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Puma Beats Most Of Stock Drop Suit Over Nerlynx Study Statements

By Brenda Sandburg

IN AN UNUSUAL MOVE, PUMA BIOTECHNOLOGY Inc. opted to go to trial rather than settle a stock drop suit alleging the company made misleading statements about its breast cancer treatment candidate *Nerlynx* (neratinib). That turned out to be a good decision. While the company was dinged for one statement made on an investor call, the jury awarded just a fraction of the damages sought by the plaintiff.

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In a Feb. 4 verdict, a jury awarded damages of $4.50 per share rather than the $87 per share requested by plaintiffs for two stock drops in 2015. The total damages awarded for 14,300 shares purchased by the lead plaintiff before the first stock drop is thus $64,350. This amounts to less than five percent of the total of about $1.349m that the lead plaintiff, Norfolk Pension Fund, had sought in damages.

Puma's co-lead counsel Andrew Clubok, a partner at Latham & Watkins, noted that since the case proceeded as a class action, plaintiffs had claimed potential class-wide damages exceeded $1bn. He added that since the named plaintiff made a profit of about $65,000 buying and selling shares during the class period, that amount could potentially be treated as a complete "offset" to the damages.

Plaintiff attorney Patrick Coughlin, of counsel at Robbins Geller Rudman & Dowd, stated that the award could be higher if other institutional shareholders make a claim. He said that 20.7 million shares were traded during the class period so damages could be anywhere from $75m to $100m.

Clubok adamantly disagreed with this figure. "That number is wildly inflated and intentionally misleading, and the plaintiff's lawyers know it," he stated. "By not properly taking into account issues like 'in and out' trades, which their own client engaged in during the class period, and holdings by certain institutions who do not typically trade with frequency, they have simply 'modeled' potential maximum damages to be effectively twice as high to make it appear as if they won more than they did. Furthermore, any actual damages would be reduced even further based on a claims process."

The litigation shows the challenges a biopharma company faces as it develops a drug and its public statements are closely scrutinized for possible legal action if there is fluctuation in the stock. Companies are routinely hit with stock drop suits and this case shows that taking a case to trial may limit liability.

Public Statements Get Close Scrutiny

The plaintiff claimed four statements Puma made on July 22, 2014 regarding results from its pivotal Phase III ExteNet trial of neratinib were false or misleading and led to two drops in Puma stock, on May 14, 2015 and June 1-2, 2015. The latter occurred after results of the study were presented at the American Society of Clinical Oncology conference.

The plaintiff, a pension fund in Norwich, England, filed the suit, HsingChing Hsu v. Puma, on June 3, 2015 in the US District Court for the Central District of California. The complaint was brought on behalf of all persons or entities who purchased Puma's common stock between July 22, 2014 and May 29, 2015. Robins Geller represents the plaintiff on a contingency fee basis.

The jury found that a statement made about disease-free survival (DFS) rates was false and misleading. But it found that the plaintiffs had not proven the three other statements –regarding the rate of Grade 3 diarrhea, Kaplan-Meier curves for DFS rates, and the discontinuation rate due to adverse events – were false or misleading.

It is very rare for a stock drop suit to go to trial. Clubok noted that in the past decade, only two securities cases of this size and nature have proceeded to a jury verdict.

"We went to trial because the plaintiff's lawyer-funded case was seeking damages that could have threatened the mission of Puma to develop safe and effective cancer treatments," said Clubok, who co-led the case with Latham partner Michele Johnson. "This verdict ensures that Puma's efforts and continuing work with its FDA-approved breast cancer treatment will not be impacted."

Press Release On Topline Results Was Okay

Clubok said that prior to the trial, the judge found Puma's press release about the topline results of the ExteNET trial was truthful. The release said the results of the trial demonstrated that treatment with neratinib resulted in a 33% improvement in disease free survival versus placebo. The four statements at issue in the trial were made in an investor call.

In the statement about disease-free survival rates, Puma CEO Alan Auerbach said the DFS of the placebo arm of the trial was "in line with other reported trials. So it's in line with the Herceptin adjuvant studies." Asked if the DFS is probably around around 86% or so in the control arm, he replied, "I would be comfortable with that number."

FDA approved Nerlynx, a tyrosine kinase inhibitor, in July 2017 for extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant therapy with Roche's *Herceptin* (trastuzumab).

The primary endpoint in the pivotal ExteNET trial was disease-free survival benefit. In the study of 2,840 patents, the drug reduced the risk of recurrence two years after randomization by 34% (94.2% on neratinib had no recurrence versus 91.9% on placebo), a statistically significant result. The positive result overall was modest and was driven by certain subgroups. The approved labeling details performance by subgroup, as well as results relative to the timing of Hercptin, but the indication covers all patients with this type of cancer *(Also see "Puma's Nerlynx Scores Broad Label Across Adjuvant Breast Cancer Subgroups" - Pink Sheet, 17 Jul, 2017.)*.

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