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Shalby/SE/2024-25/54

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The Listing Department
National Stock Exchange of India Ltd
Mumbai 400 051.

Corporate Service Department
BSE Limited
Mumbai 400 001.

Scrip Code : SHALBY

Through : <https://neaps.nseindia.com/NEWLISTINGCORP/>

Scrip Code: 540797

Through : <http://listing.bseindia.com>

Sub: Press Release – Strategic Clinical Trial Agreement with Monogram Technologies, Inc.

Dear Sir / Madam,

We are pleased to announce Strategic Clinical Trial Agreement with Monogram Technologies, Inc., an AI-driven robotics Company specializing in orthopedic surgery. We have enclosed herewith copy of Press Release titled “Shalby Limited Announces Strategic Clinical Trial Agreement with Monogram Technologies”.

You are requested to take the same on your record.

Thanking you,

Yours sincerely
For **Shalby Limited**

Tushar Shah
AVP & Company Secretary
Mem. No: FCS-7216

Encl.: as above

SHALBY LIMITED

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CIN: L85110GJ2004PLC044667

SHALBY LIMITED

NSE: SHALBY; BSE: 540797

Shalby Limited Announces Strategic Clinical Trial Agreement with Monogram Technologies

Monogram Technologies is an AI-driven robotics company focused on improving human health, with an initial focus on orthopedic surgery. The Company is developing a product solution architecture to enable patient-optimized orthopedic implants at scale by combining 3D printing, advanced machine vision, AI and next-generation robotics.

Clinical trial agreement precludes planned international launch for the mBôs TKA System

Ahmedabad Gujarat, India, August 13, 2024: Shalby Limited (NSE: [SHALBY](#)), a leading multi-specialty hospital in India, announced a strategic partnership with Monogram Technologies Inc., (NASDAQ: MGRM) an AI-driven robotics company specializing in orthopedic surgery. This collaboration will focus on conducting a multicenter clinical trial in India to demonstrate the safety and effectiveness of Monogram's mBôs TKA System, a precision robotic surgical system designed for knee replacements.

Monogram's mBôs precision robotic surgical system is designed to autonomously execute optimized paths for high-precision insertion of its FDA-cleared mPress press-fit implants. The goal is well balanced better-fitting bone sparing knee replacements. The Company initially intends to produce and market robotic surgical equipment and related software, orthopedic implants, tissue ablation tools, navigation consumables, and other miscellaneous instrumentation necessary for reconstructive joint replacement procedures. Other clinical and commercial applications for the mBôs with mVision navigation are also being explored.

The Company believes that its mBôs precision robotic surgical assistants, which combine AI and novel navigation methods (mVision), will enable more personalized knee implants for patients, resulting in well balanced better-fitting knee replacements with bone sparing implants. Monogram anticipates that there may be other clinical and commercial applications for its navigated mBôs precision robot and mVision navigation.

Under the agreement, Shalby will enroll up to patients at various sites in India for surgeons to evaluate the safety and effectiveness of the mBôs TKA System with the Consensus CKS implant, which is substantially equivalent to the Monogram mPress implants for regulatory purposes. Monogram received comments on the Clinical Investigational Plan during its February 2024 Presubmission Communications with the FDA and has incorporated feedback. Notably, the strategic Clinical Trial Agreement contemplates the post-trial transfer of a robot to the hospital system under certain conditions following the trial as the companies contemplate further collaboration.

Through this clinical agreement, Monogram will be provided access to a network of highly experienced knee replacement surgeons under the guidance of Dr. Vikram Shah.

“As the largest orthopedic hospital group in the world we have the privilege with our esteemed surgeons of evaluating the leading robots and advanced technologies on the market including pipeline products” said Dr. Vikram Shah, Chairman of Shalby Limited. *“We have seen the mBô’s TKA System and next gen pipeline firsthand and can say definitively that what they are working on will change the face of orthopedic medicine forever. We are excited to partner with Monogram and believe the market potential in the United States and globally for their system is very significant and could scale very quickly. We look forward to working with the Monogram team and broadening our relationship over the months to come.”*

“With over 200,000 TKAs annually India represents a massive market potential driven by a large population and demographic tailwinds. India is underpenetrated for robotics but rapidly growing, and we believe the market potential is likely in the hundreds of systems,” said Ben Sexson, CEO of Monogram Technologies Inc. *“Shalby is a world class organization and we have been nothing but impressed by the caliber of their surgeons and standard of care. We resonate with Shalby’s ambitions growth plans globally including in the United States and look forward to validating the value proposition of the mBô’s TKA System with real world data. Our recent 510(k) submission is a catalyst for strategic synergies.”*

“Shalby aspires to become a top 5 player in orthopedics globally within the next decade,” said Dr. Vikram Shah of Shalby. *“Many markets around the globe are completely underserved. We recognize the importance of advanced technologies to realize this ambitious goal.”*

Monogram plans to leverage the clinical data from the US study for post-launch marketing and to support international clearance and commercialization. Both Companies see a significant clinical need for a highly intuitive, safe, and accurate multi-application robotic platform. The Companies expect the relationship to extend, with additional studies on next-generation solutions like mVision to follow.

About Shalby Limited

Shalby Limited (NSE: SHALBY) is India’s leading multi-specialty hospital established by Dr. Vikram Shah and has over 30 years’ experience in delivering quality and affordable healthcare. Shalby purchased California based Consensus Orthopedics in May 2021. It currently operates a chain of 11 multispecialty tertiary hospitals and 5 Orthopedic Centers under Shalby Orthopedics Center of Excellence (SOCE) across India with an aggregate bed capacity of over 2,350 hospital beds and also diversified into Knee and Hip Implants manufacturing in the US. Shalby has performed more than 1,50,000 Joint Replacement Procedure so far and became globally the no 1 player in joint replacements by volumes. It is the largest center of Joint Replacement Surgery in India with 15% market share in organized market. Shalby has more than 4,600 plus in-house team of skilled doctors, surgeons and support staff with relevant industry experience and in-depth domain expertise, who have been leading the Company’s growth.

For more information visit www.shalby.org.

About Monogram Technologies Inc.

Monogram Technologies (NASDAQ: MGRM) is an AI-driven robotics company focused on improving human health, with an initial focus on orthopedic surgery. The Company is developing a product solution architecture to enable patient-optimized orthopedic implants at scale by combining 3D printing, advanced machine vision, AI and next-generation robotics.

Monogram has obtained FDA clearance for mPress implants and applied for 510(k) clearance for its robotic products. The Company is required to obtain FDA clearance before it can market its products. Monogram cannot estimate the timing or assure the ability to obtain such clearances.

The Company believes that its mBô's precision robotic surgical assistants, which combine AI and novel navigation methods (mVision), will enable more personalized knee implants for patients, resulting in well balanced better-fitting knee replacements with bone sparing implants. Monogram anticipates that there may be other clinical and commercial applications for its navigated mBô's precision robot and mVision navigation.

To learn more, visit monogramtechnologies.com.

For more information, please contact:

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Safe Harbour:

This release contains statements that contain "forward looking statements" including, but without limitation, statements relating to the implementation of strategic initiatives, and other statements relating to Shalby Limited's future business developments and economic performance. While these forward-looking statements indicate our assessment and future expectations concerning the development of our business, a number of risks, uncertainties and other unknown factors could cause actual developments and results to differ materially from our expectations. These factors include, but are not limited to, general market, macroeconomic, governmental and regulatory trends, movements in currency exchange and interest rates, competitive pressures, technological developments, changes in the financial conditions of third parties dealing with us, legislative developments, and other key factors that could affect our business and financial performance. Shalby Limited undertakes no obligation to publicly revise any forward-looking statements to reflect future / likely events or circumstances.