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# Zacks Small-Cap Research

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## Monogram Technologies (NASDAQ: MGRM)

**MGRM: Monogram announces it has received an Additional Information Request (AIR) from the FDA regarding its recent 510(k) submission. The company also closed on its recent public offering raising net proceeds of $11.7 million.**

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 (10/30/24) | $2.35 |
| **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 and the application passed the Administrative Review. The first live in patient surgery OUS is expected in early 2025. The company has an estimated $16.0-$17.0 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** | **$1.53** |
| **One-Year Return (%)** | **-8.2** |
| **Beta** | **N/A** |
| **Average Daily Volume (sh)** | **193,620** |
| **Shares Outstanding (mil)** | **39.0** |
| **Market Capitalization ($mil)** | **$91.2** |
| **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 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 | -$0.11 A | -$0.12 E | -$0.11 E | -$0.45 E |
| 2025 | | | | | -$0.48 E |

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

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## WHAT'S NEW

FDA Response to 510(k) Filing

On October 6, 2024, the company announced it had received an Additional Information Request ("AIR") from the U.S. Food and Drug Administration ("FDA") on September 30, 2024, regarding its 510(k) premarket filing submission for the semi-active mBôs TKA System.

The application was submitted on July 19, 2024, and passed the initial FDA Administrative Review. The FDA informed the Monogram that it had placed the application on hold pending a complete response to the AIR. The FDA has informed the company that it has 180 days from the date of the AIR to provide a complete response to their questions. AIRs from the FDA are very common for complex medical device submissions.

As Monogram responds to questions and issues raised in the AIR, the company will, in parallel, pursue a submission for its active modality with Outside the United States ("OUS") clinical data as it continues to work through the AIR for its semi-active system.

Milestones

- Obtain regulatory clearance to conduct clinical trials in India with strategic partner Shalby Hospitals, with Indian government regulatory clearance expected in early late 2024 or Q1 2025.
- Conduct OUS live-patient surgery trials and submit clinical trial data to FDA, with clinical trials expected to include 92 total knee replacement procedures with a 3 month clinical follow-up.
- Seek to obtain clearance for the mBôs™ TKA System.
- Continue exploring domestic relationships.
- Continue expanding international relationships (the company will be exhibiting at Arab Health in January 2025).

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.

Dividends on the Series D Preferred Stock are payable quarterly in arrears on or about the 15th day of January, April, July and October, beginning on or about October 15, 2024. The first dividend, which is scheduled to be paid on October 15, 2024, will be $0.033 per share of Series D Preferred Stock.

## RECENT NEWS

2nd Quarter 2024 Financial Results

Monogram reported 2nd quarter 2024 results on August 14th which were largely in line with expectations. Research and development expenses for the quarter ending June 30, 2024 were $2.4 million compared to $2.9 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 for the 2nd quarter were $1.1 million, which is comparable to the prior year period. Marketing and advertising expenses decreased to $91,715 in the quarter compared to $1.7 million in the prior year period. The decrease was largely related to expenses incurred during the 2nd quarter of 2023 that were associated with the marketing campaign related to its offering of its common stock in 2023.

Net loss for the quarter was ($3.5) million compared to a net loss of ($5.2) million in the prior year quarter. Operating cash flow was a use of cash of ($2.8) million. We expect the monthly burn rate to be approximately $1.1-$1.2 million for the remainder of 2024.

Cash and cash equivalents totaled $7.3 million as of June 30, 2024, compared to $13.6 million as of the end of 2023. Working capital was approximately $5.6 million and total stockholders' equity was $7.0 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 (see below).

FDA Submission

On August 8th, 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."*

The submission is also expected to position the company well for future funding opportunities from institutional investors.

Monogram Secures Initial Strategic Clinical Trial Collaboration

On August 12, 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.

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.

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

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

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 ($0.45) and for 2025, the EPS estimate is ($0.48). 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 $8.00.

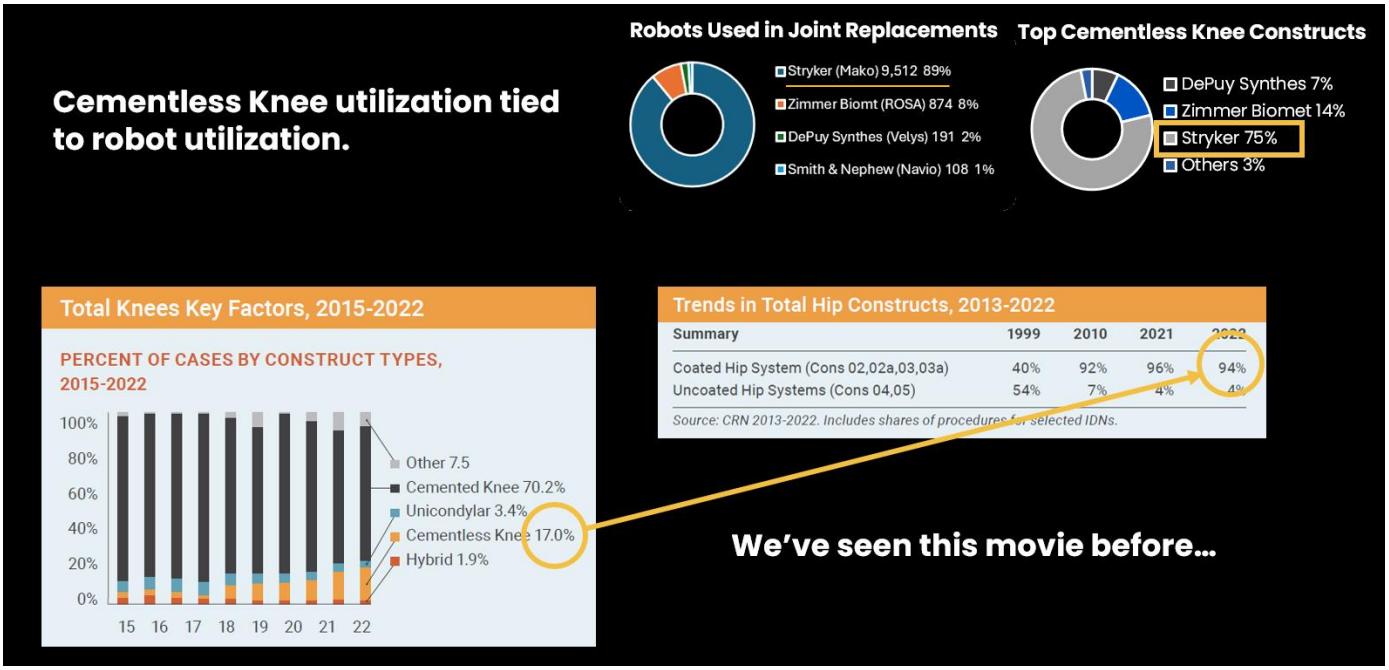
## KEY INVESTMENT POINTS



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.

- On August 8th, the company announced it had submitted its 510(k) application for its 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").




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.

- 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.

- On August 12, the company announced a strategic collaboration with Shalby Limited, 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. 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

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

- Monogram currently has no revenues at this time and research & development expenses in the 2nd quarter of 2024 were $2.4 million. The company has $7.3 million in cash as of 6/30/24 and working capital of $5.6 million. The company raised approximately $11.7 million in cash from an equity offering in the 3rd quarter of 2024. The company expects to 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.

## 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.

On August 8th, the company announced it had submitted its 510(k) application for its mBôs TKA System on July 19th to the FDA. An FDA decision is expected within 90 days of the initial submission; however, the process may be paused or extended if additional information is requested. The submission follows recent FDA written feedback regarding the company's pre-submission request and a meeting to discuss the Monogram mBôs™ TKA System verification test plan, including a proposed clinical trial protocol on an outside the U.S. (OUS) target population. Management believes the feedback was comprehensive and will be advantageous for a successful 510(k) submission to obtain clearance, commercialization, and marketing for the mBôs™ TKA System. On September 30, 2024, the company announced it has received an Additional Information Request ("AIR") from the U.S. Food and Drug Administration ("FDA").

The company'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 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. 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.

Monogram currently has no revenues at this time and research & development expenses in the 2nd quarter of 2024 were $2.4 million. The company has $7.3 million in cash as of 6/30/24 and working capital of $5.6 million. The company expects to fully commercialize its robotic system in 2025. The company went public in May 2023 and currently has a market capitalization of $85 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.

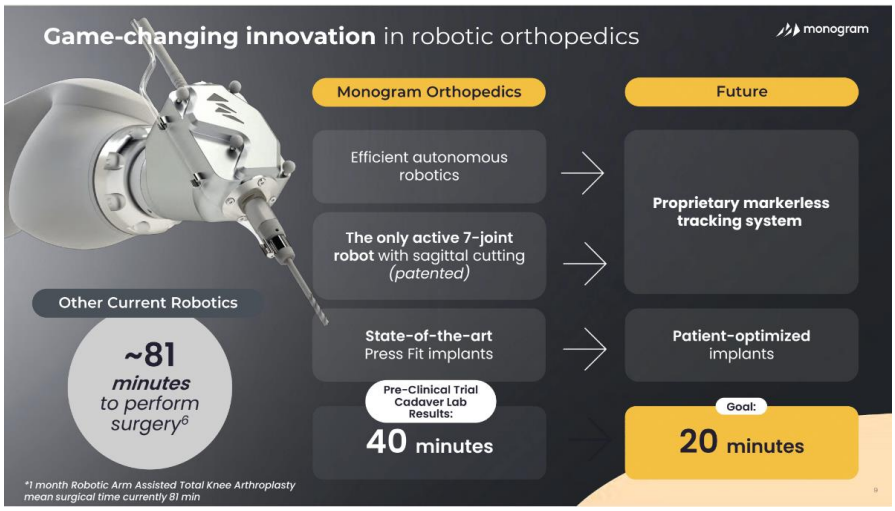
The equipment required for robotic TKA includes:

- 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.



Source: monogramorthopedics.com

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.

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."*

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

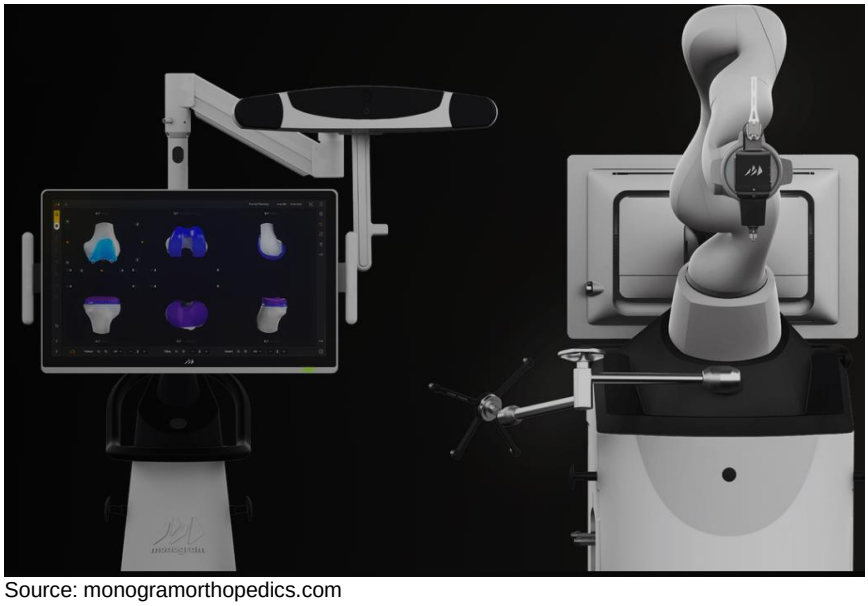
10% higher average selling price than cemented knee constructs. From 2020 to 2021, Depuy Synthes, Smith & Nephew, and Zimmer Biomet had year-over-year sales increases of 13.3%, 8.7%, and 13.2%, respectively. The Stryker Corporation realized sales increases in its knee segment of 17.6% over the same period. 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.

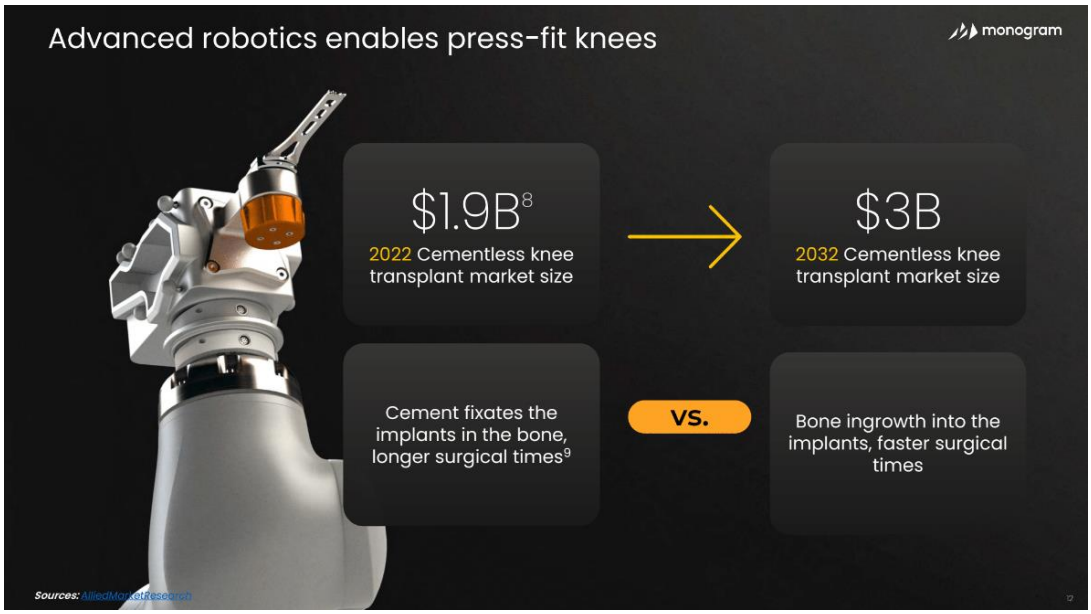
The Monogram technology platform consists of a workflow to prepare a patient-specific surgical plan from a CT scan. The CT scan images are pre-processed by proprietary algorithms using artificial intelligence and machine learning to automatically segment the bone from the images, identify the anatomy 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.



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. 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.

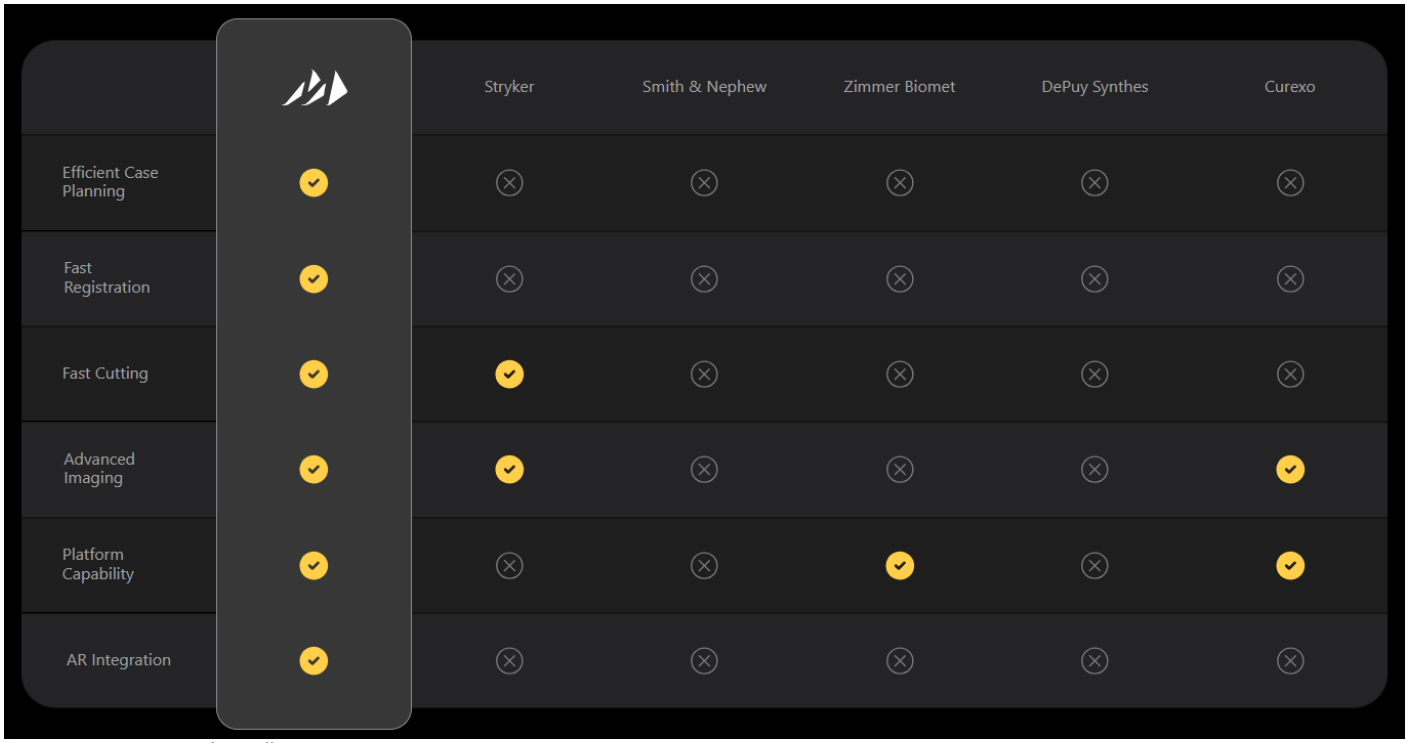
- The degrees of freedom of the robotic system. Monogram is working to commercialize a seven degree-of-freedom robotic arm.
- The use of a cutting end-effector. Some robotic systems do not utilize cutting end effectors but robotically position jigs that constrain the manual instrumentation used to execute 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.

## 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.

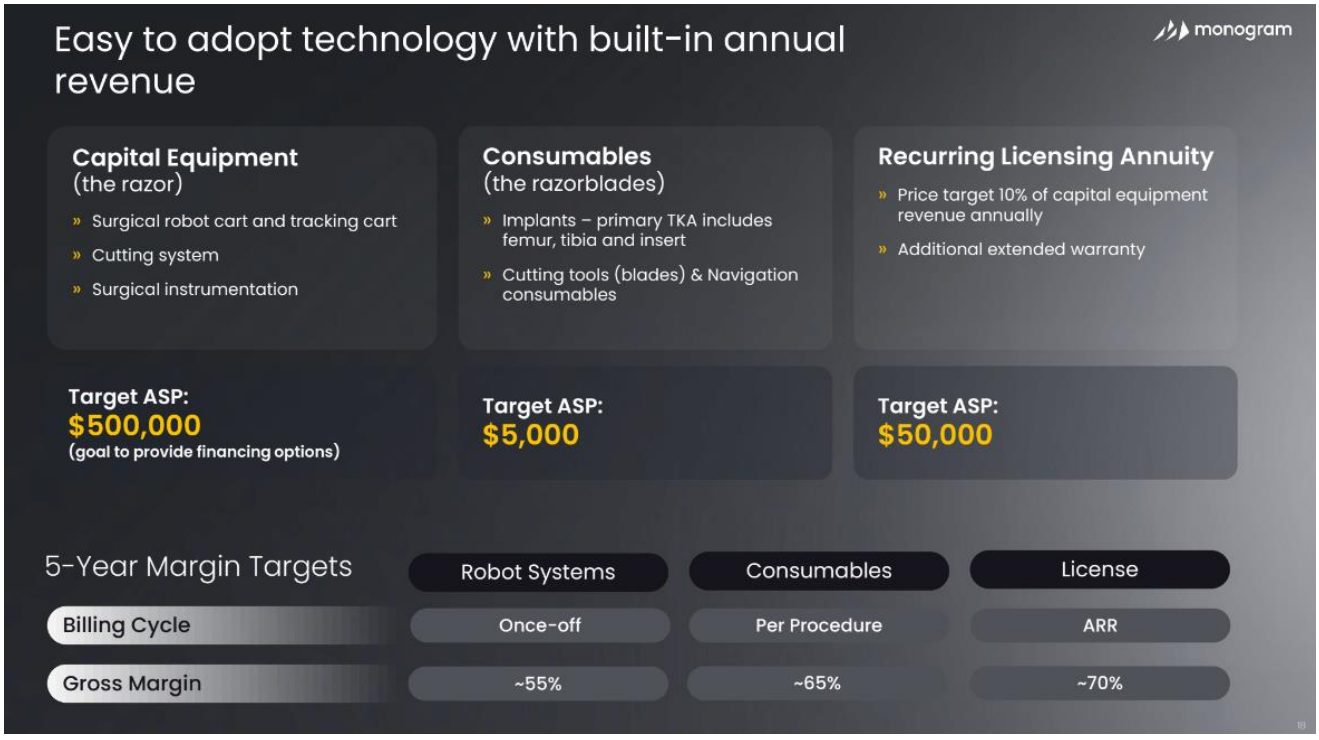
## SUMMARY

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 an advanced robotic offering.

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



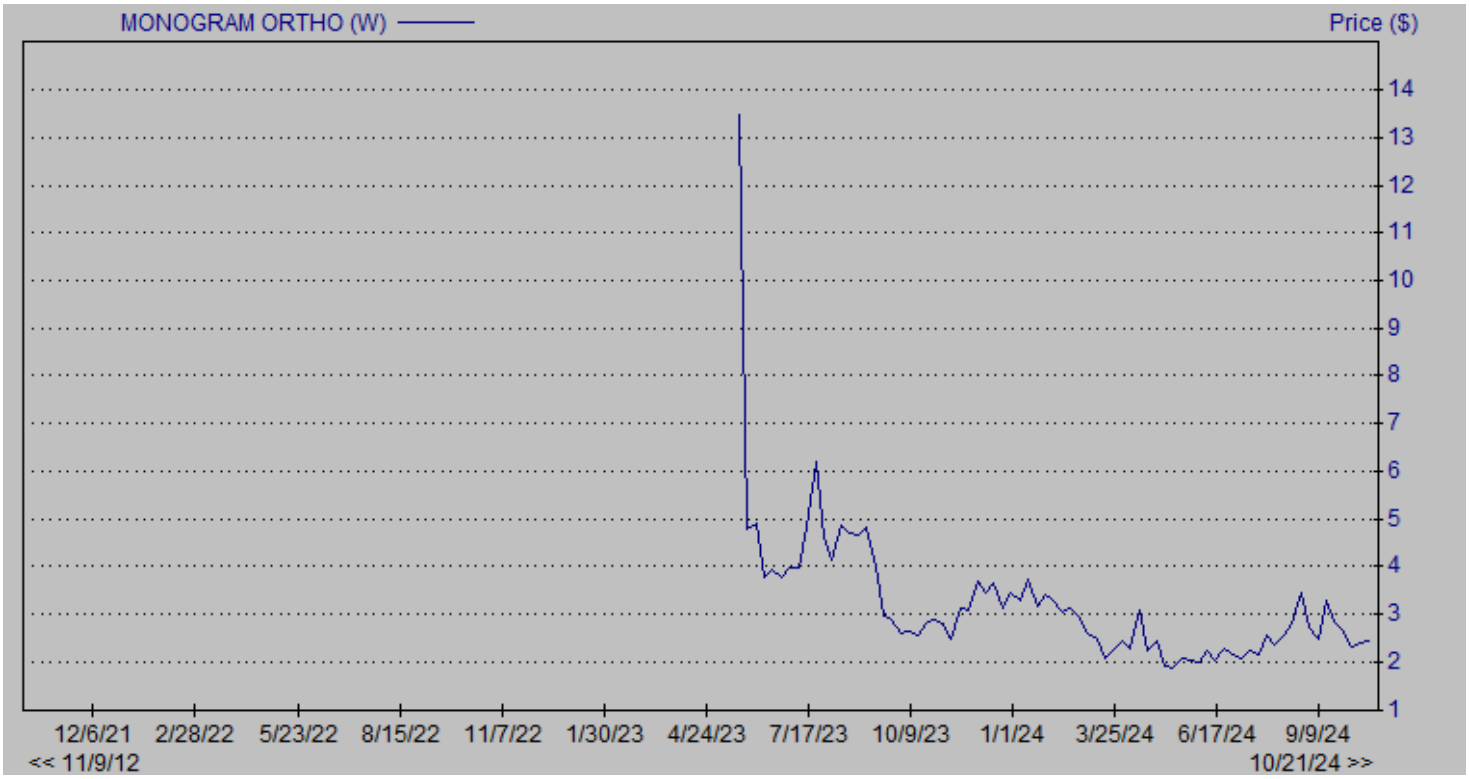

Source: monogramorthopedics.com

## PROJECTED INCOME STATEMENT

| Income Statement | Dec-22 | Dec-23 | Dec-24 | Dec-25 | Dec-26 |
|---|---|---|---|---|---|
| **Net Sales** | **0** | **364,999** | **0** | **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)** | **5,094,000** | **14,786,000** |
| *%* | *N/A* | *0.0%* | *N/A* | *90.0%* | *52.0%* |
| **Depreciation & Amort** | **0** | **0** | **0** | **0** | **0** |
| **Gross Profit** | **0** | **0** | **2,500** | **566,000** | **13,624,000** |
| *Margin* | *N/A* | *0.0%* | *N/A* | *10.0%* | *48.0%* |
| **Sales & Marketing Expenses** | **2,743,687** | **2,994,389** | **711,409** | **889,261** | **1,333,892** |
| *% of sales* | *N/A* | *820.4%* | *N/A* | *15.7%* | *4.7%* |
| **General & Administrative Expenses** | **2,484,750** | **4,052,775** | **4,398,874** | **3,739,043** | **3,178,187** |
| *% of sales* | *#DIV/0!* | *1110.4%* | *#DIV/0!* | *66.1%* | *11.2%* |
| **Research & Development** | **5,384,710** | **10,585,884** | **9,575,094** | **11,335,717** | **8,000,000** |
| *% of sales* | *#DIV/0!* | *2900.3%* | *#DIV/0!* | *200.3%* | *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)** | **(14,682,877)** | **(15,398,021)** | **1,111,921** |
| *Margin* | *#DIV/0!* | *-4731.0%* | *#DIV/0!* | *-272.0%* | *3.9%* |
| **EBITDA** | **(10,226,461)** | **(16,855,714)** | **(14,682,877)** | **(15,398,021)** | **1,111,921** |
| *Margin* | *N/A* | *-4618.0%* | *N/A* | *-272.0%* | *3.9%* |
| **Other Expenses/(Income)** | **3,077,800** | **(3,522,812)** | **(391,653)** | **(300,000)** | **72,257** |
| *%* | *N/A* | *-965.2%* | *N/A* | *-5.3%* | *0.3%* |
| **EBIT** | **(13,690,947)** | **(13,745,237)** | **(14,291,224)** | **(15,098,021)** | **1,039,665** |
| *%* | *N/A* | *-3765.8%* | *N/A* | *-266.7%* | *3.7%* |
| **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)** | **(14,291,224)** | **(15,098,021)** | **1,039,665** |
| *%* | *N/A* | *-3765.8%* | *N/A* | *-266.7%* | *3.7%* |
| **Income Tax** | **0** | **0** | **0** | **0** | **155,950** |
| *% 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)** | **(14,291,224)** | **(15,098,021)** | **883,715** |
| *%* | *N/A* | *-3765.8%* | *N/A* | *-266.7%* | *3.1%* |
| 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)** | **(0.45)** | **(0.48)** | **0.03** |
| **Zacks EPS** | **(1.42)** | **(0.61)** | **(0.45)** | **(0.48)** | **0.03** |

Source: Zacks analyst

## HISTORICAL STOCK PRICE



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