory monitoring. Having one, comprehensive infusion system enables hospitals and health systems to easily scale their infusion needs across an entire integrated delivery network and provide interoperability with EMRs. With a common Point-of-Care Unit, one interface controls all modules, which is different from other pumps on the market that have non-modular architecture. The "one system" approach offers ease, simplicity and scalability.

The BD Alaris™ Infusion System also has the largest breadth of customers, the largest number of nurses trained on its use and the broadest experience and largest number of customers with EMR interoperability. Without this type of digital connectivity, clinicians are often required to navigate time-consuming processes, taking multiple steps to manually program infusions. The BD Alaris™ Infusion System can also feed data to the BD HealthSight™ platform for enterprise medication management, which is a unique combination of connective technologies, analytics and expert services that turn information into insights among caregivers and create seamless visibility across BD medication management solutions. With this platform, health systems can view infusion status in real-time as well as access an intuitive knowledge portal with actionable information related to clinician trends and drug and fluid libraries.

"We are so grateful for the fact that for more than two decades, frontline clinicians have relied on the BD Alaris™ Infusion System and Guardrails™ Safety Software to deliver medications, fluids and blood products to support the care of their patients," said Mike Garrison, president of the BD Medical segment. "Today, a majority of hospitals in the United States use the

BD Alaris™ Infusion System to safely deliver IV therapies to patients, and this comprehensive clearance provides a foundation to support a steady, reliable cadence of innovation in infusion technologies from BD. The clearance also marks another major step in our journey to support our customers with deep clinical, operational and technical expertise in Infusion Therapy, Vascular Access and Connected Medication Management."

Supporting Our Customers

To address all open recalls and ensure all devices at customer sites are running the most recent version of the BD Alaris™ Infusion System Software, all of the current Alaris devices in the U.S. market will be remediated or replaced with the updated 510(k) cleared version. Given the large installed base of the BD Alaris™ Infusion System, BD will actively engage and start working in close partnership with its customers to undertake and complete the remediation or replacement of all devices in the field.

"Remediation of recalls will always be a top priority for BD, and our remediation plans go above and beyond all open recall requirements to ensure all devices are compliant with the 510(k) clearance, including the newest hardware, software and cybersecurity updates," said Ami Simunovich, chief quality and regulatory officer at BD. "We have made substantial investments to simplify, improve and evolve our processes, systems and policies to ensure we design, manufacture and sustain our products in compliance with changing global regulatory and safety requirements. We remain committed to delivering next-generation quality and compliance to our customers."

BD has been preparing for the updated clearance and return to full commercial operations by investing in the proper operational capacity and functional capabilities to provide customers with the best experience possible. This includes investments to increase manufacturing capacity, strengthen supply chains and increase supplier redundancy to help the company meet its remediation obligations and continue to reliably supply infusion products to customers. BD also retained its infusion implementation and service teams while products were on ship-hold to ensure support for its customers during the pandemic and enable seamless execution upon clearance.

BD has created a website dedicated to supporting customers who have questions about the updated 510(k) clearance or remediation at bd.com/explore-bd-alaris.

Updated Business Outlook

As previously disclosed, the company expects a return to full commercial operations and sales in its Infusion business to happen over time, with remediation or replacement of devices in the field taking first priority. While the company is well positioned to engage with customers and execute as quickly as possible, the lead time to shipment and installation is also dependent on customer readiness. Therefore, BD expects to begin shipping devices and recognizing revenue in FY24 and does not expect any material incremental revenue contribution from the BD Alaris™ Infusion System for the remainder of FY23. The company expects that the initial investments to return its Infusion business to full commercial operations will be absorbed within its previously announced FY23 guidance range.

The BD Alaris™ Infusion System's clearance and return to full business operations increase the company's confidence in achieving its previously disclosed BD2025 financial targets of 5.5%+ revenue growth and double-digit adjusted EPS growth, both of which exclude the impact of COVID-only testing and foreign currency.

BD will provide additional commentary during the company's previously announced third quarter earnings call being held Thursday, Aug. 3 at 8 a.m. ET.

For more information on the BD Alaris™ Infusion System, visit:https://www.bd.com/en-us/products-and-solutions/products/product-brands/alaris#overview.

About BD
BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 77,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit bd.com or connect with us on LinkedIn at www.linkedin.com/company/bd1/ and Twitter @BDandCo.

Forward-Looking Statements

This press release contains certain forward-looking statements regarding the return to full commercial operations for the BD Alaris™ Infusion System and the remediation or replacement of all BD Alaris™ Infusion System in the U.S. market, as well as BD's future performance, including, but not limited to, the impact of BD Alaris™ Infusion System on future results of operations. All such statements are based upon the current expectations of BD and involve a number of business risks and uncertainties. Actual results could vary materially from anticipated results described, implied or projected in any forward-looking statement. With respect to forward-looking statements contained herein, a number of factors could cause actual results to vary materially. These factors include, but are not limited to, risks related to BD's ability to return to full commercial operations and the remediation or replacement of such devices; risks relating to market acceptance by customers; the timing and/or amount of costs associated with remediation and replacement of such devices; and other factors listed in our 2022 Annual Report on Form 10-K and other filings with the Securities and Exchange Commission. BD expressly disclaims any undertaking to update any forward-looking statements set forth herein to reflect events or circumstances after the date hereof, except as required by applicable laws or regulations.

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