Medivation (MDVN) Earnings Report: Q4 2015 Conference Call Transcript

The following Medivation conference call took place on February 25, 2016, 04:30 PM ET. This is a transcript of that earnings call:

Company Participants

- Anne Bowdidge; Medivation, Inc.; Investor Relations
- David Hung; Medivation, Inc.; President & CEO
- Rick Bierly; Medivation, Inc.; CFO
- Mohammad Hirmand; Medivation, Inc.; Interim Chief Medical Officer
- Joe Lobacki; Medivation, Inc.; Chief Commercial Officer
- Marion McCourt; Medivation, Inc.; COO

Other Participants

- Katherine Xu; William Blair; Analyst
- Tazeen Ahmad; BofA Merrill Lynch; Analyst
- Kennen MacKay; Credit Suisse; Analyst
- Matt Roden; UBS; Analyst
- Tom Shrader; Stifel Nicolaus; Analyst
- Carter Gould; Jefferies; Analyst
- Geoffrey Porges; Leerink Partners; Analyst
- Anupam Rama; JPMorgan; Analyst
- John Newman; Canaccord Genuity; Analyst
- Mike King; JMP; Analyst
- Christine Agnew; Cowen Group; Analyst
- Biren Amin; Jefferies; Analyst

MANAGEMENT DISCUSSION SECTION

Operator:

Welcome to Medivation's fourth-quarter and full-year 2015 financial results conference call.

This call is being recorded.

(Operator Instructions)

I would now like to turn the call over to Anne Bowdidge, Senior Director of Investor Relations.

Anne Bowdidge (Investor Relations):

Thank you. Thank you, everyone, for joining us.

On the call with me today from Medivation are Dr. David Hung, Founder, President and CEO; Rick Bierly, Chief Financial Officer; Dr. Mohammad Hirmand, Interim Chief Medical Officer; Joe Lobacki, Chief Commercial Officer; and Marion McCourt, Chief Operating Officer.

We issued a press release today that you can find on our website at www.Medivation.com.

Before we begin, I'd like to remind you that various remarks we make on this call contain forward-looking statements that are made under the Safe Harbor provisions of the securities laws.

Forward-looking statements can be identified by words such as may, could, believe, intend, expect, project, and anticipate and involve risks and uncertainties that could cause Medivation's actual results to differ significantly from those discussed today. Such risks and uncertainties are discussed in Medivation's filings with the SEC, including our annual report on form 10-K for the quarter ended December 31, 2015, which we expect to file tomorrow with the SEC.

All forward-looking statements made during this call are based on information available to us as of today, and we assume no obligation to update these statements as the result of future events or otherwise.

This call is the property of Medivation, and any replay of this conference call cannot be made without Medivation's express written permission. We will also be using non-GAAP financial measures to help you understand underlying business performance. The non-GAAP to GAAP reconciliations are provided on our press release and will be posted on our website.

With that, I will turn the call over to Dr. David Hung, CEO of Medivation.

David Hung (President & CEO):

Thanks, Anne. Thank you all for joining us today.

I'm pleased to report that 2015 was a strong year for Medivation. There were several significant factors that contributed to our success.

Most notably, we saw strong worldwide XTANDI net sales at $1.9 billion which were posted by Astellas and which grew by 80% over 2014. US net sales were $1.151 billion.

Based on these results, we are guiding 2016 XTANDI US net sales within a range of $1.425 billion to $1.525 billion, which reflects a projected growth of 28% at the midpoint. Rick will discuss this in more detail in a moment.

We're proud of the significant role that XTANDI is playing and growing and impacting the treatment landscape for men with metastatic castration-resistant prostate cancer or MCRPC in the novel hormonal therapy or NHT market, which is defined as XTANDI and abiraterone treated patients. This NHT global market has grown from approximately $2 billion of sales two years ago, to approximately $4 billion today.

It is noteworthy that NHT global drug sales alone today are double the global sales of all prostate cancer drugs combined just 10 years ago, which at that time were comprised of early older hormonal and chemotherapy agents.

Since the approval of XTANDI's US pre-chemo indication in September 2014 based upon PREVAIL, the NHT market has grown by 20% from approximately 250,000 total prescriptions in 2014 to over 300,000 prescriptions in 2015. XTANDI total prescriptions grew by 64% in that period. According to IMS, in the fourth quarter of 2015, XTANDI exceeded abiraterone in new prescriptions for the first time despite XTANDI having been approved approximately two years later.

We believe that an important near-term commercial opportunity for XTANDI in MCRPC is in early new treatment lines for patients who are primarily treated by urologists. In 2015, total prescriptions written by urologists more than quadrupled over 2014. Active XTANDI urology prescribers grew from under 600 shortly after the PREVAIL launch, to over 1200 by the end of 2015.

XTANDI is currently the urology market leader among novel hormonal therapies. We believe XTANDI's

familiar methodism of action which targets the AR androgen receptor as does bicalutamide and its proven survival benefits and overall product profile have contributed to this robust adoption.

By contrast, abiraterone targets the enzyme CYP17, the same target as ketoconazole, which is prescribed by urologists 100 times less frequently than bicalutamide. We view the concomitant steroid and monetary requirements imposed by abiraterone and ketoconazole as rate limiting for both in urology adoption. We expect to see strong growth in urology in MCRPC, aided by the recent expansion and deployment of our dedicated urology specialty sales force.

In oncology, we continue to see strong growth with an estimated 40% growth in total oncology prescriptions from 2014 to 2015. We anticipate continued growth in oncology supported by our dedicated oncology specialty sales force. Over the past three years, XTANDI's estimated overall treatment duration has more than doubled from an average of less than four months in 2013 to nearly eight months at the end of 2015.

We believe that this is the result of two factors. Number one, moving farther upstream to the pre-chemo population with the PREVAIL label approval in September 2014. And number two, an increase in XTANDI use ahead of abiraterone, which correlates with NHT market share.

With a two-year head start to market, abiraterone's current duration of therapy is estimated to be 10 months or more. As XTANDI moves further ahead in market position and market share, over time, we look forward to continued increases in our average duration of therapy to 10 months and beyond.

Should XTANDI duration of therapy hit 10 months, sales growth would be 25% over current levels if the number of XTANDI treated patients remains static. However, we believe the number of XTANDI treated patients will in fact increase.

We see three significant avenues for XTANDI growth in MCRPC in the coming years. Number one, continuing share gains in oncology as XTANDI establishes NHT market leadership. Number two, expanding XTANDI growth in urology. And number three, increasing duration of therapy as we move into urology, the most upstream care providers for these patients.

We believe that establishing market leadership in urology is the most important of these three avenues of growth as the vast majority of prostate cancer patients are diagnosed and their drug treatments initiated by urologists.

We're well positioned to benefit metastatic CRPC patients managed by urologists due to XTANDI's efficacy, safety, and convenience profile; the historical precedent of bicalutamide over ketoconazole use among urologists, and a potential label update based upon our head to head data versus bicalutamide or the most commonly used prostate cancer drugs in urology.

Looking beyond metastatic CRPC, were we to be successful with our earlier stages studies, EMBARK, PROSPER and our M1 HSPC trials, we believe we have the potential to double the eligible XTANDI treatable patient population and anticipate durations of therapy in the [enzo] and HSPC populations at least as long as seen in PREVAIL, which was 17 months.

We also had several other positive developments last years that contributed to our success and foreshadow an exciting 2016. In July, we were pleased with the label update for XTANDI based on an updated overall survival analysis of the PREVAIL trial, which as you recall significantly prolonged the mean overall survival in pre-chemo MCRPC.

In January, the UK's National Institute for Health and Care Excellence, or NICE, recommended supporting the use of XTANDI for people who have no or mild symptoms after adjuvant deprivation therapy has failed

and before chemotherapy is indicated.

We also saw in early 2015 data readouts from STRIVE and TERRAIN, two phase II head-to-head trials in which enzalutamide was studied in over 800 men against bicalutamide. Both trials met their primary endpoints with robust statistical significance, and both studies were recently published in prestigious peer-reviewed journals.

At the end of December, a supplemental new drug application, or SNDA, was submitted to the FDA to update the relevant clinical sections of the label within the existing indication. And on Monday, we and Astellas announced that the FDA accepted the SNDA filing, providing a PDUFA date of October 22, 2016 for a decision. Should we receive a label update for XTANDI incorporating relevant data against bicalutamide, we believe there's an opportunity to favorably impact the practice and behavior of both urologists and oncologists.

We recently increased our specialty sales force from 90 to 129 representatives, and organized them into urology and oncology focused teams to allow us to continue to devote appropriate detailed effort to the oncology segment and better address urologists. According to our market research, approximately 80% of prostate cancer drug prescribing urologists in 2015 have not yet written a prescription for XTANDI. We believe there is a significant opportunity ahead.

Expansion of our sales force also allows us to customize our messaging to oncologists who currently comprise the largest segment of XTANDI prescribers, allowing us to grow physician choice in the oncology market.

With that introduction, I will turn the call over to Rick to discuss our financial results for the fourth quarter and year end 2015, and then I will update you on our clinical programs. Rick?

Rick Bierly (CFO):

Thank you, David. Good afternoon, everyone.

I will begin with XTANDI net sales worldwide. At the level reported by Astellas, worldwide net sales of XTANDI were approximately $547 million in the fourth quarter ended December, an increase of 53% over the fourth quarter of 2014 and just over $1.9 billion for the calendar year 2015, an increase of 80% over the prior year.

With worldwide net sales surpassing $1.6 billion for the calendar year, Medivation earned and recorded the final sales milestone of the Astellas collaboration in the fourth quarter of 2015 in the amount of $175 million. Astellas reported in late January that XTANDI net sales in the US were $315.9 million in the fourth quarter, an increase of 37% over the fourth quarter of 2014 and $1.151 billion for the full-year 2015 for year-on-year growth of 69%.

As more fully described in our 8-K dated January 29, the December quarter Astellas level US net sales results included an unfavorable adjustment of $2.6 million related to changes in Astellas' estimate of prior period gross to net deductions against gross sales. The December quarter also included an increase in channel partner inventory of just over one half week of supply. We estimate sales demand in the fourth quarter was about 40,000 prescriptions.

In January 2016, we completed the previously announced expansion and training of our specialty sales force, increasing the number of representatives by about 40. Astellas also maintains its own specialty sales force in the US, which we understand is also being expanded.

Outside the US, where Astellas conducts all sales, marketing, and distribution, local currency net sales of XTANDI at the Astellas level more than doubled in 2015. In US dollar terms, such sales were approximately

$757 million, with fluctuating currency exchange rates reducing 2015 ex-US net sales expressed in US dollars by approximately 14% compared with 2014.

Turning now to Medivation's income statement, total non-GAAP collaboration revenue was $695.4 million for the full year 2015 compared to $389.4 million a year ago, an increase of 79%. Medivation's collaboration revenue related to US net sales was $575.7 million for the full year 2015 compared with $339.9 million in 2014, an increase of 69%. As a reminder, our collaboration revenue related to XTANDI US net sales is equal to one half of the US net sales reported by Astellas.

Outside the US, Medivation's collaboration revenue related to ex-US XTANDI net sales was $119.8 million for the full year 2015, nearly 2.5 times the 2014 level. The effect of royalty rate earned for the full year was about 16%. Under the collaboration, we earned a tiered royalty that ranges between low teens and low 20s as a percent of ex-US net sales with the range resetting at low teens each calendar year.

Up front and milestone payments are excluded from non-GAAP collaboration revenue. On a GAAP basis, such revenue was $248 million in 2015 compared with $321 million a year ago. The 2014 year included several development milestones related to the PREVAIL trial approvals that we saw worldwide.

Non-GAAP operating expense was $127.1 million in the fourth quarter and $430 million for the full-year 2015, representing growth over the comparable 2014 periods of 16% and 29% respectively.

Non-GAAP SG&A expense for the 2015 year was $249.4 million compared to $200.4 million 2014. The 24% growth in non-GAAP SG&A expense primarily relates to higher XTANDI collaboration expense and royalties as well as higher administrative and personnel related costs.

Non-GAAP R&D expense for the year 2015 was $180.6 million compared with $134 million in 2014. The 35% growth in non-GAAP R&D expense primarily relates to an increase in third-party clinical and pre clinical development costs as well as increased personnel, facilities and other costs associated with higher staffing levels.

Fourth-quarter 2015 non-GAAP R&D costs related to talazoparib rights that we acquired early in the quarter from BioMarin were approximately $10.4 million.

Medivation reported non-GAAP net income of $49.5 million or $0.29 per diluted share for the fourth quarter compared with non-GAAP net income of $18 million, or $0.11 per diluted share in the prior-year fourth quarter. For the full year, Medivation reported non-GAAP net income of $170 million, or $1.01 per diluted share compared with non-GAAP net income of $34.6 million, $0.22 per diluted share in 2014.

Today's press release of course also discusses the GAAP basis results. I wanted to take a moment to comment briefly on the pidilizumab impairment charge that we took in the fourth quarter GAAP basis results.

Research and development expense on a GAAP basis includes a $30 million charge related to a writedown of the pidilizumab intangible in-process R&D asset. The non-cash impairment charge is excluded from non-GAAP results.

Our conclusions and interactions with FDA about PD-1 bonding, the IND partial clinical hold and our planned CMC manufacturing changes together give rise to changes in several inputs and assumptions to the IP R&D asset valuation, leading to the partial impairment determination. Nevertheless, we continue to believe pidilizumab's profile and clinical activity in hematologic malignancies are quite interesting, and our plan is to develop pidilizumab and DLBCL in multiple myeloma.

At December 31, we had cash and cash equivalents of approximately $226 million compared with a little over $500 million at the end of 2014. As a reminder, in the second and third quarters of 2015, we utilized

$260 million of cash to redeem convertible notes. And in October, we used $410 million of cash for the upfront payment to BioMarin to acquire talazoparib.

During the fourth quarter, we entered into a $300 million amended and restated credit agreement with several banks pursuant to which the $75 million borrowings outstanding at year end and since repaid.

I would now like to turn to guidance for 2016. In the US, with respect to XTANDI net sales at the Astellas levels, we expect 2016 XTANDI US net sales to range between $1.425 billion and $1.525 billion.

The midpoint of this 2016 guidance range reflects growth of 28% over 2015 US net sales of $1.15 billion. This guidance level assumes that XTANDI receives a label update to the clinical trial section for the TERRAIN trial data and possibly the STRIVE data on or before the October 2016 PDUFA date, although this outcome cannot be assured.

In addition, we assume a mid teens percent full-year gross to net deduction rate on gross sales, and we assume channel partner inventory levels measured in weeks supply on hand consistent with what we have seen in 2015. As you know, XTANDI gross to net and distribution are areas managed by Astellas under the collaboration.

As we have seen occur in 2015, we anticipate US net sales at the Astellas level in the March 2016 quarter could be below the $315.9 million reported in fourth quarter of 2015. This would be due at least in part to an expected high teens gross to net percentage rate in the March quarter related primarily to the annual reset of Medicare part D coverage gap. And it also anticipates the possibility of a small channel partner inventory drawdown of up to a few days.

Now, turning to the Medivation non-GAAP P&L related guidance, we expect total non-GAAP collaboration revenue in 2016 related to US and ex-US net sales to range between $900 million and $970 million. As a reminder, this revenue measure includes 50% of US net sales of XTANDI at the Astellas level as well as our collaboration revenue related to ex-US net sales.

The midpoint of non-GAAP collaboration revenue guidance for 2016 shows 34% growth over 2015. For Medivation's 2016 collaboration revenue royalty related to ex-US sales, we assumed recently observed dollar-euro exchange rate of $1.10 and a yen-dollar exchange rate of JPY112.

2016 non-GAAP operating expenses net of cost-sharing payments to and from Astellas are expected to range between $555 million and $600 million in 2016. Non-GAAP operating expenses exclude non-cash stock-based compensation expense and other items as detailed in our press release today. The midpoint of the non-GAAP operating expense range for 2016 is a 34% increase over 2015, equal to our collaboration revenue growth that I mentioned previously.

Within the total operating expense assumption, we expect our 2016 non-GAAP SG&A expense to be between $275 million and $300 million including the full-year effect of the recent sales force expansion and other 2015 hires, our share of increased outbound royalties to UCLA related to the higher sales and increased general administrative support costs. With this higher level of SG&A spend, the midpoint of the guidance range implies SG&A expense grows a little less than half of the rate at midpoint collaboration revenue growth.

We expect 2016 non-GAAP R&D expense to range between $280 million and $300 million or 61% growth at midpoint. We're clearly investing in R&D in 2016 to develop enzalutamide and importantly to progress our recently acquired pidilizumab and talazoparib assets. Operating expense guidance for 2016 does not include any deal related or post deal spending that could arise for new business development activities.

Turning to income taxes, for your models, we suggest you use 35.5% to 36% for the 2016 non-GAAP effective income tax rate, which includes a small benefit from the R&D tax credit recently made permanent by Congress. Finally, we are, for the first time, also providing non-GAAP diluted EPS guidance for 2016.

We expect non-GAAP diluted EPS to range between $1.30 and $1.40 per share. The midpoint of this range reflects 34% growth over 2015 non-GAAP EPS of $1.01.

All 2016 guidance information is included our press release filed today, and historic non-GAAP information may be found in our website at www.Medivation.com. We anticipate filing our 2015 annual report on form 10-K tomorrow.

With that, I will hand the call back over to David.

David Hung (President & CEO):

Thanks, Rick. I'd now like to update you on our progress to develop enzalutamide in earlier stages of prostate cancer, breast cancer and other indications as well as our late stage proprietary pipeline with talazoparib and pidilizumab.

I will start with prostate cancer. We have three phase III trials of [aludi] enzalutamide earlier in the prostate cancer disease spectrum: EMBARK, PROSPER, and our M1 HSPC trial, consistent with Medivation's strategy to move XTANDI to the forefront of all prostate cancer therapy.

We continue to follow patients in our phase IV PLATO trial, which completed enrollment in September 2014. The purpose of this trial is to help determine the potential clinical benefit of continuing enzalutamide treatment in combination with abiraterone in patients who progress on enzalutamide.

The global randomized double-blind placebo-controlled trial has enrolled 509 chemotherapy naive patients with metastatic CRPC. The primary endpoint of the trial is PFS, and we expect top-line data from the PLATO trial in the second half of this year.

In addition to the ongoing studies of enzalutamide in prostate cancer, enzalutamide is also being evaluated in three major subsets of breast cancer. In December, at the San Antonio Breast Cancer Symposium, we presented an exploratory analysis of updated overall survival data from our phase II trial which demonstrated that those TNBC patients on enzalutamide whose tumors tested positive for novel gene compression profile, experienced a nearly 14 month longer median survival than those TNBC patients treated with enzalutamide who were tested negative.

We are extremely encouraged by these results, particularly because no therapies have improved the increased overall survival in TNBC, and currently the standard treatment option for these women is chemotherapy. We intend to start a registrational study in the second half of 2016 and are in discussions with our partner Astellas as well as health authorities to do so.

Eleven months ago, we completed enrollment in our second phase 2 breast cancer trial evaluating enzalutamide in combination with exemestane versus exemestane alone in 247 women with advanced breast cancer that is ER positive and/or PR receptive positive and HER2 normal, which comprises about 50% of the breast cancer market. The private endpoint is PFS. We continue follow patients in this trial and expect that data from that trial will read out in the second half of this year.

In addition, enrollment continues in a third trial, a phase II study in a HER2 amplified breast cancer population. In January, Astellas enrolled the first patient in a phase II trial evaluating enzalutamide in approximately 140 patients with advanced hepatocellular carcinoma, which represents more than 75% of all liver cancer cases. We are also pleased to have strengthened and diversified our proprietary portfolio

of late stage clinical assets over the past year.

In October of last year, we acquired all worldwide rights to the PARP inhibitor talazoparib from BioMarin Pharmaceutical, which we are advancing into development as MDV3800. PARP, or poly ADP ribose polymerase, comprises a universal DNA repair mechanism that all cancers require for optimal DNA repair and replication.

The ability of tumors to repair their DNA damage is vital to their survival. And in head-to-head nonclinical studies, talazoparib has been shown to be superior to multiple other PARP inhibitors in a phenomenon known as PARP trapping, an effect that Yves Pommier at the National Cancer Institute has correlated with a superior ability to kill cancer cells in vitro.

Given talazoparib's profile, we believe that it has the potential to be used across all cancers in which DNA is, or can be compromised and that the PARP trapping ability of talazoparib may differentiate it from other PARP inhibitors, particularly if they use a combination with DNA damaging therapies like chemo and radiation.

Because of its broad mechanism and potent activity, we believe that talazoparib has the potential to address an even wider spectrum of tumor types than XTANDI with this AR focused mechanism. We are very excited about the potential for talazoparib, and we intend to develop it thoroughly. We anticipate starting studies in multiple tumor types including non-BRCA, non-BRC breast, prostate, lung, and ovarian cancers.

Currently, talazoparib is in a phase II registrational study called EMBRACA, which is targeting the enrollment of up to 430 women with deleterious germline BRC1 and BRCA2 mutations and locally advanced or metastatic breast cancer. The primary endpoint is progression free survival. The trial began enrolling patients in October 2013. We expect to complete enrollment in EMBRACA in the fourth quarter of 2016 and to report top-line results in the first half of 2017.

The next late stage asset in our pipeline is pidilizumab, referred to as MDV9300 or just 9300. We licensed pidilizumab from Cure-Tech in the fourth quarter 2014. In late 2015, we initiated a potentially pivotal phase II trial evaluating pidilizumab in patients with relapsed or refractory diffused large B-cell lymphoma or DLBCL, an aggressive form of non-Hodgkin's lymphoma. The objective of the 180 patient trial is to determine best overall response rate in patients with incomplete response following therapy or autologous stem cell transplantation.

In January, we notified the FDA that pidilizumab is not an inhibitor of PD-1, and the FDA placed the IND on partial clinical hold until we revised the investigative brochure, protocol and informed consent documents. Our January disclosure to the FDA capped a year of work following our end license of pidilizumab, in which we attempted to follow up on data sets generated from two independent labs. One data set published by Dr. Don Benson from the Ohio State University in the journal Blood in 2010, and the other data set unpublished by Dr. [Satbani Latku] at MD Anderson.

Both data sets demonstrated that pidilizumab activated NK or natural killer cells. This activity was particularly intriguing to us when we first began diligence on pidilizumab at the end of 2013 since NK activation is not a class [COP1] activity and we were aware that pidilizumab was not generated against a PD-1 androgen like other PD-1 inhibitors.

Given that very few immuno oncology drugs activate NK cells and given the fact that few immuno oncology drugs work on the innate side of immunity as opposed to the much more crowded adaptive side of immunity, and given the strong clinical activity at pidilizumab seen in several published studies, we made a decision to license pidilizumab in December 2014 for $5 million up front plus milestone and royalties.

We're still working to identify the binding target of pidilizumab. For a more detailed account of the history and strategy behind licensing pidilizumab, please see an interview I gave to FirstWord Group which was published in February 2016.

In early February, we submitted our revised documents to the FDA. The FDA has 30 days to notify us if clinical studies with pidilizumab maybe resumed, and we expect the clinical hold to be lifted sometime in March.

With regards to our next steps in our pidilizumab clinical development program, we anticipate submitting in the first half of 2016 an amendment to the chemistry and manufacturing controls or CMC section of our investigational new drug application for pidilizumab to provide for larger manufacturing lot sizes to support our clinical activities. We intend that patients in our phase II DLBCL trial will be treated with pidilizumab manufactured in accordance with the amended IND.

We will also be preparing to move forward with pidilizumab in multiple myeloma. We were particularly intrigued by the abstract at ASH by Dr. Don Benson's group for the combination of steroid sparing pidilizumab and lenalidomide regimen in a small cohort of patients with relapsed or refractory multiple myeloma.

Treatment is with the combination therapy in these patients showed a response rate of 38% despite half of the patients receiving one quarter of the highest dose of pidilizumab and low dose lenalidomide due to being in a dose escalation trial. It should be noted that 100% of patients had received prior lenalidomide and 77% had prior autologous stem cell transplantation. We look forward to updating you more on the pidilizumab program in the future.

Finally, enrollment is continuing in our phase I trial of healthy volunteers for MDV4463, our novel inhibitor of sterol regulatory element-binding protein or SREBP pathway. SREBPs are master regulators of lipid homeostasis.

In some pre clinical studies, we demonstrated that our SREBP pathway inhibitor, MDV4463, lowered triglycerides, cholesterol, glucose, insulin, and weight in animals. MDV4463 also reduced lipids in the liver in animal models of nonalcoholic steatorrhoeic hepatitis or NASH. We are excited by these findings and the potential of this asset.

Finally, I'd like to also take a moment to introduce Marion McCourt, who is also joining us today. Marion joined Medivation earlier this month in the newly created position of Chief Operating Officer.

Marion joins us from Amgen and AstraZeneca and has an impressive track record of successfully transforming and growing businesses to the next level. She will play a vital role in managing and scaling our teams, growing our existing commercial business, and helping to prepare us for the next stage as a company with multiple commercial products, a deep pipeline, and a global healthcare footprint.

I hope as you listen to the tremendous progress we made to date, you're as optimistic about Medivation's future as we are. Our entire team at Medication is energized and excited about the opportunities that lay ahead of us, and I hope you are too.

With that, we appreciate your continued support and look forward to updating you on our progress.

I will now turn the call over to the conference coordinator to open up the call to Q&A.

QUESTIONS & ANSWERS

Operator:

(Operator Instructions)

Katherine Xu, William Blair.

Katherine Xu (Analyst - William Blair):

Good evening. I'm wondering with the eight-month duration of XTANDI treatment in the real world that you talked about, can you break it down for us, oncology versus urology, pre- versus post-chemo?

David Hung (President & CEO):

I don't have that for you, but try to put that in some perspective. If you look at a metric like PSA progression, which is a metric that urologists commonly follow in clinical practice and often treat through.

If you look at the median time to PSA progression in the affirmed population, it was 83 months. In the farther upstream PREVAIL population, it was 11.2 months. In the TERRAIN trial, it was19.4 months.

And the STRIVE trial, that number was not yet reached because that number -- the mean has not been reached. But even the M1 subset of that trial had a time to PSA progression of almost 25 months.

What we would say is that, when we started our launch in 2012, basically, all of our patients were behind ZYTIGA, and therefore our treatment duration, as we know, whoever is second is much shorter than being in first. And in that time, in 2013, we were somewhere in the less than four month range, and at the end of 2015 in Q4, that number is now nearly eight months -- almost double. We would anticipate that as we move farther upstream into urology, the number will continue to increase.

As I mentioned in my script, the ZYTIGA duration today is estimated to be 10 months or longer. We see no reason that we wouldn't at least hit that number and exceed it as we move farther upstream into urology, especially given the fact that as you know from our last script, 20% of our scripts were in urology compared to ZYTIGA's 10%. We're making a better foray into urology than ZYTIGA, and we would anticipate that the farther upstream we go, the better the patients will do and the longer their treatments will be.

Katherine Xu (Analyst - William Blair):

Would you say that because ZYTIGA's duration of treatment is 10 months, your XTANDI is actually being used after ZYTIGA in oncology?

David Hung (President & CEO):

I believe that is the case. If you look at the oncology segment, given the fact that ZYTIGA was two years ahead of XTANDI, in oncology, we believe that ZYTIGA is ahead -- in the first position more often than XTANDI, but as you know, we have grown from no scripts to a significant number of scripts in the three years since launch. And as I just mentioned, total new patient starts in Q4 for the first time exceeded ZYTIGA.

So we feel like we're right at the cusp of just getting past ZYTIGA, and as I said, it is a narrow edge to go from second place to first if you're on that wall. Whoever's first is going to get a significantly longer duration than whoever's second.

Even though we are behind ZYTIGA in oncology, we see the trend very favorably. And once we cross into first place in oncology and we're already in first place in urology and growing that segment, we would expect duration to increase accordingly.

Operator:

Tazeen Ahmad, Bank of America.

Tazeen Ahmad (Analyst - BofA Merrill Lynch):

Thanks for take my question. Just a couple, David. In terms of potentially getting TERRAIN and/or STRIVE onto NCCN or AUA guidelines, do you have any sense on how long that might take?

David Hung (President & CEO):

I will let Mohammad Hirmand answer that question.

Mohammad Hirmand (Interim Chief Medical Officer):

Thank you. As you may know, both TERRAIN and STRIVE were recently published in quite prestigious peer-reviewed journals. Obviously we can't speculate in terms of if and when compendia listings may change.

What they usually do is that as data are presented at various conferences, especially as literature comes out and paper comes out, they survey literature. And as they see fit, they will change the guidelines accordingly. We believe that these are very exciting data and very important for prescribers and patients, but obviously we can't speculate again as to the timing or whether compendia listings will be modified.

Operator:

Kennen MacKay, Credit Suisse.

Kennen MacKay (Analyst - Credit Suisse):

David, on the call you mentioned about 80% of urologists have not written an XTANDI script. Some of my notes suggest about 18% to 20% of new XTANDI scripts are being written by urologists. And we've seen a pretty good uptick in urologists just over the first few weeks of 2016.

Can you maybe talk a little bit about the marketing effort to urologists, and are you still really only targeting the major urology prescribers here at the largest centers? Or has this strategy evolved a little bit?

David Hung (President & CEO):

I will let Joe Lobacki answer the question.

Joe Lobacki (Chief Commercial Officer):

Thanks for the question, this is Joe. The marketing strategy now started out, as David mentioned, with our growing sales organization focused on urology. It's really focused on across a broad group of urologists.

So, we're looking at who are the prescribing urologists in terms of prescribing drugs for prostate cancer treatments. Of that group, those are the ones that are targets and we are reaching out to. Previously it was hard to do when we were balancing oncology and urology, but now the group that we have will target directly to urologists.

We have a good focus, we have good marketing message. We will continue talk to them and try to get them to change the habits, understand metastatic disease so they feel more comfortable treating it and put XTANDI first.

Kennen MacKay (Analyst - Credit Suisse):

Thanks for taking my questions. And big congrats to yourselves and Marion for the new hire.

Marion McCourt (COO):

Thank you.

Operator:

Matt Roden, UBS.

Matt Roden (Analyst - UBS):

Thanks very much for taking the question. Congrats on all the progress in 2015. And, nice guidance. First question is on the pipeline, on PLATO study, actually.

First, David, I wondered if you can talk about any evidence exists that combining XTANDI and ZYTIGA after initial PSA progression was beneficial. Just trying to gauge your level of confidence in that trial design.

I guess, related, the implications if that study is indeed positive, we'd all imagine that PLATO could extend the real-world duration of therapy even further. But do you think there are any implications that a positive PLATO study could have on sequencing the two agents in the real-world even if ZYTIGA is generic? Thanks.

David Hung (President & CEO):

To answer the first part of your question, the combination of XTANDI plus ZYTIGA, as I mentioned in general, because both agents target the adjuvant signaling access, in general, the first agent does quite well and the second agent in that sequence does quite poorly. If you look at published studies to date, the outcome of ZYTIGA treatment after XTANDI treatment, the response rate is extremely low. I believe many studies have shown that be in the single-digit percent response rate.

We don't anticipate a significant response rate from the ZYTIGA part of the trial. The reason the trial was designed the way it was, the trial PLATO has two arms: patients who are progressing on XTANDI randomized to either continued XTANDI plus abiraterone versus just abiraterone alone.

And the reason for the abiraterone is because we still have to offer patients some therapy to justify why they're going on to have some potential benefits. But the real question being addressed is whether or not continuing enzalutamide through progression can give you additional benefits, because if it does, that will suggest that perhaps doctors should use enzalutamide like Lupon, which is never stopped after initiation.

That's the idea, and the mechanistic rationale behind that, we know that prostate cancer is a polyclonal disease, there are multiple clones. In fact, there's a very nice science paper published about a year ago showing that the clone that this particular patient died of was not the clone he was diagnosed with.

We know that there are multiple clones in patients. And if you have many clones, all it takes for your PSA to go up or for you to have radiographic progression is for one of those clones to become resistant. And response from all of the other clones is a rationale for stopping drug. That is the purpose behind PLATO.

So, to answer the question, if PLATO were positive, we believe that could provide some evidence as to why continued treatment through progression may make sense. We don't anticipate abiraterone to demonstrate dramatic efficacy after enzalutamide based on previously published literature. And to be fair, after ZYTIGA, enzalutamide is not particularly effective as well.

So we know whoever's first does well, whoever's second does poorly, which is why we believe it is so important for us to move into urology. We believe we do have a significant advantage because whoever is first in urology will take the lion's share of that market by both having more patients and longer duration of treatment.

Operator:

Tom Shrader, Stifel.

Tom Shrader (Analyst - Stifel Nicolaus):

In the prepared remarks, it sounds like there's less confidence about STRIVE getting into the label relative to TERRAIN. Is that because of the M0 patients? Do you see that as a long shot that those patients would make it in? What are your thoughts there?

Mohammad Hirmand (Interim Chief Medical Officer):

So what we have provided is the tally of the data from both TERRAIN which was all in metastatic CRPC as well as in STRIVE where there was a M0 subgroup as well as an M1. In both subgroup, we saw consistent results with enzalutamide outperforming bicalutamide. We don't anticipate the indication statement to change, so the indication statement part of the label would be metastatic CRPC.

In terms of exactly what will sharpen the various other parts of the label, whether it be parts of data for TERRAIN or STRIVE or whether it be purely M1 or with the addition of M0, I think at this stage we really cannot speculate. We will have to wait until the FDA completes the review for us to get a sense of what the final label update will look like.

Obviously we believe that a totality of the data it is very important for both physicians as well as prescribers as they're trying to find out what is the best treatment option for the patients that they see.

Tom Shrader (Analyst - Stifel Nicolaus):

Can I ask, do you in some sense pre-discuss what you are going to submit, or is this the first time they've seen it?

Mohammad Hirmand (Interim Chief Medical Officer):

We usually don't talk about the detail of our regulatory interactions, but I think it is norm in the industry that before we proceed with a submission, we undergo various interactions.

Operator:

Carter Gould, Barclays.

Carter Gould (Analyst - Jefferies):

Hello, this is Carter on for Geoff. Thanks for taking the question. On the increased sales force, are you willing to disclose what the new split is between the urologist and oncologist community? And I'm really interested in what gives you confidence that this is the right number given the magnitude of the opportunity and the promotional sensitively you talked about in this setting? Thank you.

Joe Lobacki (Chief Commercial Officer):

This is Joe, I'm happy to answer that. We also have our partner in Astellas that we are focused, so we have our increased sales force, which we increased 129. We also have the Astellas sales force which continues to focus on urology and oncology as well. So that gives us a double punch at the whole market.

But we believe that there is a group of urologists that are high prescribers of metastatic cancer -- resistant prostate cancer drugs. Those are the ones we're looking at and targeting. Smaller than the entire universe.

We will target those urologists. And we've got great programs to message around things that are holding them back of this moment.

We will focus on them with reimbursement programs as well because that has been a big key for them. So I have high confidence that with a focused effort, working along with our partner, we will be able to continue to grow into urology and get both new patient starts as well as duration there.

David Hung (President & CEO):

Just to expand on Joe's answer, we've done some market research, and we found that urologists appear to be quite call sensitive. It takes a certain number of calls to convert them to a script, and so we have done the math, and we've calculated that to be the size that we hired.

130 reps for us, and a similar number at Astellas. I think that was based on some of the recent reviews we have done over the past year.

Carter Gould (Analyst - Jefferies):

Thank you.

Operator:

Geoffrey Porges, Leerink.

Geoffrey Porges (Analyst - Leerink Partners):

I want to follow up on some of the questions about the urologist segment. David, can you give us some color about what proportion of the patients and the first generation adjuvant prescriptions in the urologist setting are M0 versus M1?

And second, whether you anticipate being able to access the M0 patient population given your current labeling and data, or whether that should be something that we don't anticipate you capturing any significant conversion of until you have the other trials. Because of course, you do have an overall survival benefit in your label, and as we know, bicalutamide does not. You would seem pretty well-positioned now.

David Hung (President & CEO):

From third party sources, we calculate that the number of M1 CRPC patients is roughly 75,000. We think there's roughly a comparable number of M0 and HSPC patients.

So, when we look at M1 CRPC, which is our current label, we're just neck and neck with J&J in oncology and slightly ahead of them in urology. We think that is a very significant opportunity upstream in urology, not only in more patients, but also more importantly increased duration because some of those patients are on drug for years as you know. So, we're making a very concerted effort there.

In the M0 patients, it is a little bit of an interesting subset. As you well know, all of the M0 patients who get any therapy Lupron or Casodex receive that therapy for a rise in PSA in general.

If you have had a definitive procedure like a prostatectomy or radiation therapy or radioactive seeds,

and you don't have a prostate, given the fact that the prostate is the only organ that makes substantial amounts of PSA, theoretically your PSA should be zero. Any PSA above zero, by definition means that you have some prostate cancer cells somewhere in your body, and if you want to call that an invert graphic metasis, that's certainly a micro metastasis.

There is a little bit of a semantic issue there between M0 and M1. If you look at our PROSPER trial, the reason that all M0 trials are ongoing, the reason that all of them have struggled so much to enroll is because when you look for M0 patients, when you do a scan, you will find that a significant number of them actually have metastatic disease. So, you have to be a little bit circumspective in what you define as M0 versus M1.

If you look at the numbers of all those patients, we think that number of M0, M1, resistant disease, it is in the range of 150,000 patients. Given where we are right now, we've captured a very small fraction of that. We think there is a very large upside, not only just numbers of patients, but maybe even more importantly, duration of therapy.

Whoever is upstream will get more patients but will also capture more duration. We think the opportunity upstream is really large. There's plenty more to go in M1, and M0 it's completely untapped. A lot of those M0s depending on how you look are going to end up being M1s.

In fact, as imaging procedures get better and better with time -- we've already seen the advent of some new imaging procedures like sodium fluoride PET as one example. You're metastases in patients that would be bone scan negative. Every year, as you get better and better technology looking for these metastases, you will see more and more patients labeled M1 as opposed to M0, but it will just take a little more time.

Geoffrey Porges (Analyst - Leerink Partners):

Thanks David.

Operator:

Tazeen Ahmad, Bank of America.

(Operator Instructions)

Anupam Rama, JPMorgan.

Anupam Rama (Analyst - JPMorgan):

Thanks for taking the question. Just a quick question on the guidance. I heard the commentary on gross and net and inventory. I'm just wondering if there is also a price increase baked into the guidance. Thanks so much.

Rick Bierly (CFO):

Thanks, this is Rick. As you know, we don't talk about the price strategy. That is something actually that Astellas takes the lead on. The last price increase was April of last year. Unfortunately, I'm not able to talk about that.

Anupam Rama (Analyst - JPMorgan):

Thanks so much for taking the question.

Operator:

John Newman, Canaccord.

John Newman (Analyst - Canaccord Genuity):

A question for David. So, you recently have published both STRIVE and TERRAIN. Congratulations on that.

I want to clarify, from a promotional perspective, given that you are currently negotiating to expand the label and potentially include the data in those studies, what specifically are your reps allowed to do and what are you instructing them to do versus to hold off on until later this year? Thanks.

David Hung (President & CEO):

We're telling them to do nothing. We cannot promote anything to do with those studies until we have the label. We have specifically told him to do nothing.

They are not to allow to disseminate publications. They're not allowed to talk about it. We really cannot put ourselves in jeopardy. We would never take the risk of any compliance infraction.

We certainly told them to do nothing. We've said in the second half this year we anticipate getting this label, and once we have a label, then they can certainly talk about it.

But right now, first of all, the publication only came out a few weeks ago. That's a recent event, but we specifically told them to do nothing until we get a label.

John Newman (Analyst - Canaccord Genuity):

Great. On the XTANDI breast cancer study you have running for ERPR positive, AR positive and HER2 normal, just curious, do you expect that when those data read out, you will be able to look specifically at response levels based on AR expression level similar to what you have been able to do in the triple negative population?

David Hung (President & CEO):

So, the answer to your question is sort of yes because, our knowledge signature does not only factor in AR. It is a complex signature of multiple genes. So, even though AR is a component of that, it is not the only component.

What we will be doing, we will be looking at the results, stratified by diagnostic positivity and diagnostic negativity, and we will see if there is a difference in response rate. I just want to reinforce that, this is not just focused on AR.

You might recall from our preclinical literature, if you look at Jennifer Richer's work, University of Colorado, XTANDI is interesting in that, yes it blocks AR signaling, but it also appears to block estrogen sinking. Because even though it does not hit the estrogen receptor per se, we know that if you give breast cancer cells estrogen, it causes them to grow, independent of testosterone. And you give them XTANDI, you can inhibit the ability of estrogen to drive their growth.

We think that the mechanism of action of XTANDI in breast cancer maybe a little bit more complex than just AR. As a result, our signature, does include AR but is not focused exclusively on AR.

What I would also want to point out is, what is interesting about XTANDI and breast cancer is that today, we're not aware of any other competitor agents that target the androgen access in breast cancer. We think this is a very novel approach for breast cancer. And, I think that is a pretty exciting place for us to be.

Operator:

Mike King, JMP Securities.

Mike King (Analyst - JMP):

Thanks for taking my questions. Many of my questions have been answered. Two quick follow-ups.

The first is just, I guess there's just some discussion about the risks of the label expansion group based on STRIVE and TERRAIN. I'm wondering if you could remind us what the data set, the size of the data set was and if there -- you feel a sufficient number that FDA will gain comfort that not only are the results reproducible and consistent, but also that there's not a tremendous amount of intra-or inter patient variability based on the relatively small numbers of those studies.

Mohammad Hirmand (Interim Chief Medical Officer):

Thanks for that question. These are two phase II studies, but these are actually quite large trials. Each trial is about 400 patients. These are randomized double-blind controlled trials.

The design was very similar to a phase III trial in terms of we had an active control as a matter fact, which was bicalutamide. These were blinded studies and randomized in a large patient population. We achieved statistical significance on the primary endpoint for both studies.

So again, the data are very robust, but obviously, we have to undergo the assessment and review. And obviously we can't speak for the FDA.

Mike King (Analyst - JMP):

Right. Thanks for the color. And then, just quickly, David, sounds to me like the Company, understandably making its bet to take XTANDI to the earlier stage population.

I just wonder, when you talk to physicians, if there's any concern in a marketplace that because, as you mentioned earlier, sequential therapy doesn't really provide benefit to patients who are getting the second drug, if there's any hesitation for doctors to do anything because once you've either failed XTANDI or ZYTIGA that your options then become less attractive? Is there any sense to make an investment in the post hormonal ablation setting for the Company in order to increase duration and drive utilization?

David Hung (President & CEO):

I think to the contrary. I think with most disease and cancer is no exception, in general the earlier you treat, the better you do.

A perfect example of that is to go through some of the data I cited for you. If you look at PSA response rates, and I mentioned earlier that our [forum] was 8.3 months of progression, PREVAIL was 11.2, TERRAIN was 19, STRIVE was 25 for the M1 and not yet reached for the M0. Clearly, much, much longer.

If you look at the control arms, in PREVAIL, whereas the drug arm increased to 11.2, the control arm was 2.8 months. If you now go upstream of that and go on to TERRAIN, there's even an increasing delta. Now the drug arm goes up to 19.4, but the control arm goes up to 5.8.

The benefit of the drug is increasing much more rapidly than the benefit of the control arm upstream, which means that the further -- the earlier you treat the patient, the better the patient does. Of course, you can always save any drug until the end and you might get some benefit, but that is not the best thing for the patient. A good drug will work early and probably work late. But, still going to give you more

benefit early.

So, I will tell you that, if it were my father, I'd probably want him to get the drug as early as possible. I think, that's a precedent that has been established many times before in oncology. I think the earlier you can treat a patient, the better that will do.

I should also remind everybody that Casodex has never been demonstrated to improve survival in any setting. And, XTANDI has been proven to improve survival in both pre-chemo and post-chemo settings of the MCRPC.

Not only do we have two well-controlled randomized studies involving more than 3000 patients showing statistically significant survival benefits, but we also now have two randomized head to head trials against the gold standard showing statistically significant improvements in every primary endpoint. So I just think that there's no rationale for trying to delay a good therapy to a later stage of disease if it is available at an earlier stage.

Mike King (Analyst - JMP):

Yes, perhaps I didn't ask the question the right way. I was really thinking about not necessarily delaying XTANDI, but for Medivation to invest in therapies that would be in the, what I guess people are calling it, neuroendocrine or anaplastic prostate cancer in order to prevent people from being hesitant about putting patients on the drug in the first place.

David Hung (President & CEO):

Yes. So, there is a significant unmet need in patients who fail what are currently gold-standard therapies.

XTANDI is certainly one of the gold standard therapies in pre and post chemo MCRPC. Still unfortunately, all too often patients still succumb to their disease and progress. So, that was the reason we bought talazoparib.

If you look at the [topub] study of olaparib in metastatic CRPC, that was one of the sickest patient populations I've ever seen. 100% had failed docetaxel, 58% had failed additional cabazitaxel, 96% also failed abiraterone, 28% also failed enzalutamide, and 26% also failed radiation therapy. So they had failed five lines of therapy for the most part.

And in spite of that, one in three patients had a response, and there 49 patients, there were 16 responses. Of the 16 responders, 14 of 16 patients dropped their circulating tumor cell count to zero. The maximum CTC reduction was 100%.

I don't know of any drug in any mechanism that has generated data like that to date. So, that was one of the reasons we believe that PARP as a class of drugs is such an exciting class because I don't know any drugs today in oncology that could generate a 33% response rate and drop 85% of CTC counts in responders to zero, other than what we have seen with PARP inhibition.

We are investing heavily in PARP, in talazoparib because we believe that not only is this a universal mechanism that's applicable to virtually every cancer. Every cancer has DNA it's got to replicate. Unlike XTANDI, which focuses on AR, talazoparib focuses on every cancer.

We've clear data in non clinical studies that demonstrate head to head that talazoparib is several thousand times more potent than other PARP inhibitors at PARP trapping and killing cancer cells. For that reason, we believe that this is a unique asset, and we believe that it's widely applicable to many cancers.

And it is the perfect drug to build a global oncology franchise on because we clearly know this asset is

unpartnered and we can move as quickly and develop as thoroughly as we need to. We are definitely making a significant investment in talazoparib.

Mike King (Analyst - JMP):

Thanks for the answer.

Operator:

Christine [Agnew], Cowen.

Christine Agnew (Analyst - Cowen Group):

Can you comment on whether there is any reimbursement today in the non metastatic setting for XTANDI? And the second one is, can you be more specific as to why so many urologists have not prescribed XTANDI and how is the label update going to help ease their concerns?

David Hung (President & CEO):

I will answer the second question first of all. I will let Joe answer the first question. Why have urologists not prescribed XTANDI?

I think that awareness among urologists is still relatively poor. We were actually told an interesting anecdote at [Geoasco], which is a few weeks ago in San Francisco where one of our colleagues was actually golfing with one of the urologists. Being at this conference, this would probably be one of the more academic urologists out there.

This urologist told our colleague -- we really like XTANDI. It is great drug, but why doesn't Medivation do a head to head trial against Casodex to show it's better? So, he didn't even know that we had done STRIVE and TERRAIN, so I think there's a lot of education to be done.

That's part of the reason that we've increased our sales force to target urology. Urologists are busy surgeons. They are running around to the OR, they are doing a lot of cases. They don't always have the time to peruse the literature. So, I think that's a perfect illustration.

If the guy's at Geoasco, he's probably one of the more academic urologists out there, and yet he wasn't even aware that we've even done STRIVE and TERRAIN. I think there's a lot of education to be done, but the good news is that, our market research indicates that if you hit them a certain number of times, we can convert them to a script.

We've done our math and we upsized our sales force to 130, 129. And Astellas has also got a significant sales force, and we think together we can make a real dent in urology and move upstream. I will let Joe answer the first question.

Joe Lobacki (Chief Commercial Officer):

Just to follow, up I would agree with David that it's extremely important we spend the time with these urologists to try to get them to change their habits and move forward. And that is how we built the sales force and the group of folks that we're focused on. Our focus is to look at MCRPC and our promotion.

So, we know when we work in a reimbursement that's what we're focused on in MCRPC. So, in terms of how a certain third-party payer would pay, that's our focus in the MCRPC setting, which, may at times for payers include other patients as well. We're not hearing of any major reimbursement problems for XTANDI, and we're making sure that patients who need it can receive it.

Christine Agnew (Analyst - Cowen Group):

I'm thinking the non-metastatic setting. You have no data on that?

Joe Lobacki (Chief Commercial Officer):

We're focused on MCRPC.

Christine Agnew (Analyst - Cowen Group):

Okay. Thank you.

Operator:

Biren Amin, Jefferies.

Biren Amin (Analyst - Jefferies):

Thanks for taking my question. Maybe to what degree does the XTANDI label update drive your increases and assumptions for treatment duration? And Rick on US XTANDI sales guidance, is there a price increase assumed in guidance?

David Hung (President & CEO):

So I will answer the first part of the question, Biren. First of all, we've guided on what we believe our sales will be over 2016. But, given the fact that the label we expect in the second half of the year, that will probably contribute a relatively small amount to our guidance. We would anticipate the label impact probably would be more in the subsequent year and the years after that.

We think that Casodex is our biggest competitor. It is the most widely used drug outside of Lupron in prostate cancer and it's also used early. So, if we have a label update that allows to promote that this is drug that is superior to Casodex and we can move it into upstream urology where bicalutamide is used, we think that would cause significant increase in duration of therapy.

We've already seen some patients on XTANDI in the pre-and post-chemo settings that are out, five, six, seven, eight years. Clearly, if you get into the Casodex range, we're talking about a lot of years. We think that the label will come in the second half. We expect the impact of that to be really solid in 2017 and beyond.

So, I think that the guidance we're giving, 28% growth over last year for this year is really based on adoption, increase in sales force, the fact that we're going to be focusing on a new message specifically in urology as well as a separate one on oncology and, getting ahead of ZYTIGA slowly. The label update clearly will be a significant factor for us. We would anticipate that impact more in the following year.

Joe Lobacki (Chief Commercial Officer):

Part two, as I mentioned, we're not at liberty to talk about price.

Operator:

That is all the time we have for questions for today.