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Zacks Small-Cap Research

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Monogram Technologies (NASDAQ: MGRM)

MGRM: Monogram reports 1st quarter 2024 financial results and provided updates on the development of its mBôs Total Knee Arthroplasty (TKA) System.

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 (6/17/24)	$2.05
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, will market its solutions to international markets in 2024, and anticipates 510(k) submission in the second half of 2024.The company has $10.1 million in cash, and we believe the company will be funded throughout 2024. 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	**$6.55**
52-Week Low	**$1.53**
One-Year Return (%)	**-46.5**
Beta	**N/A**
Average Daily Volume (sh)	**242,066**
Shares Outstanding (mil)	**31.6**
Market Capitalization ($mil)	**$67.5**
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 E	$0.00 E	$0.00 E	$0.00 E
2025					$5.70 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	-$0.09 E	-$0.10 E	-$0.10 E	-$0.40 E
2025					-$0.46 E

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

WHAT'S NEW

1st Quarter 2024 Financial Results

Monogram reported 1st quarter 2024 results on May 14th which were largely in line with expectations. Research and development expenses for the quarter ending March 31, 2024, were $2.4 million compared to $1.9 million in the prior year period. The R&D increase was primarily due to the company moving into the verification and validation phase of its robot prototype. This phase is expected to be mostly complete in the 1st half of 2024. Also contributing to R&D expense was the introduction of mVision technology during the quarter.

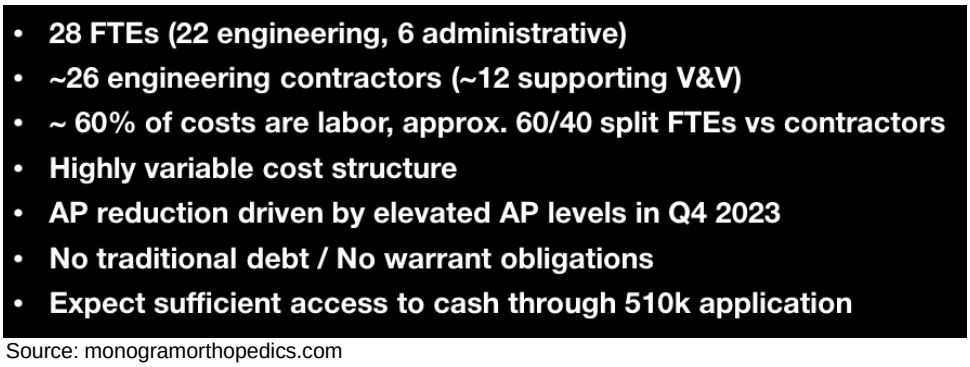
General & administrative expenses for the 1st quarter were $1.1 million compared to $0.8 million in the prior year period. The increase was primarily due to increases in consulting fees, insurance and regulatory compliance and professional fees. Marketing and advertising expenses decreased to $119,694 in the quarter compared to $1.1 million in the prior year period. The company incurred a high level of marketing and advertising expenses in the 1st quarter of 2023 which were related to its common stock offering in May 2023.

Net loss for the quarter was ($3.5) million compared to a net loss of ($3.9) million in the prior year quarter. Operating cash flow was a use of cash of ($3.6) million. We expect the monthly burn rate to be approximately $1.0 million for the remainder of 2024.

Cash and cash equivalents totaled $10.1 million as of March 31, 2024, compared to $13.6 million as of the end of 2023. Working capital was approximately $8.7 million and total stockholders' equity was $10.2 million. The company plans to continue to try to raise additional capital through available financing options which may include equity and/or debt offerings, as well as straight or convertible debt financings.

Upcoming 2024 Milestones

- The company expects to largely complete mBôs system verification and validation process in the 1st half of 2024.
- The company then plans to submit its 510(k) application to FDA at some point in the 2nd half of 2024. The time frame for FDA clearance and the commencement of commercialization of the system in the U.S. could be in the 6-9 month range following submissions.
- The company has previously announced progress towards Outside the United States (OUS) live-patient clinic surgery trials for its platform (see below).
- The company hopes to expand its international relationships in the form of partnerships and other collaborations.



Source: monogramorthopedics.com

Contract Research Organization Hire for OUS Clinical Trial

On May 13, 2024, the company announced it had engaged a global Contract Research Organization (CRO) to oversee its clinical trial activities for its mBôs Total Knee Arthroplasty (TKA) system and to represent its submission to the local regulators outside of the U.S.. The international CRO has extensive experience and successful FDA submissions from clinical investigations conducted Outside the United States (OUS).

Ben Sexson, Chief Executive Officer of Monogram stated, *"Partnering with a CRO expands our capabilities and will accelerate our product pipeline for the next-gen mBôs system. We were encouraged by the recent formal FDA feedback on the clinical trial protocol and verification plan. After integrating FDA feedback and finalizing the application, our partners at the CRO will submit it to the local regulators. We continue to expect verification and validation to be largely complete in H1 2024, with a planned FDA 510(k) submission in H2 2024. We plan to leverage the clinical data from the OUS study for post-launch marketing and to support international clearance and commercialization."*

Currently, the company is targeting approximately 100 TKA surgeries at three sites with three months of follow-up and a 25% reduction in safety event rates. This strategy could save the company significant costs and time, estimated at $1.5 million for the trial. Monogram intends to conduct the multi-center Total Knee Arthroplasty clinical trial with the mBôs TKA System using the cemented version of its FDA-cleared mPress TKA implant. The company anticipates that once approved, the centers will have sufficient volume to complete enrollment and study execution expeditiously.

Monogram developed the clinical trial study design considering FDA guidance and regulations for clinical investigations conducted outside the U.S. Good clinical practice (GCP) guidelines will be followed, including review and approval by an independent ethics committee (IEC) and informed consent from subjects. The clinical trial will be conducted to meet the FDA and local regulatory requirements on research with human subjects, Health and Human Services (DHHS) Regulations on research with human subjects, ISO 14155:2011, and ICH's Good Clinical Practices (GCP) guidelines.

While the clinical study is focused primarily on providing safety data, the Investigators may also collect additional data that could be helpful for post-launch marketing. Such data could include detailed accuracy studies (for example, physical measurements of bone cuts and post-operative laxity gaps) and time studies that researchers could correlate to surgical time and learning curve. The OUS clinical trial protocol is expected to take six weeks to three months.

Sexson also stated, *"The Company continues to see a significant and growing market opportunity for an active cutting robotic system that does not utilize haptic controls. We believe that press fit knee adoption and robot utilization go hand in hand. The IP landscape has created interesting dynamics in orthopedics. We continue to believe there is a significant and growing opportunity for a next-generation active cutting robot that can efficiently resect bone. An OUS clinical pipeline will be helpful for Monogram to try and capitalize on any potential market product gaps."*

Regulatory Update

On April 19, 2024, Monogram received written feedback from the FDA regarding the company's 1st quarter 2023 pre-submission request. Monogram then conducted a teleconference meeting with the FDA on April 24, 2024 to discuss the written feedback further and obtain feedback on the Monogram mBôs™ TKA System verification test plan, which includes a proposed clinical trial protocol on an OUS target population. Management believes the feedback was comprehensive and will be advantageous for preparing a successful 510(k) submission to obtain clearance.

The company shared with the FDA various test protocols essential for establishing the safety and effectiveness of the Monogram mBôs™ TKA System. The company also shared a synopsis of its proposed OUS clinical investigation plan with the FDA.

Based on the feedback, management assessed that:

1) the proposed testing plan generally appears acceptable to address the technical differences identified with the proposed predicate device; and

2) a clinical testing plan that includes approximately 100 knee surgeries conducted on an OUS population at three sites with three months of follow-up should generally be sufficient for evaluating the safety and effectiveness of the Monogram mBôs™ TKA System.

The FDA indicated they support a least burdensome approach to acquiring clinical data. The planned OUS clinical trial could save the company significant cost and time. As noted above, management estimates the cost to run an OUS clinical trial as proposed to be approximately $1.5 million. On March 21, 2024, the company announced that it had modified the Monogram mBôs™ TKA System to reduce the likelihood of an FDA clinical data request with its submission. The OUS clinical trial protocol is expected to take six weeks to three months.

The company believes its verification and validation testing will be largely completed in the 2nd quarter of 2024 and anticipates a 510(k) submission to follow in the 2nd half of 2024. The company's plan to aggressively accelerate 510(k) submission for its mBôs surgical system with design modifications (Semi-Active) that management believes reduce the risk of a clinical trial is on track. The protocol testing process, which requires cadaveric procedure testing performed by 15 separate, independent, orthopedic surgeons, is a major part of the Verification and Validation process required for the 510(k) submission. To date, the company has successfully completed 6 of 15 surgeries.

Rebranding Initiative

On May 14, 2024, the company announced its plan to merge its wholly owned subsidiary, Monogram Technologies Inc. (MT) into Monogram Orthopaedics Inc. With this upstream merger, the current MT will cease to exist, and Monogram's business will continue as it is currently being conducted. In addition, on May 15, 2024, the effective date of the merger, the company changed its name to Monogram Technologies Inc., and its ticker will remain "MGRM."

Benjamin Sexson, CEO of Monogram stated, *"Our new name, Monogram Technologies, reflects our continued evolution since 2016 to become the AI-driven robotics company we are today and the broadening applications for our technology long term. As we progress on our accelerated path toward a 510(k) submission this year for our Monogram mBôs™ TKA System robotic surgical system and continue development of mVision navigation, we anticipate there will be other clinical and commercial applications that could leverage our disruptive technology. As Monogram Technologies, we are dedicated to improving human health through innovation. We have built a robust IP moat around our active robotics that differentiates Monogram within the orthopedic market and positions us for growth, and we remain focused on generating long-term value for our shareholders."*

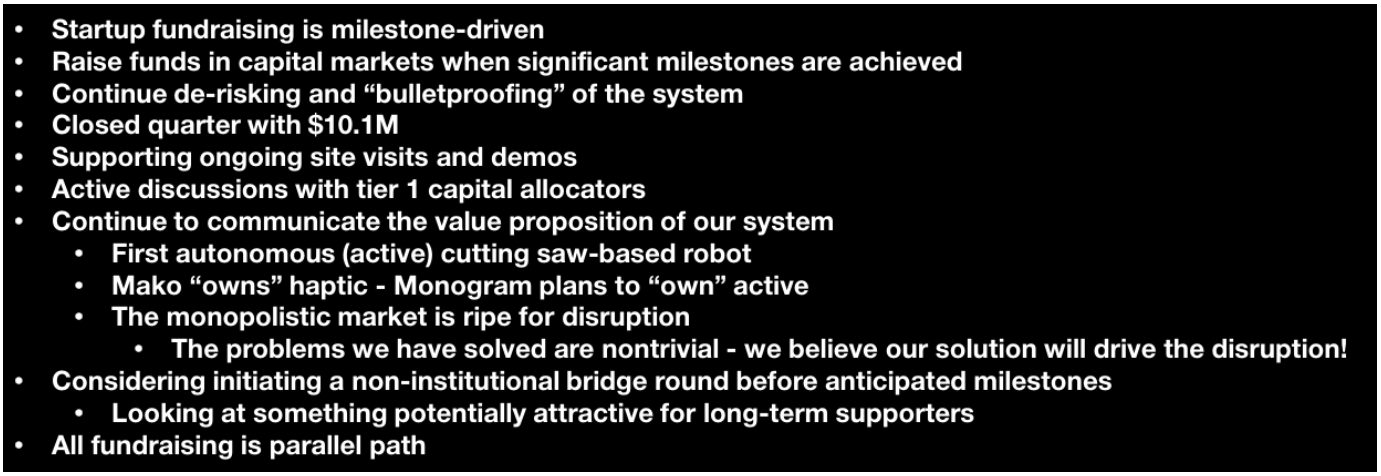
Valuation and Estimates

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.

Our 2024 full year EPS estimate is a loss of ($0.40) and for 2025, the EPS estimate is ($0.46). We are conservative in our approach to revenue projections and expect no revenues in 2024 and $5.7 million for 2025.

A peer group of companies (SYK, ZBH, SNN) are currently trading at approximately 4.25x sales on average, with the closest robotic competitor being SYK at 6.15x. This would create a relative value in the range of $4.75-$5.00 using Monogram's estimated 2027 revenues and discounted back. Using Monogram's closest competitor's price/sales ratio, a long-term relative target value would be closer to $6.00.



Source: monogramorthopedics.com

KEY INVESTMENT POINTS

Source: monogramorthopedics.com

- 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.

- 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 speed up the surgery and reduce barriers to adoption by completely eliminating point sampling based registration and navigation with large arrays.

- 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 faster and more intuitive to use.

- The company expects to largely complete its verification and validation testing in the first half of 2024 and submit the 510(k) to the FDA for clearance in the second half of 2024. In parallel, it is preparing for an OUS (Outside of the United States) clinical trial as added insurance for the 510(k) submission and for its planned OUS launch. The company recently announced the accelerated 510(k) submission timeline based on technical updates that the company indicated further improved the safety profile and device equivalence to predicates. With the company currently trading near replacement cost we suspect this development may not be fully priced into the stock.

- 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 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 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.

- 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 currently has minimal revenues at this time and research & development expenses in the 1st quarter of 2024 were $2.4 million. The company has $10.1 million in cash as of 3/31/24 and working capital of $8.7 million. The company expects to fully commercialize in early 2025.

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

OVERVIEW

Source: monogramorthopedics.com

Monogram Technologies is developing a novel product solution architecture with the long-term goal of enabling patient-optimized orthopedic implants economically at scale by linking 3D printing and robotics with advanced pre-operative imaging. The company has developed a robot it calls mBôs that can autonomously execute optimized paths for high precision insertion of implants in simulated cadaveric surgeries. The company has an FDA cleared line of press-fit implants it calls mPress. Monogram intends to produce and market robotic surgical equipment and related software, orthopedic implants, tissue ablation tools, navigation consumables, and other instrumentation tools necessary for automated reconstructive joint replacement procedures.

The company has not yet made 510(k) premarket notification submissions or obtained 510(k) premarket clearances for any of its products but is expected to do so in calendar year 2024. FDA 510(k) premarket clearance is required to market these products in the U.S. However, in parallel to its US submission, the company expects to conduct clinical trials in OUS markets in the latter half of 2024 and fully market its products in early 2025.

The company's business model and philosophy are based on ideas formulated by Dr. Douglas Unis, an Associate Professor of Orthopedic Surgery at the Icahn School of Medicine at Mount Sinai in New York City. The company's founding philosophy is that advances in technology will bring in a new way of thinking about reconstructive joint procedures and orthopedic implants. The company believes the future of orthopedic joint replacements lies in build-to-order, press-fit patient-optimized implants that rely on natural biologic fixation rather than the current method of cementation. The company believes such implants will be insertable into bone cavities prepared by high-precision robotic tools. The CT-based robotic preparation will make it easier to perform challenging surgical techniques such as kinematic alignment for total knee arthroplasty (TKA).

Advanced imaging is an integral part of this integrated robotic system. CT scans or MRIs are required to prepare the surgical plans and execute the robotic procedures for patient-optimized implants. Patient-optimized implants may require high-precision bone preparation beyond two-dimensional planar cuts or personalized alignment. For these processes to be economically scalable, they may need a high degree of optimization, which may require a high-functioning navigated surgical robot capable of executing complex cut paths. This would involve a product solution architecture with image processing, scalable, patient-optimized implant design, pre-operative planning, and robotic execution.

The company's FDA cleared press fit mPress line of implants and future 3D printed patient-optimized implants under development rely on biologic fixation and may prove to be clinically superior over time while also alleviating the large inventory burden and capital inefficiencies of generic implant distribution. A typical joint replacement facility could have tens or even hundreds of thousands of dollars in existing inventory to accommodate various sizes and shapes of the joint needed for the patient. The company believes a personalized one-implant per patent model makes more economic sense. Ideally, implants should be designed and optimized to fit and restore a patient's anatomy and that the ability of a robot to execute irregular cuts could exceed the capabilities of most skilled surgeons. Monogram believes that the use of 3D printed, patient-specific implants and robotic surgery could reduce complications and failure rates and lower overall costs considerably. This process also has the potential to lower the incidence of iatrogenic injury or readmissions which may in turn lower malpractice and insurance costs for doctors.

In 2022, in the US there were approximately one million primary knee replacement procedures and 581 thousand primary hip replacements, and those numbers are expected to increase at mid-single digit rates for the foreseeable future due to an aging population.

The company has $10.1 million in cash as of 3/31/24 and working capital of $8.7 million. We believe the company is funded to support operations through the submission of its 510(k). The company went public in May 2023 and currently has a market capitalization of $67 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 a 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 (includes femur, tibia, insert and patella)

Robotic System

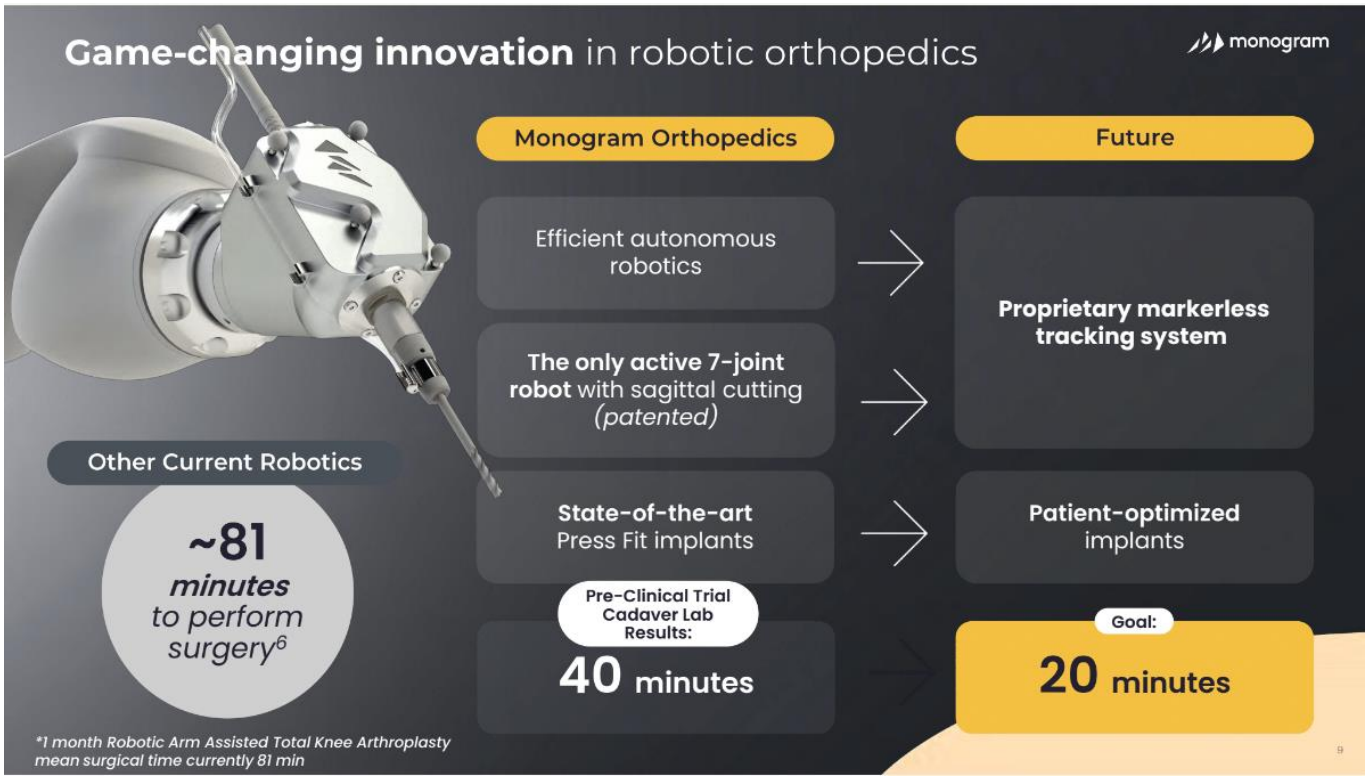
The Monogram robotic system and related hardware (end-effector) will be multi-use capital equipment and branded under the name mBôs. The company's pre-operative planning software, robotic controls, and intra-operative software are needed to use the robotic system properly. This software will be subject 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). The company's ambitious long-term goal is to try and reduce robotic surgical time that time to 20 minutes.

The mBôs is currently in the verification phase of the development process. Verification testing generally involves extensive safety testing by a multitude of medical experts and physicians. The verification and validation of this process is an important part of a 510(k) submission. The company expects to largely complete this process in the 2nd quarter of 2024 and subsequently submit the 510(k) for FDA clearance.



Source: monogramorthopedics.com

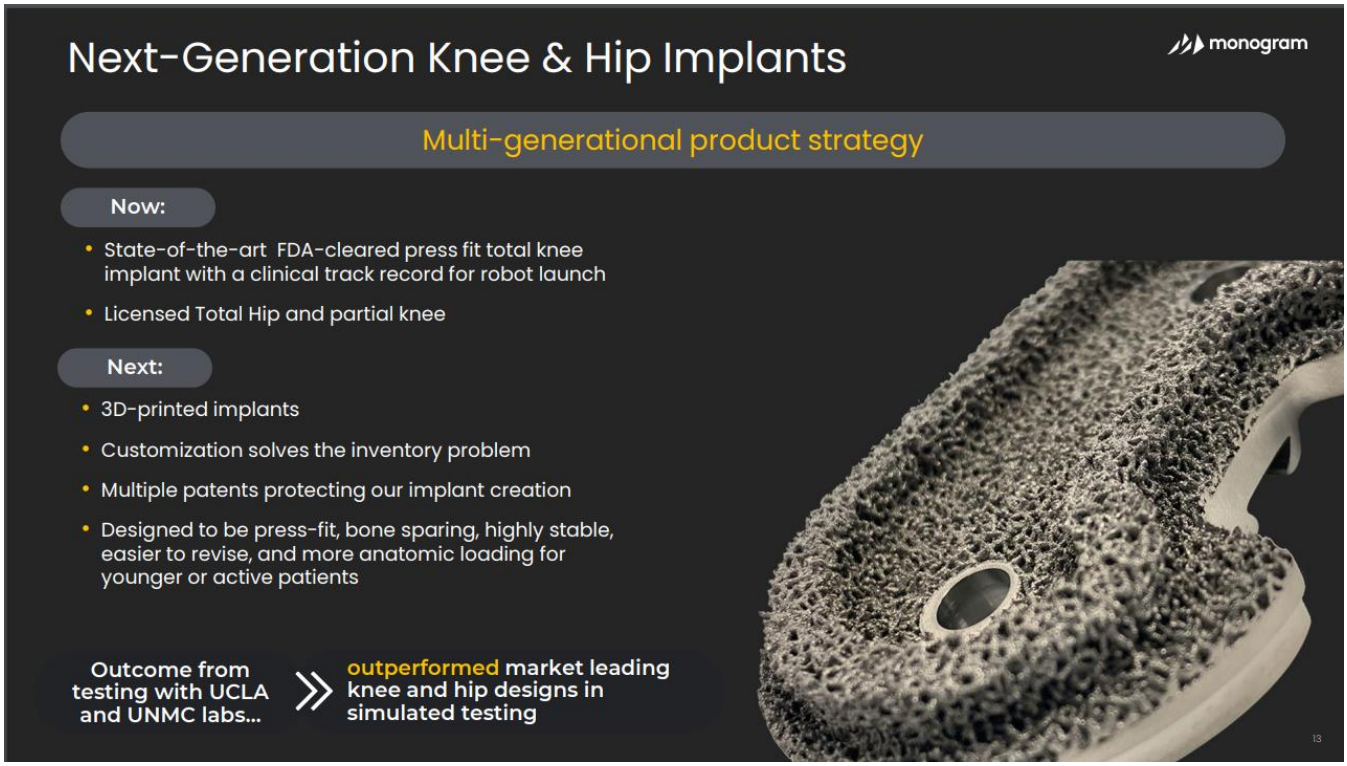
On November 28, 2023, the company delivered its first surgical robot to one of the world's largest global robotics distributors. CEO Ben Sexson stated*, "Delivering our first robot and realizing our first commercial revenues validates our technology and represents a pivotal milestone for our strategic roadmap. Our system is performing at an extremely high level. We now look forward to seeing how our robot competes and scales in the real world. We hope to see the mBôs robot contribute to advancing the standard of care for orthopedic patients worldwide."*

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. This is what drives the synergy of robotics with press-fit implants.

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. For example, surgeons may need to remove implants that become infected. The company is working on developing highly stable implants that surgeons can easily remove in a revision without causing significant damage to the remaining bone.

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.

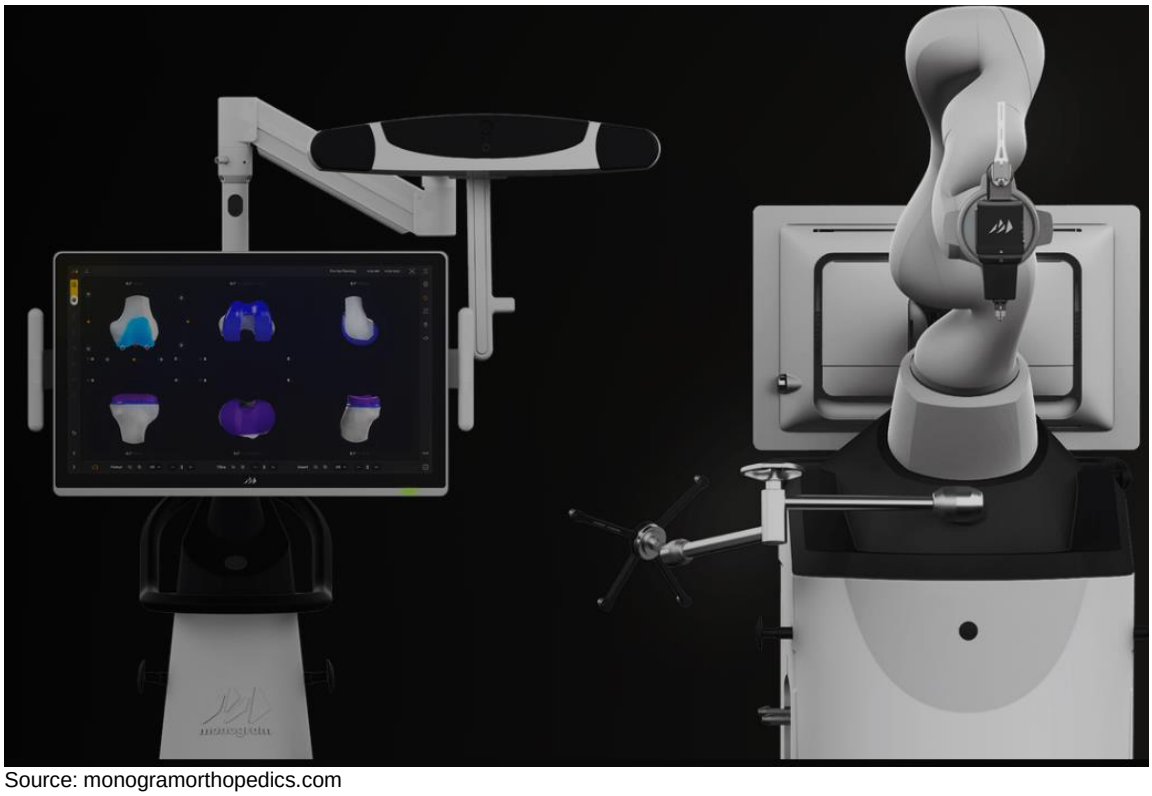
PRODUCT STRATEGY & OBJECTIVES

Monogram's vision is to create "the most effortless surgical system in the world." The company plans to commercialize its a 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.

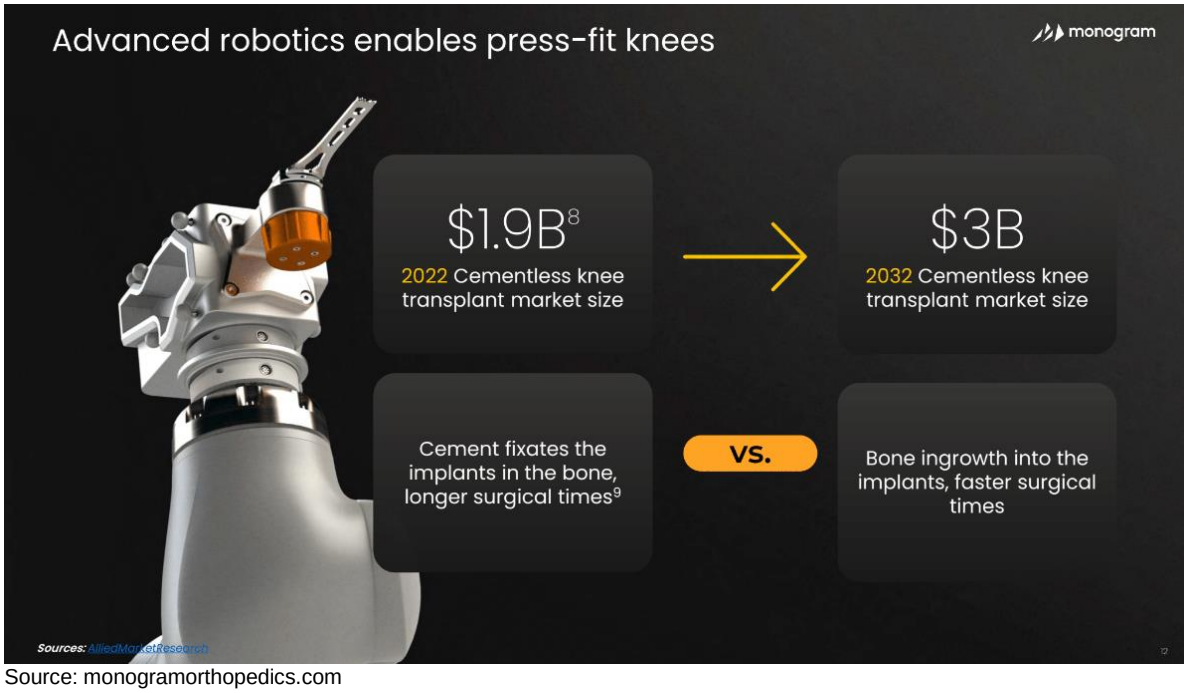
The Monogram technology platform consists of a workflow to prepare a patient-specific surgical plan from a CT scan. The CT scan images are pre-processed by proprietary algorithms using artificial intelligence and machine learning to automatically segment the bone from the images, identify the anatomy 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 is also trying to reduce the time to complete the surgery without compromising the accuracy of execution. 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



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. This would reduce the initial complexity of the development. 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.

COMPETITION

Monogram has competition from larger, well-established companies in the medical device industry and specifically in the orthopedic medical device industry. The top four market participants in the joint replacement devices market are Zimmer Biomet Holdings (ZBH), DePuy Orthopedics, a Johnson & Johnson (JNJ) company, Stryker Corporation (SYK), and Smith & Nephew (SNN). Notably Stryker is the dominant player in robotically press fit robotic knees with approximately 75% market share.

These companies, as well as other companies like privately held ConforMIS, offer implant solutions, including a combination of conventional instruments and generic implants, robotics and generic implants, or patient-specific instruments ("PSI") and cemented patient-specific implants for use in conventional total and partial orthopedic replacement surgeries.

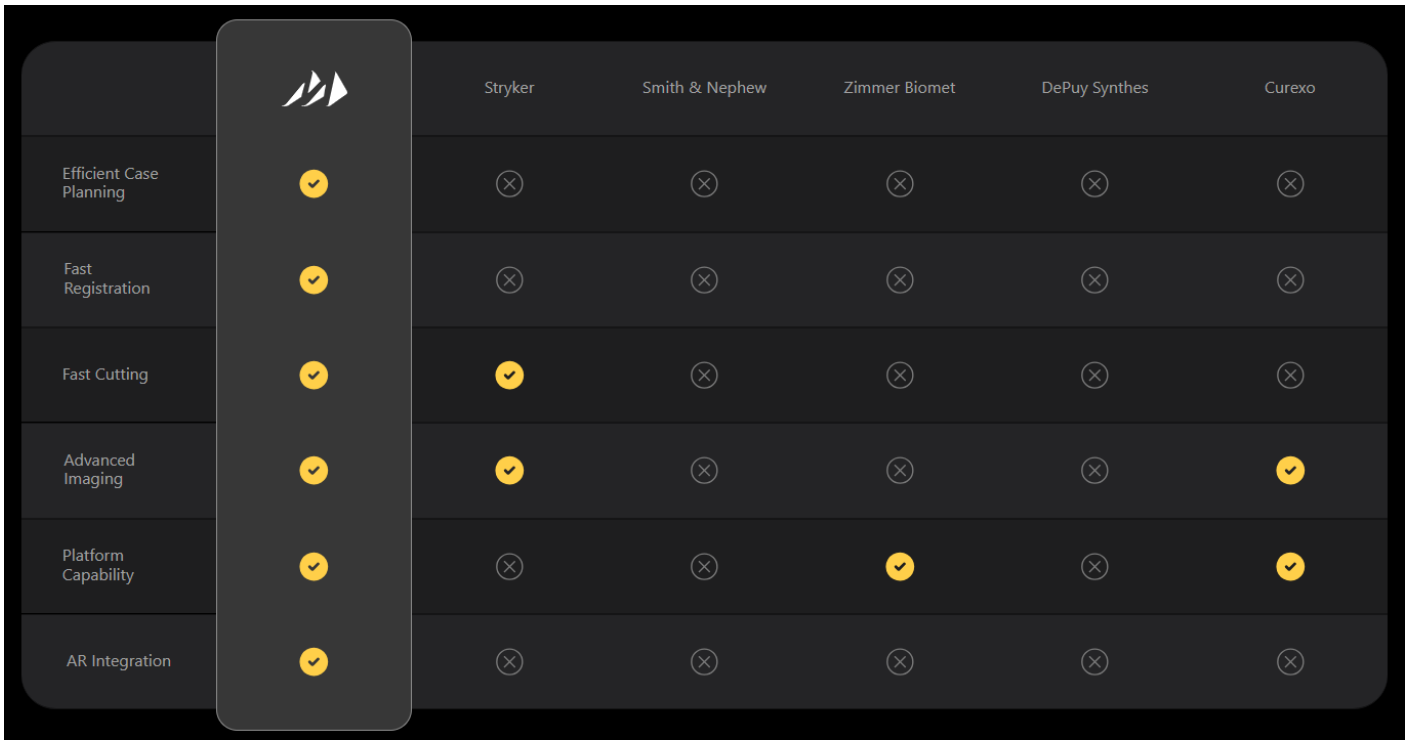
The current estimated market share by the leading participants for joint replacements is:

1. Zimmer Biomet	25.8%
2. Stryker	21.1%
3. DePuy Synthes	16.2%
4. Smith+Nephew	7.8%
5. All Others	29.1%

Relevant technical considerations for the evaluation of orthopedic surgical robotics include:

- The use of advanced imaging for pre-operative planning. The Mako Robot from Stryker uses a CT scan to develop the pre-operative plan.
- The degrees of freedom of the robotic system. Monogram is working to commercialize a seven degree-of-freedom robotic arm.

- The use of a cutting end-effector. Some robotic systems do not utilize cutting end effectors but robotically position jigs that constrain the manual instrumentation used to execute the cutting.
- The use types of cutters. Some robotic systems use rotary tools while others use a sagittal saw. Each type of cutter has distinct advantages and disadvantages.
- The execution of the surgical plan. Some robotic systems require the user to initiate the cutting and constrain the tool within a virtual cutting boundary, while in other robotic systems, the robot is "active," i.e., the robot executes preplanned cut paths.
- The use of navigation for real-time object tracking, typically with cameras. Some robotic systems do not actively track objects in the surgical field.
- The type of registration and navigation method – most navigated products require point based registration of large bone fixated arrays.



Source: monogramorthopedics.com

Currently, there is not a widely commercialized technology that combines navigated surgical robotics with patient-specific press-fit orthopedic implants or navigated surgical robotics that integrate augmented reality and machine learning based technologies like mVision into workflows. Based on general industry knowledge, the only use of robotic technology in combination with surgical navigation is to prepare the bone for the placement of generic orthopedic implants. There appears to be limited integration of AR and machine learning with surgical robotics in the market, which Monogram is actively working on integrating into their surgical robots.

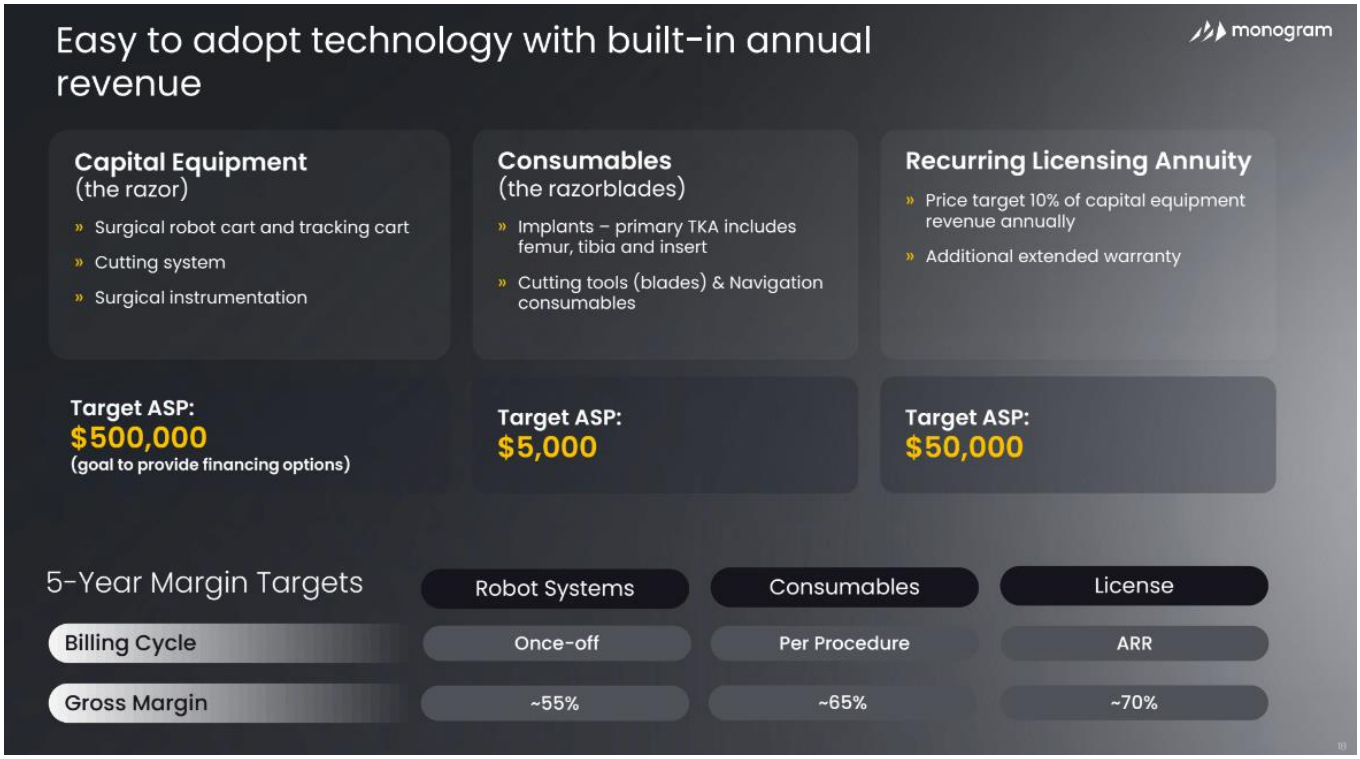
FINANCIAL REVIEW

Monogram went public in May 2023 at a price of $7.25 raising approximately $15.3 million in net proceeds. Cash on the balance sheet as of 3/31/24 was $10.1 million and working capital was $8.7 million. The company has no traditional long-term debt.

The company reported full year 2023 results on March 15, 2024. The company reported revenues of approximately $350 thousand for the year after the sale of one robot system in the 4th quarter. Research and development expenses for the year ended were $10.6 million, compared to $5.4 million in the prior year period. The R&D increase year over year was driven by increased efforts in the development of the company's sagittal cutting systems and related platform software required to operate its active navigated robotic system. The company also moved into the verification phase of the development of its robot prototype.

In 2023, General & Administrative expense increased to $4.0 million compared to $2.5 million in 2022. The increase was primarily due to increases in compensation expenses, insurance and regulatory compliance expenses, facilities expenses, and consulting and professional fees. The company has onboarded additional engineers to support commercialization and development of its product lineup. In addition, increases in G&A were also driven by adding a CFO, a requirement to become a public company. The increase in salary, driven by the headcount increase, and bonus represent approximately 6% of the total increase in G&A. Expenses related to stock options awarded in prior years increased as more options vest over time.

Net loss for the year was ($13.7) million compared to a net loss of ($13.7) million for the calendar year 2022. The net loss in 2023 was positively impacted by $3.1 million due to the change in fair market value of existing warrant obligations, while the 2022 results were negatively impacted by $3.4 million due to the change in fair market value in that period.



Source: monogramorthopedics.com

We believe the monthly burn rate for the company will be approximately $1.0-$1.2 million for the 2024 calendar year. We believe the company is funded to support operations through the submission of its 510(k) application in 2024.

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, and the products may take a long time to be reviewed and cleared, if they are cleared at all.

- 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. We may not have the resources to complete the development and commercialization of any of our proposed product candidates.

- 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.

- The company's products require a level of accuracy that may never be achieved. To obtain FDA clearance on the system under development, the company will need to demonstrate that it can accurately position implants in robotically prepared bone specimens. The KUKA LBR Med robot that is in use has never before been used or validated for this application, and it may not be able to perform to the accuracy required. Preparing bone to the accuracies required is a highly challenging task with numerous sources of error that we may never be able to overcome.

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 an advanced robotic offering.

We do not believe the market has priced in the recent disclosures the company provided regarding recent design improvements and their plans to accelerate its 510(k) submission to 2024 without a clinical trial. This could present a major catalyst for the stock.

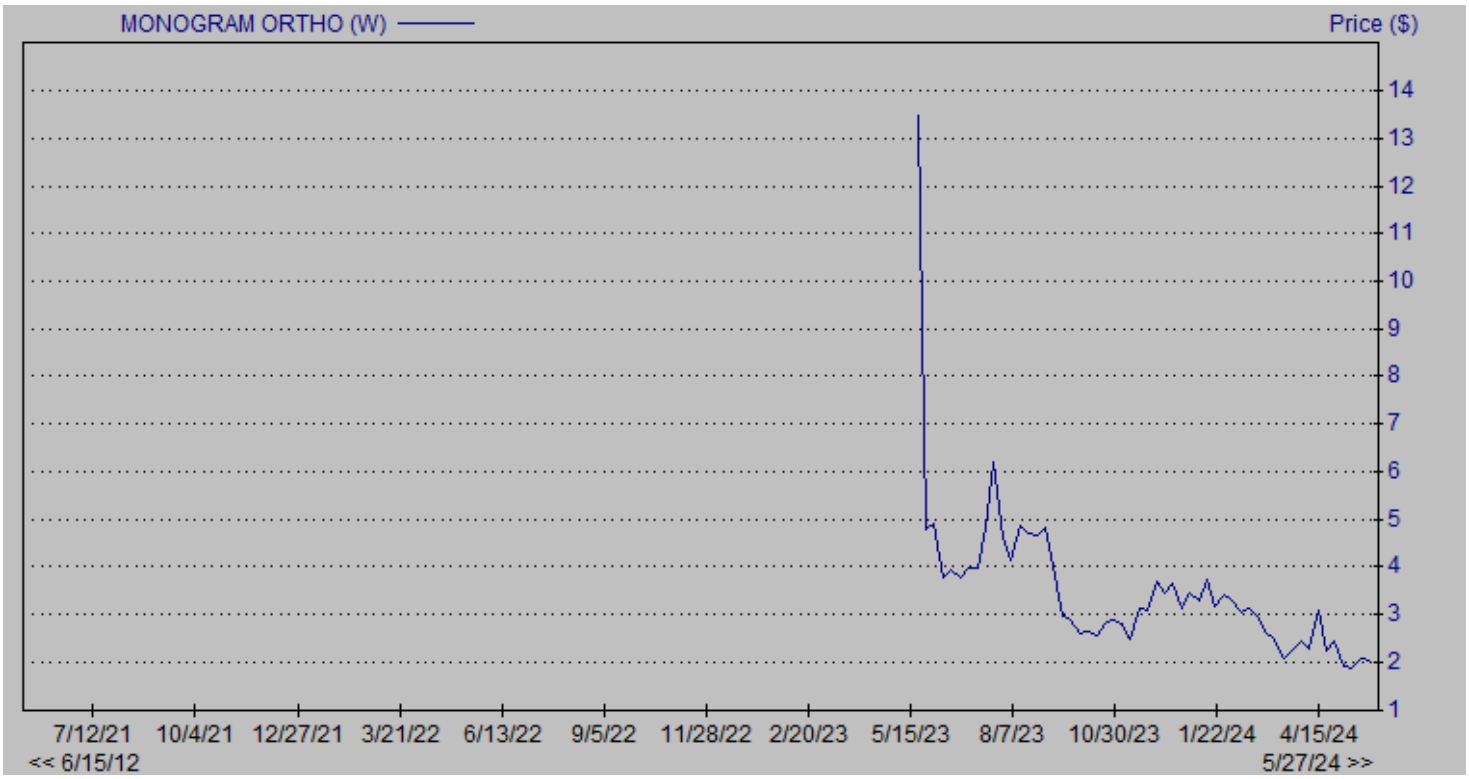
We believe our multiple valuation methods support our DCF valuation which provides a target price of **$6.00** per share.

PROJECTED INCOME STATEMENT

Income Statement	Dec-22	Dec-23	Dec-24	Dec-25	Dec-26
Net Sales	**0**	**364,999**	**0**	**5,660,000**	**28,410,000**
Growth	*-100.0%*	*#DIV/0!*	*-100.0%*	*#DIV/0!*	*401.9%*
Cost of Goods Sold	**0**	**0**	**(2,500)**	**2,948,500**	**14,786,000**
%	*N/A*	*0.0%*	*N/A*	*52.1%*	*52.0%*
Depreciation & Amort	**0**	**0**	**0**	**0**	**0**
Gross Profit	**0**	**0**	**2,500**	**2,711,500**	**13,624,000**
Margin	*N/A*	*0.0%*	*N/A*	*47.9%*	*48.0%*
Sales & Marketing Expenses	**2,743,687**	**2,994,389**	**644,694**	**805,868**	**1,208,801**
% of sales	*N/A*	*820.4%*	*N/A*	*14.2%*	*4.3%*
General & Administrative Expenses	**2,484,750**	**4,052,775**	**3,658,695**	**3,109,891**	**2,643,407**
% of sales	*#DIV/0!*	*1110.4%*	*#DIV/0!*	*54.9%*	*9.3%*
Research & Development	**5,384,710**	**10,585,884**	**8,630,244**	**13,414,488**	**8,000,000**
% of sales	*#DIV/0!*	*2900.3%*	*#DIV/0!*	*237.0%*	*28.2%*
Amortization	**0**	**0**	**0**	**0**	**0**
% of sales	*N/A*	*0.0%*	*N/A*	*0.0%*	*0.0%*
Operating Income	**(10,613,147)**	**(17,268,049)**	**(12,931,133)**	**(14,618,746)**	**1,771,792**
Margin	*#DIV/0!*	*-4731.0%*	*#DIV/0!*	*-258.3%*	*6.2%*
EBITDA	**(10,226,461)**	**(16,855,714)**	**(12,931,133)**	**(14,618,746)**	**1,771,792**
Margin	*N/A*	*-4618.0%*	*N/A*	*-258.3%*	*6.2%*
Other Expenses/(Income)	**3,077,800**	**(3,522,812)**	**(413,820)**	**26,903**	**59,696**
%	*N/A*	*-965.2%*	*N/A*	*0.5%*	*0.2%*
EBIT	**(13,690,947)**	**(13,745,237)**	**(12,517,313)**	**(14,645,649)**	**1,712,095**
%	*N/A*	*-3765.8%*	*N/A*	*-258.8%*	*6.0%*
Total Interest Exp (net)	**0**	**0**	**0**	**0**	**0**
%	*N/A*	*0.0%*	*N/A*	*0.0%*	*0.0%*
Net Profit Before Tax	**(13,690,947)**	**(13,745,237)**	**(12,517,313)**	**(14,645,649)**	**1,712,095**
%	*N/A*	*-3765.8%*	*N/A*	*-258.8%*	*6.0%*
Income Tax	**0**	**0**	**0**	**0**	**256,814**
% 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**	**0**	**0**	**0**
Net Profit	**(13,690,947)**	**(13,745,237)**	**(12,517,313)**	**(14,645,649)**	**1,455,281**
%	*N/A*	*-3765.8%*	*N/A*	*-258.8%*	*5.1%*
Non-recurring income (expense)					
Average Diluted Shares Outstanding	9,673,870	22,409,222	31,535,795	31,535,795	31,535,795
Reported FD EPS					
Zacks Cash EPS	**(1.42)**	**(0.61)**	**(0.40)**	**(0.46)**	**0.05**
Zacks EPS	**(1.42)**	**(0.61)**	**(0.40)**	**(0.46)**	**0.05**

Source: Zacks analyst

HISTORICAL STOCK PRICE



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