EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA TAMPA DIVISION

PRESCOTT ARNOLD, Plaintiff, v. **NOVARTIS PHARMACEUTICALS CORPORATION,** Defendant.	**Case No. 8:06-cv-1709-T-23MAP**

CASE MANAGEMENT REPORT

1. Meeting of Parties Telephonically

Pursuant to Local Rule 3.05(c), counsel for plaintiff and defendant met telephonically on April 17, 2012. *See* Order, ECF No. 14. The meeting was attended by Ramon Rasco on behalf of the plaintiff and Grant Hollingsworth on behalf of defendant Novartis Pharmaceuticals Corporation ("NPC"). Pursuant to Local Rule 3.05(c)(2)(C)(viii), the parties request a preliminary pretrial conference to address the disputed issues outlined below.

The parties have exchanged information described in Federal Rule of Civil Procedure 26(a)(1)(A)-(D) on various dates throughout the multi-district litigation ("MDL") process. Both parties agree to continue updating disclosures during the duration of this matter as required by the Federal Rules of Civil Procedure, and the Orders of this Court.

2. Agreed Discovery Plan for Plaintiffs and Defendants

A. Certificate of Interested Persons and Corporate Disclosure Statement

The parties have already filed respective Certificate of Interested Persons and Corporate Disclosure Statements in this matter.

B. Discovery Not Yet Completed

This is a products liability action arising out of Mrs. Cathy Arnold's use of Aredia® and Zometa®, intravenous bisphosphonate medications prescribed by oncologists to reduce the risk of pathologic fractures, spinal cord compressions, and other skeletal complications in patients with multiple myeloma and cancers that have metastasized to the patients' bone. Mrs. Arnold died from metastatic breast cancer in June 2009. Her surviving husband Mr. Prescott Arnold alleges that the administration of Aredia® and Zometa® as a treatment for bone metastases of breast cancer led to Mrs. Arnold developing osteonecrosis of the jaw ("ONJ"), and that NPC failed to adequately warn of that potential risk. Mr. Arnold seeks compensatory damages on behalf of Mrs. Arnold, loss of consortium damages, and punitive damages. NPC denies all liability.

This case was transferred to and recently remanded from the MDL styled *In re Aredia® and Zometa® Products Liability Litigation*, No. 3:06-MD-1760 (M.D. Tenn.), pending before the Honorable Todd J. Campbell in the United States District Court for the Middle District of Tennessee, Nashville Division. Fact discovery on liability was completed while the case was pending in the MDL, including corporate discovery against NPC and depositions of plaintiff and Mrs. Arnold's treating health care providers. The MDL court left all other proceedings to occur post-remand, including expert discovery; summary judgment, *Daubert*, and other case-specific motions; and damages discovery.

Currently, there are approximately 120 cases with allegations that NPC failed to adequately warn prescribing oncologists of the potential risk of ONJ occurring in patients treated with Aredia® and/or Zometa® in federal courts across the country that have either been remanded from MDL 1760 or directly filed in other courts after the Judicial Panel on Multidistrict Litigation ("JPML") discontinued transfers to the MDL. *See* Order Suspending Panel Rule 7.1(a), MDL No. 1760, ECF No. 478 (J.P.M.L. Apr. 13, 2011) (Ex. 1). At least 15 cases are currently set for trial in 2013 in various courts across the country, and over 20 cases are currently set for trial in 2014. This case is part of the eighth and most recent group of cases to proceed through fact discovery in the MDL. Dozens of other cases from this discovery group have been recently remanded and are in a similar posture of setting schedules for remaining pretrial proceedings. To date, 10 cases from the consolidated Aredia®/Zometa® litigation have proceeded to trial. NPC has prevailed in four, plaintiff has prevailed in four, plaintiff voluntarily dismissed one with prejudice after two days of trial, and one is currently underway. Additionally, NPC notes that to date it has secured over 175 dismissals of Aredia®/Zometa® cases, including 47 dismissals by summary judgment.

Plaintiff asserts claims for (a) strict liability, (b) negligent manufacture, (c) negligence – failure to warn, (d) breach of express warranty, and (e) breach of implied warranty. Plaintiff has also filed a loss of consortium claim, in which he seeks damages for his wife's alleged "bisphosphonate-related" osteonecrosis of the jaw ("ONJ"), which he alleges is a new disease that did not exist until allegedly caused by NPC's drugs and given the name "Bisphosphonate Related Osteonecrosis of the Jaw" ("BRONJ") by the American Association of Oral and Maxillofacial Surgeons ("AAOMS"). Plaintiff contends that this condition does not exist in patients who have not been exposed to bisphosphonates and the incident rate for it is highest with

intravenous ("I.V.") bisphosphonates like Zometa®. In addition, plaintiff alleges Novartis' actions warrant punitive damages under Florida law.

NPC denies plaintiff's allegations and claims. NPC contends that: (a) plaintiff has no admissible evidence that Aredia® or Zometa® caused Mrs. Arnold's jaw problem; (b) Florida law contains a rebuttable presumption, which plaintiff cannot rebut, that manufacturers of products approved by the U.S. Food and Drug Administration ("FDA") are not liable in products liability actions; (c) regardless, the FDA-approved warnings regarding Aredia® and Zometa® were adequate based on the scientific knowledge available at all relevant times; (d) under the learned intermediary doctrine, NPC complied with its duty to warn the oncologists who prescribed Aredia® and Zometa® to Mrs. Arnold; (e) any alleged risk of ONJ was far outweighed by the substantial benefits of Aredia® and Zometa®; (f) at all relevant times, Aredia® and Zometa® were the standard-of-care treatment for patients like Mrs. Arnold because both have been scientifically proven to prevent pathologic fractures, spinal cord compression, and other serious skeletal pains and complications in patients with breast cancer that has metastasized to bone; (g) plaintiff cannot carry his burden of proving proximate causation because his wife's oncologists have testified that *even if* a different warning had been provided, they would have still prescribed Aredia® and Zometa® for Mrs. Arnold; and (h) plaintiff cannot carry his burden of proving medical causation. NPC contests plaintiff's assertion that he is entitled to punitive damages and, as explained below, intends to file motions before this Court regarding punitive damages, including choice of law issues.

The MDL court directed that damages discovery take place following remand. *See* May 30, 2008 Order, No. 3:06-MD-1760 (M.D. Tenn.), ECF No. 1378 (Ex. 2). In addition to plaintiff, the Plaintiff's Fact Sheet, which constituted Rule 26 initial disclosures, names six

"damage" witnesses who have not yet been deposed. NPC may depose damages witnesses knowledgeable of the alleged medical expenses claimed by plaintiff.

The parties shall not file discovery materials with the Court except as provided in Local Rule 3.03. The parties further agree to the discovery plan outlined in this report, subject to the few remaining differences outlined below.

C. Limits of Discovery

(1) Depositions

Depositions will be governed by the Federal Rules of Civil Procedure and the Local Rules for the Middle District of Florida. Depositions of NPC's general, case-wide witnesses were completed in the MDL proceedings. Plaintiff intends to depose the sales representatives who sold NPC's bisphosphonate drugs to plaintiff's doctor to discover what safety and warning information, if any, was provided. Certain document discovery will accompany this request. NPC reserves the right to object to such requests, as all discovery of NPC was completed in the MDL. As noted above, damages discovery, including depositions of individuals identified by plaintiff as having discoverable information, remains to be completed by NPC.

(2) Interrogatories and Requests for Production

Written discovery will be governed by the Federal Rules of Civil Procedure. Written discovery was also largely completed in the MDL via the Plaintiff Fact Sheet. However, NPC has only propounded one interrogatory and two requests for production in this case, well short of the limit of five of each allotted to it by court order in the MDL and by agreement between the parties outside of the MDL. *See* July 28, 2006 Case Management Order, No. 3:06-MD-1760 (M.D. Tenn.), ECF No. 89 (Ex. 3). NPC plans to utilize some of these interrogatories and requests for production during the expert and damages phases of this case.

(3) Requests to Admit

Requests for admission shall be governed by the Federal Rules of Civil Procedure.

(4) Supplementation of Discovery

Supplementation of discovery responses will be governed by the Federal Rules of Civil Procedure and the Local Rules of the Middle District of Florida.

D. Discovery Deadline

The parties have conferred but have not yet reached agreement as to the discovery deadline dates outlined in the proposed schedule below, which sets forth proposed dates from plaintiff and proposed dates from NPC.

E. Disclosure of Expert Testimony

The parties have conferred but have not reached agreement as to the disclosure of expert reports for retained experts. NPC requests that disclosure of non-retained experts follow the same schedule and be made consistent with the MDL Agreed Order Regarding Disclosures of Non-Retained Expert Witnesses, MDL 1760, (M.D. Tenn. Jan. 26, 2009), ECF No. 2040 (Ex. 4). Plaintiff request that disclosure of non-retained experts and expert testimony follow the Federal Rules of Civil Procedure and the proposed schedule set forth below by plaintiff.

3. Electronic Discovery

The parties have discussed issues relating to disclosure or discovery of electronically stored information ("ESI"), including Pre-Discovery Initial Disclosures of Core Information in Section 2 above. The parties agree that they do not anticipate that any party will likely request or produce general information from electronic or computed-based media at this time, as production of voluminous documents by NPC has already occurred in the MDL. In the event additional information maintained in an electronic or computer-based format is identified during discovery

of individuals with knowledge of plaintiff's claims, the parties will confer regarding those issues as appropriate. Should it be necessary to file documents under seal, the parties are aware of the need to file a motion regarding sealing.

NPC requests that the confidentiality procedures and agreements adopted by the MDL court regarding preservation of documents and protection of privileged information continue to apply in this case. *See* August 15, 2006 Protective and Confidentiality Order, No. 3:06-MD-1760 (M.D. Tenn.), ECF No. 100 (Ex. 5). Plaintiff opposes this request, and requests that confidentiality and privilege procedures and protection be governed by the Federal Rules of Civil Procedure and the Local Rules, as applicable. As a corporate entity, NPC is entitled to the protection of its trade secrets, proprietary information, and other confidential business information. *See, e.g.*, *Fed. Open Market Comm. of Fed. Reserve Sys. v. Merrill*, 443 U.S. 340, 356 (1979) ("The federal courts have long recognized a qualified evidentiary privilege for trade secrets and other confidential commercial information. . . . The Federal Rules of Civil Procedure provide similar qualified protection for trade secrets and confidential commercial information in the civil discovery context."); *see also, e.g.*, Fed. R. Civ. P. 26(c)(1)(G) (permitting protective orders requiring "that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way"). Throughout this litigation, NPC has maintained its practice of keeping certain types of documents confidential to protect its intellectual property rights, trade secrets, and other confidential business information in order to protect its competitive position. *See* Aff. of Peter Tarassoff ¶ 2 ("Tarassoff Aff.") (Ex. 6); *see also* Aff. of Donald Davidson (Ex. 7) (discussing NPC policy of requiring employees to maintain confidentiality of NPC documents).

NPC requests that that this Court enter an order adopting the identical confidentiality orders from the MDL.[1] Plaintiff opposes such a request. Should it be necessary to file documents under seal, NPC is aware of the need to file a motion regarding sealing pursuant to Local Rule 1.09.

4. Proposed Case Schedule.

Event	**Proposed Deadline NPC**	**Proposed Deadline Plaintiff**
Production of plaintiff's expert reports	**7/1/2013**	**6/3/2013**
Production of defendant's expert reports	**8/1/2013**	**7/1/2013**
Rebuttal reports to each party's expert designations	**8/15/2013**	**7/16/2013**
Close of expert discovery	**11/15/2013**	**9/13/2013**
Deadline for Motions Challenging Expert Testimony and Motions for Summary Judgment	**12/16/2013**	**10/10/2013**
Deadline for Oppositions to Motions Challenging Expert Testimony and Motions for Summary Judgment	**1/16/2014**	**11/1/2013**
Deadline for Replies to Motions Challenging Expert Testimony and Motions for Summary Judgment	**1/31/2014**	**11/15/2013**
Close of Damages Discovery	**5/1/2014**	**11/29/2013**
Deadline for NPC's Motion to Apply NJ Law to Punitive Damages	**5/15/2014**	**12/13/2013**
Deadline for plaintiffs' Opposition to NPC's Motion to Apply NJ Law to Punitive Damages	**6/15/2014**	**1/8/2014**
NPC's Reply in Support of Motion to Apply NJ Law to Punitive Damages	**6/30/2014**	
Deadline for NPC's Motion to Preclude Punitive Damages Under the Applicable State's Law	**8/4/2014**	
Deadline for Opposition to NPC's Motion to Preclude Punitive Damages Under the Applicable State's Law	**9/3/2014**	
Deadline for NPC's Reply in Support of Motion to Preclude Punitive Damages Under the Applicable State's Law	**9/17/2014**	

[1] The parties recognize that this Court will enforce that agreement pursuant to L.R. 4.15.

Deadline to Exchange Exhibits and Deposition Designations	**10/01/2014**	**2/27/2014**
Deadline to Exchange Counter-Designations and Objections to Exhibits and Deposition Designations	**10/22/2014**	**3/14/2014**
Deadline to Exchange Objections to Counter-Designations	**11/5/2014**	**4/2/2014**
Deadline for Parties to Confer Telephonically or in Person Regarding Preparation of Joint Final Pretrial Statement	**12/5/2014**	**4/18/2014**
Deadline to Submit Joint Final Pre-Trial Statement	**12/19/2014**	**5/9/2014**
Deadline to Submit Disputed Motions *in Limine* and Any Other Motions	**1/9/2015**	**5/15/2014**
Deadline to Submit Oppositions to Motions *in Limine* and Any Other Motions	**1/30/2015**	**5/30/2014**
Final Pretrial Conference	**2/20/2015**	**6/12/2014**
Trial	**On or after March 26, 2015**	**On or after July 7, 2014**
Estimated Length of Trial	**2-3 Weeks**	**2-3 Weeks**
Jury/Non-Jury	**Jury**	**Jury**
Mediation	**If required (see below), 30 days after rulings on motions related to punitive damages**	**If required (see below), 30 days after rulings on motions related to punitive damages**
All Parties Consent to jurisdiction of the Magistrate Judge for final disposition, including trial.	**No**	**No**

NPC respectfully suggests that this case be set for trial on or after March 26, 2015. To date, 10 cases from the consolidated Aredia®/Zometa® litigation have proceeded to trial. Eight have proceeded to verdict, plaintiff voluntarily dismissed one with prejudice after two days of trial, and one is currently underway. All of these cases were remanded from the MDL court in a procedural posture different than this case, because until the two most recent waves, fact *and* expert discovery in the first six waves was conducted in the MDL, along with dispositive

motions briefing. For the ten trial cases remanded in that advanced posture, 17 months passed on average from when the cases were remanded to when trial commenced. Because expert discovery has yet to be conducted in this case, it is more appropriate that this complex case proceed on a 24 month timeline, in order to allow the parties to fully develop the issues.

Examples of prior cases in this district are instructive. Consider for example the three remanded cases in this district with scheduled trial dates. Unlike *Arnold*, these cases were remanded after the completion of expert discovery, as well as *Daubert* and dispositive motions briefing. The first case, *Chiles v. NPC*, was remanded to the Middle District of Florida on April 8, 2011. Trial commenced in *Chiles* over 20 months after remand on February 11, 2013 (Ex. 8). The second, *Dopson-Troutt v. NPC*, was remanded to the Middle District of Florida on May 23, 2012, and trial is scheduled for October 21, 2013 (Ex. 9). In *Dopson-Troutt*, approximately 17 months will pass between remand and the commencement of trial. The third, *Guenther v. NPC*, was remanded to the Middle District of Florida on September 5, 2012 (Ex. 10). Trial has been set to begin in *Guenther* on September 9, 2013. Therefore, over 12 months will pass between remand and the commencement of trial. Here, the *Arnold* case was remanded to the Middle District of Florida on March 21, 2013, without the benefit of completed expert disclosures, expert discovery, and *Daubert* motions and dispositive motions briefing previously completed in the MDL. NPC's proposed schedule allows approximately 12 months for the proceedings that typically have occurred in the MDL, and then about 10 months for the proceedings that have typically occurred in remand courts (faster than *Chiles*, *Guenther*, and *Dopson-Troutt*).

Federal courts in Florida and across the country have recognized the complex nature of these cases and have set their trial calendars accordingly.

Plaintiff requests that this case be set for trial at any time on or after July 7, 2014. This case was filed in September 2006 and is now over six years old. Plaintiffs and NPC use much of the same briefing, experts and discovery in these cases throughout Florida and the country. While there are always some case-specific issues to be addressed, mainly as to damages and treating physicians, plaintiff respectfully suggests that this case can be resolved expeditiously by July 2014, as opposed to NPC's proposal of scheduling trial for on or after March 26, 2015.

A. Briefing *Daubert* and Summary Judgment Motions

Unlike some previous cases remanded from the MDL to this Court, the parties in this case have yet to submit any *Daubert* or dispositive motions. NPC plans to submit both *Daubert* and summary judgment motions during the time period allotted in the proposed schedule after the completion of expert discovery. Plaintiff intends to oppose such motions.

B. Damages Discovery

As noted above, no damages discovery has taken place in this case. Plaintiff has identified six additional witnesses who may have information regarding alleged damages, though plaintiff may not call some of those witnesses at trial. NPC intends to depose at least some of these witnesses in order to prepare for trial. NPC may also depose individuals knowledgeable about plaintiff's alleged medical expenses. NPC may also serve additional written discovery.

C. Punitive Damages Briefing

Nearly every federal and state court to consider this issue – including the Jacksonville Division of this Court during the recent *Chiles* trial – has agreed with NPC's position that New Jersey law is applicable to the punitive damages issues in the Aredia®/Zometa® cases.[2] NPC will

[2] *See, e.g.*, *Chiles v. Novartis Pharm. Corp.*, No. 3:06-cv-96-J-25 JBT, 2013 WL 539891 (M.D. Fla. Feb. 7, 2013; *see also Talley v. Novartis Pharm. Corp.*, No. 3:08-CV-361-GCM, 2011 WL

make a motion to apply New Jersey law to the request for punitive damages in this case, and plaintiff will oppose this motion. Under the proposed schedule, the parties will then brief whether punitive damages are precluded under the applicable state's law.

D. Deposition Designation and Exhibits

The parties' exhibit lists and affirmative deposition designations change dramatically from case to case, based upon the bisphosphonate(s) at issue, the time period of use, the indication it was prescribed for, the availability of punitive damages, and other case-specific considerations. Plaintiffs in *Chiles v. NPC*, *Davids v. NPC*, and *Forman v. NPC* (each represented by the same counsel as Mr. Arnold) designated different portions of testimony from different non-case specific witnesses across a different number of depositions. For instance, in *Forman*, plaintiff designated thirty-three non case-specific witnesses spread over forty depositions. In *Davids*, plaintiff designated twenty-four non-case specific witnesses spread over thirty-three depositions. Yet most recently in *Chiles*, plaintiffs designated forty-one non case-specific witnesses spread over fifty-three depositions.

Additionally, in the *Forman* case, plaintiff included 580 non-case-specific exhibits on her exhibit list, while in the *Davids* case, plaintiff included 664 non-case-specific exhibits on her exhibit list. In the *Chiles* case, plaintiffs included over 1100 non-case-specific exhibits on their exhibit list. As such, NPC's designations and exhibit lists have also varied in response to those

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2559974 (W.D.N.C. June 28, 2011), *reconsideration denied*, 2011 WL 3515858 (W.D.N.C. Aug. 11, 2011), *petition for interlocutory appeal denied sub nom. Lemons v. Novartis Pharm. Corp.*, No. 12-147 (4th Cir. Apr. 9, 2012); *Zimmerman v. Novartis Pharm. Corp.*, 889 F. Supp. 2d 757 (D. Md. 2012); *Brown v. Novartis Pharm. Corp.*, No. 7:08-CV-00130-FL, 2011 WL 6318987 (E.D.N.C. Dec. 16, 2011) (Magistrate Judge's Report and Recommendation; plaintiff's objections pending); *Deutsch v. Novartis Pharm. Corp.*, 723 F. Supp. 2d 521 (E.D.N.Y. 2010); *Irby v. Novartis Pharm. Corp.*, No. MID-L-1815-08, 278, 2011 WL 5835414 (N.J. Super. Ct.

of plaintiffs. Given the fluid nature and expected volume of the deposition designation lists and exhibit lists in this litigation, it is necessary to allow time for the parties to formulate objections to the opposing party's designations and exhibits.

Counsel for the parties have had some success in past negotiations regarding deposition designation objections and exhibit list objections. Though the parties cannot incorporate the results of those negotiations to subsequent cases due to the different factual circumstances in each case, allowing at least four weeks between the final exchange of objections and submission of the Joint Final Pre-Trial Statement to this Court will allow the parties to attempt negotiations that could narrow the number of disputes requiring judicial intervention.

E. Final Pre-Trial Motions and Trial

The deadline for final pre-trial motions, including motions *in limine*, is necessarily dictated by the trial date in this case. NPC believes that a March 2015 trial date is appropriate given the amount of work yet to be completed by the parties in this case.

F. Settlement and Dispute Resolution

Pursuant to Local Rule 3.05(c)(2)(C)(v), 8.02(a)(3), and 8.05(b), the parties submit the following statement concerning their intent regarding Alternative Dispute Resolution: The parties agree that settlement is unlikely; however, if the court requires, the parties will report to the court concerning settlement at the final pretrial conference. The parties do not request a settlement conference before a Magistrate Judge. The parties do not agree to arbitrate.

The parties have not agreed to a mediator. The parties agree that 30 days after a ruling on punitive damages or 30 days prior to trial (whichever is earlier) is the last date for mediation.

Nov. 18, 2011); *Meng v. Novartis Pharm. Corp.*, Nos. L-7670-07MT, L-6027-08MT, 278, 2009 WL 4623715 (N.J. Super. Ct. Nov. 23, 2009).

April 22, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 22d day of April 2013, a true and correct copy of the foregoing Case Management Report has been filed via the Court's Electronic Case Filing System and has been served (via electronic mail), on the following:

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