

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

September 24, 2020

Benjamin Sexson Chief Executive Officer MONOGRAM ORTHOPAEDICS INC 3913 Todd Lane Austin, TX 78744

> Re: MONOGRAM ORTHOPAEDICS INC Offering Statement on Form 1-A Submitted August 28, 2020 File No. 024-11305

Dear Mr. Sexson:

We have reviewed your offering statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your offering statement and providing the requested information. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response. After reviewing any amendment to your offering statement and the information you provide in response to these comments, we may have additional comments.

#### Form 1-A Submitted August 28, 2020

## Summary, page 4

1. Please revise the Summary Overview to clarify that you have not yet made 501(k) premarket notification submissions for any of your product candidates, and that such submission is required in order to obtain clearance to market your products. Potential investors should be able to clearly ascertain from the Summary what stage of development the company is in and what steps remain prior to commercialization.

## Jury Trial Waiver, page 19

2. We note that the provision relating to an investor's waiver of a right to a jury trial applies to federal securities law claims. Please revise your disclosure to clearly state that investors cannot waive compliance with federal securities laws and the rules and regulations promulgated thereunder.

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## No Minimum Offering Amount, page 19

3. We note your statements on page 19 and elsewhere that there is no minimum offering amount and that the company may close on any funds that it receives. However, we also note your statements on pages 1 and 7 that reference a minimum amount of shares to be sold. Please revise these statements to avoid confusion and clarify the best-efforts offering structure.

## Use of Proceeds to Issuer, page 20

4. We note your statements under the Use of Proceeds discussion that the company intends to "try and fund" the development of the Monogram total knee and robotic system with proceeds received. Please revise your discussion to clarify at each capital raise level how far you anticipate the proceeds will go towards this goal (i.e., how much funding you anticipate is required to develop the system) and how you will secure the remainder of the funding needed if there is an anticipated shortfall.

## Plan of Operations and Milestones, page 31

5. Please remove your statements on pages 31 and 32 regarding the years in which you expect to receive FDA approval for your robotic system and implant, as such approval is not assured or within your control.

## Interest of Management and Others in Certain Transactions, page 36

- 6. We note your statement that payments under the License Agreement include: annual license maintenance fees, milestone payments (upon completion of certain events, such as FDA Clearance of Monogram's custom implants), running royalties (subject to certain adjustments) and sublicense fees. Please revise to disclose the material terms of the agreement, including the aggregate potential milestone payments, the royalty rate to be paid, and the term and termination provisions.
- 7. We note your disclosure that as part of the Licensing Agreement with Mount Sinai you are obligated to enter into a stock purchase agreement for the shares of Common Stock already issued to Mount Sinai before September 22, 2019, but have not yet done so. Please update your disclosure to reflect the current status of this agreement, as the date in question has already passed.

We will consider qualifying your offering statement at your request. If a participant in your offering is required to clear its compensation arrangements with FINRA, please have FINRA advise us that it has no objections to the compensation arrangements prior to qualification.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of

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action by the staff. We also remind you that, following qualification of your Form 1-A, Rule 257 of Regulation A requires you to file periodic and current reports, including a Form 1-K which will be due within 120 calendar days after the end of the fiscal year covered by the report.

You may contact Jeanne Bennett at 202-551-3606 or Terence O'Brien at 202-551-3355 if you have questions regarding comments on the financial statements and related matters. Please contact Laura Crotty at 202-551-7614 or Suzanne Hayes at 202-551-3675 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Andrew Stephenson