MEDIVATION INC (MDVN) Earnings Report: Q1 2016 Conference Call Transcript

The following MEDIVATION INC conference call took place on May 20, 2016, 08:00 AM ET. This is a transcript of that earnings call:

Company Participants

- Anne Bowdidge; Medivation; IR
- David Hung; Medivation; President & CEO
- Marion McCourt; Medivation; COO
- Rick Bierly; Medivation; Outgoing CFO
- Jennifer Jarrett; Medivation; CFO
- Mohammad Hirmand; Medivation; Interim Chief Medical Officer

Other Participants

- Geoff Meacham; Barclays Capital; Analyst
- Salveen Richter; Goldman Sachs; Analyst
- Yigal Nochomovitz; Citigroup; Analyst
- Kennen MacKay; Credit Suisse; Analyst
- Geoffrey Porges; Leerink Partners; Analyst
- John Newman; Canaccord Genuity; Analyst
- Katherine Xu; William Blair & Company; Analyst
- Do Kim; BMO Capital Markets; Analyst
- Mike King; JMP Securities; Analyst
- Eric Schmidt; Cowen and Company; Analyst
- Biren Amin; Jefferies LLC; Analyst
- Peter Lawson; SunTrust Robinson Humphrey; Analyst

MANAGEMENT DISCUSSION SECTION

Operator:

Welcome to Medivation's first-quarter 2016 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. Please go ahead.

Anne Bowdidge (IR):

Thank you. Thank you for joining us.

Just after the market closed today, a press release was issued with earnings results for the first quarter 2016. The press release and a slide presentation which will accompany this call are available in the investor relations section of our website.

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

Before we begin, I'd like to remind you that various remarks that 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, anticipate, and similar expressions.

These forward-looking statements 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-Q for the quarter ended March 31, 2016, which we filed with the SEC today.

Medivation cautions listeners not to place undue reliance on any forward-looking statement. 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 a 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'll turn the call over to Dr. David Hung, Founder, President, and CEO of Medivation . David?

David Hung (President & CEO):

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

On this call, I will update you on the factors that contributed to Medivation's landmark quarter and the important opportunities that we have in our pipeline.

As you know, last week, our Board of Directors unanimously rejected Sanofi's unsolicited proposal to acquire our Company for $52.50 per share in cash. Medivation has significant value as one of the few profitable commercial-stage oncology companies.

We have a leading oncology franchise with a blockbuster asset as well as an exciting late-stage pipeline where we hold wholly owned worldwide rights. Therefore, we believe the proposal substantially undervalues our Company.

At the end of our earnings remarks today, I will be walking through a few key points about why we believe that by executing on our current strategic plan, we will be able to deliver significantly greater value to our shareholders and the patients we help every day than Sanofi's highly opportunistic proposal.

But first, I want to begin by discussing a very strong quarter and our vision for future growth that I believe warrants your attention. We have three primary pillars of value growth at Medivation . Number one: XTANDI, our blockbuster prostate cancer drug partnered with Astellas, which is moving nicely upstream into urology and also being developed in breast cancer, liver cancer, and potentially other indications.

Number two: talazoparib, our wholly owned PARP inhibitor, which should complete enrollment in the Phase III EMBRACA breast cancer trial this year, which will read out in the first half of next year. And number three: pidilizumab, our natural killer-cell-activating antibody, which is also being developed in a potentially registrational trial in DLBCL as a first indication. A number of potentially significant value-

enhancing milestones in these programs lay ahead in just the next few quarters.

With respect to XTANDI, in just the next half of this year, we expect to one: receive word from FDA on or before October 22 on whether the XTANDI label might be amended to include TERRAIN/STRIVE data comparing XTANDI head-to-head against bicalutamide, which could further enhance urology uptake.

Two: receive data from our Phase II trial in breast cancer patients who are ER/PR-positive and HER2 normal, which comprises half of all breast cancer and therefore constitutes a sizable commercial opportunity beyond prostate cancer and triple negative breast cancer. Three: receive data from our Phase IV PLATO trial, which will inform us whether continuing XTANDI upon disease progression may lead to better outcomes and result in a potential increase in the duration of therapy.

Four: receive Astellas's agreement to initiate Phase III in triple negative breast cancer. And five: exceed enrollment of 1,200 patients in our PROSPER trial -- 1,200 patients being the targeted enrollment number of J&J's SPARTAN trial. If SPARTAN result positively, we have the option of unblinding PROSPER early if we so choose. If SPARTAN misses, we can wait to unblind to increase our chances of success.

With respect to talazoparib this year, in addition to finishing EMBRACA enrollment, we anticipate starting trials in prostate, breast, lung, and ovarian cancer pending completion of FDA discussions as well as presenting new clinical data at an upcoming medical conference which we believe highlights the differentiated mechanism and profile of talazoparib.

With respect to pidilizumab, we have made some strides in clarifying the antibody's mechanism of action. And when and if repeatedly confirmed, we may announce the mechanism of action as early as this year, which we believe may make pidilizumab an even more unique, exciting, as well as combinable asset.

Let me start with XTANDI commercial sales. We've had an extremely strong start to 2016 and I will briefly summarize some of the highlights. To begin, XTANDI sales in the US and the rest of the world are growing, reaching a growth rate of 53% in Q1 on a year-over-year basis for a total of $547.2 million in worldwide sales in the quarter.

XTANDI continues to meet our expectation, and as our COO Marion McCourt will discuss in a moment, recent developments give us further confidence for the future as we aim to extend XTANDI's leadership position in both urology and oncology. As you know, we have guided toward US XTANDI net sales of $1.425 billion to $1.525 billion in 2016, which represents a 28% increase at the midpoint over 2015. We believe that our 7% unit demand growth in Q1 2016 over Q4 2015 puts us on track to hit our 2016 US XTANDI net sales target.

And as XTANDI is increasing the use as first-line therapy in metastatic CRPC, we expect the duration of treatment to continue to increase beyond the nearly eight-month average observed late in 2015, which will lead to further sales growth.

As we look at the big picture, we have grown XTANDI, our first marketed product, to achieve blockbuster status in just a few short years. Only 3 1/2 years after its launch, XTANDI is now the eighth-largest oncology product globally by revenue, and based on estimates from Evaluate Pharma, it will be the fourth-largest oncology product by 2021. Evaluate Pharma just published a report on Tuesday projecting that XTANDI will be the second-largest product in Europe across all therapeutic categories in 2022 and the best-selling oncology product in Europe.

Just last month, we reached an important milestone when the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency issued a positive opinion recommending inclusion of data from the head-to-head TERRAIN trial of enzalutamide versus bicalutamide in XTANDI's European label. The CHMP's decision to incorporate these important, clinically meaningful comparative

data in the XTANDI label is a significant development that will further enhance clinical understanding and we believe adoption of XTANDI among urologists and oncologists throughout Europe.

In February, the US FDA accepted our SNDA filing to update the clinical sections of XTANDI's US product label to include findings from the TERRAIN and STRIVE trials. The Agency has provided a PDUFA date of October 22, this year for a decision.

Including head-to-head data of XTANDI against bicalutamide, the current standard of care, in the US label could be an important catalyst for further driving both urology and oncology adoption. Marion will discuss in much more detail how we are preparing commercially for this important event.

Beyond XTANDI, we are well positioned for long-term sustainable growth with a promising pipeline that includes two late-stage wholly owned assets: talazoparib and pidilizumab. I'll speak more about our vision for the growth of the Company later in the call.

With that introduction, I'd like to turn the call over to Marion to give some additional details on the strong commercial performance of XTANDI.

Marion?

Marion McCourt (COO):

Thank you, David. Good afternoon, everyone.

First let me say that this quarter's commercial activity was impressive and a clear demonstration of XTANDI's value proposition for both shareholders and patients. Its robust worldwide sales made meaningful contributions to our strong overall financial performance and as the most exciting product in prostate cancer treatment today.

XTANDI is a remarkable example of Medivation's commitment to scientific advancement. I joined this Company to become part of an industry-leading team dedicated to advancing the care and survival of cancer patients. Our first-quarter results demonstrate that we are doing just that. At the same time, we are working to expand XTANDI's franchise within oncology as well is into other therapeutic areas, such as urology, so that we can continue to do so into the future.

During the first quarter, XTANDI's worldwide net sales reached approximately $547 million. This represents an increase of over 53% over the first quarter of 2015. Now turning to the US net sales, approximately $308 million in the first quarter of 2016, which represents an increase of $84 million or a 37% increase over the first quarter of 2015.

In the novel hormonal therapy, or NHT market, which is defined as XTANDI and abiraterone-treated patients, we continue to make significant gains securing market and competitive share growth. XTANDI captured over 50% of the total NHT market for Q1 according to IMS data and continues to be the market leader for new prescriptions. For the first time, XTANDI has surpassed abiraterone in total prescriptions written during any quarter.

In addition, US XTANDI unit demand grew approximately 7% to an estimated 42,000 prescription bottles during the first quarter compared to the fourth quarter of 2015. We're encouraged by these metrics and our recent market research gives us even further confidence.

The top two reasons physicians choose XTANDI as the preferred agent in the NHT market are demonstrated efficacy and ease-of-use. Most recent survey data shows that approximately 65% of oncologists and 77% of urologists indicate XTANDI is their preferred NHT product. Since preference is a leading indicator of future performance, we are well positioned to extend our leadership position in the

growing NHT market.

XTANDI continues to enjoy broad coverage across US Medicare and commercial prescription plans. The majority of third-party payers reimburse XTANDI at parity with oral oncology products.

In March, we completed the expansion of our specialty sales force, which included training an additional 40 sales representatives and further strengthening our sales leadership team. Market analysis suggested that expanding our sales force into dedicated urology and oncology teams would advance our urology sales' impact and strengthen our leadership in oncology.

Because our new sales representatives did not hit the ground in a significant way until March, we will see increasing impact of the sales force expansion in later quarters this year.

In addition to providing the framework for customized content and messaging, this new sales footprint has allowed us to significantly increase our call volume reach and frequency to the most important prescribers. XTANDI's share of voice as measured by third-party sources has significantly increased in urology and we are now the market leader in both urology and oncology.

While today most XTANDI prescriptions are written by oncologists, urology is our most significant near-term growth opportunity and we are excited about our progress in Q1. In this quarter, we saw a robust 68% growth in urology prescriptions over the prior year as reported by IMS.

Total and new urology prescriptions grew at 14% and 12%, respectively, versus the previous quarter. Currently, over 20% of XTANDI business is in urology, with new urology XTANDI prescriptions in Q1 accounting for approximately 26% of new patient starts.

In this quarter, our active base of urology prescribers grew by 62% to over 1,300 from approximately 800 in Q1 2015. We believe our expanded sales force will further increase our reach and frequency with important metastatic CRPC prescribers in coming quarters.

Today, XTANDI is the number one most frequently prescribed novel hormone therapy in urology. But let me tell you why we see significant growth ahead. Third-party data shows that approximately 80% of prostate-cancer-drug-prescribing urologists have not yet written a prescription for XTANDI.

Barriers to urology adoption include habit and general lack of awareness, which we believe we can particularly address with TERRAIN/STRIVE data, but which we cannot promote until we receive a label amendment. We believe the increase in our urology-focused sales force sets the stage for us to shift the current treatment paradigm. And we are seeing early signs of success.

Transitioning now to oncology, this segment accounts for the majority of our current sales, and XTANDI continues to grow in this important line of business. In this quarter, we saw 19% growth in prescriptions versus the same period last year as reported by IMS. Total and new prescriptions grew this quarter at 6% and 7%, respectively, versus prior quarter.

As we have outlined today, overall XTANDI sales were driven by increases in new patient starts, competitive share gains, and market growth. Another key driver for XTANDI is duration of therapy, or average number of months on therapy.

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 now greater than eight months. Given that abiraterone launched ahead of XTANDI, abiraterone's current duration of therapy is longer than XTANDI's, estimated to be 10 months or more. We expect XTANDI's duration of therapy trend to continue to increase as XTANDI moves earlier into the treatment paradigm.

At Medivation , our focus is on serving patients. And our mission is to have a remarkable impact on their lives. Since launch, approximately 60,000 patients have been treated with XTANDI in the US alone. We're delivering on our mission to make a difference in the lives of men with prostate cancer and their families.

I'll now turn it back over to David.

David Hung (President & CEO):

Thanks, Marion. Before Jen provides an update on the financials, I'd like to turn the call over to Rick Bierly for a few words.

As you know, Rick has made a decision to retire. Rick has been instrumental in helping us to become the strong, fully integrated commercial company that we are today. I'd like to thank Rick for his many contributions and wish him the very best from all of us.

Rick?

Rick Bierly (Outgoing CFO):

Thanks, David. Good afternoon, everyone. I wanted to first take just a moment to extend my thanks and best wishes to all of you who I've had the pleasure of working with over the past couple years since I joined Medivation . As most of you know, I have announced my retirement in the coming months and I look forward to returning to the East Coast later this year.

Medivation is a truly great company doing great work to benefit patients, their caregivers, and families every day. And it has been an honor and privilege to work closely alongside David and the team here to move the Company forward and to bring the Medivation story to all of you.

At this point, I also wish to warmly welcome Jen Jarrett to Medivation as Chief Financial Officer. Jen will take you through the financial section of the prepared remarks.

Jen?

Jennifer Jarrett (CFO):

Thank you, Rick. Good afternoon, everyone.

I have known David and the Medivation team for over 10 years, and I'm thrilled to be working closely with the executive team and preparing the Company for its next phase of growth as we approach the potential label amendment for XTANDI in October and launch of talazoparib within the next two years.

I would like to now direct everyone to the slides on the webcast. Starting with US sales, XTANDI net sales as reported by Astellas were approximately $308 million in the first quarter of 2016, a 37% increase over the first quarter of 2015.

As a reminder, our 2016 guidance for XTANDI US net sales at the midpoint represents approximately 28% growth over 2015. Based on this robust first-quarter growth rate, we are confident in reaffirming our 2016 US XTANDI net sales guidance.

These first-quarter results were consistent with our internal expectation and with the guidance we provided on our year-end call that 2016 first-quarter net sales would be below the level reported in the fourth quarter of 2015 due to seasonal items that we typically experience in the first quarter and that I will now walk you through.

First, gross demand sales were approximately $374 million based on unit demand of approximately

42,000. As David mentioned earlier, this represents a sequential growth rate of approximately 7%.

Second, channel partner inventory decreased by approximately 1/2 week, which offset underlying demand growth by $11 million or 3%. This is consistent with our historical seasonal patterns, where we observe a drawdown in inventory in the first quarter following a buildup of inventory in the last quarter of the year.

Third, our current-period gross to net accrual rate was approximately 16%. The higher gross to net accrual rate in the first quarter of 2016 compared to the fourth quarter of 2015 is largely related to the annual reset of the so-called donut hole associated with Medicare Part D. Separate from our current period gross to net accrual rate, net sales benefited from a $4.2 million favorable adjustment this quarter related to a true-up of prior-period reserves.

Outside the US, where Astellas conducts all sales marketing and distribution, net sales were approximately $240 million in the first quarter of 2016, an increase of 80% compared to the first quarter of 2015. The year-over-year increase was primarily driven by growth in Germany, France, and Japan.

Turning now to Medivation's income statement, total non-GAAP collaboration revenue was $182.5 million for the first quarter 2016 compared with $127.8 million in 2015, an increase of 43%. Collaboration revenue relates related to XTANDI US net sales was $153.8 million for the first quarter of 2016 compared to $112 million in 2015, an increase of 37%. 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.

Medivation collaboration revenue related to ex-US sales was $28.7 million for the first quarter of 2016 compared with $15.8 million in the year-ago quarter, an increase of 82%. Under our collaboration with Astellas, we earn a tiered royalty rate that is based on sales that reset at the beginning of each calendar year. As such, our royalty rate on ex-US sales will increase throughout the year.

As a point of reference, the effective quarterly royalty rates for 2015 were 12%, 14%, 16%, and 19% for Q1 through Q4, respectively. And the royalty rate can tier up to the low 20's.

Now I'll turn to operating expenses. Non-GAAP R&D expense for the quarter ended March 31 was $68.4 million compared with $37.9 million for the first quarter 2015, an increase of 81%. The year-over-year increase in non-GAAP R&D expense is primarily a result of R&D expenses related to talazoparib, which we acquired in October of 2015, and our assumption of expenses for all talazoparib activities. The quarter-over-quarter growth in R&D expenses was 11% and this sequential growth rate should decline in the second half of the year.

Non-GAAP SG&A expense for the first quarter 2016 was $83.8 million compared with $67.4 million for the same period in 2015, an increase of 24%, which was well below our year-over-year revenue growth. This moderate increase in SG&A expense is despite the expansion of our sales force, which Marion described earlier.

Our first-quarter SG&A expenses were impacted by annually recurring collaboration expenses incurred by Astellas that are expensed with almost entirely in the first quarter of the year. You will see on slide 11 that we were impacted by these same expenses in the first quarter of last year. As such, we expect that our non-GAAP SG&A expenses will decrease in subsequent quarters, similar to the trend we observed in 2015.

Medivation reported non-GAAP net income of $18.8 million or $0.11 per diluted share for the first quarter of 2016 compared with non-GAAP net income of $13.4 million or $0.08 per diluted share in the prior-year first quarter. This represents year-over-year non-GAAP EPS growth of 35%.

Consistent with what we observed in 2015, as you will see on slide 12, our first-quarter 2016 non-GAAP EPS is generally lower due to the resetting of the royalty rate on ex-US XTANDI sales, the higher GTN accrual rate by Astellas on US net sales, the inventory drawdown, and the previously mentioned higher non-GAAP SG&A expenses due to the timing of certain collaboration expenses incurred by Astellas, which occurs primarily in Q1.

As such, we expect our quarterly non-GAAP EPS to significantly increase in coming quarters. And are therefore reaffirming our 2016 full-year non-GAAP EPS guidance of $1.30 to $1.40.

Turning quickly to our balance sheet, at March 31, we had cash and cash equivalents of approximately $317 million compared with approximately $226 million at the end of 2015. The increase of approximately $92 million was primarily due to the receipt of $175 million sales milestone for Astellas, which was earned in the fourth quarter of 2015 and received in the first quarter of 2016, offset by the repayment of $75 million on our credit facility in January.

Lastly, we are reaffirming the 2016 full-year guidance we provided on our February 25 year-end conference call. The 2016 guidance information is included in our press release filed today. Historic non-GAAP information may be found on our website at medivation.com.

With that, I'll now hand the call back over to David.

David Hung (President & CEO):

Thanks, Jen.

Before we start, I'd like to refer you to our forward-looking statements. I would now like to spend the next 30 minutes talking about Sanofi's unsolicited proposal and our rejection of it.

Our Board unanimously believes that the continued successful execution of our well-defined strategic plan will deliver greater value to Medivation's shareholders than Sanofi's substantially inadequate proposal.

While we would hope that many of the near-term value catalysts are evident from the discussion of our quarterly results, we want to provide much more detail around our strategy for the future and address why our Board concluded that Sanofi's opportunistically timed proposal substantially undervalues our Company and its exciting prospects.

As I mentioned at the beginning of this call, we have posted a presentation on our website, which I will now walk you through. Slide 20 summarizes everything that I would like to cover with you today. Let's start with slide 22 and what our mission is.

Since I founded Medivation in 2003, our focus has been on patients. Let me start with the story of Graeme, an XTANDI patient and close friend of Medivation . In 2010, Graeme had failed all standard of care therapies, including chemotherapy, and was told that he had three weeks to live. You can see him on the left in a hospital bed, his face bloated from the steroids he had to take with his chemotherapy.

At that time, we enrolled Graeme in AFFIRM, our first pivotal trial for XTANDI. He had a remarkable response. His PSA went from above 55 -- normal would be less than 4 -- to zero. Graeme is now on his sixth year of XTANDI, treatment, and as you will see in the picture on the right, Graeme is thriving.

He has seen all three of his kids married and witnessed the birth of three new grandchildren. He visited several Medivation several months ago to thank us for what we did for him and then embarked upon a backpacking trip to Canada by himself.

Graeme was one of tens of thousands of patients who have benefited from XTANDI and one of the many XTANDI patients who I have stayed in touch with. In fact, I just received an email from Graeme this week and he continues to do extremely well. His PSA continues to waver between zero and 0.1, and he is grateful for the many years that XTANDI has given him.

While helping patients is a top priority, we have been and continue to be focused on creating value for our shareholders. On slide 23, I want to summarize some of the extraordinary accomplishments that we have achieved and how we will continue to build value for Medivation and its shareholders over the coming years.

First, in just over three years, we have established XTANDI as the world's leading prostate cancer therapy based on sales. XTANDI is now generating $2.2 billion in annualized worldwide net sales and we in-licensed XTANDI and took it from preclinical lead discovery to full FDA approval in just seven years, one of the fastest development times in biopharmaceutical history.

Our success with XTANDI has allowed us to make strategic investments in new opportunities that leverage our existing strengths and capabilities. As a result of these investments, we have been able to acquire two exciting wholly owned late-stage oncology assets: talazoparib and pidilizumab.

By continuing to execute on our strategy to maximize XTANDI's potential and develop talazoparib and pidilizumab, we expect that non-GAAP revenue will grow from $695 million in 2015 to over $2.5 billion by 2020 or approximately 30% on a compounded annualized basis. I am confident that the value that we can create with just these three current assets is significantly higher than Sanofi's proposal.

XTANDI's success has benefited our shareholders. Because of a steady ramp in revenue, as seen on the upper-left graph on slide 24, and a very short time to profitability compared to our biotech peers, Medivation has generated over 950% total shareholder return over the last five years and over 4,000% total shareholder return over the last 10 years, significantly better than the NASDAQ Biotechnology Index. Since our first public financing in December 2004, Medivation has generated shareholder returns of more than 15,000%.

I also want to emphasize how conscientious we have been on being capital efficient and minimizing shareholder dilution. Our last equity capital raise was over four years ago when we completed a $225 million convertible offering.

In fact, prior to this convertible offering in 2012, during the first eight years of the Company's growth from 2004 to 2012, we raised only approximately $175 million to generate a market cap in 2012 of more than $3 billion. We have since redeemed this convertible when it was significantly in the money and have not raised any equity capital since that offering.

On slide 25, XTANDI, as we have discussed, has significant potential to serve much larger prostate cancer patient populations as well as patients with breast cancer and other solid tumors. This pipeline chart summarizes all of our ongoing trials for XTANDI, each of which represents a very significant commercial opportunity for Medivation .

While we are clearly best known today for XTANDI, we are now leveraging the clinical expertise that contributed to the success of XTANDI to advance the rest of the pipeline. Current and future indications for XTANDI, talazoparib, and pidilizumab combined represent an addressable market of more than $50 billion.

With all these ongoing and planned trials, we are approaching an inflection point in Medivation's growth trajectory. We find ourselves in a fortunate position today and believe that our shareholders, not Sanofi's, should be the ones to benefit from the full value of XTANDI, talazoparib, and pidilizumab.

Each of our products has multiple near-term milestones that will further increase their value. As you can see on slide 26, many of these are expected in just the next 12 months, with some of the most significant highlighted in the red boxes being the October 22 PDUFA date for the XTANDI label amendment, top-line data for XTANDI in ER/PR-positive HER2 normal breast cancer, and Phase III data for talazoparib in the EMBRACA trial in BRCA-mutated advanced breast cancer.

While we have highlighted three milestones here, we believe that all of the events on this slide have the potential to create significant value for our shareholders. Sanofi is obviously aware of the significant share price appreciation likely to follow these events, which is why they chose to make an opportunistic unsolicited approach a few weeks ago. I will talk more about these important value-creating events later in my presentation.

Turning to slide 27, let's talk about XTANDI and our strategy for continuing to maximize the value and revenue potential of our leading oncology franchise. On slide 28, I touch on this on our earnings call, but I want to reemphasize how significant a product we have created with XTANDI.

As you can see on slide 28, in 2015, XTANDI was the eighth-largest oncology product by worldwide sales. In 2021, XTANDI has been projected by Evaluate Pharma to be the fourth-largest oncology product globally in the midst of one of the most exciting and competitive areas of drug development in oncology. And importantly, as we expect to have more than 10 years of protection from today on our composition of matter patent, we can continue to grow XTANDI well into the future.

Slide 29 -- just this past week, Evaluate Pharma forecasted that by 2022, XTANDI will be the second-largest product in Europe across all therapeutic categories. In fact, XTANDI is projected to be bigger than several other prominent oncology products, such as Celgene's REVLIMID, which has been on the market much longer than XTANDI, and Bristol Meyer's OPDIVO.

I'll now get into the specifics as to why we are so confident in the growth profile and commercial potential of XTANDI. Slide 30. First of all, we continue to take share of the NHT market from our competitor J&J. As a reminder, J&J launched ZYTIGA 16 months ahead of XTANDI. Despite their significant lead, we surpassed them in terms of market share just this last quarter, which you can see from the dotted lines crossing on the right of the slide.

This is important because whichever drug is used first gets a longer duration of therapy. Having just exceeded Zytiga in market share this last quarter, we believe that we are starting to get used in first position more and more, which we believe will increase our duration of use.

Another point the left graph makes is how much the NHT market has grown during this time period. In fact, the NHT market, defined as worldwide sales of XTANDI and ZYTIGA, has grown from just $1 billion in 2012 to $4.1 billion in 2015. We expect the market to continue to grow and Medivation to continue to take share from J&J, given recent surveys showing preference of XTANDI over ZYTIGA due to XTANDI's clinical efficacy and ease-of-use -- a profile particularly important in urology.

During the earnings portion of the call, we discussed how XTANDI's sales were driven by increases in new patient starts, competitive share gains, and market growth. Now I want to elaborate on another critical and powerful growth driver for XTANDI: duration of therapy, or the average number of months on therapy.

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 eight months today. Having reached the market before XTANDI, abiraterone's current duration of therapy is estimated to be 10 months or more.

Slide 31. We expect XTANDI's duration of therapy trend to continue to increase as XTANDI moves earlier into the treatment paradigm. Physicians, especially urologists, often continue therapies until PSA

progression and then switch if they believe a patient is failing.

As shown on slide 31, median time to PSA progression was 11.2 months in PREVAIL and 19.4 months in TERRAIN, both metastatic CRPC trials, but TERRAIN patients were less clinically advanced than those in PREVAIL. Therefore, we anticipate XTANDI's duration of therapy will over time be at least in the midpoint of the range, which is approximately 15.3 months in the metastatic CRPC setting.

Furthermore, the median time to PSA progression was nearly 25 months in the M1 population of STRIVE, and the median was not yet reached in the M0 population of STRIVE, suggesting a time to PSA progression exceeding 25 months for this trial. Clearly, moving further upstream affords longer potential treatment durations, and that is our goal. And as Marion said earlier, given that we have exceeded J&J in total scripts for the first time in Q1 and that we continue to have a substantial competitive lead in urology, it is becoming the reality.

Slide 32. Needless to say, the total market opportunity for us in just prostate cancer is massive. Within our current label, the addressable population is 73,000 patients in the US alone. We believe that a TERRAIN/STRIVE amendment to our label for XTANDI in metastatic CRPC should accelerate XTANDI's adoption by the urologists who manage the majority of these patients.

In addition, we have a number of ongoing Phase III trials to evaluate enzalutamide even earlier in the prostate cancer treatment continuum. These studies include PROSPER in non-metastatic CRPC; EMBARK, a nonmetastatic hormone-sensitive prostate cancer trial, which includes a head-to-head comparison to Lupron, the most widely and earliest-used prostate cancer drug; and ARCHES, a metastatic hormone-sensitive prostate cancer trial which Astellas is running, which will compare enzalutamide plus androgen deprivation therapy to ADT alone.

These three trials increase the additional patient opportunity by 60,000 patients, nearly doubling the current addressable patient population for XTANDI. But importantly, because these studies address earlier stage patients in whom the duration of therapy can be significantly longer, label expansions into these indications could significantly increase revenue from duration of use as well as from increased patient numbers.

Slide 33. As you can see here, we believe that challenging XTANDI's position as a leader in the treatment paradigm for prostate cancer will be a daunting task. Any potential new competitors who aspire to displace current agents would need to go up against standard care.

The standard of care menu options list has increased significantly recently from none post Taxotere just six years ago to now five new agents with proven clinical benefits and indications ranging from post-chemo to pre-chemo. These five are XTANDI, ZYTIGA, PROVENGE, Xofigo, and Jevtana, with XTANDI and ZYTIGA particularly widely used.

Of note, of these [five] (corrected by company after the call) drugs, only ZYTIGA and XTANDI have demonstrated both overall survival and progression-free survival benefits in a broad label covering both pre- and post-chemo patients. But only one -- XTANDI -- has also demonstrated head-to-head superiority over a standard of care in urology, Casodex.

As you can see on this slide, this differentiated profile is already translating into market leadership by sales. And for any new potential competitors, trying to show benefits over multiple other drugs with robust benefits is an exceptionally difficult task. And we believe likely contributed to the recent Phase III failure of TAK-700, OGX-111, and tasquinomod.

By 2016, XTANDI is projected to be the number one agent for prostate cancer, with $2.9 billion in sales versus $2.3 billion for ZYTIGA. So we believe that the XTANDI franchise will continue to thrive and

generate and sustain high value for a long time to come.

Let me now talk to you about a completely different tumor type that we are targeting for XTANDI: breast cancer, on slide 34. Just last year, total breast cancer drug sales, despite many of these drugs being generic, totaled $15 billion worldwide.

We are pursuing multiple subtypes of breast cancer with XTANDI. The first subtype is triple negative breast cancer, or TNBC, which accounts for 15% of all breast cancer. TNBC is one of the most aggressive types of breast cancer and survival statistics are some of the worst of any tumor type. That is why we are so excited about the trial data that we presented just five months ago at the 2015 San Antonio breast cancer symposium.

In this Phase II trial, which enrolled 118 women with advanced TNBC, enzalutamide conferred a nearly 14 month longer median survival benefit in women who tested positive for a novel diagnostic signature versus diagnostic-negative women. 50% of TNBC patients are positive for our diagnostic signature, potentially allowing XTANDI to target 7.5% of all breast cancer.

We are particularly encouraged about these results because the standard treatment option for these women is chemotherapy. And most women with TNBC on chemo progress very rapidly and have an extremely poor prognosis. We think our TNBC data are unprecedented. In the second half of 2016, we intend to start a registrational study in TNBC upon receiving agreement from our partner Astellas.

14 months ago, we completed enrollment in our second Phase II breast cancer trial evaluating enzalutamide in 247 women with advanced breast cancer that is ER/PR-positive and HER2 normal. This population comprises about 50% of all breast cancers, so a significantly larger opportunity than even TNBC. We expect data from the ER/PR-positive trial to read out in the second half this year.

In addition, enrollment continues in our Phase II study in HER2-amplified breast cancer, which comprises 15% of all breast cancer. So with our three trials, we are targeting approximately 70% of all breast cancers.

Let's move to slide 35. The patients we are targeting with our currently ongoing or planned breast cancer trials represent a total addressable patient population of at least 75,000 in the US alone. In addition, just four months ago, Astellas enrolled the first patient into a Phase II trial evaluating enzalutamide in approximately 140 patients with advanced hepatocellular carcinoma, or HCC.

HCC represents more than 75% of all liver cancer cases, and it could increase the addressable patient population for XTANDI by 15,000 patients in the US alone. This Phase II trial is expected to read out in 2018 and could identify yet another indication to support future growth of XTANDI. This additional opportunity of 90,000 patients with breast cancer and liver cancer represents a total US revenue opportunity of greater than $3.5 billion.

And as yet another potential opportunity which we have not put into a slide, researchers from the NCI presented data at AACR on April 19 that showed that XTANDI has potential immune-activating properties in prostate cancer and may be synergistic with immuno-oncology agents. This could also represent another significant opportunity for XTANDI, particularly by prolonging the duration of response and treatment in patients.

Slide 36. Before we leave XTANDI, I want to remind everyone of all the recent milestones we have achieved with this product that we are just now starting to see benefit from. For example, we just completed the expansion and bifurcation of our sales force in March, and we expect to see the impact of that increased calling effort on XTANDI sales in the coming quarters.

Our TERRAIN and STRIVE data were published in top-tier journals. The CHMP issued a positive opinion to put TERRAIN data into the European label. We also have a number of very near-term clinical and regulatory events that will drive future share price appreciation for Medivation , including our October 22 PDUFA date for TERRAIN and STRIVE label amendment; exceeding enrollment of 1,200 patients in PROSPER, the targeted enrollment of J&J SPARTAN trial; announcing top-line data from the PLATO study, a trial that will evaluate whether continuing enzalutamide through disease progression may provide benefit to metastatic CRPC patients, thereby potentially increasing duration of use; announcing top-line data from our ER/PR-positive Phase II breast-cancer trial; and initiating our Phase III TNBC trial.

We view Sanofi's proposal as being very opportunistic by coming at a time when we are just starting to see the benefits of our significant and thoughtful investment in XTANDI and just ahead of a number of other important inflection points for this product.

Slide 37. And in terms of longer-term growth, we are well positioned as we expand XTANDI uses into other indications with potential FDA approvals for PROSPER in TNBC in 2019, EMBARK in ER/PR-positive breast-cancer in 2020, ARCHES in 2021, and liver cancer in 2022.

Slide 38. Now I'd like to spend some time discussing our two wholly owned late-stage assets talazoparib and pidilizumab. So let's go to slide 29 (sic - 39). I'll start with our PARP inhibitor talazoparib.

You are all aware that seven months ago, we acquired all of the worldwide rights to talazoparib from BioMarin. We believe that talazoparib is a differentiated PARP inhibitor based upon its mechanism of action -- namely its unique PARP-trapping ability.

The clinical data generated in ovarian and breast cancer are compelling. The PARP inhibitor class has been validated by the recent approval of AstraZeneca's Olaparib. Despite only being approved in one narrow indication, Olaparib is generating approximately $175 million in annualized revenues approximately one year after launch. So we like that talazoparib's mechanism has been validated both clinically and commercially.

But most importantly, we believe that talazoparib has a superior profile that is starting to be demonstrated through clinical data. We'll discuss this in much more detail in a bit.

I believe strongly that talazoparib has blockbuster potential even greater than XTANDI, given that while androgen receptor signaling appears to be important for certain cancers like prostate, breast, and liver. DNA repair and replication, which talazoparib targets, is essential for all cancers.

Also, given that two of the initial indications we are targeting with talazoparib are breast and prostate cancer, this asset is also highly synergistic with our existing development and commercial infrastructure and areas of expertise.

Slide 40. So why do I believe that talazoparib might be even bigger than XTANDI? Just to put the power of PARP inhibition in some perspective for you, a recent publication in the New England Journal of Medicine examined the effects of PARP inhibition in a very heavily pretreated population of metastatic CRPC patients. Of the 50 patients in that study, 100% had received one or more regimens of chemotherapy, 96% had received the ZYTIGA, and 28% had received XTANDI.

PARP inhibition in this study resulted in responses in 16 of 49 evaluable patients. And of the 16 responders, 13 of 16 reduced their circulating tumor cell count, or CTCs, to zero, a level of CTC reduction correlated with survival benefits in other published studies. We believe that patient responses like these, even post ZYTIGA and XTANDI, is remarkable and speaks to the power of PARP inhibition.

J&J further validated the potential of PARP inhibition in prostate cancer when they in-licensed the

rights to just the prostate cancer indication for Tesaro's PARP inhibitor. J&J will make up to $500 million in payments, plus double-digit royalties for these rights.

Importantly, given the unique properties of talazoparib, particularly its synergy with chemotherapy, which I'll talk about soon, and our leadership in the prostate cancer field, we are extremely well positioned to capitalize on this opportunity in prostate cancer. In a few minutes, I'll discuss our plans to initiate two late-stage clinical trials in prostate cancer by year end.

But before going on, I've heard some investors express concern that PARP inhibitors have failed in the past, citing Sanofi's failed Phase III development of iniparib, which Sanofi acquired and characterized as a PARP inhibitor. Yes, Sanofi took iniparib into pivotal trials in both breast and lung cancer and both trials failed.

However, it was discovered in 2012 that iniparib was not a true PARP inhibitor. So to date, the only true PARP inhibitor which has applied for FDA approval, Olaparib, has received it. We believe the PARP inhibitor class is validated by this recent approval.

Another question I receive from investors is if talazoparib is so good, how did Medivation beat all the other larger pharma companies for it? And if the commercial opportunity is so large, how did you get it for the price you paid?

We believe it was a very competitive bidding process for talazoparib, but we were able to move quickly and execute the transaction prior to the New England Journal of Medicine publication mentioned earlier, prior to FDA granting breakthrough therapy designation for a PARP inhibitor in prostate cancer, and before LYMPARZA was generating annualized sales of over $175 million, despite a narrow label. I also believe that we had a particular appreciation for certain scientific mechanistic differences between talazoparib and other PARP inhibitors that others might not have had.

Furthermore, in 2005, when I in-licensed XTANDI from UCLA, there were other large pharma companies looking at that asset, but we managed to acquire what became a blockbuster product. I do believe that at Medivation , we have been able to identify underappreciated value in assets and rapidly and aggressively acquire them, in spite of a crowded pharma environment.

Let's go to slide 41. So what is PARP? PARP, or poly ADP ribose polymerase, is a protein that all cancers require for optimal DNA repair and replication. Because cancers tend to divide rapidly and therefore need to replicate their DNA frequently, their repeated replication also makes them likely to incur more mistakes in their DNA, which can lead to their death if they are not repaired by PARP, one of the major DNA repair pathways. There are five PARP inhibitors in late-stage development and only one is approved in BRCA-deficient ovarian cancer.

So why is talazoparib different? There are two primary pathways by which PARP inhibitors can kill cancer cells. The first pathway is inhibiting PARP enzyme, and the second is PARP trapping.

If you look at the graph on the left, whose y-axis goes from zero to 9, you can see that talazoparib inhibits the PARP enzyme roughly three to eight times better than other PARP inhibitors. However, if you look at the middle graph, which compares the ability of different PARP inhibitors that kill cancer cells, the y-axis here goes from zero to 2,000. And here you can see that talazoparib is orders of magnitude better than other PARP inhibitors at killing cancer cells.

So why is this cancer kill effect so out of proportion to the PARP enzyme-inhibiting ability of different PARP inhibitors? Well, it is because Yves Pommier at the NCI has shown that PARP trapping appears to be much more important in killing cancer cells with PARP inhibitors than just inhibiting PARP enzyme.

So what is PARP trapping? Normally, PARP bounces around and finds single-stranded DNA breaks and fixes them. However, when talazoparib binds to PARP sitting on a single-stranded DNA break, it is locked or trapped on DNA and that DNA cannot replicate.

Two of the most common ways that oncologists create single-stranded DNA breaks today is with alkylation chemotherapies and radiation therapy. One of the most widely used chemotherapies that creates single-stranded breaks -- sites for PARP trapping -- is temozolomide, the standard of care in brain cancer.

So if you look at the graph on the far right, whose y-axis goes from zero to 2,500, you are seeing the comparative ability of different PARP inhibitors to potentiate cancer cell kill by temozolomide. This reflects the ability of different PARP inhibitors to trap PARP. And here you can see that talazoparib is orders of magnitude better than other PARP inhibitors in this regard.

And whereas cell kill by PARP alone in the middle graph does not correlate with PARP enzyme inhibition in the far left graph, it does correlate beautifully with the ability to potentiate temozolomide on the far right graph, which reflects PARP-trapping ability.

Based upon talazoparib's unique PARP-trapping mechanism, we made the point at the JPMorgan conference this year that one might expect to see synergy in talazoparib-mediated cancer cell killing in combination with therapies that cause single-stranded DNA breaks, which become sites for PARP trapping.

So on slide 42, we were very pleased to see our PARP-trapping hypothesis validated in patients at a presentation two weeks ago at AACR in New Orleans by [Dr. Zeb Wainberg], Associate Professor of Medicine at UCLA and codirector of the GI oncology program.

In this study, in 40 patients who were very heavily pretreated across a wide variety of advanced malignancies, talazoparib generated a clinical benefit rate of 58% when combined with low-dose chemotherapy, a dose far below standard chemo doses. It is noteworthy that the only approved PARP inhibitor, Olaparib, was approved based upon an objective response rate, or ORR, of 34% in BRCA-deficient ovarian cancer.

In Dr. Wainberg's study, when talazoparib was used in combination with either low-dose temozolomide or low-dose irinotecan, the objective response rate, or ORR, in non-BRCA-mutated ovarian cancer patients was 57%, with four of seven heavily pretreated patients responding to talazoparib. Six of seven individuals, or 86%, had clinical benefit and 86% of patients had a 50% or greater reduction in a blood marker called CA125, which is a marker in ovarian cancer analogous to PSA for prostate cancer.

These results are important since for the first time, we now have evidence in patients that suggests that talazoparib in combination with low-dose chemotherapy is active in tumors with defects in DNA repair that extend beyond BRCA deficiency, a larger market than BRCA. And in fact, one patient who responded to talazoparib did not appear to have any defects in DNA repair, which could represent an even larger patient population.

Slide 43. Clinical data supports talazoparib's best-in-class potential. On this slide, we have shown a very intriguing table compiled by Barclays biotechnology analysts. The table summarized the results of several studies conducted for three PARP inhibitors: Olaparib, niraparib, and talazoparib in metastatic breast cancer with BRCA mutation.

The data demonstrates robust response rates and progression-free survival for talazoparib. And we believe they derisk our ongoing EMBRACA study.

So what about safety? Let's go to slide 44. BioMarin put together a graph comparing the safety profile of

talazoparib to three other PARP inhibitors in development. Each horizontal bar represents a different adverse event class, and the length of the bar shows the percent of patients with the adverse event.

The 15% highlighted in red means that 15% or more of these patients experience the adverse events listed. Whereas the 10% highlighted on the left means that only 10% or more of the patients experienced the adverse events listed. Overall, I would say that talazoparib compares quite favorably to other PARPs in tolerability.

Slide 45. We are confident in the success of the EMBRACA trial for several reasons. First of all, in BioMarin's talazoparib Phase I/II trial, BRCA-mutated advanced breast cancer patients treated with our Phase III talazoparib dose of 1 milligram per day experienced an 86% clinical benefit rate and 50% objective response rate. 36% of these patients were still on therapy one year later.

Secondly, EMBRACA is rolling 430 patients, which is significantly more than the BRCA breast trials for TESARO's niraparib or AstraZeneca's Olaparib.

And if all the primary endpoint of these three Phase III studies is PFS, because of the larger patient population being enrolled in EMBRACA, we believe that EMBRACA is powered to potentially demonstrate a survival advantage. Eventually having overall survival data in the label would obviously provide us with a significant commercial advantage.

Slide 46. The EMBRACA study is just the beginning. We recently met with the FDA and aligned on a clinical trial design with the potential for accelerated approval in prostate cancer, testing talazoparib as monotherapy in genetically selected patients.

We also plan to start in 2016 a second prostate cancer trial studying talazoparib in combination with low-dose chemotherapy in an all-comers patient population. That is in patients without genetic selection.

This quarter, we will also meet with FDA to align on a registrational program for small cell lung cancer, testing talazoparib in combination with low-dose temozolomide in all comers. Based on public disclosures at the moment, there are no pivotal studies ongoing with a PARP inhibitor in either prostate or small cell lung cancer. So we believe that we may have an opportunity to be a development leader in these two important cancer indications.

Furthermore, we also plan to initiate a clinical trial in advanced breast cancer beyond BRCA mutations in 2016. We are considering both monotherapy in combination low-dose chemotherapy in beyond BRCA-mutated breast cancer. We are unaware of any other companies with ongoing registrational trials in this indication. So we believe again that we may have the opportunity to be first in class in the beyond BRCA-advanced breast cancer population.

We also plan to initiate a clinical trial in ovarian cancer in 2016. Given our recent AACR ovarian cancer data, we believe that combination talazoparib and low-dose chemotherapy may improve outcomes in ovarian cancer patients over the current standard of care. We also believe that this strategy may eventually support talazoparib use in a larger patient population than Olaparib.

Finally, we are also considering development strategies for talazoparib in non-small cell lung cancer and glioblastoma multiforme brain tumor and other malignancies.

Slide 47. We are approaching our talazoparib clinical development plan in a strategic and disciplined way, seeking out indications where we believe we have an advantage and where we can yield the highest return.

As an example, this is a graph showing the growth of small cell lung cancer xenografts. The blue line is untreated small cell lung cancer, and clearly that tumor is growing very rapidly. The red line is a very low

dose of temozolomide and again, the tumor grows rapidly because that's a dose of temozolomide well below standard chemo doses. The green line is also a very low dose of talazoparib.

But when you combine talazoparib with temozolomide, which creates sites for PARP trapping, you can see that you get the purple line: a nearly flat line cancer cell kill in purple. Clearly there is impressive synergy with combination talazoparib and low-dose temozolomide in small cell lung cancer, which published literature suggests is due to the PARP-trapping potency of talazoparib.

Our planned registrational combination talazoparib and low-dose temozolomide trial in small cell lung cancer noted previously is targeting all comers because of robust preclinical data showing synergy in small cell lung cancer cells with the combination that you can see on this slide. And because we believe that we can be the first PARP inhibitor approved in this indication, and because we feel that it is worthwhile to take some risk in being first in such a large commercial opportunity.

However, in other indications, we plan to take a more conservative and derisked approach. As an example, in prostate cancer, we plan to further test our combination talazoparib and low-dose chemotherapy hypothesis in Phase II before fully committing to Phase III development.

We believe that we may be able to have data from this trial as early as next year to help guide our subsequent development decisions. Therefore, we are trying to balance risk and potential reward in the portfolio trials that we are conducting to fully explore and exploit talazoparib's potential.

In addition to our clinical development plans, there are multiple ongoing investigator-sponsored trials for talazoparib, highlighting the significant interest in this product in the oncology community. I already mentioned the combination talazoparib/low-dose chemo data from the IST conducted at UCLA, which was just presented at AACR.

Slide 48. So how big is the market opportunity for talazoparib? We believe that the addressable market opportunity here for Medivation is greater than $30 billion for just the US and Europe.

Slide 49 -- pidilizumab. The next late-stage asset in our pipeline is pidilizumab, which we licensed from CureTech in the fourth quarter of 2014. As I alluded at the beginning of the earnings portion of the call, we have made some important strides in clarifying the antibody's mechanism of action and when and if repeatedly confirmed, we may announce pidilizumab's mechanism of action as early as this year.

We believe this has the potential of making pidilizumab an even more unique, exciting, as well as combinable asset. Pidilizumab is already generating clinical data in both follicular lymphoma and diffuse large B cell lymphoma, or DLBCL, that are very compelling. For example, the 52% complete response rate in follicular lymphoma. Both of these data sets have been published in prominent medical journals.

We believe that defining a mechanism of action will further enhance pidilizumab's value by giving potential partners more comfort in how the drug is working and in which combinations it would make sense to use. We have initiated a potentially registrational Phase II trial for pidilizumab in relapse or refractory DLBCL.

This trial will enroll 180 patients into two parallel cohorts: one with patients who have received an autologous stem cell transplant and the other with patients who have received salvage chemotherapy but are transplant-ineligible. Basically, these are DLBCL patients who have exhausted all treatment options.

Because we are using a primary endpoint of overall response rate, this study could read out relatively quickly. We will also be preparing to move forward with pidilizumab in multiple myeloma. So please stay tuned.

Slide 50. As you might imagine, given the significant growth opportunity and potential value inherent in all three of our assets, we are confident that we can create significantly more value than what has been publicly announced in Sanofi's proposal.

Slide 51. As our Board evaluated Sanofi's proposal and unanimously decided to reject the proposal, they considered several factors. First of all, Medivation is a unique opportunity as one of the few profitable and sizable oncology-focused biopharma companies. The fact that we are and have been highly profitable further increases our scarcity value.

Second, the Sanofi proposal does not appropriately value our rapidly expanding multibillion-dollar XTANDI franchise. We just overtook ZYTIGA in market share in Q1. As we discussed, we believe XTANDI alone can generate over $2.5 billion of revenues for Medivation by 2020, at which time we would still have seven additional years of patent protection or more.

Third, the Sanofi proposal does not recognize the value of our wholly owned pipeline of two other differentiated late-stage oncology assets. Lastly, this proposal was extremely opportunistic in timing. Sanofi approached us during a period of significant market dislocation for biotech. The proposal was well below our 52-week high.

Sanofi also acted aggressively and did not even wait two weeks for our Board to complete its evaluation of their proposal before making it public. Most importantly, Sanofi is acting before a number of key milestones and value-creating inflection points for Medivation . This proposal if accepted would prevent Medivation shareholders from benefiting from any of these events and would result in a significant transfer of value away from our shareholders to Sanofi's shareholders.

Slide 52. As I touched on in the prior slide, the timing here is key. And Sanofi's bid coincided with the bottom of the biotech market and was made just after a period of significant market dislocation in the industry. As you probably remember, Sanofi's proposal referenced a premium to an unaffected price, which was based on a two-month VWAP.

As you will see on this slide, the reference price period that Sanofi used almost exactly coincided with the bottoming of the biotech market. We therefore view Sanofi's approach as extremely ill-timed for Medivation shareholders. A two-month VWAP is also a completely artificial and subjective time period that has no relevance for purposes of calculating an implied premium.

Slide 53. Medivation is unique as an oncology company, with both a commercial stage blockbuster product and a late-stage pipeline that includes two wholly owned late stage assets. The only company on this page that we believe is comparable to Medivation for having a blockbuster oncology product is Pharmacyclics , although Pharmacyclics did not have a pipeline with two other late-stage oncology assets like Medivation .

Slide 54. We are continuing to see proof of the significant value of our assets. Royalty Pharma's $1.14 billion acquisition of a portion of UCLA's rights to the 4% royalty on sales of XTANDI has provided third-party validation by a very well-respected investor of XTANDI's growth prospects.

And J&J's recent in-licensing of the worldwide rights, excluding Japan, to TESARO's niraparib for just prostate cancer for $500 million in equity investment upfront payments and milestones plus double-digit royalties on sales indicates a significant value of a PARP inhibitor.

Slide 55. I've spent significant time today discussing all of our upcoming milestones and growth drivers. On the left-hand side of this slide, I've outlined some of the key variables that account for the differences between our internal revenue expectations for 2020 versus Street consensus. The difference between our internal expectations for revenue growth and consensus is highlighted to the right.

I've spent the last 30 minutes telling you why we are so confident about capitalizing on all of the opportunities outlined on the left. Why should our stockholders be asked to accept a proposal that does not appropriately value the potential of all of our upcoming milestones?

So I want to close on slide 57 by reiterating how well we performed as an independent company, developing the world's leading prostate cancer drug and delivering extraordinary shareholder returns that have dwarfed any index.

I also want to reinforce how excited and confident we are in the growth opportunities we've discussed. Simply put: we are executing on a plan that is delivering real and superior value to shareholders. We are extremely confident that our strategy will deliver more value to you and other shareholders than Sanofi's proposal, which significantly undervalues our potential and is highly opportunistic.

With that, we appreciate your continued support and the excitement about our performance and the future that we hope you share. And we look forward to updating you on our continued progress over the coming weeks.

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

QUESTIONS & ANSWERS

Operator:

(Operator Instructions)

Geoff Meacham, Barclays.

Geoff Meacham (Analyst - Barclays Capital):

Thanks for all the detail. It's kind of a drop-the-mic presentation. I wanted to talk to you a little bit, David, about the 2020 assumptions because they definitely sort of underlie a lot of the value.

Can you talk a little bit about what percent of your revenue assumptions are indications for XTANDI you don't have today, say M0 or talazoparib? And then for M0 prostate, where do you think that you could get to with respect to the duration of therapy and adoption? Just given the fact that urologists' adoption today has been limited, but theoretically with an M0 label, you could get a majority of the market? Thank you.

Jennifer Jarrett (CFO):

This is Jen. I'll start trying to answer your question, and then I'll turn it over to David maybe to talk a little bit about duration. We're not going to provide any more of a revenue breakout than we did, so we're not going to break down the components of the $2.5 billion.

You can look at the timeline that we provided in terms of when we expect approvals for the ongoing studies. And that will give you a sense in terms of when different revenue streams might start to kick in for XTANDI as well as other products. But we're not prepared to provide any detail beyond that.

David Hung (President & CEO):

And with regard to the duration of therapy, Geoff, as you know, as you move upstream, XTANDI appears to be working a lot better. And if you look at just the numbers I outlined, the PREVAIL at time of PSA progression was 11.2 months; TERRAIN, 19.4. So if we just take the midpoint of that range, that's over 15 months.

Something that may not be apparent is that whoever moves first gets the lion's share of that. Because whoever gets second has a much shorter duration of therapy. So we believe that just in the M1 population, we 're looking at -- at some point, we're going to reach at least the midpoint of that range. And if we ever get to a patient population that are less advanced like TERRAIN, we should be approaching the 19-month mark.

But if you look at the STRIVE trial, that trial enrolled both M0 and M1. And they were even less sick than TERRAIN. So if you look at the M1 portion of STRIVE, those patients were almost 25 months out and we didn't even hit median for the M0 population.

So if you look at that overall STRIVE time to PSA progression, overall, we didn't even reach median. So you are looking at conceivably very long times. As I explained earlier, when Graeme started XTANDI, he started it six years ago and he still on the drug. And his PSA bounced around a bit, as I said, between zero and 0.1. So he needs to keep this drug, but he's on it for a long time.

And we've had a number of patients on the drug for years. So we think that as you start -- and he was a post-chemo patient. So we think that as you get to earlier stages of therapy, there is quite a significant potential for long duration.

Geoff Meacham (Analyst - Barclays Capital):

Okay. Great. Thank you very much.

Operator:

Salveen Richter, Goldman Sachs .

Salveen Richter (Analyst - Goldman Sachs):

Thanks for taking my questions. David, could you help us understand the potential October label update and how that will impact KOLs versus community urologists? Should that differ in terms of the messaging here versus data that would come in 2018 and beyond?

And then for talazoparib, could you talk about synergies potentially with PD-1s and PD-L1s? And what about use in microsatellite instability colorectal cancer or other tumor type? And I have a follow-up. Thanks.

David Hung (President & CEO):

I may have to ask you to repeat the second part. But on the first part, I'll start and I may turn it over to Marion. But we think that the PDUFA date could be significant for us because right now, the biggest market opportunity is in urology.

And urologists really use Casodex a lot. Over half a million scripts in just the US alone are written for Casodex and most of that is urology. People may not be aware of this, but Casodex has not been demonstrated to confer a survival benefit for patients and yet, it still widely used.

So being able to promote in a label that we have a drug that is superior to Casodex in terms of PFS would be a significant thing that we can do in the field. I believe that that would be quite compelling to urologists and having field-tested that, that seems to resonate with urologists.

Marion, do you want to add some comments?

Marion McCourt (COO):

Sure. I'm happy to. So you know, the inclusion of TERRAIN/STRIVE data in the label would be a really important component to our future promotion and sales force activity, in particular with urologists. We are pleased with what we are seeing so far in terms of urology uptake and the source of growth today in XTANDI prescribing, but that would be a pivot point for us. And certainly we look forward to the potential for promotion in that area.

David Hung (President & CEO):

And then Salveen, I believe that your second question was about combination of XTANDI with immunotherapy. There is actually some pretty compelling data -- I don't know if you are familiar with a paper by Jennifer Bishop that was published last year showing that patients after XTANDI seem to upregulate PD-L1.

So one of the issues for immunotherapy and prostate cancer is that prostate tumors don't appear to express a lot of PD-L1. But after XTANDI, they do appear to upregulate that. So the possibility of combining XTANDI with PD-1 makes a lot of sense. And in fact, there's an ongoing trial at Hopkins right now looking at that. So we think that that is potentially significant. And if you look at breast cancer, it may be the same story there.

So we do think that XTANDI has potential application in immunotherapy. There's also very good literature that when you inhibit androgen-receptor signaling, that process alone upregulates the activity of the thymus gland. We've shown that thymus function and size and weight are increased by XTANDI treatment.

Why is the thymus important? The thymus is where all your white cells go to differentiate and learn what to attack and not to attack. So there are many preclinical studies showing that XTANDI upregulates T cell activity and improves the ability of those cells to kill cancer cells, even prostate cancer cells. We actually had a slide on that at in one of our investor decks.

And what's important about AACR is that we're now seeing those effects in patients. So all that other preclinical literature is now being supported in patients. So we do think that XTANDI has potential as an immunotherapy agent, especially in those cancers that don't have a lot of PD-L1. Because you need that to see PD-1 activity.

Salveen Richter (Analyst - Goldman Sachs):

Thanks. And then, David, there's speculation in the press or reports in the press that many companies are interested in Medivation , apart from Sanofi. So would you be open here to entering an auction process to attain the value that you laid out? Or are you looking to kind of drive this longer term? Just any thoughts would be helpful.

David Hung (President & CEO):

I just can't comment on rumors like that and what the intentions of others are. We're here to run our business and create as much value as we can for our shareholders.

Salveen Richter (Analyst - Goldman Sachs):

All right. Thank you.

Operator:

Yigal Nochomovitz, Citigroup .

Yigal Nochomovitz (Analyst - Citigroup):

Thanks for taking my question. David or Jen, if you could just speak regarding the guidance for 2016. How much of that range is levered to assumptions of a price increase for XTANDI this year?

And secondly, how much of that guidance is levered on an assumption of increasing the duration for XTANDI above the eight months that you've cited? Thank you.

Marion McCourt (COO):

So this is Marion. I'm happy to start the comment on pricing first. As a policy, we haven't been commenting on pricing. And I remind everyone that Astellas controls price for XTANDI. What I will absolutely confirm for you, and Jen and David might want to add to this, but that we are committed to the guidance that was affirmed today.

Jennifer Jarrett (CFO):

And just to add on that, our guidance is really based on a mix of both duration and volume. So it's really a mix of those two things. (multiple speakers) over time; that's why we included the slide in the presentation that shows the duration of therapies for the different studies, just to give you a sense for how we think duration could trend during the course of the year as well as into the future.

Yigal Nochomovitz (Analyst - Citigroup):

Okay. Thank you. And then switching over to breast cancer, we've been getting a lot of questions from investors on the different trials that are ongoing. It might be helpful if you could spend a few minutes just giving us some more scientific rationale on the potential for XTANDI in the HER2 normal ER/PR-positive and then HER2 positive?

Specifically with respect to the percentage or degree of androgen receptor expression in those patients to help us there? Thank you.

David Hung (President & CEO):

So I'll start with TNBC. So TNBC is triple negative. That means ER negative, PR negative, and HER2 negative. And a cancer cell has got to grow with something, so if you are not being fueled by estrogen, progesterone, or HER2, you've got to grow with something. It turns out that a lot of those patients are driven by androgen receptor, so that's why the rationale there is strong.

But if you look at the structure of estrogen and testosterone, they are remarkably similar. So if you look at -- all steroids, they have an A, B, C, D ring. And if you look at the difference between the male and female hormones, three of those four rings are identical. They only differ in the A ring, and it's by a very subtle difference.

So there is suggestion that possibly there might be crosstalk between different hormones and different receptors -- crosstalk between estrogen and androgen receptors. But there's also published data by a professor at the University of Colorado named Jennifer Richer. And she did a very interesting experiment.

So she showed, as you would expect, if you take breast cancer cells and you give them testosterone in a certain subset of them, they can be fueled by that. And if you give them XTANDI, you can block that growth. That makes sense.

But if you give them estrogen without giving them testosterone -- you give them estrogen, they grow -- of course, they do. But then you give them XTANDI and now you block their growth. So that does not appear to be AR mediated because the effect of estrogen is an estrogen-signaling effect.

So there is literature that suggests that XTANDI has not only anti-androgen signaling effects, but also

anti-estrogen signaling effects. Now whether or not that made be due to crosstalk or a common pathway distal to both receptors, we don't fully understand. But there are clear effects in the preclinical literature that support that XTANDI would work or have effects in estrogen signaling. So we think that's important.

The other thing that's important to note is that there are currently no androgen receptor antagonists in development in breast cancer. So this is a unique class for the field. So we think that this could be quite a differentiated product. There so we are excited about that.

HER2 -- we don't really know. There's not a lot of literature on it. But again, breast cancers tend to express a large variety of receptors. And because they are hormonally driven since puberty, they tend to be driven by hormonal receptors.

So whether or not it will work in HER2 amplified, again, we don't know. But we think it's certainly worth a shot. We are certainly seeing robust effects in patients in TNBC and at least so far in preclinical models of the ER/PR-positive subset.

Yigal Nochomovitz (Analyst - Citigroup):

Okay. Thank you very much.

Operator:

Kennen MacKay, Credit Suisse.

Kennen MacKay (Analyst - Credit Suisse):

Thank you for taking my question. A really good presentation, and I agree that the offer from Sanofi really substantially undervalued the business and the pipeline and especially talazoparib.

Obviously when we are thinking about valuation, we have to apply risk and time discounts to forecasted sales estimates. David, specifically relating to XTANDI, maybe can you talk a little bit about how the risk from ZYTIGA going generic and the J&J SPARTAN trial might be overstated, especially in some investors' eyes?

David Hung (President & CEO):

So certainly we're aware of the possibility of ZYTIGA going generic. And from our patent counsel, we think that the earliest that could be would be roughly sometime late in 2018.

But first of all, if we get a expanded label -- amended label to include superiority to Casodex, and that's something that generic ZYTIGA will never have. So I think that that would be quite a big differentiator.

And secondly, just -- I don't know if you are familiar. So XTANDI inhibits the AR, as does Casodex, which is a first-generation sort of XTANDI. And ZYTIGA inhibits an enzyme called CYP17, but it's not the first drug to do that. There's another drug called Ketoconazole that inhibits CYP17 and it's been around for years, and that drug is generic.

And last year in the US, there was 120 times more bicalutamide use among urology than Ketoconazole use. So even though Ketoconazole has been generic for a long time, urologists just aren't using it. To use a CYP17 inhibitor, you've got to deal with steroids. There's liver monitoring. There are other adverse events and urologists just don't like that.

So we think that we are really pushing our franchise into urology. It's where most of the patients are; you get longer therapy. But once you are in urology, history has already shown us that urologists don't use ketoconazole. They don't use a generic CYP17 inhibitor -- or we don't believe that once we are in urology

that the urologist will change their historical practice which spans decades.

Kennen MacKay (Analyst - Credit Suisse):

And then maybe just relating to the SPARTAN trial?

David Hung (President & CEO):

The SPARTAN trial -- so ARN-509, as you know is doing a similar trial. Our trial is called PROSPER; their trial is called SPARTAN. Our trial is over 1,550 patients and SPARTAN is enrolling about 1,200 patients.

Number one: SPARTAN has not done any survival studies. So we already have two Phase III studies which have demonstrated robust survival benefit in AFFIRM and PREVAIL. SPARTAN is not going to have that.

Secondly, the endpoint for both the SPARTAN and PROSPER trials is metastasis-free survival. And we don't know exactly when J&J will unblind that study, but you might recall that when we conducted PREVAIL, which is over 1,700 patients, and J&J did their pre-chemo study, which was called 302. 302 unblinded first and missed and we waited on PREVAIL and hit it. So we were able to use our competitor's move to decide what we were going to do.

PROSPER similarly is significantly larger than SPARTAN. So as I alluded to on the call, this year, we were going to exceed the target number of enrollment for SPARTAN. So if J&J pulls the trigger on SPARTAN and if they miss it, well, we will just sit on PROSPER and continue to follow that study, enroll it, and to accrue for patients and power our study even higher.

If they pull the trigger and they hit it, we have the option of unblinding early and matching them. And if we were to match them, we can't imagine doing worse than them. We will have a drug -- both will have MFS benefits, but only one will have also overall survival and progression-free survival and a many year head start in the market.

Kennen MacKay (Analyst - Credit Suisse):

Thanks so much. I think that's incredibly helpful. Appreciate you taking the questions.

Operator:

Geoffrey Porges, Leerink.

Geoffrey Porges (Analyst - Leerink Partners):

David, appreciate the questions and wonder where all this information was for the last three years. It's very helpful now.

First of all, just in terms of the PDUFA date TERRAIN and STRIVE, is your base case assumption that M0 is included in that label? And that it's broken out separately, the comparison there, or alternatively is it excluded? I'm just wondering how you are thinking about that.

And secondly, could you comment on how the fact that you've received this unsolicited offer affect your relationship and your obligations to your partner Astellas? And then thirdly, could you just comment -- to make sure that I understand the point of your presentation, is it that the offer under depreciates the value or that you can create more value independently of Sanofi or indeed anyone else?

And if so, could you just summarize what it is that you think you can uniquely do as an independent Medivation that an acquirer couldn't do with these assets?

David Hung (President & CEO):

Okay. So number one on the M0 and M1, I think we've been pretty consistent in saying that we are anticipating a label amendment in October, but we've always focused on M1. It's within our label. So that's what we've always been consistently saying.

So if we got M0, that would be unbelievable, but we are not counting on that. We've not really talked about that. That would be total icing. So we are looking at M1. With regard to Astellas, I can't really comment on what this does to Astellas.

And on your last question -- what could be do that a larger company couldn't do? Well, number one, if you look at the number of companies, I found XTANDI in 2005. And that drug was -- actually, we didn't even have a real lead. We were actually looking for a lead and we were still in screening in cells. And we took that compound from cell screening to FDA approval in seven years.

There is a nice review in Tufts -- from Tufts about the average time of drug development for a large pharma company. And if you look at that, the average time of drug development for a large pharma is in the range of 10 to 15-plus years for an average cost of about $2.6 billion.

As I told you, for the first eight years of Medivation's history, our total capital raise was $175 million to generate a market cap of about $3 billion. And to get our drug into patients and an FDA approval in seven years after licensing it. So I just don't think they -- and I would challenge anyone to find a lot of big pharma companies that can move that quickly. That's the first thing.

The second thing is what could we do differently that a big company can't do? Well, we can pick a PARP inhibitor that works. Sanofi picked iniparib and it failed. And we've got clinical data already showing activity with talazoparib. And many key opinion leaders believe that a best-in-class opportunity.

And we believe we can move that a lot faster than larger, less-agile companies. So we think that we can create a lot more value for our shareholders, and we've proven it by our past performance.

Geoffrey Porges (Analyst - Leerink Partners):

Great. Thanks very much, David.

Operator:

John Newman, Canaccord.

John Newman (Analyst - Canaccord Genuity):

Thanks for taking the question. Just two questions here. So the first one is if you think back before we saw the first pivotal data readout for XTANDI and you think about the similarities in terms of the mechanism of action of XTANDI and Casodex in prostate cancer. And fast-forward to where we are today. And then if you also consider that interestingly enough, it seems that there's some evidence that Casodex also has activity in breast cancer, does it make sense mechanistically that there is maybe a lower risk than people think that XTANDI also works in breast cancer?

And then the second question I had is just regarding your collaboration agreement with Astellas. I think the collaboration agreement with Astellas initially had a standstill in place until September of 2016. And obviously just asking you to speculate a bit here.

Do you think it is just coincidental that Sanofi decided to come out when they did, given that they knew if they didn't, Astellas wasn't going to be able to potentially act until then? Thanks.

David Hung (President & CEO):

So I think, John, you're right that there is some literature that suggests that Casodex has some activity in breast cancer, even though we know that if you look at preclinical studies, the potency -- if you look at our science paper, as an example, Casodex potency against AR is about one log less than ours. So I think you're right, though, that if Casodex can show any activity at all, we think that that does support further the use of the rationale for going after breast cancer with XTANDI.

And clearly, we wouldn't be making the sizable investment if we didn't think it was going to yield return for us. So I think you're right. We think that the literature is strong to support the use of an AR antagonist in breast cancer.

And just another point of differentiation: this is not a target we believe that you can go after with ZYTIGA. Because when you inhibit CYP17, one of the reflex hormonal alterations is that you get an increase in progesterone. In some cases, up to several hundred fold. And that, if you look at breast cancer that has a progesterone receptor, that may not be a good idea.

So we believe that XTANDI -- it may be uniquely suited as an androgen signaling inhibitor in breast cancer. So that's a differentiator, too. But with regard to what Sanofi is thinking about the Astellas standstill, I have no idea. I can't speculate on that.

John Newman (Analyst - Canaccord Genuity):

Okay. Great. Well, thank you.

Operator:

Katherine Xu, William Blair.

Katherine Xu (Analyst - William Blair & Company):

Good evening. I'm just wondering also on the Astellas agreement. So there's a standstill until September, but does that expire on an active bid from a third party? That's my first question.

And the second one is from your market projections, if you look at prostate cancer, you have about $15 billion market opportunity. And then you look at breast cancer, you are looking at about half of the prostate cancer addressable population and you are looking about $3.5 billion or even -- if you don't count the HTC, it is probably less than that.

So I'm just wondering what were the differences in the underlying assumptions there? Thank you.

David Hung (President & CEO):

So I really can't comment on the Astellas standstill. What we have filed about it in our filings, you can read about. I'm not sure I quite understand the second question. But maybe, Jen, if you --?

Jennifer Jarrett (CFO):

Yes. We had a little bit of a hard time understanding your second question. Maybe you can repeat it?

Katherine Xu (Analyst - William Blair & Company):

So I'm just looking at your slides -- the addressable population on the prostate cancer side. And it looks like breast cancer looks like is it's twice as many patient population for breast cancer -- sorry, for prostate cancer versus breast cancer. But the market opportunity assessment is almost five time difference. So I'm just wondering what were the major assumptions that underlie those kind of differences?

Jennifer Jarrett (CFO):

I think probably the key differences -- within breast, we are obviously going after subsegments of the breast cancer patient population. So it's not 100% of all breast cancer patients, like it is for prostate.

We tried to lay out some of the detail in the slide presentation. For example, TNBC is 20% of the breast cancer population. And then we are assuming that we can address 10% of that patient population. Does that make sense?

Katherine Xu (Analyst - William Blair & Company):

Okay. And then any duration assessment assumption?

Jennifer Jarrett (CFO):

We are not going to disclose our duration assumption by indication. We obviously have different duration assumptions depending on the indication.

Katherine Xu (Analyst - William Blair & Company):

Okay. Thank you.

Operator:

Do Kim, BMO Capital Markets.

Do Kim (Analyst - BMO Capital Markets):

Thanks for taking my question. Just on the CHMP recommendation for the European label update, was the STRIVE data also submitted for consideration? And what aspects of the TERRAIN data could we expect to be included in the label? And if you could give us a time frame of when the label update will actually happen?

Mohammad Hirmand (Interim Chief Medical Officer):

So this is Mohammed -- thanks for that question. As you know, Astellas has commercial responsibilities in Europe, so we can't really going to detail and comment on the activities in Europe. But what we were very happy with was the European authorities agreement with us that head to head data were important to include in the European label after we look forward to our PDUFA date with the FDA. And hopefully see a similar assessment in the US.

For Europe, actually the European update can go into effect immediately. It's basically the primary comparative data that will be in the FMPC, which is the European label.

Do Kim (Analyst - BMO Capital Markets):

Okay. Thank you. My next question is on the pipeline. And the Phase II trial in ER/PR-positive and HER2 normal breast cancer, you are having a subgroup analysis by AR positive versus negative.

How should we think about that comparison? Could we take that as a validation that your novel diagnostic assay is reliable for predicting XTANDI benefit? And does XTANDI -- or does the effect that XTANDI has on the estrogen receptor sort of muddle that result?

Mohammad Hirmand (Interim Chief Medical Officer):

And thanks for the question. So obviously, it's hard to kind of speculate on what the results will be. What we will look after we unblind the study, and we expect to do that in the second half the year, is to look at

the totality of the data.

And obviously, we are going to specifically interrogate the data for any patterns, including the diagnostic that we have developed in TNBC to see how we might be able to optimize any responses. So again, kind of hard to speculate what the data will show. So certainly regarding looking at totality of data and if necessary interrogate several approaches to that.

Do Kim (Analyst - BMO Capital Markets):

Okay. Great. Thank you for taking my questions.

Operator:

Mike King, JMP Securities.

Mike King (Analyst - JMP Securities):

Thank you, guys, for taking the question. And let me also commend you guys for doing such a thorough analysis of the Company and presenting it in such a compelling way. I guess my questions are kind of related to the points that Geoff Porges was getting at earlier, which was keeping in mind the wants and needs of the other shareholders.

And so two questions related to that. One, David, is that is there not a price that which you would considering a sale of the Company to any third party? And second, what communications have you had with your large shareholders lately about what their desires and intentions are?

David Hung (President & CEO):

We are all about value and we and our Board believe that we can deliver significantly more value by executing on our strategic plan versus Sanofi's proposal. So that's our focus right now. We think $52.50 is just a completely lowball proposal. And we, as I've highlighted, we think that this is not the basis to commence any discussions. And we think that we are going to create a lot of value.

Mike King (Analyst - JMP Securities):

Well, obviously, the market has told you you're right on the $52.50. But -- so we know that nothing is going to get done at that price. But I'm not talking about $52.50; I'm talking about something well above that.

David Hung (President & CEO):

I'm not going to speculate on that. We are noses down and trying to get as much done as we can to create the most value we can for our shareholders.

Mike King (Analyst - JMP Securities):

And your conversations with your largest shareholders, you feel that they are confident in that?

David Hung (President & CEO):

The conversations we've had, they've been very supportive. So I would say that we feel very good about where we are and we think that our shareholders agree with us that we can create a lot more value for them than Sanofi's proposal. So that's where we are.

Mike King (Analyst - JMP Securities):

Okay. Thanks so much again for taking my questions.

Operator:

Eric Schmidt, The Cowen Company (sic).

Eric Schmidt (Analyst - Cowen and Company):

Thanks for taking my questions. In the gross to net discount in Q1, I think you said it was 16% -- is that correct? And where do you think that's going to go for the remainder of the year?

Jennifer Jarrett (CFO):

It was approximately 16% for the first quarter. And consistent with what we've seen over prior years, it's always the highest in the first quarter. And again, consistent with prior years, it will be 1 or 2 percentage points lower for the remainder of the year. We obviously feel good about (inaudible) and it's significantly lower than what some of our peers are experiencing.

Eric Schmidt (Analyst - Cowen and Company):

And maybe for, David, the JCO editorial that accompanied the STRIVE trial suggested that maybe the dose of bicalutamide that was used as a comparator arm there wasn't necessarily ideal. I don't know if you have any thoughts scientifically on that?

David Hung (President & CEO):

It's the dose that's used. So that's what was used in the clinic, and we think that this is the first data set ever to show a superiority of any drug over a standard care in urology. So we are pretty thrilled with that.

Eric Schmidt (Analyst - Cowen and Company):

Last question. You pointed out that you think the top-line expectations for 2020 amongst the consensus analysts are too low. Do you also believe that the consensus estimate of -- I think it's $3.89 in 2020 EPS is too low?

Jennifer Jarrett (CFO):

We really can't comment on our 2020 earnings. We provided revenue guidance today for 2020, but that's all that we are really prepared to provide in terms of specific guidance.

Eric Schmidt (Analyst - Cowen and Company):

Thank you.

Operator:

Biren Amin, Jefferies.

Biren Amin (Analyst - Jefferies LLC):

Thanks for taking my questions. Maybe, David, I think you mentioned on the SPARTAN trial that J&J is looking at doing an interim. What's the bar on that on a hazard ratio?

Mohammad Hirmand (Interim Chief Medical Officer):

This is Mohammed. I don't think we are aware of where J&J is in their enrollment and whether there is an interim involved. I think what David was alluding to is that in case they unblind before we do, if they

succeed, then obviously that's going to be very helpful information for us. And that might give us an opportunity to also expedite our plan to unblind and also succeed.

And if they miss, that would also be good information for us to see whether we need to potentially change our plans, perhaps enroll more patients, or delay our unblinding trigger. So again at this stage, we can't really speculate where SPARTAN is and what their plans are. But certainly we are going to be looking at that.

Biren Amin (Analyst - Jefferies LLC):

And maybe a follow-up for David. Regarding your 2020 revenue projection, what do you think the Street is missing versus your revenue projection for 2020?

David Hung (President & CEO):

I think number one, I think the Street has been skeptical about our movement into urology. We do believe that we will move into urology very nicely. I think Marion is showing you that we are getting significant traction there. So I think that's number one.

I think that on talazoparib, when I acquired the asset six months ago, all I heard from most people was that they are all the same. And I don't think that they are all the same. I don't think there's a wide appreciation for how different these assets are and how significant PARP trapping is as a differentiating factor.

If you talk to Yves Pommier, who has done a lot of this work, he thinks that PARP trapping is a significantly more important mechanism in cancer cell kill with PARPs than PARP enzyme inhibition, as I showed you on that slide. So I think that's being really missed by the Street.

And as I said in the call, XTANDI is a fantastic drug. But AR signaling it's relevant to prostate and breast, liver, maybe a few things. But every cancer cell has DNA and they have to replicate their DNA or they are going to die. All cancers divide rapidly and they've got to replicate right or they are going to die.

So we think that the mechanism of action of talazoparib covers a lot more cancers than does even XTANDI. And if you look at that TOPARP study, the data I showed on PARP inhibition in the New England Journal of Medicine study.

Just to appreciate the significance of that, 100% of those patients failed docetaxel. And on top of that, 58% failed cabazitaxel. And on top of that, 96% failed abiraterone. And on top of that, 28% failed -- had received enzalutamide.

So we just think that that's about as sick a population as you can imagine and to see a 33% response rate -- the 16 to 49. And of those 16 responders, have 13 of 16 drop their CTC's to zero, we think is a remarkable effect. We think that that really speaks to the power of PARP inhibition. And this is a PARP inhibitor, by the way, which is orders of magnitude weaker than talazoparib in PARP trapping and cancer cell kill.

So we think that talazoparib has the potential to be best in class. We think our mechanism is differentiated. We think that the mechanism is a lot more universal potentially than XTANDI. So we think that's being missed.

On pidilizumab, I appreciate that without complete clarity on method of action, it may be hard for some people to assess. But what Don Benson and Saatva Neelapu at Ohio State and MD Anderson, respectively, have shown pidilizumab activates natural killer cells.

And we made the point earlier on other calls that if you look at the immune system, it is divided into kind of two buckets. There is the innate immunity side and adaptive immunity side. And there are very few agents on the innate side.

So there are more than 100 immuno-oncology agents out there, but the vast majority are on the adaptive side. And to our knowledge, there are few -- like BMS is here and Innate Pharma's drug on the innate side. But they are orders of magnitude less on the innate side than the adaptive side.

So we're pretty confident that at some point, immunotherapies are going to require combination therapy. And it would make a lot of sense to combine -- if you want to reconstitute your entire immune system, why would you have two agents on the adaptive side? We think it makes a lot more sense to combine an innate side agent and an adaptive side agent. Then you reconstitute your entire immune system.

So we think that being one of a few agents on the innate side makes that really attractive. We think that one of the issues for any partner that we can understand is that (technical difficulty) around that.

Operator:

Peter Lawson, SunTrust.

Peter Lawson (Analyst - SunTrust Robinson Humphrey):

David, just wondering if you could talk through the morale of the sales force, if there's been any change with the Sanofi bid and if you've lost anybody?

David Hung (President & CEO):

What was the question?

Marion McCourt (COO):

This is Marion. I would be very happy to take the question related to our sales force. And we are really pleased with how our sales force is operating; the traction in market.

As I mentioned earlier, we had 40 new representatives join us. They are now fully trained as of March. And I would share that my observation is that our sales force is incredibly effective. I've been very, very impressed with the group, many of whom have been with Medivation for, many, many years; built XTANDI's success. And the new team members we've added are absolutely top-notch.

David Hung (President & CEO):

And I would agree with that -- with Marion. So Marion and I had a call with the sales force just a few days ago. And they are just the best of the best. So we love our sales force and we think that they are doing a great job.

Marion McCourt (COO):

And specific to the question you asked about have we lost anyone from our sales force? And absolutely not.

Peter Lawson (Analyst - SunTrust Robinson Humphrey):

Okay. And there's been no distraction from this Sanofi bid?

Marion McCourt (COO):

Our team is committed and they are very much focused on XTANDI promotion in market. And certainly, we have a very fine group of sales leaders that are working closely with the team.

Peter Lawson (Analyst - SunTrust Robinson Humphrey):

Just -- final question. On the non-GAAP SG&A, the uptick, is that a sensible number to be thinking about for the rest of the year? Are there any one-timers in there?

Jennifer Jarrett (CFO):

There are some one-time expenses that are related to our Astellas collaboration. They are annual expenses the way they hit our P&L are almost entirely in the first quarter. So I would not use our first-quarter SG&A number as a base.

And you can look at the trend that we saw last year to get a sense for what the decline from Q1 SG&A to Q2 might be. You are going to see probably a very similar trend for 2016.

Peter Lawson (Analyst - SunTrust Robinson Humphrey):

Perfect. Thank you so much.

Operator:

Ladies and gentlemen, this concludes today's conference.