

1 POMERANTZ LLP  
Jennifer Pafiti (SBN 282790)  
2 1100 Glendon Avenue, 15th Floor  
Los Angeles, California 90024  
3 Telephone: (310) 405-7190  
4 jpfafiti@pomlaw.com

5 *Attorney for Plaintiff*

6 *[Additional Counsel on Signature Page]*

7  
8 UNITED STATES DISTRICT COURT  
9 NORTHERN DISTRICT OF CALIFORNIA

10 BILL TSANTES, Individually and On  
11 Behalf of All Others Similarly Situated,  
12  
13 Plaintiff,

14 v.

15 BIOMARIN PHARMACEUTICAL INC.,  
16 JEAN-JACQUES BIENAIMÉ, BRIAN R.  
MUELLER, and HENRY J. FUCHS,

17 Defendants.  
18

Case No.

CLASS ACTION

COMPLAINT FOR VIOLATIONS OF THE  
FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

1 Plaintiff Bill Tsantes (“Plaintiff”), individually and on behalf of all other persons similarly  
2 situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants, alleges  
3 the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and  
4 information and belief as to all other matters, based upon, *inter alia*, the investigation conducted  
5 by and through Plaintiff’s attorneys, which included, among other things, a review of the  
6 Defendants’ public documents, conference calls and announcements made by Defendants, United  
7 States (“U.S.”) Securities and Exchange Commission (“SEC”) filings, wire and press releases  
8 published by and regarding BioMarin Pharmaceutical Inc. (“BioMarin” or the “Company”),  
9 analysts’ reports and advisories about the Company, and information readily obtainable on the  
10 Internet. Plaintiff believes that substantial additional evidentiary support will exist for the  
11 allegations set forth herein after a reasonable opportunity for discovery.  
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### 13 NATURE OF THE ACTION

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15 1. This is a federal securities class action on behalf of a class consisting of all persons  
16 and entities other than Defendants that purchased or otherwise acquired BioMarin securities  
17 between February 28, 2020 and August 18, 2020, both dates inclusive (the “Class Period”), seeking  
18 to recover damages caused by Defendants’ violations of the federal securities laws and to pursue  
19 remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange  
20 Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.  
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22 2. BioMarin was founded in 1996 and is headquartered in San Rafael, California.  
23 BioMarin is a biotechnology company that develops and commercializes therapies for people with  
24 serious and life-threatening rare diseases and medical conditions. The Company’s product  
25 candidates include, among others, valoctocogene roxaparvovec, an investigational adeno-  
26 associated virus (“AAV”) gene therapy, which is in Phase 3 clinical development for the treatment  
27 of patients with severe hemophilia A.  
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1           3.       Based on BioMarin’s Phase 1/2 study results, the investing and medical community  
2 viewed valoctocogene roxaparvovec as a likely candidate for becoming the first gene therapy  
3 approved by the U.S. Food and Drug Administration (“FDA”) for hemophilia in the U.S.

4           4.       In May 2019, BioMarin announced the interim results from its Phase 3 study of  
5 valoctocogene roxaparvovec for adults suffering from severe hemophilia A. The results, although  
6 showing the treatment’s effectiveness, disappointed the market because they indicated a reduction  
7 in durability of effectiveness from the results shown in the Phase 1/2 results. That is, under the  
8 Phase 3 results, it was not clear whether valoctocogene roxaparvovec’s effectiveness would last as  
9 long as indicated in the Phase 1/2 study, and thus, whether valoctocogene roxaparvovec would be  
10 a single treatment, or one requiring more than one treatment over the life of a patient. These  
11 concerns echoed those that first arose in 2018, after the Company reported a disappointing two-  
12 year update from the Phase 1/2 study, which showed factor VIII levels waning over time.

13           5.       Apparently dismissing these concerns, in December 2019, BioMarin submitted a  
14 Biologics License Application (“BLA”) to the FDA for valoctocogene roxaparvovec for adults  
15 with hemophilia A based on the interim analysis of the ongoing Phase 3 study of valoctocogene  
16 roxaparvovec, as well as three-year data from the Company’s Phase 1/2 study of valoctocogene  
17 roxaparvovec. BioMarin also announced that the European Medicines Agency (“EMA”) validated  
18 the Company’s Marketing Authorization Application (“MAA”) for valoctocogene roxaparvovec  
19 for adults with severe hemophilia A, with the MAA review to commence in January 2020 under  
20 accelerated assessment.

21           6.       Throughout the Class Period, Defendants made materially false and misleading  
22 statements regarding the Company’s business, operational and compliance policies. Specifically,  
23 Defendants made false and/or misleading statements and/or failed to disclose that: (i) differences  
24 between the Phase 1/2 and Phase 3 study of valoctocogene roxaparvovec limited the reliability of  
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1 the Phase 1/2 study to support valoctocogene roxaparvec's durability of effect; (ii) as a result, it  
2 was foreseeable that the FDA would not approve the BLA for valoctocogene roxaparvec without  
3 additional data; and (iii) as a result, the Company's public statements were materially false and  
4 misleading at all relevant times.

5  
6 7. On August 19, 2020, BioMarin announced receipt of a Complete Response Letter  
7 ("CRL") from the FDA to the Company's BLA for valoctocogene roxaparvec. BioMarin  
8 advised investors that in the CRL, "the FDA introduced a new recommendation for two years of  
9 data from the Company's ongoing 270-301 study (Phase 3) to provide substantial evidence of a  
10 durable effect using Annualized Bleeding Rate (ABR) as the primary endpoint" and  
11 "recommended that the Company complete the Phase 3 Study and submit two-year follow-up  
12 safety and efficacy data on all study participants." In explaining the new recommendation, the  
13 "FDA concluded that the differences between Study 270-201 (Phase 1/2) and the Phase 3 study  
14 limited its ability to rely on the Phase 1/2 study to support durability of effect."

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16 8. On this news, BioMarin's stock price fell \$41.82 per share, or 35.28%, to close at  
17 \$76.72 per share on August 19, 2020.

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19 9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline  
20 in the market value of the Company's securities, Plaintiff and other Class members have suffered  
21 significant losses and damages.

### 22 JURISDICTION AND VENUE

23 10. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of  
24 the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the  
25 SEC (17 C.F.R. § 240.10b-5).

26 11. This Court has jurisdiction over the subject matter of this action pursuant to 28  
27 U.S.C. § 1331 and Section 27 of the Exchange Act.



1 19. Defendants Bienaimé, Mueller, and Fuchs are sometimes referred to herein as the  
2 “Individual Defendants.”

3 20. The Individual Defendants possessed the power and authority to control the  
4 contents of BioMarin’s SEC filings, press releases, and other market communications. The  
5 Individual Defendants were provided with copies of BioMarin’s SEC filings and press releases  
6 alleged herein to be misleading prior to or shortly after their issuance and had the ability and  
7 opportunity to prevent their issuance or to cause them to be corrected. Because of their positions  
8 with BioMarin, and their access to material information available to them but not to the public, the  
9 Individual Defendants knew that the adverse facts specified herein had not been disclosed to and  
10 were being concealed from the public, and that the positive representations being made were then  
11 materially false and misleading. The Individual Defendants are liable for the false statements and  
12 omissions pleaded herein.  
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15 21. BioMarin and the Individual Defendants are sometimes collectively, in whole or in  
16 part, referred to herein as “Defendants.”

17 **SUBSTANTIVE ALLEGATIONS**

18 **Background**

19 22. BioMarin was founded in 1996 and is headquartered in San Rafael, California.  
20 BioMarin is a biotechnology company that develops and commercializes therapies for people with  
21 serious and life-threatening rare diseases and medical conditions. The Company’s product  
22 candidates include, among others, valoctocogene roxaparvovec, an investigational AAV gene  
23 therapy, which is in Phase 3 clinical development for the treatment of patients with severe  
24 hemophilia A.  
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26 23. BioMarin touted valoctocogene roxaparvovec as a potential one-time treatment  
27 gene therapy for patients suffering from severe hemophilia A, which is marked by a deficiency of  
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1 the FVIII protein to help with blood clotting and to prevent painful, potentially life-threatening  
2 bleeding from even modest injuries. Both the market and medical community hoped study results  
3 would show that after a single treatment of the valoctocogene roxaparvovec gene therapy, patients  
4 suffering from severe hemophilia A would no longer require a prophylactic regimen of Factor VIII  
5 infusions administered intravenously because the gene therapy promised to potentially rid patients  
6 of the FVIII protein deficiency for the life of the patient. As such, valoctocogene roxaparvovec  
7 was considered a potential “blockbuster” treatment with a projected price tag of \$1-\$3 million per  
8 treatment, representing potentially billions of dollars in sales.

10 24. Based on BioMarin’s Phase 1/2 study results, the investing and medical community  
11 viewed valoctocogene roxaparvovec as a likely candidate for becoming the first gene therapy  
12 approved by the FDA for hemophilia in the U.S. However, expectations of the treatment were  
13 somewhat reduced in 2018, after the Company reported a disappointing two-year update from the  
14 Phase 1/2 study, which showed factor VIII levels waning over time.

16 25. On May 28, 2019, BioMarin announced interim results from the Phase 3 study of  
17 valoctocogene roxaparvovec for adults suffering from severe hemophilia A (the “May 2019 Press  
18 Release”). That press release reported, among other results, a 94% reduction in mean Factor VIII  
19 usage, whereas, in May 2018, the Company reported a 98% drop in average FVIII usage, implying  
20 a diminishing treatment effect, and causing investors to question whether the Company anticipated  
21 working on a retreatment paradigm if it turned out that valoctocogene roxaparvovec’s treatment  
22 effect diminished over time.

24 26. Following release of the May 2019 Press Release, BioMarin’s stock price fell \$4.53  
25 per share, or 5.09%, to close at \$84.50 per share on May 28, 2019. Despite this decline in  
26 BioMarin’s stock price, the Company’s securities continued to trade at artificially inflated prices  
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1 because of Defendants’ misstatements regarding valoctocogene roxaparvec’s market viability  
2 based on the Phase 1/2 study and interim results from the Phase 3 study.

3 27. For example, in the May 2019 Press Release, Defendants touted that BioMarin’s  
4 “investigational gene therapy, valoctocogene roxaparvec, for adults with severe hemophilia A  
5 achieved pre-specified clinical criteria for regulatory review in the U.S. and Europe”; that, “[a]s  
6 of May 28, 2019, eight patients in the 20-patient cohort of the Phase 3 GENEr8-1 study achieved  
7 Factor VIII levels of 40 international units per deciliter (IU/dL), or more, at 23 to 26 weeks,  
8 meeting the pre-specified criteria for Factor VIII activity levels”; and that “[t]he company will  
9 meet with the [FDA] and [EMA] to review the phase 3 data and the other elements of a submission  
10 and intends to announce the timing for its planned marketing applications in 3Q 2019.”

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12 28. The May 2019 Press Release also quoted Defendants Fuchs, who touted, in relevant  
13 part, that “[r]eaching this pre-specified clinical endpoint is an important milestone that brings  
14 [BioMarin] one step closer to a potential regulatory submission in both the U.S. and Europe for  
15 valoctocogene roxaparvec to treat adults with severe hemophilia A,” that Defendants’  
16 “discussions with the FDA and EMA underscore the high level of unmet need in the hemophilia  
17 community,” and that Defendants “look forward to continuing [their] productive dialogue on the  
18 submissions.”

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20 29. On July 8, 2019, BioMarin issued a press release announcing that “based on recent  
21 meetings with health authorities in the U.S. and Europe, the [C]ompany plans to submit marketing  
22 applications to both the [FDA] and [EMA] in 4Q 2019 for its investigational gene therapy,  
23 valoctocogene roxaparvec, for adults with severe hemophilia A” (the “July 2019 Press  
24 Release”). That press release represented, in relevant part, that “[t]hese submissions will be based  
25 on the updated three-year Phase 1/2 data and the recently completed Phase 3 interim analysis of  
26 patients treated with material from the to-be-commercialized process”; that “[b]oth submissions  
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1 are expected to represent the first time a gene therapy product for any type of hemophilia will be  
2 reviewed for marketing authorization by health authorities”; that “[b]oth the FDA and EMA  
3 continue to prioritize interactions related to the review of valoctocogene roxaparvovec through the  
4 Breakthrough Therapy Designation program in the U.S and the Priority Medicines (PRIME)  
5 regulatory initiative in Europe”; and that “[v]aloctocogene roxaparvovec is one of the first  
6 therapies to go through the new PRIME initiative.”  
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8         30. The July 2019 Press Release also discussed an “ISTH [International Society on  
9 Thrombosis and Haemostasis] Late-Breaking Abstract,” touting, in relevant part, that “[e]arlier  
10 today, Professor Pasi presented data in a late-breaking abstract session on the efficacy and safety  
11 of valoctocogene roxaparvovec in an ongoing Phase 1/2 study at the 27th [ISTH] 2019 Congress”;  
12 that “[t]he three-year update of the 6e13 vg/kg dose cohort in the Phase 1/2 study demonstrated  
13 that bleed rate control and reduction in Factor VIII usage was maintained for a third year following  
14 a single administration of valoctocogene roxaparvovec”; that, “[i]n the year prior to study entry,  
15 the mean Annualized Bleed Rate” (“ABR”) “was 16.3 and the median was 16.5”; that, “[o]ver  
16 three years, the ABR was reduced to a mean of 0.6 and a median of zero”; that “[t]his represents a  
17 96% reduction in participants’ mean ABR, and there is 100% resolution of target joints”; that  
18 “[t]here was also a 96% reduction in participants’ mean annualized Factor VIII usage rate over  
19 three years, and all participants remain off Factor VIII prophylaxis”; that “Factor VIII levels  
20 sustained over a three-year period were sufficient to achieve striking hemostatic efficacy”; and  
21 that “Factor VIII expression has entered a plateau phase where the rate of decline has substantially  
22 slowed, which could be indicative of durable, long-term expression.”  
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25         31. Additionally, the July 2019 Press Release quoted Defendant Fuchs, who touted, in  
26 relevant part, that Defendants “applaud the FDA’s efforts to incorporate the patient voice in the  
27 regulatory review process”; that “[p]owerful and moving testimonials from clinical study  
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1 participants have helped serve as a critical element in the FDA’s considerations of potentially the  
2 first commercially available gene therapy for any type of hemophilia”; that, “[a]s important,  
3 [Defendants] commend the EMA PRIME initiative for enabling enhanced interactions and early  
4 dialogue that have optimized our development plans and have helped speed up evaluation of this  
5 novel investigational gene therapy”; that Defendants “have been moving efficiently through the  
6 development process, in no small part because of [Defendants’] ability to treat clinical trial  
7 participants with valoctocogene roxaparvovec produced using [their] commercial process”; and  
8 that “[u]tilization of to-be-commercialized material during Phase 3 studies significantly de-risks  
9 the program, as no production or facility changes need to be made to support commercial demand.”  
10

11 32. On December 23, 2019, BioMarin issued a press release announcing that it had  
12 submitted a BLA to the FDA for its investigational AAV gene therapy, valoctocogene  
13 roxaparvovec, for adults with hemophilia A (the “December 2019 Press Release”). That press  
14 release represented, in relevant part, that the BLA’s “submission is based on a Phase 3 interim  
15 analysis of study participants treated with material from the to-be-commercialized process, and the  
16 three-year Phase 1/2 data”; that “[s]ubject to completion of the FDA’s filing review, BioMarin  
17 anticipates the BLA review to commence in February 2020”; and that “BioMarin will provide an  
18 update in February 2020”; while touting that “[t]his submission marks the first marketing  
19 application submission for a gene therapy product for any type of hemophilia in the United States.”  
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21 33. The December 2019 Press Release further touted that, also on December 23, 2019,  
22 “the EMA validated the Company’s [MAA] to the EMA” for valoctocogene roxaparvovec, and  
23 that “BioMarin anticipates the start of the MAA review to commence in January 2020 under  
24 accelerated assessment,” which further indicated to investors valoctocogene roxaparvovec’s  
25 readiness for marketing approval.  
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1           34.     On February 20, 2020, BioMarin issued a press release announcing that the FDA  
2 “has accepted for Priority Review the [BLA] to the FDA for its investigational AAV5 gene  
3 therapy, valoctocogene roxaparvovec, for adults with hemophilia A” (the “February 2020 Press  
4 Release”). That press release represented, in relevant part, that “[t]his acceptance by the FDA  
5 marks the first marketing application accepted for a gene therapy product for any type of  
6 hemophilia in the United States”; that “[t]he application is based on a Phase 3 interim analysis of  
7 study participants treated with investigational product manufactured by the to-be-commercialized  
8 process and three-year Phase 1/2 data”; and that “[t]he FDA has informed the company that they  
9 are not currently planning to hold an advisory committee meeting to discuss the application.”

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11           35.     The February 2020 Press Release also quoted Defendant Fuchs, who touted, in  
12 relevant part, that “[v]alococogene roxaparvovec has the potential to be the first gene therapy  
13 approved in any type of hemophilia”; that “the acceptance of this application and its priority review  
14 status marks a significant milestone for gene therapies in general and for the hemophilia  
15 community specifically”; that, “[a]s pioneers in gene therapy, [Defendants] are proud of the  
16 medical and technological innovation represented in valoctocogene roxaparvovec, which is  
17 possible because of the scientists who did the early research, clinical investigators, the hemophilia  
18 community and the people who work” at BioMarin; and that Defendants “look forward to working  
19 with the FDA to bring this groundbreaking therapy to people with hemophilia A.”

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21           **Materially False and Misleading Statements Issued During the Class Period**

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23           36.     The Class Period begins on February 28, 2020. On February 27, 2020, during after-  
24 market hours, BioMarin filed an annual report on Form 10-K with the SEC, reporting the  
25 Company’s financial and operating results for the quarter and year ended December 31, 2019 (the  
26 “2019 10-K”). The 2019 10-K touted regulatory review of valoctocogene roxaparvovec for the  
27 treatment of severe hemophilia A, stating, in relevant part, that “[o]n February 20, 2020,  
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1 [Defendants] announced that the [FDA] accepted for priority review [the BLA] for valoctocogene  
2 roxaparvovec for the treatment of adults with severe hemophilia A”; that “[t]he Prescription Drug  
3 User Fee Act (PDUFA) target action date for the BLA has been set for August 21, 2020”; that  
4 “[o]n December 23, 2019, [Defendants] announced that the [EMA] validated [the MAA] for  
5 valoctocogene roxaparvovec, which has been in review under accelerated assessment since  
6 January 2020”; that “[t]he submissions are based on [BioMarin’s] Phase 3 interim analysis and the  
7 three-year Phase 1/2 data of patients treated with valoctocogene roxaparvovec”; and that “[b]oth  
8 submissions represent the first time a gene therapy product for any type of hemophilia indication  
9 is under review for marketing authorization by health authorities.”

11 37. The 2019 10-K also reported that “[o]n May 28, 2019, [BioMarin] announced a  
12 three-year update to [its] previously reported results from the Phase 1/2 dose-escalation study for  
13 valoctocogene roxaparvovec in patients with severe hemophilia A”; that this update “demonstrated  
14 that bleed rate control with the 6e13 vg/kg dose was maintained for a third year with a median  
15 [ABR] of 0 and mean ABR of 0.7 in that year”; that “factor VIII levels in the 6e13 vg/kg dose  
16 appeared to be approaching a plateau in year three”; that “[f]actor VIII levels measured with the  
17 chromogenic substrate” (“CS”) “assay at the end of year three were mean and median of 32.7  
18 international units per deciliter (IU/dL) and 19.9 IU/dl, respectively, compared with mean and  
19 median of 36.4 IU/dL and 26.2 IU/dL, respectively, at the end of year two”; and that, “[i]n January  
20 2020, the New England Journal of Medicine . . . published results from the three-year update from  
21 the Phase 1/2 study”; all of which indicated to investors the market viability of valoctocogene  
22 roxaparvovec, and an increased likelihood of the FDA’s acceptance of the BLA for that drug, given  
23 the updated Phase 1/2 study results.

26 38. With respect to BioMarin’s Phase 3 study program for valoctocogene  
27 roxaparvovec, the 2019 10-K represented, in relevant part:  
28

1 The global Phase 3 study program with valoctocogene roxaparvovec includes two  
2 studies, one with the 6e13 vg/kg dose (GENEr8-1) and one with the 4e13 vg/kg  
3 dose (GENEr8-2). In July 2019, we announced the discontinuation of the GENEr8-  
4 2 study given the overwhelming preference by patients to be treated with the 6e13  
5 vg/kg dose. The GENEr8-1 study is an open-label single-arm study to evaluate the  
6 efficacy and safety of valoctocogene roxaparvovec as well as evaluate superiority  
7 of the product candidate compared to standard of care. The primary endpoint is  
8 based on the factor VIII activity level achieved following treatment with  
9 valoctocogene roxaparvovec, and the secondary endpoint measures annualized  
10 factor VIII replacement therapy use rate and ABR. We announced on May 28, 2019  
11 that data from a 20-patient cohort of the Phase 3 GENEr8-1 study achieved pre-  
12 specified clinical criteria for regulatory review in the U.S. and Europe. As of May  
13 28, 2019, eight patients in the cohort achieved factor VIII levels of 40 or more  
14 IU/dL using the CS assay at 23 to 26 weeks, meeting the pre-specified criteria for  
15 factor VIII activity levels. As of the April 30, 2019 data cutoff, between weeks 23  
16 to 26, seven of 16 study participants in the cohort reached or exceeded the pre-  
17 specified factor VIII levels of 40 IU/dL using the CS assay. Subsequent to the April  
18 30, 2019 cutoff, one additional participant met that criteria, bringing the total to  
19 eight participants. For the 16 patients who had reached week 26 since  
20 administration of valoctocogene roxaparvovec by the April 30, 2019 cutoff, the  
21 estimated median ABR was zero and the estimated mean ABR was 1.5,  
22 representing a reduction of 85% from baseline levels where all patients were on  
23 standard of care. In addition, there was a 98% reduction in median annualized factor  
24 VIII usage and a 94% reduction in mean factor VIII usage annualized between  
25 weeks 5 and 26. Between weeks 23 and 26, the mean factor VIII level using the CS  
26 assay was 36 IU/dL and the median was 33 IU/dl. We have dosed 134 study  
27 participants in the full GENEr8-1 study and the 52-week results are anticipated in  
28 the first quarter of 2021.

18 While these statements further supported the market viability of valoctocogene roxaparvovec, and  
19 an increased likelihood of the FDA's acceptance of the BLA for that drug, which was based in part  
20 on the Phase 3 study's data, they nonetheless failed to disclose what, if any, impact the differences  
21 between the Phase 3 study and Phase 1/2 study would have on the reliability of the Phase 1/2 study  
22 to support the BLA for valoctocogene roxaparvovec.

23 39. Additionally, the 2019 10-K contained generic, boilerplate representations  
24 concerning risks inherent in BioMarin's potential failure to successfully obtain regulatory approval  
25 for one or more of its product candidates. For example, with specific respect to valoctocogene  
26 roxaparvovec, the 2019 10-K advised, *inter alia*:

1 With respect to valoctocogene roxaparvovec, we may experience challenges  
2 specific to gene therapy that cause significant delays or unanticipated costs, or that  
3 cannot be solved. Although numerous companies are currently advancing gene  
4 therapy product candidates through clinical trials, the FDA has only approved a  
5 very small number of vector-based gene therapy products thus far. Moreover, there  
6 are very few approved gene therapy products outside the U.S. As a result, it is  
7 difficult to determine how long it will take or how much it will cost to obtain  
8 regulatory approvals for valoctocogene roxaparvovec in any jurisdiction.  
9 Regulatory requirements governing gene and cell therapy products are still  
10 evolving and may continue to change in the future. Regulatory review agencies and  
11 the new requirements and guidelines they promulgate may lengthen the regulatory  
12 review process, require us to perform additional or larger studies, increase our  
development costs, lead to changes in regulatory positions and interpretations,  
delay or prevent approval and commercialization of our treatment candidate or lead  
to significant post-approval studies, limitations or restrictions. Delay or failure to  
obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring  
valoctocogene roxaparvovec to market could have a negative effect on our business  
and financial condition. Even if we do obtain regulatory approval, ethical, social  
and legal concerns about gene therapy arising in the future could result in additional  
regulations restricting or prohibiting sale of our product.

13 Plainly, this risk warning was a generic, catch-all provision that was not tailored to BioMarin's  
14 actual known risks regarding the BLA application for valoctocogene roxaparvovec, much less  
15 what, if any, impact the differences between the Phase 3 study and Phase 1/2 study would have on  
16 the reliability of the Phase 1/2 study to support the BLA for valoctocogene roxaparvovec.

17  
18 40. Appended as an exhibit to the 2019 10-K were signed certifications pursuant to the  
19 Sarbanes-Oxley Act of 2002, wherein Defendants Bienaimé and Mueller certified that “the [2019  
20 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange  
21 Act of 1934,” and that “the information contained in the [2019 10-K] fairly presents, in all material  
22 respects, the financial condition and results of operations of the Company.”

23  
24 41. On May 31, 2020, BioMarin issued a press release announcing “an update to its  
25 previously reported results of an open-label Phase 1/2 study of valoctocogene roxaparvovec, an  
26 investigational gene therapy treatment for adults with severe hemophilia A,” with “[t]he data  
27 hav[ing] been submitted as a late-breaking abstract to the World Federation of Hemophilia . . .  
28 Virtual Summit” (the “May 2020 Press Release”). That press release reported, in relevant part,

1 that “[t]he four-year update for the 6e13 vg/kg and three-year update for the 4e13 vg/kg cohorts  
2 demonstrated that all subjects in both cohorts remain off prophylactic Factor VIII treatment since  
3 receiving their single dose of valoctocogene roxaparvovec”; that “[c]umulative mean [ABR]  
4 remain less than one (1) in both cohorts and below pre-treatment baseline levels”; that “[t]he mean  
5 ABR in year four for the 6e13 vg/kg cohort was 1.3, and the mean ABR in year three for the 4e13  
6 vg/kg cohort was 0.5”; that “[o]ver the past year, six of the seven participants in the 6e13 vg/kg  
7 cohort and five of the six participants in the 4e13 vg/kg cohort remain free of spontaneous bleeds”;  
8 and that “Factor VIII activity levels declined commensurate with the most recent years’  
9 observations and remain in a range to provide hemostatic efficacy”; all of which further indicated  
10 to investors the market viability of valoctocogene roxaparvovec, and an increased likelihood of  
11 the FDA’s acceptance of the BLA for that drug, given the updated Phase 1/2 study results.

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14 42. Additionally, the May 2020 Press Release quoted Defendant Fuchs, who touted, in  
15 relevant part, that “BioMarin is proud to have advanced the community’s knowledge of the  
16 potential for gene therapy to transform lives”; that “[i]n just over four years since starting clinical  
17 trials in patients, [BioMarin has] submitted applications for marketing authorizations globally”;  
18 that BioMarin “continue[s] to contribute to the growing body of scientific data in gene therapy for  
19 hemophilia A with five studies underway”; and that Defendants “continue to move forward with  
20 health authorities to make this treatment available for people with severe hemophilia A.”

21  
22 43. On June 17, 2020, BioMarin issued a press release announcing “additional data  
23 from its previously reported four-year update of an open-label Phase 1/2 study of valoctocogene  
24 roxaparvovec, an investigational gene therapy treatment for severe hemophilia A,” the results of  
25 which “were presented during a late-breaking oral presentation at the World Federation of  
26 Hemophilia . . . Virtual Summit” (the “June 2020 Press Release”). Specifically, that press release  
27 provided several slides that purportedly further supported valoctocogene roxaparvovec as a gene  
28

1 therapy treatment for severe hemophilia A, as well as discussions of the beneficial data observed  
2 in the individual cohorts of the Phase 1/2 study.

3 44. With respect to ABR and Factor VIII use in the 6e13 vg/kg Cohort, the June 2020  
4 Press Release stated, in relevant part, that “[i]n the six study participants who were previously on  
5 Factor VIII prophylaxis in the 6e13 vg/kg cohort, the data showed substantial and sustained  
6 reductions in bleeding that required Factor VIII infusions”; that “[i]n the year prior to treatment  
7 with valoctocogene roxaparvovec, the mean [ABR] was 16.3 and the median was 16.5”; that  
8 “[d]uring the four years following treatment with valoctocogene roxaparvovec, the cumulative  
9 mean ABR was 0.8, which represents a 95% reduction from baseline”; that, “[i]n the fourth year,  
10 the mean ABR was 1.3 and the median was zero”; that “[t]here was a 96% reduction in mean  
11 Factor VIII usage to 5.4 infusions per year cumulatively over four years from the baseline of 135.6  
12 infusions per year”; that “[a]mong all seven study participants in the 6e13 vg/kg cohort, 86% or  
13 six out of seven were bleed-free in the fourth year”; and that “[a]ll participants remain off Factor  
14 VIII prophylaxis therapy.”  
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17 45. With respect to ABR and Factor VIII use in the 4e13 vg/kg Cohort, the June 2020  
18 Press Release stated, in relevant part, that “[s]imilarly, in the six study participants in the 4e13  
19 vg/kg cohort, the data showed substantial and sustained reductions in bleeding requiring Factor  
20 VIII infusions following treatment with valoctocogene roxaparvovec”; that “[a]ll participants  
21 remain off Factor VIII prophylaxis therapy”; that “[i]n the year prior to treatment with  
22 valoctocogene roxaparvovec, the mean ABR was 12.2 and the median was 8.0”; that “[t]he  
23 cumulative mean ABR was reduced by 93% to 0.9 with continued absence of target joint bleeds  
24 in 5 of 6 subjects during the three years observed, which represents a 93% reduction from  
25 baseline”; that “[d]uring the third year of follow-up, the mean ABR was 0.5 and the median was  
26 zero (0), and 67% or four out of six study participants were bleed-free”; that “[f]ive out of six  
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1 participants had no spontaneous bleeds”; and that “[t]here was a 96% reduction in mean Factor  
2 VIII usage to 5.7 infusions per year cumulatively over three years from the baseline of 142.8  
3 infusions per year.”

4 46. With respect to Factor VIII activity levels for 6e13 vg/kg and 4e13 vg/kg cohorts,  
5 the June 2020 Press Release stated, in relevant part, that “[f]or the 6e13 vg/kg and 4e13 vg/kg  
6 cohorts, mean Factor VIII activity levels over four and three years, respectively, support the  
7 observed reductions in bleed rates and annualized Factor VIII usage”; that “[a]ll study participants  
8 had severe hemophilia A at baseline, defined as less than or equal to 1 IU/dL of Factor VIII  
9 activity”; that “[a]t the end of the fourth-year post-infusion with valoctocogene roxaparvovec, all  
10 patients continue to produce their own endogenous factor with the mean Factor VIII activity level  
11 of the 6e13 vg/kg cohort at 24.2 IU/dL as measured by the [CS] assay and at 35.4 IU/dL as  
12 measured by the One-Stage” (“OS”) “assay”; that “[t]he median Factor VIII activity levels at the  
13 end of the fourth year was 16.4 IU/dL as measured by the CS assay and 23.4 IU/dL as measured  
14 by the OS assay”; that “[t]hese measurements are based on six of the seven participants, as an  
15 evaluable sample for the seventh study participant was not available”; that “[m]ean Factor VIII  
16 activity levels over three years similarly support the observed reductions in bleed rates and  
17 annualized Factor VIII usage for the 4e13 vg/kg cohort”; that “[a]t the end of the third year post-  
18 infusion with valoctocogene roxaparvovec, mean Factor VIII activity level of the 4e13 vg/kg  
19 cohort was 9.9 IU/dL as measured by the CS assay and 14.9 IU/dL as measured by the OS assay”;  
20 and that “[t]he median Factor VIII activity levels at the end of the third year was 7.9 IU/dL as  
21 measured by the CS assay and 12.3 IU/dL as measured by the OS assay.”

22 47. Additionally, the June 2020 Press Release touted BioMarin’s “[r]obust [c]linical  
23 [p]rogram” for valoctocogene roxaparvovec, touting, in relevant part, that “[t]he global Phase 3  
24 study of valoctocogene roxaparvovec at the 6e13 vg/kg dose (GENEr8-1) evaluates superiority of  
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1 valoctocogene roxaparvovec to the current standard of care, FVIII prophylactic therapy”; that  
2 “[t]he sample size of the GENEr8-1 study is approximately 130 total participants”; that “BioMarin  
3 has five clinical studies underway in its comprehensive gene therapy program for the treatment of  
4 severe hemophilia A”; that, “[i]n addition to the global Phase 3 study GENEr8-1, the Company is  
5 running a Phase 1/2 Study with the 6E13kg/vg dose of valoctocogene roxaparvovec in  
6 approximately 10 participants with pre-existing AAV5 antibodies”; that “[t]he Company is also  
7 running two additional and separate studies, one to study AAV seroprevalence in people with  
8 severe hemophilia A and one non-interventional study to determine baseline characteristics in  
9 people with hemophilia A”; and that “[p]articipants in the Phase 1/2 dose escalation study will  
10 continue to be monitored as part of the global program underway.” All of these statements, in  
11 addition to the other statements from the June 2020 Press Release referenced herein, further  
12 indicated to investors the market viability of valoctocogene roxaparvovec, and an increased  
13 likelihood of the FDA’s acceptance of the BLA for that drug.  
14

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16 48. Indeed, the June 2020 Press Release quoted Professor John Pasi, M.B., Ch.B.,  
17 Ph.D., from Barts and the London School of Medicine and Dentistry and Chief Investigator for the  
18 Phase 1/2 study, who touted, in relevant part, that “[w]ith four years of data, this study represents  
19 the longest duration of clinical experience for any gene therapy in hemophilia A”; that “[i]t is  
20 exciting to observe that all study participants remain off Factor VIII prophylaxis therapy, while  
21 also experiencing a greater than 90 percent reduction in bleeding episodes from a single  
22 administration of valoctocogene roxaparvovec”; that “[t]hese data demonstrate the very real  
23 potential of a paradigm shift in the treatment of hemophilia A”; and that “ongoing research into  
24 gene therapies could represent an entirely new way to approach meeting the high unmet need in  
25 patients with severe hemophilia A.”  
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1 during development or review”; that the FDA “recommended that the Company complete the  
2 Phase 3 Study and submit two-year follow-up safety and efficacy data on all study participants”;  
3 that the “FDA concluded that the differences between [the Phase 1/2 study] and the Phase 3 study  
4 limited its ability to rely on the Phase 1/2 study to support durability of effect”; that “[t]he Phase  
5 3 study was fully enrolled in November 2019, and the last patient will complete two years of follow  
6 up in November 2021”; that “[t]he Company plans to meet with the [FDA] in the coming weeks  
7 to align on the next steps to obtain approval”; and that “[t]he ongoing valoctocogene roxaparvec  
8 clinical trials will continue while BioMarin is exploring next steps to obtain approval.”

9  
10 52. The August 2020 Press Release also quoted Defendant Bienaimé, who represented,  
11 in relevant part, that Defendants “are surprised and disappointed that the FDA introduced new  
12 expectations for the first time in the Complete Response Letter.”

13  
14 53. Following BioMarin’s issuance of the August 2020 Press Release, the Company’s  
15 stock price fell \$41.82 per share, or 35.28%, to close at \$76.72 per share on August 19, 2020.

16 54. Although Defendants largely shifted the blame for the valoctocogene roxaparvec  
17 BLA’s rejection onto the FDA for moving the goal post forward in terms of what was required for  
18 the BLA’s acceptance, analysts quickly noted that Defendants’ should have been aware of issues  
19 with the BLA ahead of time. For example, an article published by *Fierce Biotech* on August 19,  
20 2020, observed that “[t]hree-year data on [BioMarin’s] candidate were reported last May but  
21 sparked concerns about the durability of the therapy after factor VIII levels seemed to fall off after  
22 12 to 18 months, raising the possibility that patients might need to be re-dosed to maintain  
23 protection against bleeds,” and that “it is durability the FDA has concerns over, though BioMarin  
24 contends this is the first it’s heard about it.” Similarly, an article published by *Evaluate Vantage*  
25 on August 20, 2020, remarked that “[t]he problem of [valoctocogene roxaparvec]’s waning  
26 efficacy has been rumbling for some time,” and that, “[a]s such BioMarin’s claim that the US FDA  
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1 had moved the goalposts in demanding long-term data before approving [valoctocogene  
2 roxaparvovec] . . . a central point of yesterday’s complete response letter, rings hollow.”  
3 Additionally, RBC Capital analyst Kennen Mackay downgraded BioMarin to sector perform from  
4 outperform, cutting his share-price target to \$92 from \$123, noting that the FDA’s action is “thesis-  
5 changing” and reduced management credibility.  
6

7 55. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline  
8 in the market value of the Company’s securities, Plaintiff and other Class members have suffered  
9 significant losses and damages.

#### 10 **Post-Class Period Developments**

11 56. On September 9, 2020, BioMarin filed a current report on Form 8-K with the SEC,  
12 disclosing that the EMA had delayed the marketing application for valoctocogene roxaparvovec.  
13 Specifically, the Form 8-K advised, in relevant part, that “the Company received the [EMA] Joint  
14 Assessment Report (the ‘Report’) related to the EMA’s ongoing review of the Company’s [MAA]  
15 for valoctocogene roxaparvovec for severe hemophilia A”; that “[t]he Report requests that the  
16 Company submit to the EMA the full 52-week results from the 134 patients in the ongoing Phase  
17 3 study of valoctocogene roxaparvovec with the 6e13 vg/kg dose”; that “[t]he Company expects  
18 the last patient will reach 52 weeks of follow-up in November 2020, and BioMarin is working with  
19 the EMA to enable a potential submission of the requested data by the end of the first quarter of  
20 2021”; that, “[a]s a result of the EMA’s request, the review of the Company’s MAA has reverted  
21 from an accelerated assessment to a standard review”; and that “BioMarin plans to provide  
22 additional information about its expectations regarding the timing of the MAA review after the  
23 Company has further interactions with the EMA.”  
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**PLAINTIFF’S CLASS ACTION ALLEGATIONS**

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2 57. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil  
3 Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise  
4 acquired BioMarin securities during the Class Period (the “Class”); and were damaged upon the  
5 revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein,  
6 the officers and directors of the Company, at all relevant times, members of their immediate  
7 families and their legal representatives, heirs, successors or assigns and any entity in which  
8 Defendants have or had a controlling interest.

9  
10 58. The members of the Class are so numerous that joinder of all members is  
11 impracticable. Throughout the Class Period, BioMarin securities were actively traded on the  
12 NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can  
13 be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or  
14 thousands of members in the proposed Class. Record owners and other members of the Class may  
15 be identified from records maintained by BioMarin or its transfer agent and may be notified of the  
16 pendency of this action by mail, using the form of notice similar to that customarily used in  
17 securities class actions.  
18

19 59. Plaintiff’s claims are typical of the claims of the members of the Class as all  
20 members of the Class are similarly affected by Defendants’ wrongful conduct in violation of  
21 federal law that is complained of herein.  
22

23 60. Plaintiff will fairly and adequately protect the interests of the members of the Class  
24 and has retained counsel competent and experienced in class and securities litigation. Plaintiff has  
25 no interests antagonistic to or in conflict with those of the Class.  
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1           61. Common questions of law and fact exist as to all members of the Class and  
2 predominate over any questions solely affecting individual members of the Class. Among the  
3 questions of law and fact common to the Class are:

- 4           • whether the federal securities laws were violated by Defendants' acts as alleged  
5 herein;
- 6           • whether statements made by Defendants to the investing public during the Class  
7 Period misrepresented material facts about the business, operations and  
8 management of BioMarin;
- 9           • whether the Individual Defendants caused BioMarin to issue false and misleading  
10 financial statements during the Class Period;
- 11           • whether Defendants acted knowingly or recklessly in issuing false and misleading  
12 financial statements;
- 13           • whether the prices of BioMarin securities during the Class Period were artificially  
14 inflated because of the Defendants' conduct complained of herein; and
- 15           • whether the members of the Class have sustained damages and, if so, what is the  
16 proper measure of damages.

17           62. A class action is superior to all other available methods for the fair and efficient  
18 adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the  
19 damages suffered by individual Class members may be relatively small, the expense and burden  
20 of individual litigation make it impossible for members of the Class to individually redress the  
21 wrongs done to them. There will be no difficulty in the management of this action as a class action.

22           63. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-  
23 on-the-market doctrine in that:

- 24           • Defendants made public misrepresentations or failed to disclose material facts  
25 during the Class Period;
- 26           • the omissions and misrepresentations were material;
- 27           • BioMarin securities are traded in an efficient market;

- 1 • the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- 2
- 3 • the Company traded on the NASDAQ and was covered by multiple analysts;
- 4 • the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- 5
- 6 • Plaintiff and members of the Class purchased, acquired and/or sold BioMarin securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.
- 7
- 8

9 64. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a  
10 presumption of reliance upon the integrity of the market.

11 65. Alternatively, Plaintiff and the members of the Class are entitled to the presumption  
12 of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v.*  
13 *United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in  
14 their Class Period statements in violation of a duty to disclose such information, as detailed above.

15 **COUNT I**

16 **(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder**  
17 **Against All Defendants)**

18 66. Plaintiff repeats and re-alleges each and every allegation contained above as if fully  
19 set forth herein.

20 67. This Count is asserted against Defendants and is based upon Section 10(b) of the  
21 Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

22 68. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and  
23 course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions,  
24 practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other  
25 members of the Class; made various untrue statements of material facts and omitted to state  
26 material facts necessary in order to make the statements made, in light of the circumstances under  
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1 which they were made, not misleading; and employed devices, schemes and artifices to defraud in  
2 connection with the purchase and sale of securities. Such scheme was intended to, and, throughout  
3 the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members,  
4 as alleged herein; (ii) artificially inflate and maintain the market price of BioMarin securities; and  
5 (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire BioMarin  
6 securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan  
7 and course of conduct, Defendants, and each of them, took the actions set forth herein.  
8

9         69. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the  
10 Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly  
11 and annual reports, SEC filings, press releases and other statements and documents described  
12 above, including statements made to securities analysts and the media that were designed to  
13 influence the market for BioMarin securities. Such reports, filings, releases and statements were  
14 materially false and misleading in that they failed to disclose material adverse information and  
15 misrepresented the truth about BioMarin's finances and business prospects.  
16

17         70. By virtue of their positions at BioMarin, Defendants had actual knowledge of the  
18 materially false and misleading statements and material omissions alleged herein and intended  
19 thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants  
20 acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose  
21 such facts as would reveal the materially false and misleading nature of the statements made,  
22 although such facts were readily available to Defendants. Said acts and omissions of Defendants  
23 were committed willfully or with reckless disregard for the truth. In addition, each Defendant  
24 knew or recklessly disregarded that material facts were being misrepresented or omitted as  
25 described above.  
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1           71. Information showing that Defendants acted knowingly or with reckless disregard  
2 for the truth is peculiarly within Defendants' knowledge and control. As the senior managers  
3 and/or directors of BioMarin, the Individual Defendants had knowledge of the details of  
4 BioMarin's internal affairs.

5           72. The Individual Defendants are liable both directly and indirectly for the wrongs  
6 complained of herein. Because of their positions of control and authority, the Individual  
7 Defendants were able to and did, directly or indirectly, control the content of the statements of  
8 BioMarin. As officers and/or directors of a publicly-held company, the Individual Defendants had  
9 a duty to disseminate timely, accurate, and truthful information with respect to BioMarin's  
10 businesses, operations, future financial condition and future prospects. As a result of the  
11 dissemination of the aforementioned false and misleading reports, releases and public statements,  
12 the market price of BioMarin securities was artificially inflated throughout the Class Period. In  
13 ignorance of the adverse facts concerning BioMarin's business and financial condition which were  
14 concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise  
15 acquired BioMarin securities at artificially inflated prices and relied upon the price of the  
16 securities, the integrity of the market for the securities and/or upon statements disseminated by  
17 Defendants, and were damaged thereby.

18           73. During the Class Period, BioMarin securities were traded on an active and efficient  
19 market. Plaintiff and the other members of the Class, relying on the materially false and misleading  
20 statements described herein, which the Defendants made, issued or caused to be disseminated, or  
21 relying upon the integrity of the market, purchased or otherwise acquired shares of BioMarin  
22 securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the  
23 other members of the Class known the truth, they would not have purchased or otherwise acquired  
24 said securities, or would not have purchased or otherwise acquired them at the inflated prices that  
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1 were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true  
2 value of BioMarin securities was substantially lower than the prices paid by Plaintiff and the other  
3 members of the Class. The market price of BioMarin securities declined sharply upon public  
4 disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

5  
6 74. By reason of the conduct alleged herein, Defendants knowingly or recklessly,  
7 directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5  
8 promulgated thereunder.

9  
10 75. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the  
11 other members of the Class suffered damages in connection with their respective purchases,  
12 acquisitions and sales of the Company's securities during the Class Period, upon the disclosure  
13 that the Company had been disseminating misrepresented financial statements to the investing  
14 public.

15 **COUNT II**

16 **(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)**

17 76. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing  
18 paragraphs as if fully set forth herein.

19  
20 77. During the Class Period, the Individual Defendants participated in the operation  
21 and management of BioMarin, and conducted and participated, directly and indirectly, in the  
22 conduct of BioMarin's business affairs. Because of their senior positions, they knew the adverse  
23 non-public information about BioMarin's misstatement of income and expenses and false financial  
24 statements.

25  
26 78. As officers and/or directors of a publicly owned company, the Individual  
27 Defendants had a duty to disseminate accurate and truthful information with respect to BioMarin's  
28

1 financial condition and results of operations, and to correct promptly any public statements issued  
2 by BioMarin which had become materially false or misleading.

3 79. Because of their positions of control and authority as senior officers, the Individual  
4 Defendants were able to, and did, control the contents of the various reports, press releases and  
5 public filings which BioMarin disseminated in the marketplace during the Class Period concerning  
6 BioMarin's results of operations. Throughout the Class Period, the Individual Defendants  
7 exercised their power and authority to cause BioMarin to engage in the wrongful acts complained  
8 of herein. The Individual Defendants therefore, were "controlling persons" of BioMarin within the  
9 meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful  
10 conduct alleged which artificially inflated the market price of BioMarin securities.  
11

12 80. Each of the Individual Defendants, therefore, acted as a controlling person of  
13 BioMarin. By reason of their senior management positions and/or being directors of BioMarin,  
14 each of the Individual Defendants had the power to direct the actions of, and exercised the same  
15 to cause, BioMarin to engage in the unlawful acts and conduct complained of herein. Each of the  
16 Individual Defendants exercised control over the general operations of BioMarin and possessed  
17 the power to control the specific activities which comprise the primary violations about which  
18 Plaintiff and the other members of the Class complain.  
19

20 81. By reason of the above conduct, the Individual Defendants are liable pursuant to  
21 Section 20(a) of the Exchange Act for the violations committed by BioMarin.  
22

23 **PRAYER FOR RELIEF**

24 **WHEREFORE**, Plaintiff demands judgment against Defendants as follows:

25 A. Determining that the instant action may be maintained as a class action under Rule  
26 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;  
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1 B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason  
2 of the acts and transactions alleged herein;

3 C. Awarding Plaintiff and the other members of the Class prejudgment and post-  
4 judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

5 D. Awarding such other and further relief as this Court may deem just and proper.  
6

7 **DEMAND FOR TRIAL BY JURY**

8 Plaintiff hereby demands a trial by jury.

9 Dated: September 25, 2020

Respectfully submitted,

10 **POMERANTZ LLP**

11 */s/ Jennifer Pafiti*

12 Jennifer Pafiti (SBN 282790)  
13 1100 Glendon Avenue, 15th Floor  
14 Los Angeles, California 90024  
15 Telephone: (310) 405-7190  
16 jpfafiti@pomlaw.com

17 **POMERANTZ LLP**

18 Jeremy A. Lieberman  
19 (*pro hac vice* application forthcoming)  
20 J. Alexander Hood II  
21 (*pro hac vice* application forthcoming)  
22 600 Third Avenue, 20<sup>th</sup> Floor  
23 New York, New York 10016  
24 Telephone: (212) 661-1100  
25 Facsimile: (212) 661-8665  
26 jalieberman@pomlaw.com  
27 ahood@pomlaw.com

28 **POMERANTZ LLP**

Patrick V. Dahlstrom  
(*pro hac vice* application forthcoming)  
10 South La Salle Street, Suite 3505  
Chicago, Illinois 60603  
Telephone: (312) 377-1181  
Facsimile: (312) 377-1184  
pdahlstrom@pomlaw.com

*Attorneys for Plaintiff*