Tsantes v. BioMarin Pharmaceutical Inc., et al

COURT: United States District Court for the Northern District of California
CASE NUMBER: 3:20-cv-06719
CLASS PERIOD: 02/28/2020 - 08/18/2020
CASE LEADERS: Katherine M. Sinderson, Jeroen van Kwawegen, Avi Josefson, Jonathan D. Uslaner, Abe Alexander
CASE TEAM: Thomas Sperber, William E. Freeland

On September 25, 2020, a class action lawsuit was filed in the U.S. District Court for the Northern District of California alleging violations of the federal securities laws against BioMarin Pharmaceutical Inc. ("BioMarin" or the "Company") and certain of the Company's senior executives (collectively, "Defendants"). The lawsuit was brought on behalf of investors in BioMarin that purchased BioMarin stock between February 28, 2020 and August 18, 2020, inclusive (the "Class Period").

Throughout the Class Period, Defendants made materially false and misleading statements regarding the likelihood that the Company's December 23, 2019 Biologics License Application (BLA) would be approved by the FDA by August 21, 2020 on the basis of preliminary Phase 3 trial data. Defendants knew of the FDA's concerns that the initial Phase 3 trial data showed potential issues with the long-term effectiveness of the drug due to a decline in Factor VIII levels in patients over time. According to Defendants' own subsequent admissions, Defendants had no dialogue whatsoever with the FDA from mid-April 2020 to June 2020, at which point Defendants learned that a facility inspection—required for FDA approval—would not occur prior to August 21, 2020. Despite this knowledge, BioMarin assured investors that the FDA approval process was "going quite well," that the FDA had been "quite collaborative" and in a "mesh" with Defendants, and that the drug would "launch[] in the second half of" 2020.

The truth emerged on August 19, 2020, when BioMarin announced that the Company had received a Complete Response Letter from the FDA, which included the FDA's concerns about the initial Phase 3 data's indication of a declining durability of effect. BioMarin disclosed that the FDA declined to approve the BLA and would require that BioMarin complete its Phase 3 trial and submit two-year follow-up safety and efficacy data on all participants before any possible approval. Accordingly, FDA approval of BioMarin's BLA for Valrox cannot happen until at least 2022. In response to these disclosures, BioMarin's stock price dropped $41.82 per share, or 35.28%, to close at $76.72 per share on August 19, 2020.

On December 22, 2020, the Court appointed Arbejdsmarkedets Tillægspension lead plaintiff, and approved BLB&G as lead counsel. Lead Plaintiff filed an Amended Class Action Complaint on February 22, 2021. Defendants filed a Motion to Dismiss on April 22, 2021. On January 6, 2022, the Honorable William Orrick III denied the Motion to Dismiss and sustained the Complaint in its entirety. Lead Plaintiff filed its motion for class certification on October 17, 2022. Defendants' brief in opposition is due on December 16, 2022, and Lead Plaintiff's reply in support of the motion is due on February 14, 2023. The case is in discovery.

Case Documents

- February 22, 2021 - Amended Class Action Complaint for Violations of the Federal Securities Laws

- December 22, 2020 - Order Appointing Arbejdsmarkedets Tillægspension as Lead Plaintiff and Approving its Selection of Lead Counsel