Biogen (BIIB) Earnings Report: Q4 2015 Conference Call Transcript

The following Biogen conference call took place on January 27, 2016, 08:30 AM ET. This is a transcript of that earnings call:

Company Participants

- Matt Calistri; Biogen Inc. ; Senior Director of IR
- George Scangos; Biogen Inc. ; CEO
- Al Sandrock; Biogen Inc. ; Chief Medical Officer
- Paul Clancy; Biogen Inc. ; CFO

Other Participants

- Geoff Meacham; Barclays Capital ; Analyst
- Eric Schmidt; Cowen and Company ; Analyst
- Brian Abrahams; Jefferies & Company ; Analyst
- Mark Schoenebaum; Evercore ISI ; Analyst
- Michael Yee; RBC Capital Markets ; Analyst
- Matthew Harrison; Morgan Stanley ; Analyst
- Chris Raymond; Raymond James & Associates Inc. ; Analyst
- Unidentified Participant; Goldman Sachs ; Analyst
- Matt Roden; UBS ; Analyst
- Ying Huang; BofA Merrill Lynch ; Analyst
- Cory Kasimov; JPMorgan ; Analyst
- Unidentified Participant; Wells Fargo ; Analyst

MANAGEMENT DISCUSSION SECTION

Operator:

At this time, I would like to welcome everyone to the Biogen fourth-quarter and year-end 2015 financial results and business update.

(Operator Instructions)

I would now like to turn the call over to Mr. Matt Calistri, Senior Director of Investor Relations. You may begin your conference.

Matt Calistri (Senior Director of IR):

Thank you. Welcome to Biogen's fourth-quarter and full-year 2015 earnings conference call.

Before we begin, I encourage everyone to go to the investor section of Biogen.com to find the press release and related financial tables, including a reconciliation of the GAAP to non-GAAP financial measures that we will discuss today. Our GAAP financials are provided in tables 1 and 2. Table 3 includes a reconciliation of our GAAP to non-GAAP financial results.

We believe non-GAAP financial results better represent the ongoing economics of our business, and reflect how we manage the business internally. We have also posted slides on our website that follow the

discussions related to this call.

I would like to point out that we will be making forward-looking statements which are based on our current expectations and beliefs. These statements are subject to certain risks and uncertainties, and our actual results may differ materially. I encourage you to consult our SEC filings for additional detail.

On today's call I am joined by our Chief Executive Officer, Dr. George Scangos; Dr. Al Sandrock, our Chief Medical Officer; and our CFO, Paul Clancy. Now I'll turn the call over to George.

George Scangos (CEO):

Thank you, Matt, and good morning, everyone, and thanks for joining us today. In 2015, Biogen generated revenues of $10.8 billion, an 11% increase over 2014, and non-GAAP EPS of $17.01, a 23% increase over 2014. Although the revenues were less than we had anticipated at the beginning of last year, I am pleased that we were able to take appropriate action in the second half of the year to maintain healthy earnings growth while we continued to advance the potentially transformative therapies in our pipeline.

TECFIDERA's demand has been stable in the US, and combined with growth in Europe, we expect TECFIDERA to continue to drive our global leadership in multiple sclerosis. TECFIDERA is now not only the most prescribed oral MS therapy worldwide, it is also the most prescribed of all MS therapies in Germany, France, and the UK. Overall, more than 170,000 patients have been treated with TECFIDERA.

Our hemophilia products, ELOCTATE and ALPROLIX, generated over $0.5 billion of revenue in their first full year on the market in the US. In November, the European Commission approved ELOCTA for the treatment of hemophilia A in the EU, which we believe will help to contribute growth in hemophilia this year, as our collaboration partner Sobi commercializes ELOCTA in additional markets.

We also made progress in business development. We acquired Convergence Pharmaceuticals and raxatrigine, their lead compound. Raxatrigine is an oral, small molecule NAV 1.7 blocker with promising phase 2 data that will move into phase 3 this year.

We licensed Amiselimod, or MT-1303, from Mitsubishi Tanabe Pharma, a late-stage S1P1 inhibitor for ulcerative colitis and Crohn's disease. We entered into a collaboration agreement with AGTC to develop gene-based therapies for multiple ophthalmic diseases.

And this month, BENEPALI was approved in the EU. BENEPALI, the first etanercept biosimilar approved in the EU is the first of three potential anti-TNFs to advance under our Samsung Bioepis joint venture with Samsung Biologics. Under our agreements with Samsung Bioepis, we will manufacture and commercialize BENEPALI in the EU.

Meanwhile, we continued investing in 2015. We purchased land in Solothurn, Switzerland, and this Friday, January 29th, we will break ground on an advanced, next-generation Biologics manufacturing facility there. We purchased these sized drug product manufacturing facility and supporting infrastructure in Research Triangle Park, North Carolina.

We also took actions to return capital and change the capital structure of the business. We fully implemented our $5 billion share repurchase program, and a portion of that repurchase was funded through the $6-billion debt offering that we completed in September.

In R&D, we moved forward several exciting mid- and late-stage assets in our pipeline. It may seem like a long time ago now, but it was Q1 2015 that we presented the aducanumab data, showing a statistically significant removal of plaque and slowing of cognitive decline in Alzheimer's patients.

We presented data suggesting that our anti-LINGO antibody is biologically active in remyelination, and the phase 2 data for nusinersen, generated by our partner Ionis, looks increasingly encouraging as potential therapy for spinal muscular atrophy.

We also initiated phase 1 trials in ALS and Parkinson's disease. Al will discuss the many advances we made in our pipeline in more detail, but I think this progress is a testament to our commitment to patients and our world-class capabilities across the breadth of R&D.

We also continue to strengthen our early stage clinical and research capabilities. We bolstered research talent in our neuroscience group and established collaborations with first-rate academic centers around the world. As a result, I believe we are now in a better position than ever to both discover novel therapies and accelerate drug development while minimizing risk.

Lastly, summarizing 2015 would not be complete without commenting on the restructuring we implemented in October. Although it was a difficult decision, we've already seen positive results from the steps that we took. With the majority of the restructuring now completed, there's a palpable reinvigorated focus on our key commercial initiatives and high potential pipeline candidates, and our operating expenses are trending at a rate that we believe can continue to provide healthy earnings leverage going forward.

So all in all, it was a busy and eventful year, and we believe that the progress we made and actions we took positioned us well for a potentially transformative 2016 and beyond. With that, I'll pass the call along to Al for an update on R&D.

Al Sandrock (Chief Medical Officer):

Thanks, George. 2015 was a productive year for the R&D organization. We advanced the next wave of potential medicines through the pipeline, added important assets through business development and acquisitions, and expanded our research leadership by hiring world-class scientists. I believe our pipeline and our Organization are stronger than they have ever been.

Starting with Alzheimer's disease, last year, we presented compelling interim phase 1B data for aducanumab, the first investigational drug for Alzheimer's disease to demonstrate both a statistically significant reduction of amyloid plaque, as well as slowing of cognitive decline. In August, we began enrolling patients into two pivotal phase 3 trials of aducanumab and early Alzheimer's disease.

We are pleased with the progress of these studies, but recognize the inherent challenges in recruiting patients with early Alzheimer's disease and the limited availability of PET scanners. Fortunately, owing to the strong results from our clinical trials to date, there has been substantial interest in the program, which we believe has helped with recruitment.

That said, we continue to anticipate that the phase 3 enrollment duration will be similar to other large clinical trials in Alzheimer's disease. Looking ahead, in the second half of 2016, we expect to share additional safety data from the ongoing titration arms of the phase 1B prime study for aducanumab.

Our other two mid-stage clinical candidates for AD that are partnered with Eisai continued to advance. Eisai had indicated that they anticipate releasing interim safety data this year for E2609, a small molecule BACE1 inhibitor, and we are also expecting to see top-line efficacy and safety data for BAN2401, a monoclonal antibody targeting beta amyloid.

Moving to anti-LINGO, you may recall that last year, we presented phase 2 data in acute optic neuritis. To our knowledge, this was the first clinical trial to show evidence of remyelination following an acute inflammatory demyelinating injury in humans. And we believe that these results support our ongoing

development efforts.

Our phase 2 SYNERGY study in MS is a 418 patient double-blind multi-center study assessing four doses of anti-LINGO versus placebo when added to interferon beta therapy. It utilizes the composite endpoint, comprising outcome measures of disability, cognition, and physical function. We believe that a separation from placebo on any of these measures could be clinically meaningful.

We are also looking at imaging end points that reflect the integrity of myelinated nerve fibers. Any differences in treatment effect between pre-existing and newly acquired lesions will also be of interest. We believe that the robust design of this clinical trial will enable a better understanding of the therapy's potential in MS. And if the results are positive, the trial should provide valuable insight into the design of our phase 3 program. Results for SYNERGY are anticipated in mid 2016.

Now turning to nusinersen, our partner, Ionis, recently completed target enrollment of the phase 3 CHERISH study in children with childhood onset SMA. And by the first half of this year, we hope to complete enrollment in ENDEAR, the phase 3 study evaluating nusinersen in infants with infantile onset SMA. This progress sets the stage for data from both of these trials to be available in the first half of 2017.

Where as the data from the early stage open-label clinical trials are encouraging when compared to data from natural history studies, the well controlled phase 3 studies are designed to definitively assess the safety and efficacy of nusinersen. We are meeting frequently with regulators from Europe, Japan, and the United States, with the goal of making the drug available to SMA patients as rapidly as possible.

Moving on to our hemophilia therapies, last month at the 57th American Society of Hematology annual meeting, we presented new data demonstrating that ELOCTATE and ALPROLIX effectively managed bleeding into joints and maintained low annualized bleeding rates in people with severe hemophilia A and B, reaffirming the benefits of these two therapies. In addition, teams from the University of Pittsburgh, the Hemophilia Center of Western Pennsylvania, and the University of Texas Southwestern Medical Center presented data showing that immune tolerance induction using ELOCTATE was successful in three children with inhibitors, including a child previously failing recombinant factor 8 immune tolerance induction. The time to achieving tolerance in the study was 4 to 12 weeks, which appears to be significantly shorter than with the standard of practice, which can take several months to several years.

During the quarter, we, in collaboration with Ionis, also announced the initiation of a phase 1/2 clinical study of an antisense drug against superoxide dismutase, or SOD1, in patients with amyotrophic lateral sclerosis. I am pleased to announce that last week, we dosed our first patient in the trial. Mutations in the SOD1 gene result in the second most common form of familial ALS, affecting approximately 2% of all ALS patients.

We also continue to make excellent progress towards initiating multiple late stage clinical trials in 2016. Next month, we anticipate sharing additional phase 2 study results for TYSABRI in acute ischemic stroke at the International Stroke Conference in Los Angeles. While a single dose of administered -- of natalizumab administered up to nine hours after stroke onset did not reduce focal infarct volume, treatment was associated with meaningful improvements in clinical outcomes over the course of 90 days. The clinical profile and treatment window supports further investigation of natalizumab as a potential novel approach for treating acute ischemic stroke, and we intend to conduct a phase 2B trial.

Amiselimod, or MT-1303, an S1P1 inhibitor for inflammatory bowel disease is anticipated to advanced to phase 3 trials this year. In the second half of the year, we plan to initiate phase 3 studies for both ulcerative colitis and Crohn's disease. We currently have no plans for the asset in MS, but expect to continue to evaluate other options for the molecule in collaboration with our partner Mitsubishi Tanabe.

Raxatrigine, a small molecule inhibitor of the NAV 1.7 sodium channel, is in development for several pain

indications. In the second half of the year, we anticipate initiating a phase 3 trial to confirm the efficacy of raxatrigine in patients with trigeminal neuralgia. We also plan to initiate a phase 2 trial in patients with sciatica later this year.

I'll now pass the call over to Paul.

Paul Clancy (CFO):

Thank you, Al. Our GAAP diluted earnings per share were $3.77 in the fourth quarter and $15.34 for the full year. Our non-GAAP diluted earnings per share were $4.50 in the fourth quarter and $17.01 for the full year. Total revenue for Q4 grew 8% year over year to approximately $2.8 billion, and grew 11% for the full year to $10.8 billion. Foreign exchange, offset by hedging, weakened fourth-quarter revenue by approximately $35 million versus prior year, and by approximately $227 million for the full year versus prior year.

Global Q4 TECFIDERA revenue was $993 million. We recorded revenues of $785 million in the US and $208 million outside the US. TECFIDERA US revenue benefited from an increase in wholesale inventory by approximately $30 million versus prior quarter.

At this point, we believe TECFIDERA safety perceptions and physician intent to prescribe have largely stabilized in the US. We are seeing positive leading indicators for the recently launched marketing campaign for TECFIDERA, including increased visits to our website and higher call volume into our patient services organization.

In Europe, TECFIDERA continued its trend of solid patient growth this quarter, especially in more recently launched markets such as the UK, Italy, and Spain. The European label for TECFIDERA was updated in December, and we're actively educating physicians on appropriate patient monitoring.

For the full year, worldwide TECFIDERA revenues were $3.6 billion, consisting of $2.9 billion in the US and $730 million in sales outside the US. Foreign exchange impact offset by hedging weakened full-year TECFIDERA revenue by approximately $27 million versus prior year.

Interferon revenues, including both AVONEX and PLEGRIDY, were $740 million during the fourth quarter, which includes $506 million in the US and $233 million in sales outside the US. For the full year, worldwide interferon revenues were $3 billion, consisting of $2 billion in the US and $951 million in sales outside the US. Foreign-exchange impact offset by hedging weakened full-year interferon revenues by approximately $88 million versus prior year.

TYSABRI continued to add patients this quarter, with worldwide revenues of $481 million. These results were comprised of $278 million in the US and $203 million internationally. For the full year, worldwide TYSABRI revenues were approximately $1.9 billion.

We recorded US revenue of $1.1 billion and $783 million internationally. Foreign-exchange impact offset by hedging weakened full-year revenue for TYSABRI by approximately $90 million versus prior year. Physicians continue to choose site TYSABRI for patients requiring high efficacy, and nearly 10 years after approval, we believe its well understood safety profile positions TYSABRI well.

Turning to hemophilia business, ELOCTATE revenue for the quarter was $101 million and $320 million for the full year. ALPROLIX revenue in Q4 was $71 million and $234 million for the full year.

Turning to our anti-CD20, unconsolidated joint business, which includes our profit share for RITUXAN and GAZYVA in the US, as well as our profit-sharing royalties on sales of rituximab outside the US. We recorded $334 million for Q4 and $1.3 billion for the full year.

While there was a slight inventory draw down for RITUXAN in the fourth quarter, we ended the year with a higher inventory level than we had anticipated. We also benefited from a $6 million payment from Roche in exchange for access to data supporting the development of ocrelizumab.

Corporate partner revenues were $69 million for the fourth quarter compared to $40 million in the prior quarter. The increase was related to contract manufacturing for Samsung Bioepis and another strategic partner. For the full year, corporate partner revenues were $189 million.

During the quarter, we booked a total GAAP charge of approximately $93 million related to the restructuring announced in October.

Now turning to the non-GAAP expense lines on the P&L. Q4 cost of goods sold were $332 million, or 12% or revenue. For the full year, COGS were $1.2 billion, or 12% of revenue.

Q4 non-GAAP R&D expense was $542 million, or 19% of revenue, which includes a $60 million payment to Mitsubishi Tanabe. For the full year, non-GAAP R&D expense was $2 billion, or 19% of revenue.

Q4 non-GAAP SG&A expense was $583 million, or 21% of revenue. For the full year, non-GAAP SG&A expense was $2.1 billion, or 20% of revenue.

Other net expense was approximately $82 million in the fourth quarter, which includes $67 million in interest expense, primarily related to our recent bond offering. Full-year other net expense was $124 million, including approximately $96 million in interest expense.

Our Q4 non-GAAP tax rate was approximately 23% for the fourth quarter, as we benefited from the reinstated R&D tax credit. Our full-year tax rate was approximately 24%.

During the year, we repurchased approximately 16.8 million shares of our common stock, completing our previously authorized $5 billion share repurchase program. Our weighted average diluted share count was approximately 221 million for Q4, 231 million for the full year, and we ended the year with approximately 219 million basic shares outstanding.

This brings us to our non-GAAP diluted earnings per share [were] $4.50 for the fourth quarter and $17.01 for the full year, representing a 23% increase for the full year. We ended the year with approximately $6.2 billion in cash and marketable securities, split approximately 40/60 between the US and ex-US. Overall, we had a strong quarter benefiting from favorable inventory dynamics with TECFIDERA, stronger-than-anticipated contract manufacturing in RITUXAN revenue, and the reinstatement of the R&D tax credit.

Let me turn to our full-year 2016 guidance. We expect revenues of approximately $11.1 billion to $11.3 billion.

Starting with multiple sclerosis. Our plan assumes relatively stable demand for TECFIDERA in 2016 in the United States. While we are hopeful our recently launched marking campaign can reaccelerate growth, we remain cautious as we believe we will not ascertain the impact until the second quarter of this year.

In Europe, we anticipate constant pricing for the rest of the year and continued patient growth, particularly in recently launched markets. For TYSABRI, we believe the therapy will remain on a stable trajectory.

We believe the number of patients using AVONEX and PLEGRIDY combined will continue to climb, as patients moved toward orals, though we remain well-positioned within this segment of the market. Our financial guidance assumes no US price increasing for AVONEX, PLEGRIDY, and TECFIDERA for the

remainder of the year.

With respect to foreign exchange, our plan is based on the current spot rates. Of note, we had an approximately $170 million in hedge gains in 2015. Given our hedges are usually placed 12 months forward, we expect limited hedge gains in 2016. So the year-over-year comparison is less favorable.

Moving to our hemophilia therapies. We anticipate continued growth with ELOCTATE, as we believe there remains a significant portion of the patient population that can benefit from long-acting therapies. We're assuming moderating patient adds for ALPROLIX, given the rapid uptake in penetration so far.

In 2016, we are assuming our profit share for RITUXAN and GAZYVA will decrease to 39% from 40% upon FDA approval of GAZYVA and RITUXAN refractory indolent non-Hodgkin's lymphoma. Our plan assumes ocrelizumab will launch in 2017.

Moving to an expense perspective. We anticipate slight upward pressure on cost of goods sold rate, largely due to increases in contract manufacturing, biosimilars, and increased hemophilia royalties.

We anticipate R&D expense between 19% and 20% of sales, which includes approximately $100 million earmarked for business development activity. We plan to invest in a number of R&D programs across our late-stage pipeline, including aducanumab, nusinersen, raxatrigine, and amiselimod for inflammatory bowel disease.

SG&A expense is expected to be approximately 17% to 18% of revenue. The headcount reduction and restructuring announced in October is expected to benefit operating expenses by approximately $250 million. We've also planned to reduce targeted fees and services expenses, which are largely reflected in SG&A.

From a tax perspective, we anticipate upward pressure on our 2016 tax rate as our profitability mix shifts toward the US. We anticipate non-GAAP earnings per share results between $18.30 and $18.60, and GAAP EPS to be between $16.85 and $17.15. Our plan assumes share stabilization, with a weighted average diluted share count of approximately $219 million.

From a cash perspective, we expect to pay $1.2 billion in CBR payments to Fumapharm in 2016 related to the sales of TECFIDERA. And we anticipate capital expenditures of approximately $800 million to $850 million, an increase over 2015, primarily driven by the investment in the Swiss manufacturing plant. So the business plan is designed to provide investment to support TECFIDERA, surgically look to control spending, and ensure we're utterly focused on investing in and progressing the pipeline.

I'll turn the call over to George.

George Scangos (CEO):

Okay, thank you, Paul. Clearly the commercial trajectory of TECFIDERA was not what we thought it would be at the beginning of last year, and as a result, our revenues fell short of our initial projections. While obviously not happy with that, I'm very pleased with the way the Company responded.

We put additional marketing muscle behind TECFIDERA, we reduced cost and focused the Company, and we accelerated our stock repurchase program. As a result, we maintained healthy earnings growth at the same time as we continued our investments in aducanumab, LINGO, and the other exciting programs in our pipeline.

We also continued to invest in additions to our pipeline. We acquired Convergence and its lead compound raxatrigine, we licensed Amiselimod from Mitsubishi Tanabe, we completed the gene therapy relationship with AGTC, and we brought additional compounds into the clinic from our own and our

partners' research efforts.

Our commercial portfolio continued to expand globally, as we extended our position as the worldwide leader in multiple sclerosis and significantly grew our hemophilia business.

In 2016, we plan to remain focused on commercial execution and advancing our pipeline, which we expect to be the primary source of value creation over the long term. We are looking forward to many updates over the next year, including insight into the potential impact of TECFIDERA's recently launched marketing campaign by the second quarter, phase 2 top-line results for anti-LINGO in MS in the middle of the year, phase 2 data for BAN-2401 and E2609, continued phase 2 data from nusinersen from Ionis, followed by phase 3 data next year, and phase 1b titration data for aducanumab in the second half of the year.

We expect to launch up to three compounds this year, BENEPALI in Europe, following approval from the European Commission earlier this month; ZINBRYTA, pending approval in the first half of the year; and potentially an infliximab biosimilar, also in Europe.

Thinking even further ahead, we believe that we are entering the early years of a potentially transformative era in neurogeneration drug discovery and development, and we believe that our commitment to research has the potential to yield results that are truly meaningful for patients and shareholders. As I said at the recent JPMorgan conference, I believe that our pipeline and our approach, which has the risk inherent in all truly innovative and groundbreaking approaches, is measured and thoughtful.

The combination of a much better understanding of disease biology, the focus on genetically validated targets, the use of biomarkers to learn early whether or not our compounds are having the desired biological effects, and the adoption of multiple therapeutic modalities may meaningfully increase success rates and identify those projects likely to fail early in the process before large amount of time and money are spent. Our strategy is evident in the design of the aducanumab phase 1b trial, the phase 2 study of nusinersen, the phase 2 studies of anti-LINGO, and in our recently initiated phase 1 trial for SOD1 in ALS. We have additional examples, some of which we'll talk about as the year goes on.

In closing, and as always, I would like to thank our employees, who are dedicated to making a positive impact on patients lives, and also the patients and physicians who are involved in our clinical development programs. The achievements we made together could not have been realized without their passion and commitment.

So, thank you all for joining us this morning.

Operator, we'll now open up the call for questions.

QUESTIONS & ANSWERS

Operator:

(Operator Instructions)

Geoff Meacham from Barclays.

Geoff Meacham (Analyst - Barclays Capital):

Good morning, guys. Thanks for taking the question. I just have a couple quick ones -- one on the commercial side.

I know it's early days, but are there any initial metrics on the tech DTC campaign, when you look at things

like new starts or returning patients?

And then the second one is on the pipeline. When you look at the ENGAGE and EMERGE studies, Al, are there lessons to be learned from Lilly in terms of managing PET Scan facilities? And what do you think identification of early-stage Alzheimer's patients means to the market opportunity? Thank you.

Paul Clancy (CFO):

Thank you, Geoff. Let me start with a tech DTC question. I would reinforce what we said in our prepared remarks around that really to try to discern we are going to be looking in the Q2 time period. Clearly, Q2 is not a light switch to determine that. We are seeing the early data with respect to, as I had mentioned, hits to the website, conversations into our patient services organization, which lean us to think that it's positive.

We haven't seen a discernable yet change with respect to specifically your question. But our judgment is that this takes a little bit of time. It was really first week of October. Obviously script data, as we come through the holiday time period, as everybody knows, gets a little bit noisy in Thanksgiving and December. So we are going to look really hard, probably 60, 70, 90 days out from now.

Al Sandrock (Chief Medical Officer):

Hi Jeff, this is Al. Well, we have learned a lot from our predecessors, including Lilly and others. And we are employing actually pretty innovative ways of finding where the patients are and where the sites are, which includes where the PET scans are. Because the scanners have to be pretty close to where the [litgens] are made, and of course, the patients have to get there. The other thing we're doing is to screen patients before they need PET scans by using a neuropsychological test battery to make sure that by the time to they get to the PET scanner, there's a high likelihood they'll actually have amyloid.

And then in terms of early AD, what we mean by early AD are prodromal and the earlier stages of mild Alzheimer's. In terms of what it means for the marketplace, I do believe that there is going to be a change, ultimately, in the way the patients are diagnosed early. Perhaps -- and certainly before their functional deficits, but when they have mild cognitive impairment, I believe the healthcare system will set up ways of identifying those patients who need treatment early. And we're working on many of those too, along with many colleagues outside who are also thinking about the same thing.

Operator:

Eric Schmidt from Cowen and Company.

Eric Schmidt (Analyst - Cowen and Company):

Another one for Al. It looks you're going to be faced with a couple of go, no-go decisions on phase 3 programs in 2016. I'm thinking specifically for LINGO and for the BACE compound E2609. Just wondering what kind of hurdle you set for yourselves in terms of going forward. And maybe you could also further justify if the hurdle is going to be the low-end hurdle. I sensed that's what you'd been signaling to investors, why it makes sense to move forward with two fairly risky programs of lowish-end hurdle.

Al Sandrock (Chief Medical Officer):

I wouldn't say that the hurdle is very low. I think what I'm trying to say with LINGO is that this is a phase 2 trial and it's pretty novel territory we are on, where not too many people have looked at repair strategies for any neurologic disease including MS. I would say that we're going to look at the totality of the data we are going to combine the clinical outcome measures along with the imaging outcome measures, learn as much as we can, and really decide does the program deserve a continued investment? And if so, can

we go to phase 3?

Are we ready to go to phase 3? Because in phase 3, we are going to have to employ outcome measures that everybody agrees, including regulators obviously, but also the MS community, everybody agrees will provide answers on whether or not the treatment effect is clinically meaningful.

And in the case of the BACE inhibitor, the main thing we are going to be looking at is safety. And I don't think it is uncommon, in fact, I think all of our competitors have gone from early-stage safety data right to large registrational trials. And I think there are good reasons for that.

We are confident in the pharmacodynamic effect that we see, in that when we look at A beta 42 levels in CSF, we get nice, very strong dose-dependent decreases in A beta 42. So we're not going -- as George said, we want to manage the risk by making sure we have the desired biological effect, and we're pretty confident already that we have that.

Operator:

Brian Abrahams from Jefferies.

Brian Abrahams (Analyst - Jefferies & Company):

Hi, thanks for taking my question. Two quick ones on TYSABRI. It looks like you're seeing stabilization. Wondering if you can talk a little bit about the dynamics you are seeing there amongst patients, since the SPMS data was reported?

And then for Paul, just curious you earmarked $100 million for BD next year, how the sector pullback amongst the smaller biotechs might influence your capital allocation strategy this year. Thanks

Paul Clancy (CFO):

I will try to take the TYSABRI one as well, but Al can chime in here. Thanks, Brian, for the question. We did not see a discernible change coming out of the SPMS read out. It may be early, it may not, and I think that was to some extent our thesis as well. Patients that are doing very, very well and have an individual experience with TYSABRI that is generally quite positive.

With respect to the earmarking for $100 million, it's -- we always debate this internally. Should be more than that, should it be less? Should we trade it off against R&D dollars, all that type of stuff.

But we try to earmark some level of money that obviously is expense money, which has been -- we have been a little bit biased that way. With the earlier stage biotechs over the last number of years have had opportunities, right, the IPO window has been open, it has been very open for them to continue on. There is a potential that with the change in the biotech sector that as we've looked at corporate development business development-type deals, clearly one of the last hurdles to get through is financial valuation. There is a change that that dynamic is changing in favor for us.

George will maybe add some comments as well.

George Scangos (CEO):

Look, if you're you are in a smaller biotech company and it's pretty commercial, and you have to raise revenue, there are only a couple of ways to do that. And as it gets more difficult and less attractive to raise money from the financial markets, obviously other alternatives become more attractive. And we hope that and we believe that we will all move in the favor of companies like us who are out to in-license or acquire additional compounds.

So we'll see. It takes a while for that to happen. We will take a -- the current views of the market to hold for a while or deteriorate further. If that happens, then I believe there will be interesting opportunities for us.

Operator:

Mark Schoenebaum from Evercore ISI.

Mark Schoenebaum (Analyst - Evercore ISI):

Hey guys. Hey Paul, Al, George, thanks for all the transparency. After the guidance lowering last year and on the call today, I really appreciate it. I think the street does too.

Just a couple questions, since everyone is breaking the one question rule.

George Scangos (CEO):

I think you started that trend Mark.

Mark Schoenebaum (Analyst - Evercore ISI):

No, I'm like the fifth question. Everyone's asked two, so it's not me. I'm a good boy.

On TECFIDERA, Paul, I remember last year -- and I know you're not providing TECFIDERA guidance for 2016. But I think last year you gave some color on your expectations. I'd be curious to know if you'd be willing to do that this year.

Specifically, what are you expecting for price and volume in 2016 in the US? Should we be modeling any price, any volume? And then on LINGO, Al, this has come up in prior questions, but just to push you a little bit, when you say separation, should we think of that as common sense separation on the clinical endpoints would be clinically relevant? Or in that we don't necessarily need a statistically a P value under 0.05 when you're analyzing the data in order to make a go decision into phase 3? Thanks a lot.

Paul Clancy (CFO):

Mark, this is Paul. The only additional -- really don't want to provide anything additional, no comments further, just like reinforce what I did say in the prepared remarks. On TECFIDERA, our plan assumes stable demand for TEC in the United States. We're looking and aspiring for more, but that's what the plan assumes, and that's really what we have seen for a number of quarters.

On the US pricing side, our financial guidance assumes no US pricing for TECFIDERA for the remainder of the year.

Al Sandrock (Chief Medical Officer):

On LINGO, Mark, we have a trial with about 80 patients per arm, so it's not -- it's a robust trial. But I think, yes, we are more on the common sense side, as you put it. We want to know -- and we can look at separation in several ways.

We can look for proportion of patients who are improving relative to placebo. We can look at patients who are slowing -- their progression has slowed. So we can look at both ways. That's sort of what I mean by separation.

But I think it's more on the common sense side. And I tried to indicate that there's a lot of exploratory pieces to this trial, because some of these endpoints have really never been employed in any significant way in large trials. So that's what I was trying to say, Mark.

George Scangos (CEO):

I think, Mark -- this is George. The decision on the LINGO trial will be whether or not we have a meaningful clinical impact on endpoints that the regulators would consider approvable endpoints in a phase 3 trial. There are many endpoints that we're going to be looking at in the trial, and there could be some combination of them. So we're not going to have a low bar, but it is a phase 2 exploratory study.

And as we look at those endpoints, we'll make decisions. But I wouldn't characterize it as a low bar; I'd characterize it right now as a little bit of an undefined bar until we see the data.

Operator:

Michael Yee from RBC Capital Markets.

Michael Yee (Analyst - RBC Capital Markets):

Thanks for the question. On SMN-Rx, and I refer to it as that, because I can't pronounce your new name. Could you just talk a little bit about some of the data you have seen so far and how your -- some of your commentary has changed around that a little bit to the positive, which is fine. It always comes down to comparing the historical literature and there's a lot of different things out there.

Al, can you maybe just talk a little bit about your confidence in the literature and the range of median survival there and what you think is going on here? You previously talked about weight gain, but haven't really heard about that. So maybe talk a little bit about that and what you're seeing and why versus historical literature you feel (inaudible) gets a little bit better.

Al Sandrock (Chief Medical Officer):

So the main data we are looking at is the type 1 SMA, or the infantile onset. And as you know, we are comparing it -- we an I -- with our partner Ionis, are comparing it to natural history. And those things are always tricky, because natural -- the care of patients change over time and stuff like that.

And you have to find matching patients, patients that are similar to the ones that you looked at in your open-label study. My confidence grows with every passing day, because as you know, these children are supposed to -- their median survival is two years. And so we are at the point where many of these babies are getting to that point or going beyond it.

And so I think that if they are surviving, our confidence grows. And also, we are also looking at whether or not they are gaining -- whether they are making improvements. These children generally don't improve. And they are hitting motor milestones that are not commonly seen in the natural history.

So we believe the data are looking promising, but there are caveats to comparison to natural history studies. And we have to be cautious because everybody, including parents and the whole world wants to see a cure for these babies. So our bias is certainly leaning toward wanting to see something, and we have to be cautious about that. So the phase 3 trials are sham-controlled, they are blinded, and I think that's where we believe the definitive data will come from.

Operator:

Matthew Harrison from Morgan Stanley .

Matthew Harrison (Analyst - Morgan Stanley):

Great, thanks and good morning, everybody. So I'm going to ask two.

One on Alzheimer's, we've recently had a handful of physician feedback that there's a dearth of skilled readers for some of these endpoints in these studies. Can you just talk a little bit about what you're doing to make sure the readers are well-trained, especially given the -- that a small change in the endpoint is likely to demonstrate the benefit of the drug?

And then just on LINGO, can you remind us what our expectations should be? I remember in 2015 when you moved out the timelines, you said that a small internal group would be seeing some of the LINGO data ahead of the full analysis and they would be planning for phase 3. Should we expect, if you decide to move ahead for phase 3, you'll be able to talk about that pretty quickly when we see the data? Thanks.

Al Sandrock (Chief Medical Officer):

Let me get the second question first. I want to be sure that the trial remains fully blinded, nobody at Biogen has broken the blind and looked at the unblinded data. So that small team -- there is no small team looking at any data.

And in terms of the AD, there are -- it is an art to read PET scans. I don't know if that's what you're referring to, but the readers of these images have to be trained, and we actually employed a quality control step in a blinded way where we had somebody in Minnesota, an expert reviewing every single scan.

Moreover, in terms of the cognitive testing, the clinical outcome measures, we -- the main thing we want is consistency over time. And we have to -- and we're doing a lot of the things that we actually do in MS where we have we do a lot of training, we have examining neurologists, and we separate them from the neurologist that actually treat the patients for side effects and things. So I think we have employed state-of-the-art methods for collecting these data, and hopefully avoided many of the pitfalls.

Operator:

Chris Raymond from Raymond James.

Chris Raymond (Analyst - Raymond James & Associates Inc.):

Hey, thanks guys. Just a couple of quick commercial questions.

Paul, on TECFIDERA, you guys called out the $30 million of inventory during the quarter, and I think Q3 saw $10 million to $15 million, if I recall correctly. So how should we think about Q1? Are we talking about $40 million to $45 million that needs to be burned off, or is there some other dynamic there that we should be modeling?

And then also on PLEGRIDY, just wondering if you could share any insights as the launches progress. Any change specifically in the source of patients, either from AVONEX or other beta interferons? I ask this question because some of our checks seem to indicate there has been a shift, where PLEGRIDY is taking patients now from other beta interferons versus more from AVONEX early on. I'm wondering if that's what you're seeing too, if there's something else going on there. Thanks.

Paul Clancy (CFO):

Chris, great question. This is Paul. TECFIDERA, let me just level set and just clarify, because you are exactly on it. What we had noted in Q3 is that our estimate at the time was that there was about $10 million to $15 million of build in the SPP, in the specialty pharmacy part of the combined channel. And that was mostly what we believe related to a government purchase, related to their fiscal-year timing.

I think our belief is that that's largely burned through. On a quarter-to-quarter basis within specialty

pharmacies, there is sometimes ebbs and flows on inventory levels, and we will try to do our best to point that out. But we think it's at -- and I would think that we may have things like what we had in Q3.

But I think that is largely burned through. What we noted in Q4 is actually related to the wholesaler portion of the channel, and on a quarter-over-quarter basis that there was a little bit of build. I think as we move into Q1, we are really probably dealing with the $30 million to get to on a sequential quarter/quarter basis.

We always just to complete the thought, we always deal with Q1 -- Q4 to Q1 dynamics that sometimes we don't have great visibility on. The so-called shoe-box effect, the change in Q1 with respect to patients on insurance, which is related obviously to shoe box. So Q1 oftentimes, in gross to net changes, so discounts and allowances rate goes up in Q1 as well for us as well as the industry, so we're always be mindful of that.

On PLEGRIDY, it's very interesting, your checks are probably consistent with what we are seeing as well. We saw early on, and to some extent, it was our marketing strategy early on was a conversion of AVONEX patients. And we hit some speed bumps along that early on in the launch in the first -- in the last quarter of 2014 and going into early into 2015.

We are starting to see both from what we are trying to do on a marketing strategy, but we're also starting to see the benefits of PLEGRIDY being seen as sourcing volumes from the other interferons. Look, this is a great product, vis-a-vis capturing our -- and penetrating and capturing share within that interferon segment of the marketplace. Great question, thanks, Chris.

Operator:

Terence Flynn from Goldman Sachs .

Unidentified Participant (Analyst - Wells Fargo):

Hi, this is Cameron filling in for Terrence. Thanks for taking our question and congratulations on your approval of your Enbrel biosimilar in the EU. I was wondering, is there anything you can share regarding your pricing and commercialization strategy there? Thanks.

Paul Clancy (CFO):

Cameron, obviously we are in discussions country by country, but really can't share anything, so no comment on that. We will try to, as we begin to post revenues, to try to provide some commentary.

Operator:

Matt Roden from UBS.

Matt Roden (Analyst - UBS):

Great thanks for taking the question and thanks for delivering a nice quarter and guidance here. I think as a sector, we needed some good news.

I had a specific on the BACE inhibitor E2609. The phase 2 study is in 700 patients, but my understanding is that the data that will get on this year's disclosures is just on safety from the initial cohorts, not the whole 700 patients.

Can you just clarify what we should expect to see from this disclosure this year? And help us understand what exactly you would be looking for and how this information would pertain to go/no-go decision? And then lastly, just when we'll get initial efficacy findings from this program. Thank you.

George Scangos (CEO):

You are right, Matt, we are going to look at the first cohort. And the original plan was that the first cohort would then trigger a second cohort. I am not -- the main thing we are going to look at is the safety data from the first cohort and also to confirm the pharmacodynamic effect that we saw with our phase 1 study. So it's really safety, and repeat or confirmation of pharmacodynamic effect in the CSF.

Matt Roden (Analyst - UBS):

Okay, and then does that pertain to any go/no-go decision? And then when should we expect to see initial efficacy?

George Scangos (CEO):

With the number of patients in the first cohort, I have low expectations in terms of efficacy. And it will lead to a go/no-go decision to phase 3.

Operator:

Ying Huang from Bank of America Merrill Lynch.

Ying Huang (Analyst - BofA Merrill Lynch):

Good morning. Thanks for taking my questions. Maybe for Al, you mentioned that we should expect the full enrollment of aducanumab phase 3 similar to the timeline of the other phase 3 trials. Does that mean we should probably expect 18 to 24 months or potentially even longer for the enrollment to be [accrued]?

And then also secondly, I was curious your thought on TYSABRI, because ocrelizumab could be approved probably towards the end of this year. We know that about 30% of JCV-positive patients are on TYSABRI -- I mean 30% of TYSABRI patients are JCV- positive. And then there's also a certain level of off-label use from PPMS and SPMS, so if you could provide some thought on that. Thank you.

Al Sandrock (Chief Medical Officer):

In terms of enrollment, I don't want to hazard a guess as to exactly how long it's going to take to enroll patients. I think we are pleased with what we've seen so far, but it's early days. And right now, our time lines are assuming the enrollment rate on a patients-per-site basis to what we've seen with other phase 3 trials.

And then in terms of ocrelizumab, it's great to have a new drug for patients, particularly for PPMS patients. I don't think there were a lot of PPMS patients who were on TYSABRI, if that's what you're asking. There probably are some people who are -- who have SPMS on TYSABRI, because our label says relapsing forms of MS. And patients with SPMS have relapses in the early stages of SPMS.

So it would be on label to be on TYSABRI if you have relapsing SPMS. Now, ocrelizumab I don't think will have a label for SPMS, as far as I understand. I don't recall the data trial on SPMS, so I don't see how that would affect the SPMS piece very much.

Operator:

Cory Kasimov from JPMorgan .

Cory Kasimov (Analyst - JPMorgan):

Good morning, guys, and thank you for taking the questions. First for Paul, on capital allocation, now that

you are finished the $5 billion share repurchase program, do you have plans to start another one? I'm just curious how we should be thinking about share count in 2016.

And then also, Paul, on your comment with regard to price increases not being assumed in your 2016 guidance, can you just remind us how you've built that into past guidance in prior years? And is this a change that is simply the result of the current pricing environment and controversy? Thank you.

Paul Clancy (CFO):

With respect to -- let's start on capital allocation and share repurchases. You are right, we've exhausted the $5 billion share authorization that was authorized and approved by the Board back in the spring of 2015. George and I are in constant contact, in constant dialogue, in constant discussion about best deployment of capital.

I think our thinking right now is a bit focused on strategic deployment, and -- but I would continue to emphasize that we always frame this as one or the other. And it's over a long period of time, it's appropriately a mix. I think the cash flow generation of the Company remains quite robust, such that we can deploy capital in a lot of different ways, all with the objective of increasing intrinsic value per share.

So we'll look towards a lot of different means. I know I'm being a little bit vague and opaque, but I think it's just because that's a little bit where we are right now in thinking through all the dynamics of that. No real comment on the pricing dynamics for the balance of the year. The financial guidance for this year does not assume it.

Operator:

Jim Birchenough from Wells Fargo .

Unidentified Participant (Analyst - Wells Fargo):

This is Nick in for Jim this morning. A couple of quick questions.

In terms of the remyelination programs, you have the oral remyelination agent BIIB61. Clearly, remyelination is a very complex process. Have you looked at combining that with anti-LINGO?

Do you see remyelination as a single drug opportunity, or do you think it's going to need combination therapy in perhaps in subsets of patients? And then for the Ionis SOD1 trial, for these kinds of trials where you're looking at these very rare to find mutations or correction opportunities, do you see the pattern repeating that we saw with nusinersen that you can generate enough compelling data in a phase 1 trial and affected patients that you can jump into a potentially registration enabling trial? Thank you.

Al Sandrock (Chief Medical Officer):

Thank you for those questions, Jim. On the remyelination, right now, we're thinking of it that we would use one agent for remyelination based on our pre-clinical studies. Of course, the remyelinating drug would probably be combined with anti-inflammatory or an immuno-modulatory drug, and that's exactly how we're conducting the SYNERGY of anti-LINGO 1 in MS; we're adding it to interferon. But right now, we don't have any plans to combine the two remyelinating drugs that we have in our pipeline. That may change over time, but that's our current plan.

And then in terms of the Ionis SOD1 phase 1 trial, yes, we've done a lot of work. We, meaning Biogen, also the ALS community on biomarkers, and not only in human studies, because you'll recall that there was a prior antisense study with a less potent antisense in SOD1 patients. And there's been some -- a lot of animal work, and we actually have CSF measures that we could employ that we think will predict

parenchymal spinal cord SOD1 levels.

The whole point of what we're trying to do is to reduce levels of SOD1, because we believe that the mutated forms of SOD1 are toxic. We have actually validated we believe very good measures that we can use to take the program from the current trial to a registrational study.

George Scangos (CEO):

This is George, I think that's often the case and the advantage of working on genetically homogeneous disease as a result of a single gene.

Look, I want to thank everybody for your attention this morning and for your interest. We are going to go back to work and do our best to deliver a great 2016 for everyone. Thank you.

Operator:

This concludes today's conference call.