July 23, 2025

Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

Tom Kerr, CFA
312-265-9417
tkerr@zacks.com

scr.zacks.com

101 N. Wacker Drive, Chicago, IL 60606

Monogram Technologies (NASDAQ: MGRM)

MGRM: Monogram to be acquired by large medical device company Zimmer Biomet.

Utilizing a Discounted Cash Flow process containing conservative estimates combined with other valuation methodologies, we believe MGRM could be worth **$6.00** per share.

Current Price (7/22/25)	$5.75
Valuation	**$6.00**

OUTLOOK

Monogram Technologies (NASDAQ: MGRM) is a medical device company developing a product solution architecture to enable patient-optimized orthopedic implants at scale by linking 3D printing and robotics with advanced pre-operative imaging. On 5/17/25, the company received clearance from the FDA on its 510(k) submission for its mBôs TKA System. The first live in patient surgery OUS is expected in 2025. The company has $13.3 million in cash as of 3/31/25. We believe MGRM stock to be undervalued at this time with several significant potential catalysts within the next 12 months.

SUMMARY DATA

52-Week High	**$6.02**
52-Week Low	**$1.82**
One-Year Return (%)	**172.2**
Beta	**N/A**
Average Daily Volume (sh)	**297,161**
Shares Outstanding (mil)	**35.6**
Market Capitalization ($mil)	**$208.8**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**32**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**N/A**
P/E using 2025 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Medical Device**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	$0.00 A	$0.00 A	$0.00 A	$0.00 A	$0.00 A
2023	$0.00 A	$0.00 A	$0.00 A	$0.36 A	$0.36 A
2024	$0.00 A	$0.00 A	$0.00 A	$0.00 A	$0.00 A
2025	$0.00 A	$0.00 E	$0.00 E	$0.00 E	$0.00 E

EPS / Loss Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.47 A	-$0.19 A	-$0.44 A	-$0.31 A	-$1.42 A
2023	-$0.40 A	-$0.27 A	-$0.03 A	$0.09 A	-$0.61 A
2024	-$0.11 A	-$0.11 A	-$0.16 A	-$0.13 A	-$0.51 A
2025	-$0.10 A	-$0.09 E	-$0.10 E	-$0.11 E	-$0.39 E

Quarterly revenues may not equal annual revenues due to rounding.
Quarterly EPS may not equal annual EPS due to rounding or dilution.

© Copyright 2025, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Zimmer Biomet to Acquire Monogram Technologies

On July 14, 2025, the company announced they were being acquired by leading medical device company Zimmer Biomet (NYSE: ZBH). The following press release was issued in conjunction with the announcement:

> WARSAW, Indiana and AUSTIN, Texas, July 14, 2025 (GLOBE NEWSWIRE) -- Zimmer Biomet Holdings, Inc. (NYSE and SIX: ZBH), a global medical technology leader, and Monogram Technologies Inc. (NASDAQ: MGRM), an orthopedic robotics company, today announced they have entered into a definitive agreement for Zimmer Biomet to acquire all outstanding shares of stock of Monogram for an upfront payment of $4.04 per share in cash, corresponding to an equity value of approximately $177 million and an enterprise value of approximately $168 million. Monogram common stockholders will also receive a non-tradeable contingent value right (CVR) entitling the holder to receive up to $12.37 per share of common stock in cash if certain product development, regulatory and revenue milestones are achieved through 2030. The respective boards of directors of Zimmer Biomet and Monogram have unanimously approved the proposed transaction.
>
> Monogram's semi- and fully autonomous robotic technologies are expected to add new and differentiated capabilities to expand Zimmer Biomet's flagship ROSA ® Robotics platform and broad suite of navigation and enabling technologies. Monogram has developed a CT-based, semi-autonomous, AI-navigated total knee arthroplasty (TKA) robotic technology, which received FDA 510(k) clearance in March 2025 and is expected to be commercialized with Zimmer Biomet implants in early 2027. Additionally, Monogram is developing a fully autonomous version of the technology with the potential to significantly increase safety, efficiency and outcomes, as well as additional applications beyond TKA. Upon closing of the proposed transaction, Zimmer Biomet expects to have a clear pathway to become the first and only company in orthopedics to offer a fully autonomous surgical robot.
>
> "Monogram's technology is a major leap forward, demonstrating our commitment to becoming the boldest and broadest innovator in surgical robotics and navigation," said Ivan Tornos, Chairman, President and Chief Executive Officer of Zimmer Biomet. "Upon closing, our customer-centric portfolio will consist of the most comprehensive and flexible technology ecosystem to support the varying preferences of a vast array of surgeons – now and into the future. With Monogram's proprietary technology, Zimmer Biomet has the potential to become the first company to deliver fully autonomous capabilities and redefine both the standard of care and the future of orthopedic surgery."
>
> The proposed transaction expands Zimmer Biomet's extensive suite of orthopedic robotics, enabling solutions and analytics to address the needs of surgeons pre-, intra- and post-operatively. Zimmer Biomet's broad portfolio features imageless robotics through its ROSA platform; a licensed CT-based handheld robot; mixed reality navigation; AI-based surgical navigation; and a pathway to advanced semi- and fully autonomous robotics capabilities. Increasingly, Zimmer Biomet is uniquely positioned to solve for the diverse preferences of a wide range of surgeons globally and address multiple styles of surgical techniques, such as CT and non-CT; robotic and non-robotic; and manual, surgeon-centered methods or semi- or fully autonomous technologies.
>
> The ROSA platform, which is the cornerstone of Zimmer Biomet's robotics offering, is rapidly approaching 2,000 installations worldwide and is a market leader outside of the United States. Zimmer Biomet is committed to continuing to advance the ROSA platform and is investing in a robust R&D pipeline featuring several new product and software applications expected between

now and 2027. This includes ROSA Knee with OptimiZe, which has been submitted to the FDA and 510(k) clearance is anticipated later this year, as well as ROSA Posterior Hip and the full commercial launch of ROSA Shoulder.

"Since our inception, we have been singularly focused on advancing orthopedic robotics with technology designed to safely, efficiently and accurately support surgeons with total knee arthroplasty," said Benjamin Sexson, Chief Executive Officer of Monogram. *"We are thrilled by the opportunity to add our technology to Zimmer Biomet's leading portfolio of surgical robotics, navigation solutions and trusted implants and to benefit from their deep industry expertise and global scale."*

Zimmer Biomet plans to fund the proposed transaction through a combination of cash on the balance sheet and other available debt financing sources. Zimmer Biomet expects to maintain a strong balance sheet and to continue to support its stated capital allocation priorities.

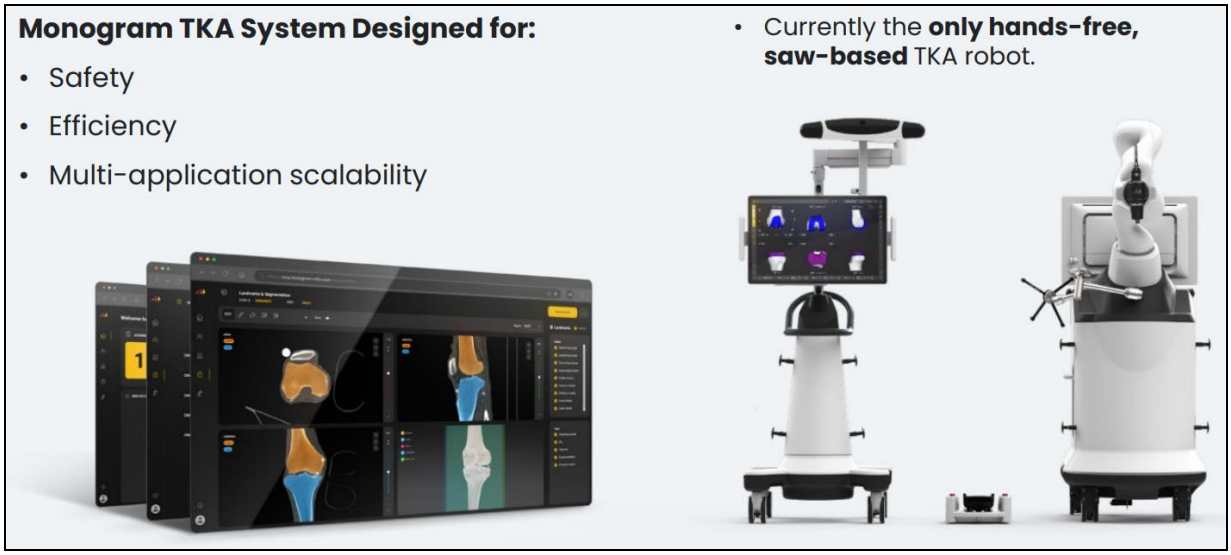
Zimmer Biomet believes this proposed transaction and the CVR structure is compelling from both a strategic and financial standpoint. The acquisition of Monogram further strengthens Zimmer Biomet's capabilities in robotics, one of the fastest growing segments within orthopedics. Zimmer Biomet expects the acquisition will contribute to revenue growth in 2027 and beyond by improving the Company's robotic knee adoption in the U.S., increasing share of wallet through reaching new customers with a broader product range, and expanding the Company's industry-leading global knee offerings.

Zimmer Biomet anticipates the acquisition will be neutral to adjusted earnings per share in 2025, 2026 and 2027, and accretive in 2028 and beyond. Additionally, the transaction is projected to generate high-single digit return on invested capital (ROIC) by year five, with an increasing contribution thereafter.

Closing of the proposed transaction is subject to receipt of required regulatory approvals, approval by Monogram's common stockholders and other customary closing conditions, and the merger is anticipated to close later this year.

Morgan Stanley & Co. LLC is serving as exclusive financial advisor to Zimmer Biomet and Hogan Lovells US LLP is serving as legal advisor.

Wells Fargo Securities, LLC is serving as exclusive financial advisor to Monogram and Duane Morris LLP is serving as legal advisor.



Source: monogramorthopedics.com

Valuation and Estimates

Monogram has the potential to deliver strong revenue growth and positive earnings over the next 10 years after commercialization of its robotic system and customized press-fit implants. We believe the company can generate average annual revenue growth in the range of 25%-35% over the next 10 years and improve margins to industry averages over time.

Our primary valuation tool utilizes a Discounted Cash Flow process. Under the scenario described above, our DCF based valuation target is approximately **$6.00** per share. Our target price may be conservative as it utilizes a high discount rate of 15.0% due to the unpredictability of earnings, higher prevailing interest rates, and the timeline of commercialization of the company's products in the U.S.

RECENT NEWS

1st Quarter 2025 Financial & Operating Results

Monogram reported 1st quarter 2025 financial results on May 14, 2025, which were largely in line with our expectations. Research and development expenses for the quarter were $2.26 million compared to $2.41 million in the prior year period. The R&D decrease was primarily due to the company moving into the verification and validation phase of its robot prototype. The move into the validation phase, which consisted largely of testing and documenting the system components and protocols led to decreases in prototype material and contractor services which are largely associated with the verification phase. The decrease in R&D was partially offset by a $250,000 performance-based compensation accrual during the quarter from the FDA 510(k) clearance grant for the mBôs™ TKA System.

General & administrative expenses in the quarter were $1.0 million, which was a slight decrease from $1.1 million in the prior year period. Marketing and advertising expenses were $44,000 million in the quarter compared to $120,000 in the prior year period. The decrease was largely caused by market conditions that significantly influenced the effectiveness of fundraising efforts, which impacted both the cost of investor acquisition and the overall success of a crowdfunded capital raise.

The company continues to operate a highly variable cost structure with 27 full-time employees working mostly in R&D and engineering. Other engineers are outsourced and can be used as needed on an adjustable basis.

Net loss for the 1st quarter was ($3.2) million compared to a net loss of ($3.5) million in the prior year period. EPS was a loss of ($0.10) per share compared to a loss of ($0.11) per share 1st quarter of 2024. For the 1st quarter, operating cash flow was a use of cash of ($2.3) million. We expect the monthly burn rate to be approximately $1.2-$1.3 million in 2025 which takes into account the cost of the OUS clinical trial in India.

Cash and cash equivalents totaled $13.3 million as of March 31, 2025, compared to $15.7 million at the end of 2024. Net working capital was approximately $11.3 million and total stockholders' equity was $11.7 million.

FDA Clearance on the mBôs TKA System

On March 17, 2025, the company announced that the FDA had granted 510(k) clearance for its Monogram mBôs TKA System. This determination means that the company can move forward with upgrades and begin the commercialization process.

The mBôs TKA System is designed to deliver safety, efficiency, and accuracy in robotic-assisted total knee arthroplasty. The system is developed to eventually support multiple orthopedic applications beyond knee replacement. Despite the increasing role of robotics in joint reconstruction, the market remains underpenetrated and highly consolidated, leaving significant room for innovation and growth.

The FDA clearance opens up substantial opportunities for Monogram, both domestically and internationally. Over the coming months, the company will integrate recent upgrades to the cutting system and other system enhancements into the cleared mBôs TKA System to strengthen its competitiveness. The company is focused on initial placements with key surgeon KOLs in strategic geographies to establish clinical experience and demonstrate the system's advantages in real-world surgical settings.

Monogram will utilize a disciplined, long-term commercialization strategy and will take a measured and strategic approach to market adoption. The orthopedic robotics market operates on a long sales cycle, however, this clearance significantly de-risks the platform and validates the company's technology and positions Monogram for new strategic opportunities as it executes its growth strategy.

Ben Sexson, Monogram CEO, stated, *"This FDA 510(k) clearance is a defining moment for Monogram. It marks the culmination of years of relentless effort, innovation, and teamwork. Bringing a new technology to market in the medical field is an immense challenge, and this milestone is a testament to the dedication and resilience of our entire team. We have navigated obstacles, refined our technology, and remained steadfast in our mission to advance orthopedic robotics. Today, we take a significant step forward."*

Shalby Limited Clinical Trial

In August 2024, Monogram announced a strategic collaboration with Shalby Limited, a global multi-specialty hospital chain, to conduct a multicenter clinical trial to evaluate the safety and effectiveness of the mBôs TKA system. In January 2025, the company shipped a robot to support clinical trial training. An Investigator Meeting was held at a Shalby Hospital in Ahmedabad, India, on January 31 and February 1, 2025. The meeting was organized by Reliance Life Sciences and attended by principal investigators, surgeons, and other staff. The purpose of the meeting was to review study protocols, regulatory requirements, and operational procedures related to mBôs TKA system.

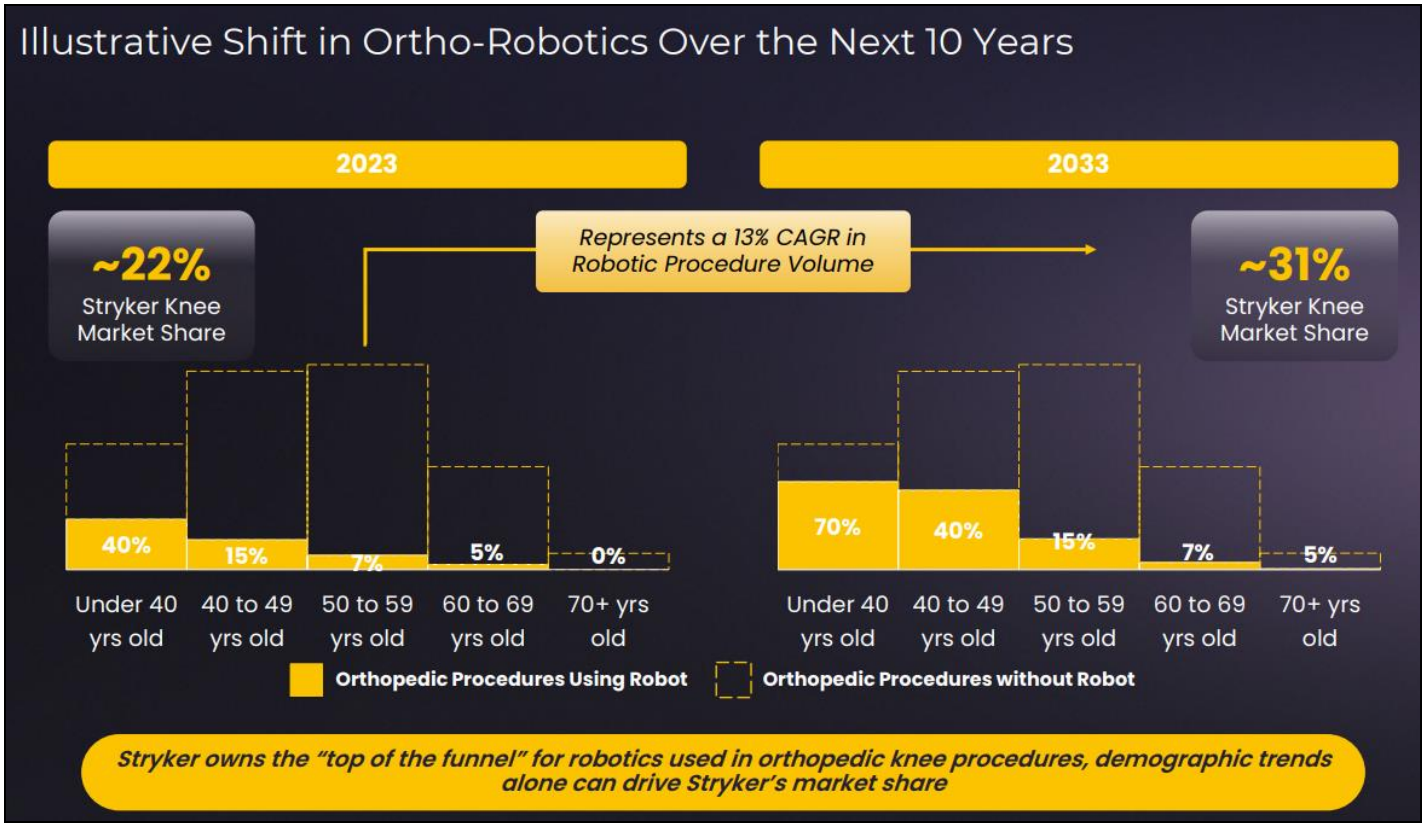
Reliance Life Sciences manages the regulatory submission and communications for the clinical trial in India. As the regulatory sponsor, Reliance Life Sciences is overseeing the submission process and engagement with India's regulatory authorities. Monogram has submitted its system for regulatory clearance to run the clinical trial and will provide updates as they occur.

On April 29, 2025, the company announced that it had obtained regulatory approval from India's Central Drugs Standard Control Organization (CDSCO) to import its mBôs TKA system to conduct a 102-patient, multi-center clinical investigation evaluating the safety and effectiveness of the Monogram TKA System.

The approval to begin clinical trial activities marks a major milestone for the company and further advanced efforts to de-risk the value proposition of the mBôs TKA system. This trial allows the company to demonstrate performance in real surgical settings, including what will likely include technically demanding cases. Patient enrollment for the trial is expected to begin soon, with the first live patient surgeries anticipated within 90 business days.

New Market Dynamics

The end-market dynamics continue to turn positive for the company. The underlying market is fundamentally changing in an interesting and rapid fashion that may be underappreciated by investors.



Source: monogramorthopedics.com

The percentage of fellowship programs that have access to a MAKO robot is 70% of fellowship programs. If a new doctor is going to try and get into orthopedic medicine and large joint reconstruction they usually require a fellowship. More than 90% of orthopedic residents seek a fellowship. Although robotic knee replacements are still dominated by MAKO, some studies suggest that by 2030, one in two knee replacements will be robotic.

In addition, 60% of orthopedic surgeons in the U.S. will be over the age of 65 in a similar timeframe. The market is changing very quickly. The way knee replacements are done now is not the way they are going to be done in the future. The combination of surgeon attrition from retirement and new younger fellowship surgeons entering the market bodes well for Monogram's advanced robotic technologies.

Closing of Upsized and Oversubscribed $13 Million Public Offering

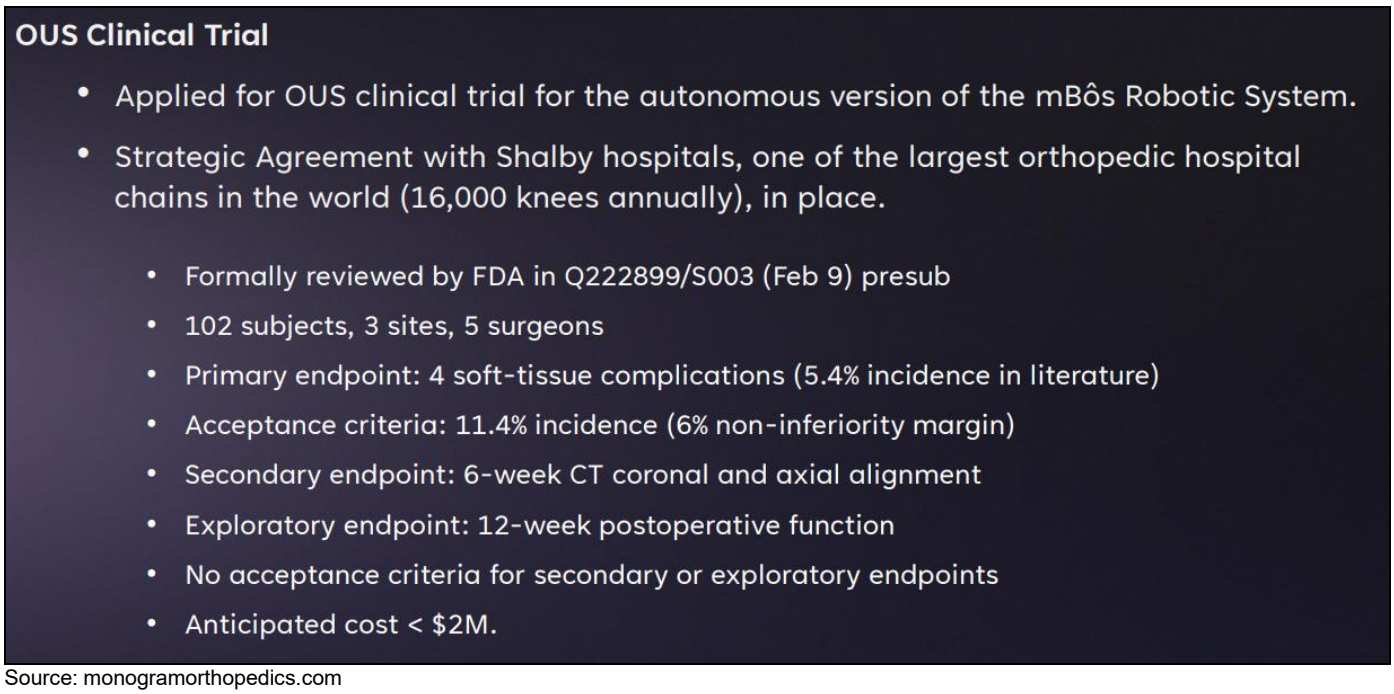
The company closed on its previously announced equity offering on October 1, 2024. The company sold 5,790,479 units, with each unit consisting of one share of Series D Preferred Stock and one common stock purchase warrant. The warrant allows the holder to purchase one share of the company's common stock. The company received gross proceeds of approximately $13.0 million (net proceeds of $11.7 million).

Monogram intends to use the net proceeds of the offering to fund general corporate and business purposes, operational needs, and various strategic initiatives.

Monogram Secures Initial Strategic Clinical Trial Collaboration

On August 12, 2024 the company announced a strategic collaboration with Shalby Limited (NSE: SHALBY), a global muti-specialty hospital chain and one of India's prominent orthopedic hospital groups, to conduct a multicenter clinical trial to demonstrate the safety and effectiveness of the mBôs TKA System. Shalby is the largest orthopedic hospital chain in the world employing over 4,000 people at 14 hospitals in 13 cities with more than 3 million patients treated. Shalby represents approximately 15% of

the organized arthroplasty market in India, which has an approximate market size of 200,000 TKAs per year, with a CAGR of approximately 20%. Shalby currently operates in eight countries and has aggressive multi-continent international expansion plans.



Source: monogramorthopedics.com

Under the collaboration, Shalby will enroll 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 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 into its 510(k) application submitted to the FDA on July 19, 2024 which passed the FDA Administrative Review.

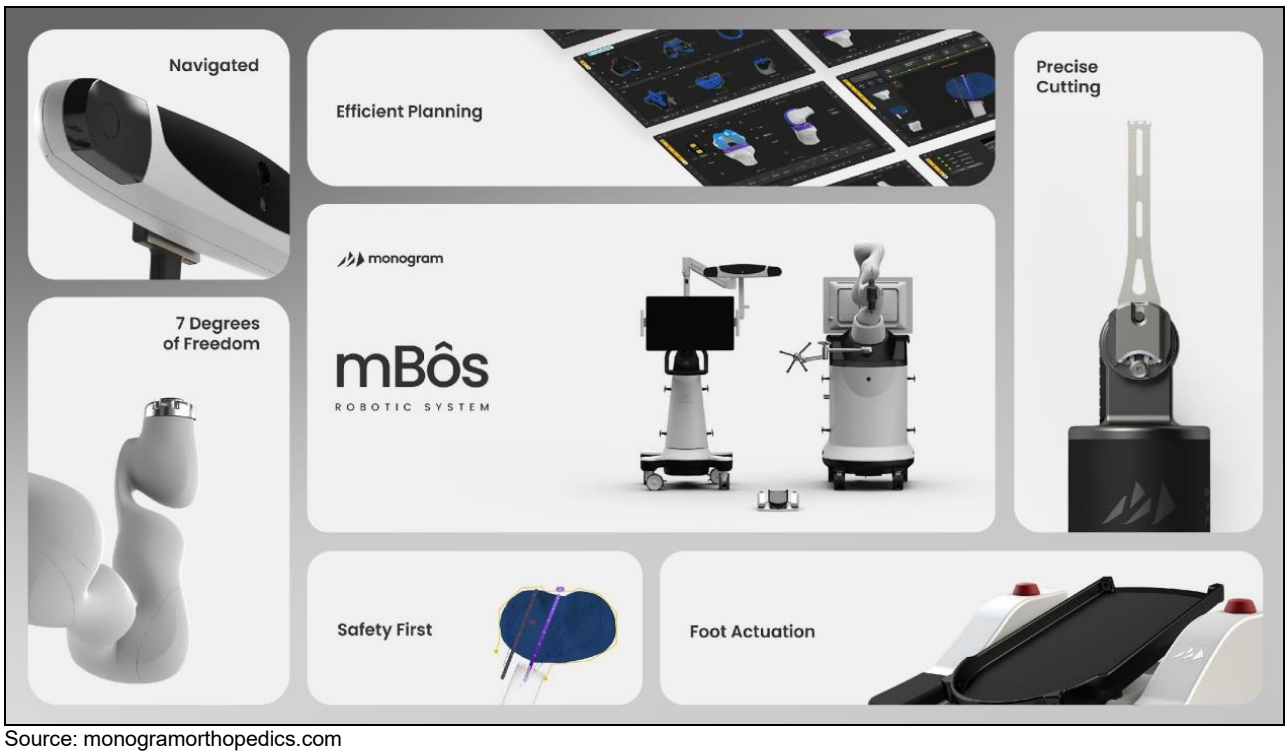
Monogram plans to leverage clinical data from the US study for post-launch marketing and to support international clearance and commercialization. Both companies see a significant clinical need for a highly intuitive, safe, and accurate multi-application robotic platform.

KEY INVESTMENT POINTS

- Monogram Technologies (NASDAQ: MGRM) is a medical device company developing a product solution architecture to enable patient-optimized orthopedic implants at scale by linking 3D printing and robotics with advanced pre-operative imaging. Monogram 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.

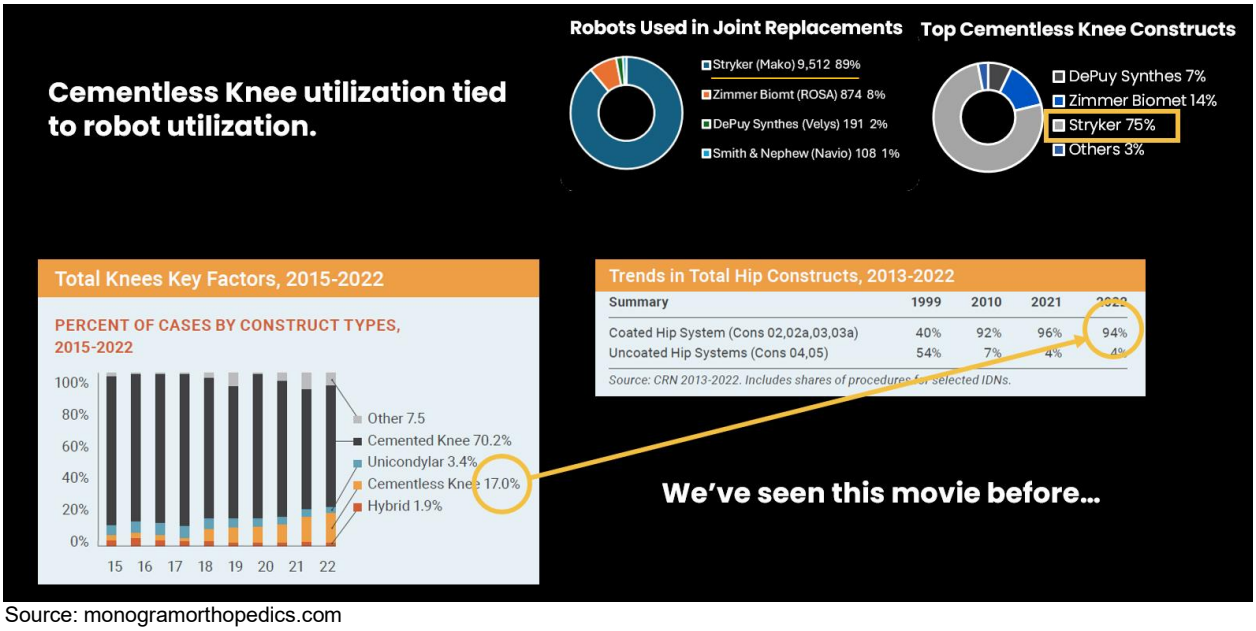
- On August 8th, 2024, the company announced it had submitted its 510(k) application for its semi-active mBôs TKA System on July 19th to the FDA. The submission follows recent FDA written feedback regarding the company's pre-submission request and a meeting to discuss the Monogram mBôs™ TKA System verification test plan, including a proposed clinical trial protocol on an outside the U.S. (OUS) target population. Management believes the feedback was comprehensive and will be advantageous for a successful 510(k) submission to obtain clearance, commercialization, and marketing for the mBôs™ TKA System. On September 30, 2024, the company announced it has

received an Additional Information Request ("AIR") from the U.S. Food and Drug Administration ("FDA"). The company received FDA clearance on March 17, 2025.



Source: monogramorthopedics.com

- Monogram's vision is to create "the most effortless surgical system in the world." The company's differentiating technology includes mBôs with mVision navigation and proprietary custom 3D-printed implants for which the company has issued patent(s). The mBôs is designed for active cutting under full surgeon control for uncompromised accuracy and unprecedented speed. The plan is to execute a "one robot for the operating room" model with a state-of-the-art robot for multiple applications. With mVision, the company aims to optimize surgery time and reduce barriers to adoption by completely eliminating point sampling based registration and navigation with large arrays.



Source: monogramorthopedics.com

- The company sees an opportunity to unlock new growth within this attractive market by providing a solution to the vulnerabilities in the existing economic model for robotics – namely, increased surgical time, increased consumables cost, and poor multi-modality efficiency. The Company aims to address the sluggish adoption of robotics (88% of knee surgeries still use generic manual instruments) with a system that reduces surgical time and consumables cost, enables novel implants, and is more accurate and more intuitive to use.

- Currently, robots on the market add surgical time versus manual procedures. Some literature suggests the length of time to complete a knee replacement with current robotic systems is approximately 81 minutes and approximately 70 minutes with manual instruments. Monogram is pushing to reduce surgical time to parity with manual surgery. The company has indicated they have completed the knee replacement cuts in 40 minutes in simulated cadaveric surgeries with mBôs. The company's ambitious long-term goal is to reduce robotic surgical time to 20 minutes.

- The joint replacement market size was approximately $22.3 billion in 2022 and is expected to grow to $38.0 billion by 2030 driven by an aging population. The market for orthopedic robotics could double over a comparable period. Notably, the market for robotics and press-fit implants is highly concentrated and growing – 74% of TKA's remain cemented, with Stryker accounting for 75% of uncemented implant volume. The company believes that robotic adoption has helped drive uncemented volume because of the generally smoother and more uniform cut surfaces. Monogram already has FDA-cleared uncemented implants. Stryker owns the haptic robotic market, and Monogram aims to own the active robotic market.

- The surgical robot under development is fully autonomous with no input force to the arm required by the orthopedic surgeon. It is the only orthopedic robot with seven joints and autonomous sagittal cutting capabilities. The mBôs was the first system to ever perform a fully remote simulated knee replacement (https://youtu.be/j0OQk8mT-bs). The company recently announced that they have made technical updates that could improve cutting efficiency and the safety profile of the device and potentially reduce the risk of requiring a clinical trial with the 510(k) submission.

- The company's long-term vision is to combine state-of-the-art robotics with 3D printed implants designed to be press-fit, bone sparing, highly stable, easy to revise, and more anatomic loading for younger or healthier patients. The orthopedic market is an oligopoly in part due to the significant barriers to entry caused by the inventory burden of generic implants. The company believes that combining pre-operative imaging and 3D printing could reduce the cost of delivering care over time.

- Monogram is positioning itself as an attractive acquisition target. As the market moves towards press fit knees (as it did with hips because it saves time and lasts longer) the monopoly position which Stryker has in press fit knees because of Mako will become increasingly painful to companies that don't have a compelling robot. Stryker owns "haptics", Monogram will own "active" robotics. Also, obtaining regulatory clearance is a major derisking event that makes companies attractive.

- The executed strategic agreement with Shalby hospitals is a key step towards accelerating commercialization. Monogram plans to leverage 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 company has $13.3 million in cash as of 3/31/25. Net working capital was approximately $11.3 million and total stockholders' equity was $11.7 million.

PRODUCT DESCRIPTIONS

The company plans an incremental, multi-generational product release strategy, starting with its FDA cleared mPress generic knee implants prepared with its mBôs robotic system. Over time, the goal is to introduce and obtain 510(k) premarket clearance for patient-optimized 3D printed robot-only implants, but only after first launching with the cleared mPress line. The mPress implants are based on licensed implants that have been modified through collaboration with the licensor and submission of a Letter to File. Upon successful commercialization of the mBôs orthopedic robot and provided the company has sufficient capital and market interest, they will pursue additional clinical applications such as hip, spine, and shoulder replacements.

The equipment required for robotic TKA includes:

- Navigated surgical robots with optical tracking equipment and a cutting end-effector (notably the company's mVision navigation could be marketed as a standalone product),
- Pre-operative and intra-operative software guidance application,
- Consumable Tissue ablation tools, and
- Navigation consumables (fiducial markers, tracked retractors, etc.)
- Orthopedic TKA implants (including femur, tibia, insert and patella)

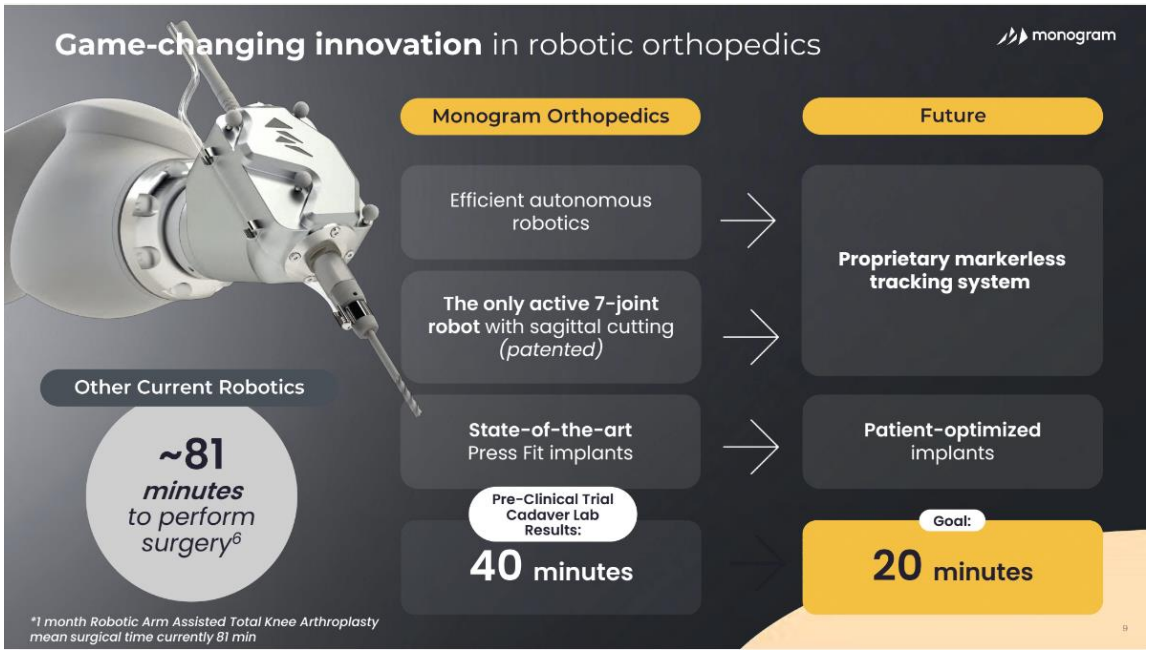
Robotic System

The Monogram robotic system and related hardware (end-effector) will be multi-use capital equipment and branded under the name mBôs. The company's pre-operative planning software, robotic controls, and intra-operative software are needed to use the robotic system properly. This software will be subject to an annual license billed based on the clinical scope of use, for example, total knee arthroplasty (joint replacement or TKA). A mix of reusable and single-use instrumentation is needed during the procedure. The elements of the system are sold individually but generally must be used with the system to perform its intended clinical function properly.

Monogram intends to outsource much of the manufacturing of its products, including implants and instrumentation needed to execute reconstructive joint replacements, to established suppliers. These suppliers may already be approved suppliers for the most significant market participants and may have decades of product-specific manufacturing expertise.

According to an analysis conducted by Orthopedic Network News (Vol 34, No 3, September 2023) on orthopedic procedures, as of 2022, the average cost of implant components for all total hip procedures was approximately $5,007 and for all total knee procedures was $4,220. Monogram expects to price its products consistent with the market. The company is on track to be the first company to the market with a CT-based navigated seven-joint robot arm that can autonomously cut with a sagittal saw.

Currently, some literature suggests the length of time to complete a knee replacement under the only widely available robotic system is approximately 81 minutes and 70 minutes for manual knee replacements. Monogram is pushing to reduce surgical time to parity with manual surgery. The company aims to combine cutting efficiency with novel mVision navigation to eliminate numerous setup and registration steps. The company has indicated they have completed the knee replacement cuts and completed the task in 40 minutes in simulated cadaveric surgeries with mBôs (under cadaver trials).

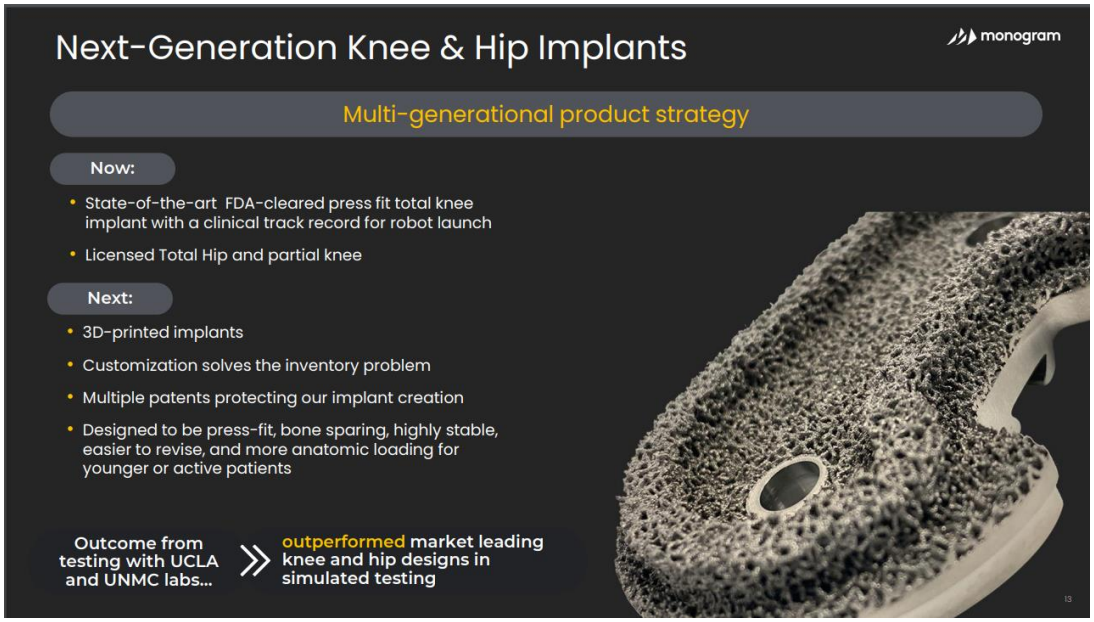


Source: monogramorthopedics.com

Implants

Press-fit orthopedic implants may be generally expected to perform better when surgeons achieve high initial stability. Stability may depend on design features and a tight fit. It is not always straightforward to design implants that surgeons can easily insert or remove (in a revision) while remaining highly stable.

Subsequent to its launch with the FDA-cleared mPress implant line, Monogram will design its second-generation 3D-printed press-fit implants to maximize cortical (outer surface) contact and, therefore, stability while remaining insertable. The company will design its future implants to reconstruct the patient's individual anatomy as closely as possible. A challenge with press-fit orthopedic implants is removal. As noted, Monogram intends to launch its mBôs robotic system with its mPress generic press-fit implants that are insertable with manual instrumentation. In the future, assuming a successful launch with its mPress implant system, the company intends to develop and potentially commercialize patient-optimized implants with features as described above.



Source: monogramorthopedics.com

INDUSTRY & ADDRESSABLE MARKET

According to analysis conducted by Orthoworld in "*The Orthopedic Industry Annual Report*" published June 2023, the orthopedic devices market is highly concentrated, with the top seven participants accounting for almost 2/3rds of total sales as of 2022. The company's primary target market, the joint reconstruction market, is even more concentrated, with the top four market participants accounting for approximately 3/4ths of total market sales.

Monogram's first addressable market, knee reconstruction, is likewise consolidated, with the four most significant players controlling 81% of the market and no other company controlling more than 2.2%. In the U.S. In 2022, the number of primary hip replacement procedures was estimated to be 581,043 and the number of primary knee replacements was estimated to be 1,083,061.

The joint replacement market size was approximately $20.0 billion in 2022 and is expected to grow to $38 billion by 2030 due to an aging population. The worldwide hip and knee implant market was approximately $17.2 billion in 2022, with other extremities totaling $2.8 billion. The global spinal implant market was valued at $9.9 billion in 2022 and is expected to grow to $18.0 billion by 2030. Joint reconstruction technology has remained largely unchanged for over 50 years. Approximately 88% of knee replacement surgeries, the company's first addressable market, are still manual. By 2027, approximately 50% of knee replacement surgeries are expected to be robotic.

The company believes that the market for robotics and surgically prepared press-fit implants will outpace average market growth because of the limited market penetration and the observed increase of competitors like Stryker Corporation (SYK), which utilizes navigated robotics and press-fit implants. The company has been aware of Stryker's performance in the CT-based robotically prepared press-fit knee market. Stryker markets the MAKO, a robotic-arm-assisted technology that uses a CT-based preoperative plan to help surgeons provide patients with a personalized surgical experience.

According to Orthopedic Network News (Vol 34, No 3, September 2023), Stryker has a 75% market share in cementless knee constructs, which, according to the same source, could have as much as a 10% higher average selling price than cemented knee constructs. From 2020 to 2021, Depuy Synthes, Smith & Nephew, and Zimmer Biomet had year-over-year sales increases of 13.3%, 8.7%, and 13.2%, respectively. The Stryker Corporation realized sales increases in its knee segment of 17.6% over the same period. Monogram believes this outperformance demonstrates the differentiation of the Mako system and the expanding market and acceptance of robotic systems.

PRODUCT STRATEGY & OBJECTIVES

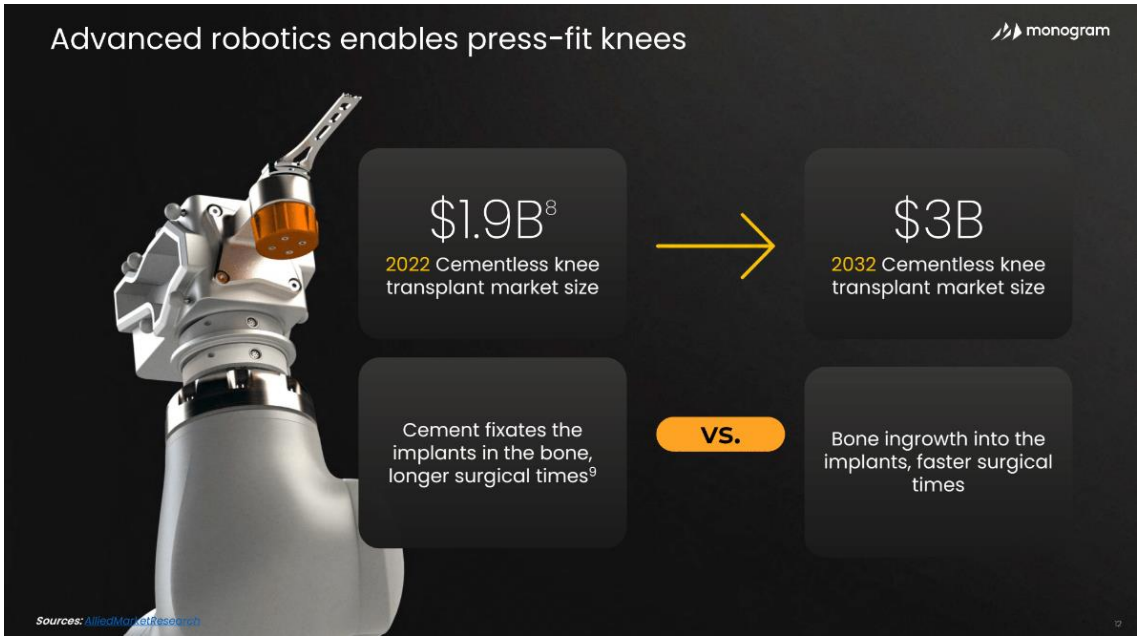
Monogram's vision is to create "the most effortless surgical system in the world." The company plans to commercialize its unique robotic system called mBôs with its FDA cleared orthopedic implant line called mPress. The company also has a standalone navigation product called mVision that will integrate into mBôs. The vision in the future is to facilitate the rapid delivery of press-fit orthopedic implants at scale. Monogram's robotic system is designed to decrease surgical time, lower total placement cost, and enable robotics for many other orthopedic-related applications.

The Monogram technology platform consists of a workflow to prepare a patient-specific surgical plan from a CT scan. The CT scan images are pre-processed by proprietary algorithms using artificial intelligence and machine learning to automatically segment the bone from the images, identify the anatomy of clinical interest, identify landmarks of clinical interest, and reconstruct the slices into a 3D model. The output from this process is the input for the robotic guidance application. The navigated robot executes cut paths

that may be optimized for time to surgically prepare the corresponding bone for the high-precision placement of the implants.

Monogram's navigated robot features several enhancements that may improve the user experience compared to the current robots in use. The robot features seven degrees of freedom with control algorithms that leverage the kinematic redundancy of the arm to eliminate the need for intraoperative tool changes and minimize patient repositioning during the cutting process. Monogram has also integrated quick-change capabilities into the robotic system to allow users to leverage the efficiencies of various cutting instruments for different applications, for example, a sagittal saw for large bone removal or a rotary tool for fine finishing and customization.

The company believes that a highly dependable robot that reduces surgical time while executing high accuracy cuts is the highest priority for successful market adoption. In addition, the robotic system integrates Augmented Reality ("AR") into various robotic workflows such as the registration of tracking arrays to reduce surgical time and minimize the risk of a failed registration. Instantaneous registration is a key competitive advantage when compared to the current standard of a fixed marker system.



Source: monogramorthopedics.com

Monogram sees several limitations to the use of generic implants as the standard of care. Generic implants can be geometric instead of organic in shape, limiting the amount of direct bone contact required for initial stability and long-term biological fixation. There is currently no commercially viable way to produce implants matching both the internal bone cavity and the external biomechanics of the joint. The challenges of designing implants that restore anatomy, are highly stable, and easily revisable are significant. There are currently limited methods for precisely sculpting an implant's exact complement in the bone.



Source: monogramorthopedics.com

The company's approach will attempt to use additively manufactured ("AM") press-fit tibial knee implants that require robotically milled complementary cavities to be insertable. For the first generation of patient optimized products, the company will be combining a novel Monogram tibial design with components of its mPress system, a generic implant system that consists of a femoral implant, inserts, and locking mechanism. To try and reduce the regulatory risk, mPress will be insertable with manual instrumentation and robotically so that it can submit the robot and any newly designed, second-generation implants requiring 510(k) premarket clearance to the FDA as separate submissions.


Source: monogramorthopedics.com

The company has conducted preliminary testing that appears to support their hypothesis that more accurate restoration of patient anatomy and robotic bone preparation of patient-specific implants may improve initial stability and warrants further research. The company will continue to focus its R&D efforts on high accuracy, time-efficient robotic execution.

In addition to stability testing, R&D efforts will also test the mechanical strength requirements mandated by the FDA. The initial launch will couple a generic press-fit implant also insertable with manual instrument with our robotic system when the robotic system receives 510(k) premarket clearance.

Robotic bone preparation for the insertion of implants is challenging as the robot must be properly calibrated, the patient bone must be accurately correlated to the pre-operative plan, and the robotic arm control must efficiently execute the plan. Numerous sources of potential errors make it challenging to prepare bone with sufficient accuracy.

The company believes its equipment and devices may be cheaper and more capital efficient than traditional knee and hip replacement systems. For example, the Mako robot produced by Stryker is the dominant leader in navigated surgical robotics, with approximately 1,500 robots installed globally as of the of 2022. In previous commentary, Stryker has indicated it was selling its Mako robots for $1,000,000 while reporting gross margins on its robot sales of approximately 62%. Monogram believes that this could imply a production cost of approximately $380,000 per robot. The company estimates that the cost to produce its robotic system will be below this cost level.

RISKS

- The company is currently in product development stage and has not recognized any revenues to date. The ability to generate revenue depends heavily on the successful completion of one or more development programs leading to submission of an acceptable 510(k) medical device clearance application to FDA and the ability to seek and obtain 510(k) premarket clearances. In addition, the company must successfully commercialize its products and receive positive market acceptance.

- The company is subject to substantial governmental regulation relating to the manufacturing, labeling, and marketing of its developmental products, and will continue to be for the lifetime of our company. The FDA and other governmental authorities in the U.S and internationally regulate the manufacturing, labeling, marketing, distribution, and various other aspects of the types of medical devices the company is developing. The process of obtaining regulatory clearance to market a medical device can be expensive and lengthy.

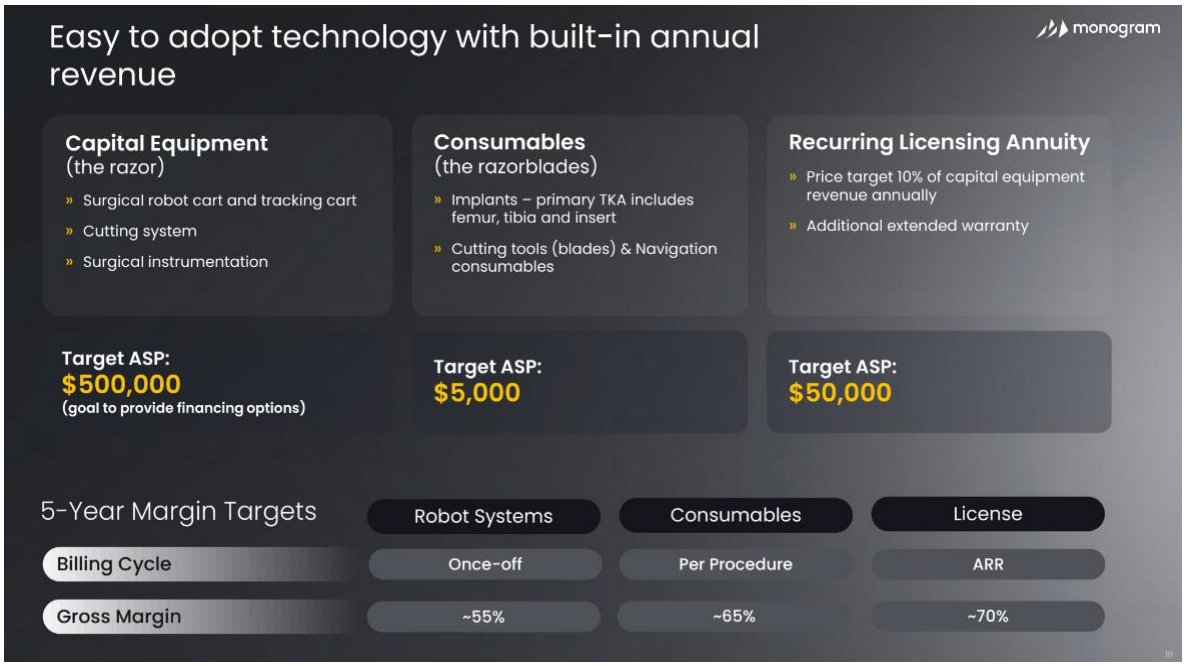
- The company may need to raise substantial additional capital in the future to fund operations and may be unable to raise such funds when needed or on acceptable terms. Developing medical device products, including conducting clinical studies, and establishing manufacturing capabilities, requires substantial funding.

- The company has no manufacturing experience and relies on third-party manufacturers and service providers to produce the medical device product candidates. The third-party partners provide a variety of essential business functions, including distribution, manufacturing, and others. It is possible that some of these third parties will fail to perform their services or will perform them in an unacceptable manner.

SUMMARY

We believe Monogram's transformative product solution architecture that enables patient-optimized orthopedic implants at scale by linking 3D printing and robotics with advanced pre-operative imaging will provide a long-term platform for profitable growth. The joint replacement addressable market size was approximately $22.3 billion in 2022 and is expected to grow to $38.0 billion by 2030 due to an aging population. Just achieving minimal levels of market share would produce significant revenues.

Monogram has the potential to grow both revenues and earnings at very robust double-digit growth rates starting in 2025 if it is able to execute its commercialization plans. The company's current stock price does not likely reflect that potential level of profitable growth going forward when commercialization becomes widespread, and we believe the stock to be significantly undervalued at this time. It's also possible that Monogram would make an important acquisition candidate for medical device companies that do not have advanced robotic offerings.



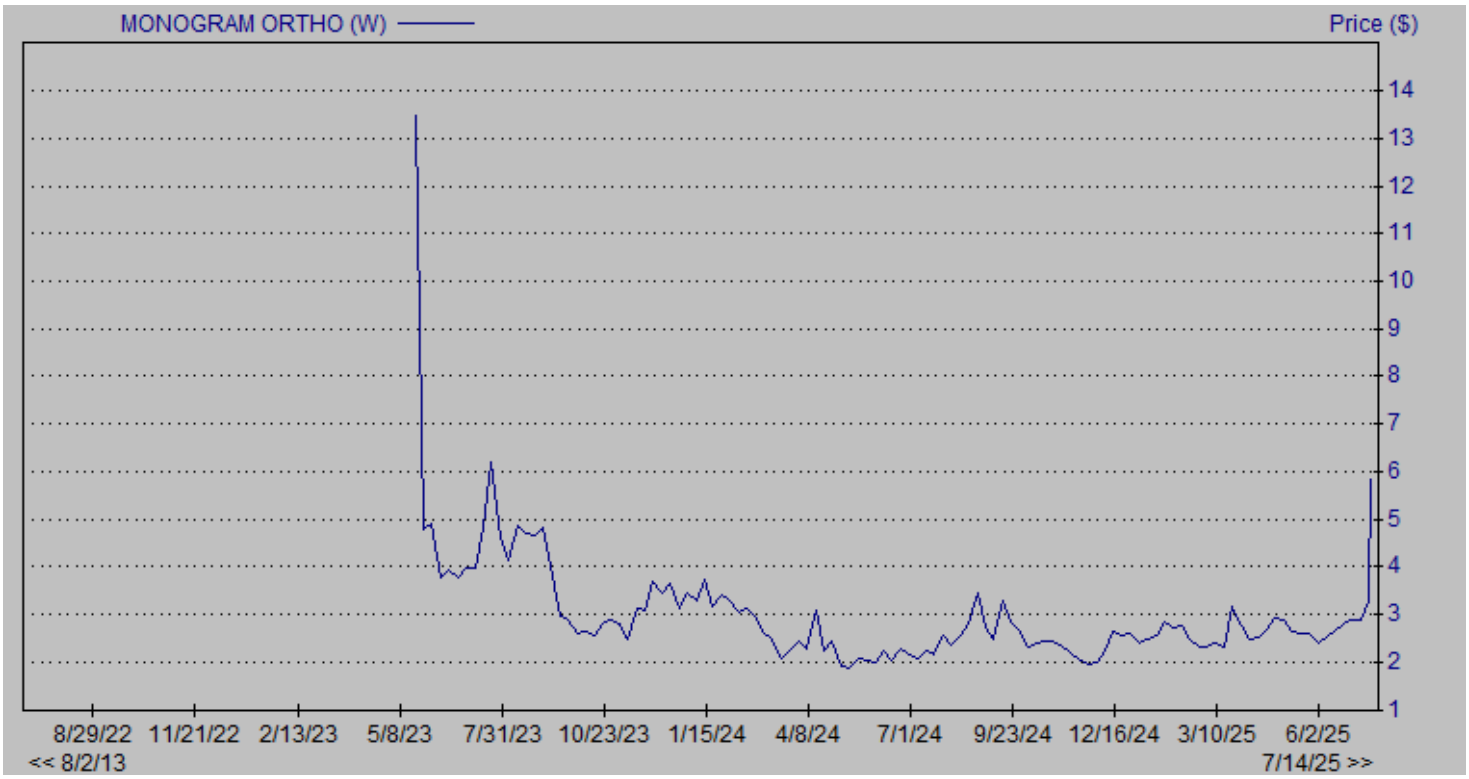
Source: monogramorthopedics.com

PROJECTED INCOME STATEMENT

Income Statement	Dec-22	Dec-23	Dec-24	Dec-25	Dec-26
Net Sales	**0**	**364,999**	**0**	**0**	**13,410,000**
Growth	-	-	-	-	-
Cost of Goods Sold	**0**	**0**	**0**	**0**	**5,536,000**
%	*N/A*	*0.0%*	*N/A*	*N/A*	*41.3%*
Depreciation	**176,686**	**0**	**0**	**0**	**0**
Gross Profit	**0**	**0**	**0**	**0**	**7,874,000**
Margin	*N/A*	*0.0%*	*N/A*	*N/A*	*58.7%*
Sales & Marketing Expenses	**2,743,687**	**2,994,389**	**2,108,000**	**469,000**	**703,500**
% of sales	*N/A*	*820.4%*	*N/A*	*N/A*	*5.2%*
General & Administrative Expenses	**2,308,064**	**4,052,775**	**4,412,000**	**3,678,000**	**3,126,300**
% of sales	-	*1110.4%*	-	-	*23.3%*
Research & Development	**5,174,710**	**10,173,884**	**8,360,000**	**8,995,654**	**7,000,000**
% of sales	-	*2787.4%*	-	-	*52.2%*
Amortization	**210,000**	**412,000**	**430,000**	**432,000**	**432,000**
% of sales	*N/A*	*112.9%*	*N/A*	*N/A*	*3.2%*
Operating Income	**(10,613,147)**	**(17,268,049)**	**(15,310,000)**	**(13,574,654)**	**(2,955,800)**
Margin	-	-	-	-	*-22.0%*
EBITDA	**(9,839,775)**	**(16,443,714)**	**(14,880,000)**	**(13,142,654)**	**(2,523,800)**
Margin	*N/A*	*-4505.1%*	*N/A*	*N/A*	*-18.8%*
Other Expenses/(Income)	**3,077,800**	**(3,522,812)**	**1,018,000**	**(465,247)**	**(4,970)**
%	*N/A*	*-965.2%*	*N/A*	*N/A*	*0.0%*
EBIT	**(13,690,947)**	**(13,745,237)**	**(16,328,000)**	**(13,109,407)**	**(2,950,830)**
%	*N/A*	*-3765.8%*	*N/A*	*N/A*	*-22.0%*
Total Interest Exp (net)	**0**	**0**	**0**	**0**	**0**
%	*N/A*	*0.0%*	*N/A*	*N/A*	*0.0%*
Net Profit Before Tax	**(13,690,947)**	**(13,745,237)**	**(16,328,000)**	**(13,109,407)**	**(2,950,830)**
%	*N/A*	*-3765.8%*	*N/A*	*N/A*	*-22.0%*
Income Tax	**0**	**0**	**0**	**0**	**(442,625)**
% Effective Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
% Cash Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Minority Interests	**0**	**0**	**151,000**	**804,000**	**804,000**
Net Profit	**(13,690,947)**	**(13,745,237)**	**(16,479,000)**	**(13,913,407)**	**(3,312,206)**
%	*N/A*	*-3765.8%*	*N/A*	*N/A*	*-24.7%*
Non-recurring income (expense)					
Average Diluted Shares Outstanding	9,673,870	22,409,222	32,571,470	35,510,827	35,510,827
Reported FD EPS					
Zacks Cash EPS	**(1.39)**	**(0.59)**	**(0.49)**	**(0.38)**	**(0.08)**
Zacks EPS	**(1.42)**	**(0.61)**	**(0.51)**	**(0.39)**	**(0.09)**

Source: Zacks analyst

HISTORICAL STOCK PRICE



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Tom Kerr, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.