March 13, 2025

Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

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

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Monogram Technologies (NASDAQ: MGRM)

MGRM: Monogram reported 4th quarter and full year 2024 financial and operating results which were largely in line with our expectations. FDA approval on its mBôs TKA robotic system could occur in 2025.

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 (3/12/25)	$2.32
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. The company delivered its first surgical robot in November 2023 and submitted its 510(k) on July 19th, 2024, and the application passed the Administrative Review. The first live in patient surgery OUS is expected in early 2025. The company has $15.7 million in cash after the recent equity offering. 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	**$4.90**
52-Week Low	**$1.53**
One-Year Return (%)	**-1.7**
Beta	**N/A**
Average Daily Volume (sh)	**48,643**
Shares Outstanding (mil)	**35.2**
Market Capitalization ($mil)	**$79.5**
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 E	$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 E	-$0.10 E	-$0.11 E	-$0.13 E	-$0.44 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

4th Quarter and Full Year 2024 Financial Results

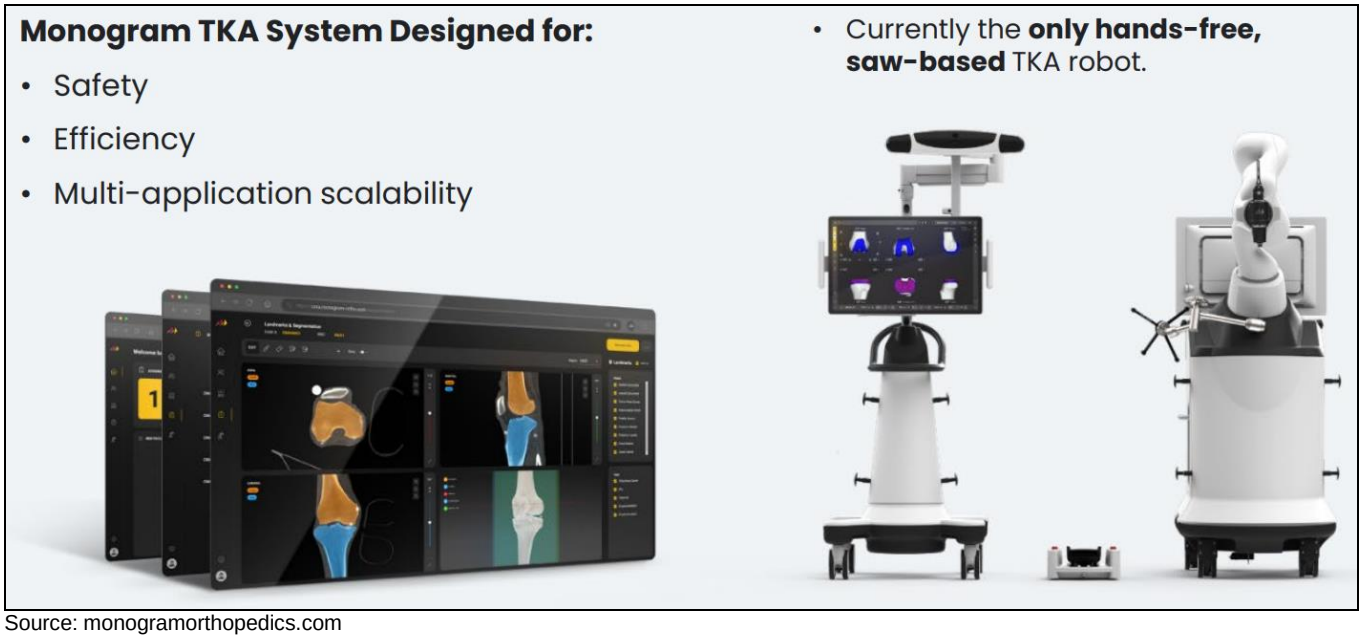
Monogram reported 4th quarter and full year 2024 financial results on March 12th which were largely in line with our expectations. Research and development expenses for 2024 were $8.8 million compared to $10.6 million in the prior year period. The R&D decrease was primarily due to the company moving 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.

General & administrative expenses in 2024 were $4.4 million, which was a slight increase from $4.1 million in 2023. Marketing and advertising expenses decreased to $2.1 million in the quarter compared to $3.0 million 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 full year was ($16.5) million compared to a net loss of ($13.7) million in the prior year. EPS was a loss of ($0.51) per share compared to a loss of ($0.61) per share in 2023. For 2024, operating cash flow was a use of cash of ($14.0) 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 $15.7 million as of December 31, 2024, compared to $13.6 million as of the end of 2023. In 2024, the company raised a total of $16.3 million in net proceeds from equity and preferred stock offerings. Net working capital was approximately $14.7 million and total stockholders' equity was $14.5 million.



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%-40% 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.

We adjust our 2025 revenue estimates to zero and our 2025 EPS to a loss of ($0.44) per share. This is a conservative estimate as it's possible that revenues can be generated in 2025 if FDA approval of its mBôs TKA System is received earlier than expected.

RECENT NEWS

Regulatory Update

On February 26, 2025, Monogram announced an update regarding its 510(k) premarket filing submission to the FDA for the company's mBôs TKA System. The company stated it had completed all supplemental testing and submitted its formal response to the Additional Information Request (AIR) by the FDA which was received in September 2024. There are no more submissions required at this time as the company awaits the FDA decision.

At this time, Monogram does not anticipate further requests for information from the FDA. Assuming a favorable decision by the FDA following receipt of the AIR, the next event is expected to be a clearance decision for the mBôs™ Total Knee Arthroplasty (TKA) System. If granted, that would enable the commercialization and marketing of the TKA system in the U.S.

Upon approval by the FDA, the company plans on enhancing components of the prototype before commercialization. Monogram continues to refine and enhance its next-generation technology in parallel with its regulatory and clinical trial preparations. The most significant advancement has been in the cutting system, which has facilitated an approximately 300% increase in feed rate. A video demonstrating these next-gen improvements can be found here.

Dr. Douglas Unis, Monogram's Chief Medical Officer, stated, *"The latest advancements in Monogram's robotic system are a game changer. The new cutting system enables cutting speeds that are becoming competitive with manual surgery while maintaining the accuracy and functionality expected from robotic-assisted procedures. The performance is truly remarkable for a completely hands-free, unconstrained autonomous system. With these improvements, we are on track to deliver one of the most impressive robotic solutions on the market today."*

Monogram remains focused on developing a multi-application robotic system that is time-competitive with manual surgery without compromising accuracy or safety. The company continues to refine its technology to improve system performance and usability as it progresses toward commercialization.

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. The company remains confident in its submission and the strength of its strategic partnerships with Reliance Life Sciences and Shalby to support the process.

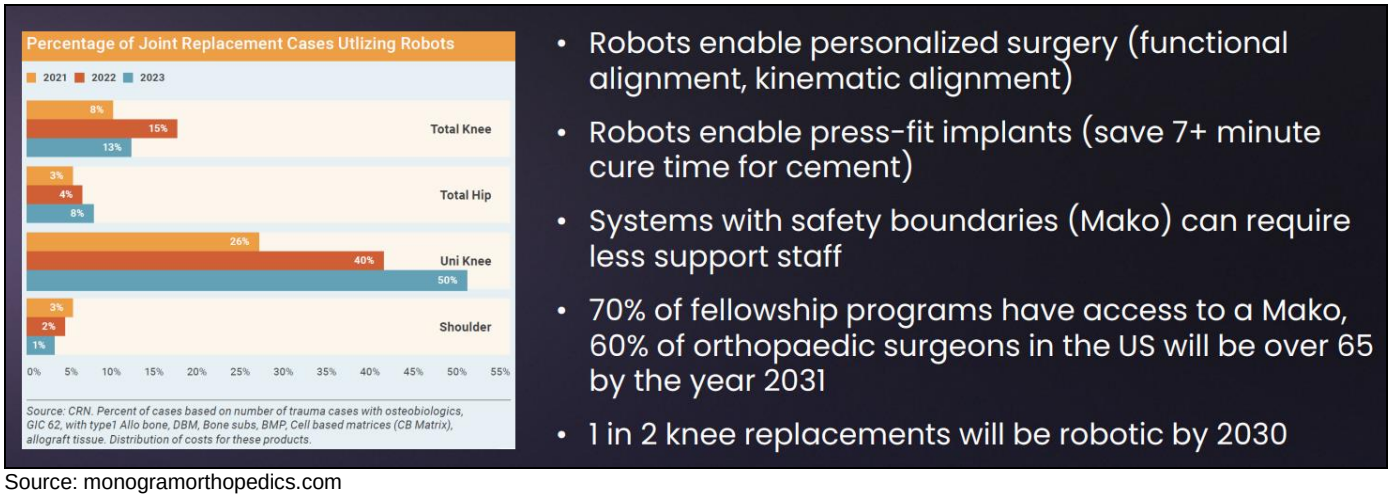
Dr. Ajaykumar Yadav, Group Head of Clinical Research at Reliance Life Sciences stated, *"The Investigator Meeting was a successful milestone in the preparation for Monogram's clinical trial. Bringing together key stakeholders, the meeting provided an opportunity for in-depth discussions on study protocols and a demonstration of the mBôs technology, reinforcing the collaborative approach to this clinical trial. Monogram has submitted a strong and comprehensive application, and we continue to support the regulatory process as expected. Reliance Life Sciences remains committed to advancing innovation in healthcare and looks forward to contributing to the successful execution of this study."*

Upon receiving clearance from Indian regulators, the company expects it will take 2-3 months before the first life patient surgery will occur.

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.

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.



Source: monogramorthopedics.com

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, including among other things, new technology development and potential acquisitions.

FDA Submission

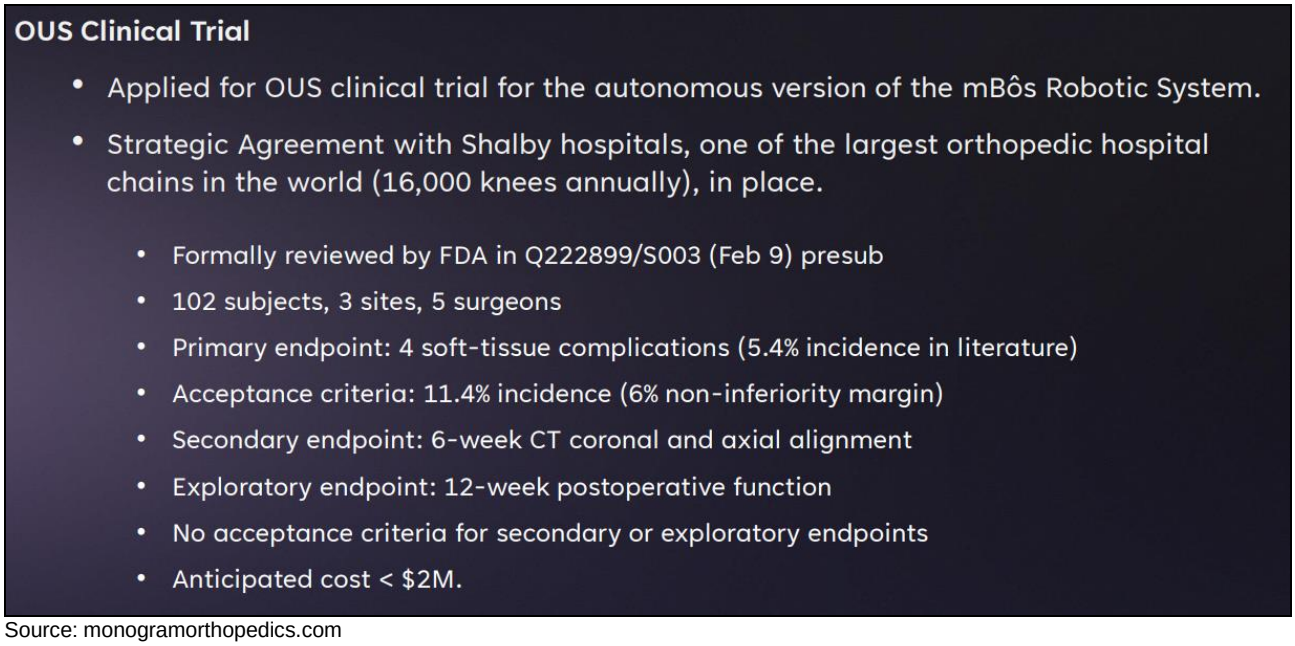
On August 8th, 2024 the company announced it had submitted its 510(k) application for its mBôs TKA System on July 19th to the FDA. According to MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027, for 510(k) submissions received in FY 2024, the average total time to decision goal for FDA and industry is 124 calendar days.

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.

CEO Ben Sexson stated, *"The 28,214-page submission is the culmination of over eight years and thousands of hours, comprising verification and validation from numerous, extremely rigorous tests including simulated cadaveric surgeries by fifteen surgeons. This FDA submission for the mBôs TKA System represents a significant milestone for Monogram in our journey to improve human health with our precision robotic surgical system and should be an essential catalyst for institutional engagement."*

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. Notably, the strategic collaboration contemplates the post-trial transfer of a robot to the hospital system under certain conditions following the trial as the companies contemplate further collaboration.

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

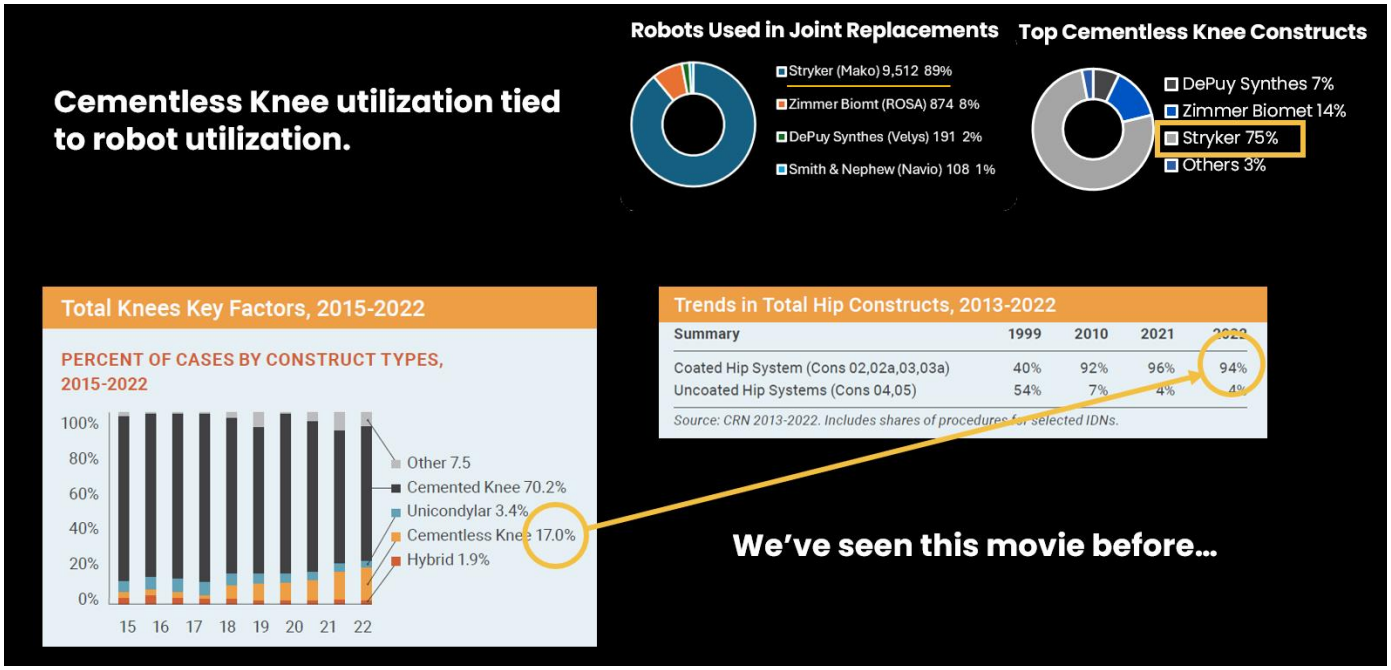
- Monogram Technologies (NASDAQ: MGRM) is a medical device company developing a product solution architecture to enable patient-optimized orthopedic implants at scale by linking 3D printing and robotics with advanced pre-operative imaging. Monogram intends to produce and market robotic surgical equipment 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 response was sent to the FDA in the 1st quarter of 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.

- Monogram currently has no revenues at this time and research & development expenses in 2024 were $8.4 million. The company has $15.7 million in cash as of12/31/24 and working capital of $14.7 million. The company raised approximately $11.7 million in cash from an equity offering in the 3rd quarter of 2024. It's possible that the company can commercialize its robotic system in 2025.

- We believe MGRM stock is worth **$6.00** based on a conservative discounted cash flow (DCF) calculation and peer multiple comparisons.

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)

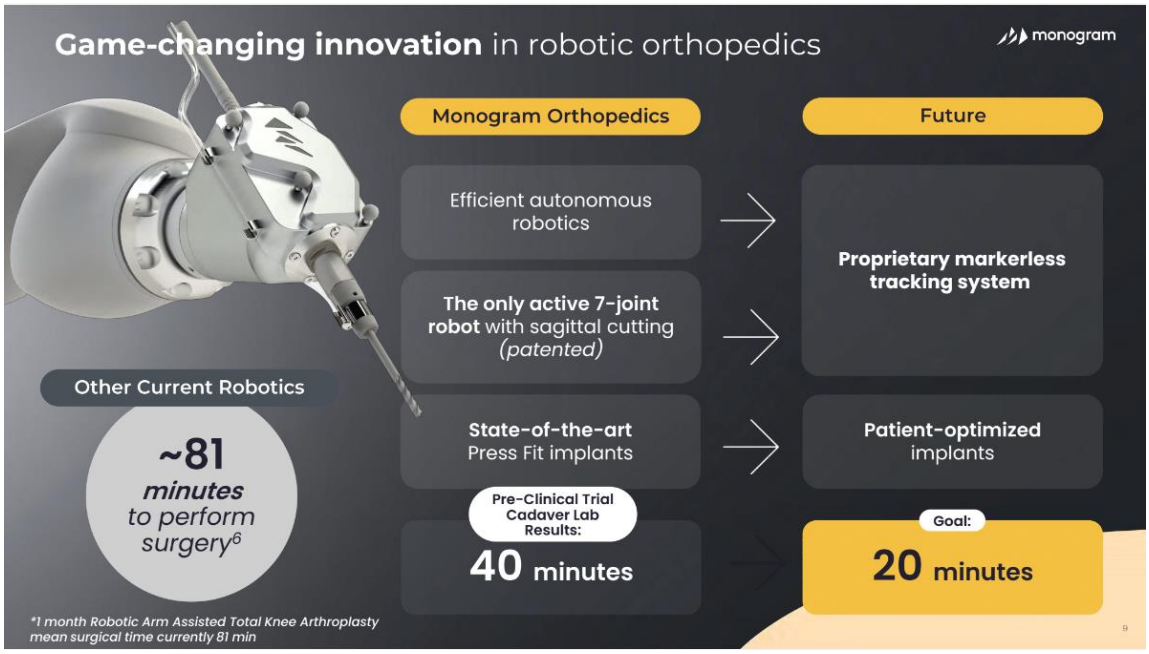
Robotic System

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).

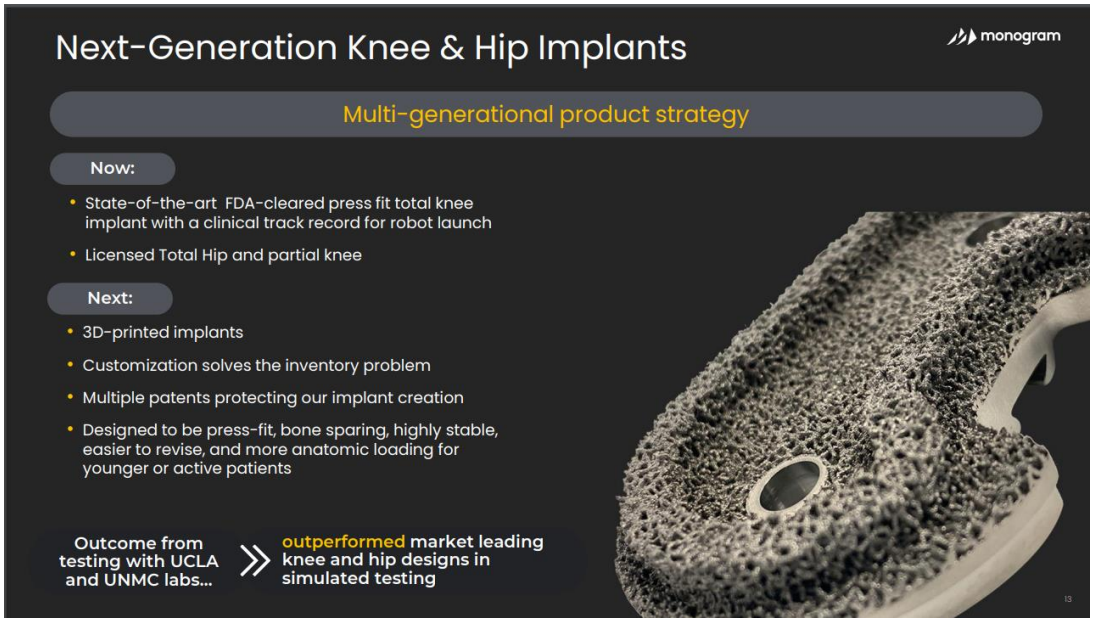


Source: monogramorthopedics.com

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.

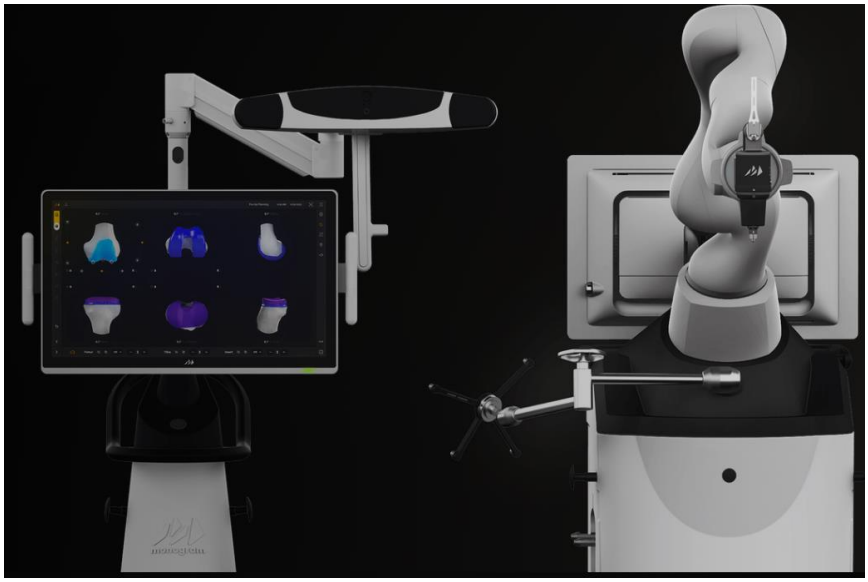
PRODUCT STRATEGY & OBJECTIVES

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

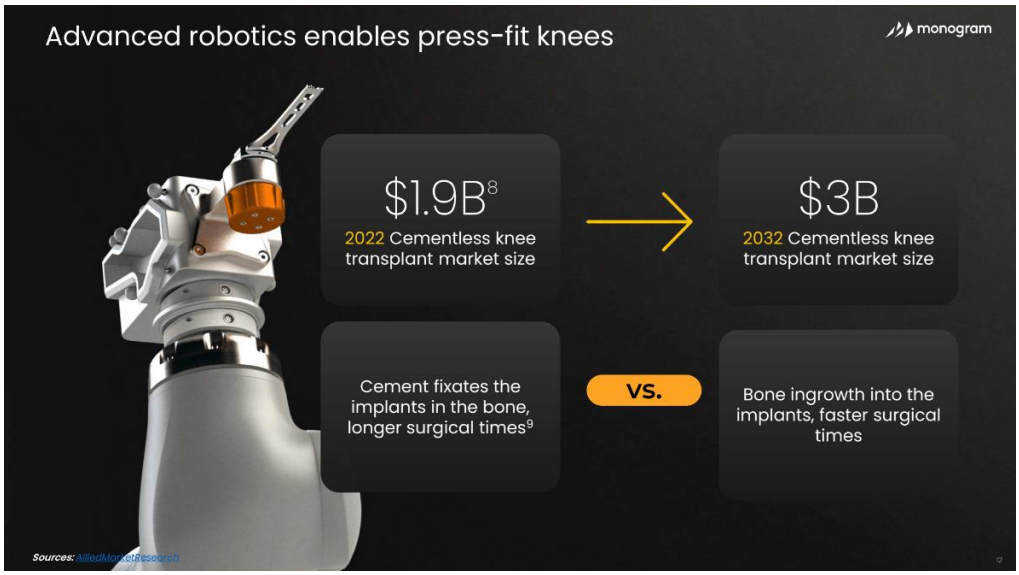
that may be optimized for time to surgically prepare the corresponding bone for the high-precision placement of the implants.

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.



Source: monogramorthopedics.com

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. The testing will likely include benchtop comparisons with implants that may represent the existing standard of care as a benchmark to demonstrate that the company's implants' initial stability shows less micromotion than their generic counterparts.

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. It is important to prove the stability of the entire system over a range of scenarios and under rigorous use.

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.

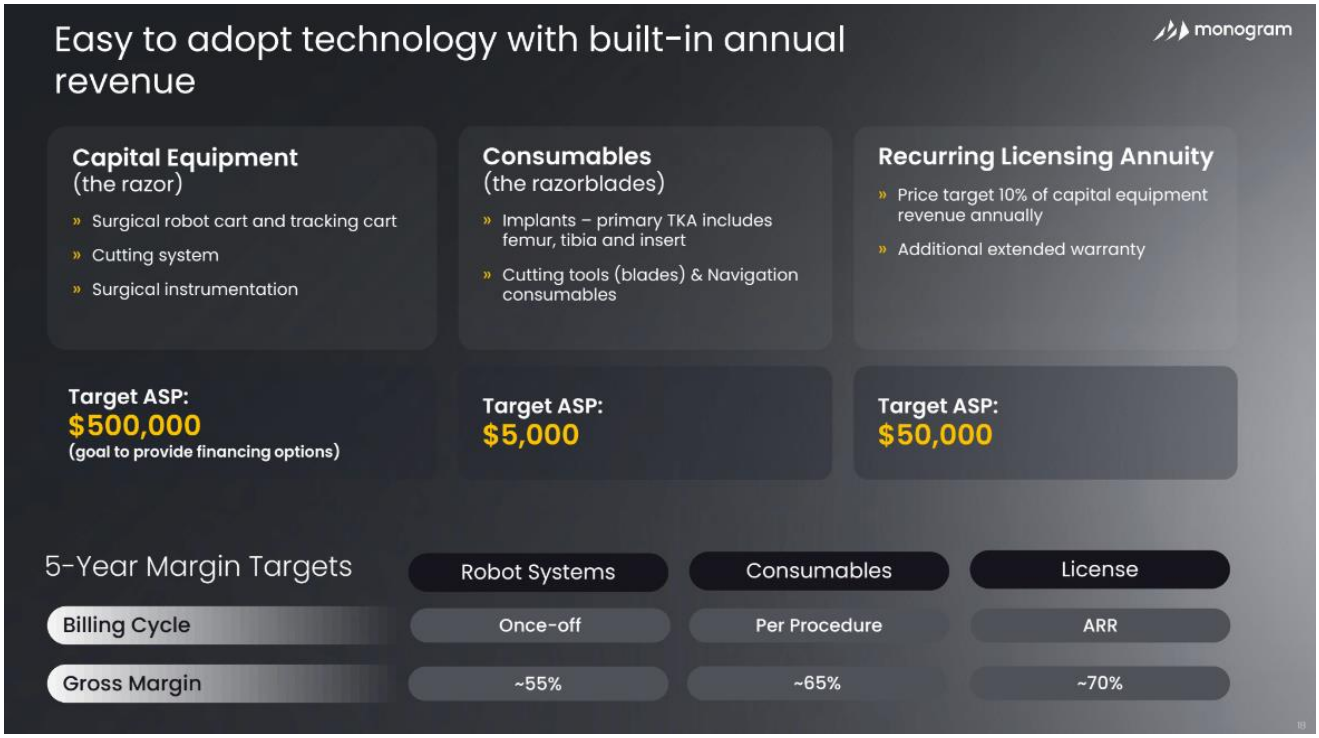
SUMMARY

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 billion by 2030 due to an aging population. Just achieving minimal levels of market share would produce significant revenues for the company.

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.

We believe our multiple valuation methods support our DCF valuation which provides a target price of **$6.00** per share.



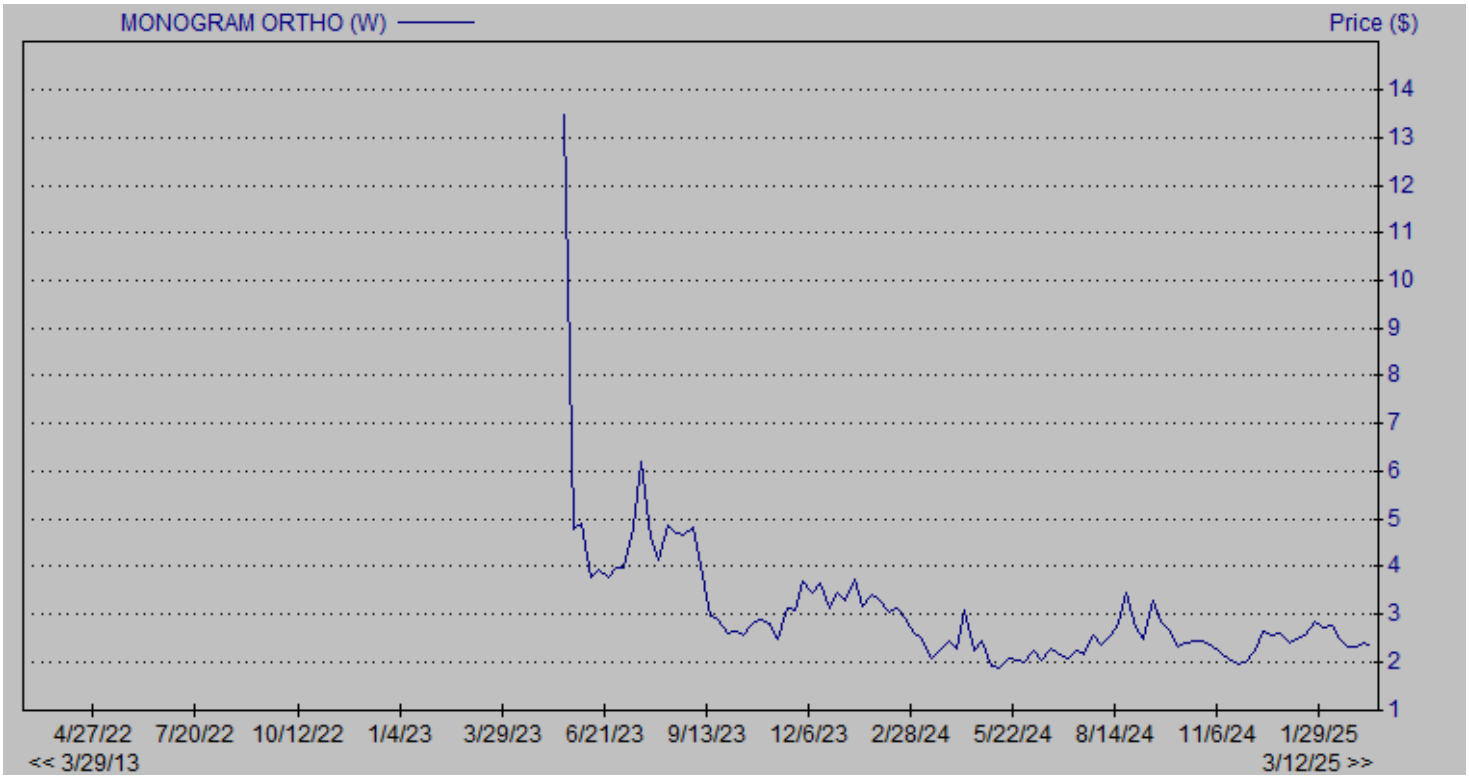
Source: monogramorthopedics.com

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**	**2,635,000**	**3,952,500**
% of sales	*N/A*	*820.4%*	*N/A*	*N/A*	*29.5%*
General & Administrative Expenses	**2,308,064**	**4,052,775**	**4,412,000**	**3,750,200**	**3,187,670**
% of sales	-	*1110.4%*	-	-	*23.8%*
Research & Development	**5,174,710**	**10,173,884**	**8,360,000**	**9,151,000**	**7,000,000**
% of sales	-	*2787.4%*	-	-	*52.2%*
Amortization	**210,000**	**412,000**	**430,000**	**430,000**	**430,000**
% of sales	*N/A*	*112.9%*	*N/A*	*N/A*	*3.2%*
Operating Income	**(10,613,147)**	**(17,268,049)**	**(15,310,000)**	**(15,536,200)**	**(6,266,170)**
Margin	-	-	-	-	*-46.7%*
EBITDA	**(9,839,775)**	**(16,443,714)**	**(14,880,000)**	**(15,106,200)**	**(5,836,170)**
Margin	*N/A*	*-4505.1%*	*N/A*	*N/A*	*-43.5%*
Other Expenses/(Income)	**3,077,800**	**(3,522,812)**	**1,018,000**	**(300,000)**	**7,844**
%	*N/A*	*-965.2%*	*N/A*	*N/A*	*0.1%*
EBIT	**(13,690,947)**	**(13,745,237)**	**(16,328,000)**	**(15,236,200)**	**(6,274,014)**
%	*N/A*	*-3765.8%*	*N/A*	*N/A*	*-46.8%*
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)**	**(15,236,200)**	**(6,274,014)**
%	*N/A*	*-3765.8%*	*N/A*	*N/A*	*-46.8%*
Income Tax	**0**	**0**	**0**	**0**	**(941,102)**
% 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**	**151,000**	**151,000**
Net Profit	**(13,690,947)**	**(13,745,237)**	**(16,479,000)**	**(15,387,200)**	**(5,483,911)**
%	*N/A*	*-3765.8%*	*N/A*	*N/A*	*-40.9%*
Non-recurring income (expense)					
Average Diluted Shares Outstanding	9,673,870	22,409,222	32,571,470	35,289,000	35,289,000
Reported FD EPS					
Zacks Cash EPS	**(1.39)**	**(0.59)**	**(0.49)**	**(0.42)**	**(0.14)**
Zacks EPS	**(1.42)**	**(0.61)**	**(0.51)**	**(0.44)**	**(0.16)**

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.