

Abraxis BioScience, Inc.
Form 425
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The following is an excerpt of the transcript relating to an analyst conference call held on July 29, 2010 in connection with the announcement by Celgene Corporation (Celgene) of its 2010 second quarter operating and financial results that included certain updates regarding its proposed acquisition of Abraxis BioScience, Inc. (Abraxis BioScience).

Forward-Looking Statements

This material contains certain forward-looking statements which involve known and unknown risks, delays, uncertainties and other factors not under Celgene s control. The Celgene s actual results, performance, or achievements could be materially different from those projected by these forward-looking statements. The factors that could cause actual results, performance, or achievements to differ from the forward-looking statements include the risk that the acquisition of Abraxis BioScience may not be consummated for reasons including that the conditions precedent to the completion of the acquisition may not be satisfied; the possibility that the expected benefits from the proposed merger will not be realized, or will not be realized within the anticipated time period; the risk that Celgene s and Abraxis BioScience s businesses will not be integrated successfully; the possibility of disruption from the merger making it more difficult to maintain business and operational relationships; any actions taken by either of the companies, including but not limited to, restructuring or strategic initiatives (including capital investments or asset acquisitions or dispositions); and other risks that are discussed in Celgene s filings with the Securities and Exchange Commission (SEC), such as Celgene s Form 10-K, 10-Q and 8-K reports and in Abraxis BioScience s filings with the SEC, such as its Form 10-K, 10-Q and 8-K reports. Given these risks and uncertainties, you are cautioned not to place undue reliance on the forward-looking statements.

Participants in Solicitations

Celgene, Abraxis Bioscience and their respective directors, executive officers and other members of their management and employees may be deemed to be participants in the solicitation of proxies from stockholders of Abraxis Bioscience in connection with the merger. Information regarding Celgene's directors and officers is available in Celgene's proxy statement on Schedule 14A for its 2010 annual meeting of stockholders and Celgene's 2009 Annual Report on Form 10-K, which were filed with the SEC on April 30, 2010 and February 18, 2010, respectively. Information regarding Abraxis Bioscience's directors and executive officers is available in Abraxis Bioscience's proxy statement on Schedule 14A for its 2009 annual meeting of stockholders and Abraxis' 2009 Annual Report on Form 10-K, which were filed with the SEC on October 30, 2009 and March 12, 2010, respectively. Additional information regarding the interests of such potential participants will be included in the proxy statement and the other relevant documents filed with the SEC when they become available.

Additional Information about the Transaction and Where to Find It

This material shall not constitute an offer of any securities for sale. The acquisition will be submitted to Abraxis Bioscience's stockholders for their consideration. In connection with the acquisition, Celgene and Abraxis Bioscience have filed a registration statement on Form S-4 and a preliminary proxy statement/prospectus with the SEC on July 29, 2010 and intend to file other relevant materials with the SEC, including amendments and supplements to such registration statement and preliminary proxy statement/prospectus and other relevant documents concerning the merger. Investors and stockholders of Celgene and Abraxis Bioscience are urged to read the registration statement, the proxy statement/prospectus and other relevant documents filed with the SEC when they become available, as well as any amendments or supplements to the documents because they will contain important information about Celgene, Abraxis Bioscience and the merger.

Stockholders of Celgene and Abraxis Bioscience can obtain more information about the proposed transaction by reviewing the Form 8-K to be filed by Celgene and Abraxis Bioscience in connection with the announcement of the entry into the merger agreement, and any other relevant documents filed with the SEC when they become available. The registration statement, the proxy statement/prospectus and any other relevant materials (when they become available), and any other documents filed by Celgene and Abraxis Bioscience with the SEC, may be obtained free of charge at the SEC's web site at www.sec.gov. In addition, investors and stockholders may obtain free copies of the documents filed with the SEC by directing a written request to: Celgene Corporation, 86 Morris Avenue, Summit, New Jersey, 07901, Attention: Investor Relations, or Abraxis Bioscience Inc., 11755 Wilshire Blvd., Los Angeles, CA, 90025, Attention: Investor Relations. Investors and stockholders are urged to read the registration statement, the proxy statement/prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the merger.

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**Jul. 29. 2010 / 1:00PM, CELG Q2 2010 Celgene Corp. Earnings Conference Call
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Celgene Corp. Director, IR

Bob Hugin

Celgene Corp. CEO

Dave Gryska

Celgene Corp. CFO

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PRESENTATION

Operator

Good day, ladies and gentlemen. Welcome to the Celgene second quarter earnings call. At this time all participants are in a listen-only mode. Later we will conduct a question-and-answer session and instructions will follow at that time. (Operator Instructions) As a reminder, this conference call is being recorded.

I would now like to turn the conference over to Tim Smith, Director of Investor Relations at Celgene Corp. Tim.

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Tim Smith - *Celgene Corp. Director, IR*

Good morning, everyone, and thank for joining us this morning. I would like to welcome you to Celgene's Second Quarter conference call. The press release reporting our operating results was issued earlier this morning and is also available on our corporate website. In addition, today's conference call webcast will include a presentation which you can access by going to the Investor Relations section of our website at www.Celgene.com. Joining me this morning are David Gryska, our Chief Financial Officer, Bob Hugin, our Chief Executive Officer and Dr. Sol Barer, our Executive Chairman.

Before we start, we want to remind you that our discussions during this conference call will include forward-looking statements. All such forward-looking statements exclude the effects of the proposed acquisition of Abraxis Bioscience unless noted. Our actual results, performance or achievements could be materially different from those projected by these forward-looking statements. The factors that could cause actual results, performance or achievements to differ from our forward-looking statements are discussed in our filings with the Securities and Exchange Commission, such as our Form 10-K, 10-Q and 8-K reports. Given these risks and uncertainties, you're cautioned not to place undue reliance on our forward-looking statements. Also our discussions during this conference call will include certain non-GAAP financial measures. Non-GAAP financial measures provide investors and management with supplemental management of operating performance and trends that facilitate and comparisons between periods before and after certain items that would not otherwise be apparent on a GAAP basis.

Reconciliations of these non-GAAP financial measures to the most comparable GAAP measures are available as part of our earnings releases on Celgene's website at www.Celgene.com in the Investor Relations section. I will now turn the call over to our Chief Executive Officer Bob Hugin.

Bob Hugin - *Celgene Corp. CEO*

Thank you. The Second Quarter was outstanding across all functions and geographies. Our exceptional global teams produced both excellent operating results and achieved multiple significant milestones that have the potential to create meaningful benefits for patients and strong returns for shareholders for years to come.

Earlier this morning, we announced record financial results with total revenue growing 36% year-over-year to \$850 million and non-GAAP earnings per share increasing 50% year-over-year to \$0.69.

Before we review the specific operating and financial results of the quarter, I would like to highlight several of the key strategic developments of the last three months. Though not yet completed, the announced Abraxis Bioscience acquisition broadens our therapeutic focus into the solid tumor market. Their lead product Abraxane which is approved for the treatment of metastatic breast cancer in the United States and international markets has also shown significant promise in pancreatic and non-small cell lung cancer in clinical trials. The transaction provides the opportunity for us to leverage our global commercial, clinical and regulatory organizations and further strengthens our pipeline with multiple candidates from the Abraxis proprietary NAB technology portfolio. Advancing our hematology pipeline is also a strategic imperative. At the American Society of Clinical Oncology and European hematology meetings in June, there were many presentations that highlighted important new data supporting our key products and programs. Perhaps the most significant data were results from three Phase III studies demonstrating the substantial benefit achieved by multiple myeloma patients receiving continuous REVLIMID therapy. Our international expansion strategy continues to be an important growth driver for our products. On June 25, REVLIMID was approved in Japan for the treatment of second line multiple myeloma. Governmental reimbursement was achieved in less than a month following approval. Accurately reflecting the importance of REVLIMID therapy in myeloma and a validation of the quality of the planning and execution of the Celgene team in Japan.

We are now in the early stages of a thoughtfully planned commercial launch in this, the second largest oncology market in the world. The investments we have made in Japan and other international markets will enable us to capture the full value of REVLIMID and the many other opportunities in our pipeline in all major markets.

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During the quarter, substantial progress was achieved in advancing multiple pipeline programs highlighted by initiation of our first pivotal Phase III trial for our lead anti-inflammatory product Apremilast in psoriatic arthritis and the initiation of our Phase I cancer clinical study of our novel dual our kinase inhibitor CC223, a product of our research labs in San Diego. The significant progress in this quarter further strengthens our belief that sustained long-term growth comes best through an unwavering commitment to invest in multiple programs designed to produce breakthrough therapies for patients with serious unmet medical needs. I would like now to hand the call over to Dave Gryska, our Chief Financial Officer who will review our Second Quarter financial results. Dave.

Dave Gryska - Celgene Corp. CFO

Thanks, Bob. Now I'll take you through our record financial results. Non-GAAP total revenue for the second quarter was \$850 million, a 36% increase versus the second quarter of 2009. Non-GAAP net income for the Second Quarter was \$323 million and non-GAAP diluted earnings per share was \$0.69. Total non-GAAP net product sales increased to \$821 million for the Second Quarter, up 38% from \$596 million in the year ago quarter. Second Quarter REVLIMID net product sales were \$587 million, an increase of 48% over the Second Quarter of 2009. Turning to VIDAZA, net product sales for the quarter were \$132 million, an increase of 43% from the year ago quarter. THALOMID net sales were \$98 million for the quarter down 7% as compared to a year ago quarter.

The Second Quarter sales of REVLIMID in the US were \$351 million, representing an increase of 15% on a sequential quarter basis. And a 44% increase when compared to the Second Quarter of 2009. International sales were \$236 million, representing an increase of 5% on a sequential quarter basis and a 54% increase when compared to the Second Quarter of 2009.

Our non-GAAP product gross margin for the Second Quarter of 2010 was approximately 92.4%, gross margins were slightly negatively impacted for the quarter by non-recurring inventory manufacturing charges. It's important to note that inventory levels were virtually unchanged as compared to the First Quarter. We continue to expect gross margins to be approximately 93% for the full year.

Turning now to expenses, non-GAAP R&D expense during the Second Quarter was \$202 million, an increase of 9% over the First Quarter of 2010. We are continuing to strategically invest in developing new products that will enhance our long-term growth, during 2010 our development efforts will evaluate multiple compounds in more than 20 pivotal and Phase III clinical trials. Our key development programs are evaluating REVLIMID in all stages of multiple myeloma as well as pivotal Phase III trials of NHL and CLL. We are also conducting late stage trials for apremilast, pomalidomide, amrubicin, vidaza, and istodax. In addition, we're continuing to advance more than 16 promising compounds in preclinical and early stage development and expect all of these activities to accelerate in the second half of the year. We now expect non-GAAP R&D expenses to be in a range of \$845 million to \$865 million for the full year.

Taking a look at SG&A, non-GAAP selling, general, administrative expenses were \$197 million during the Second Quarter. An increase of approximately 5% from the First Quarter of 2010. We now expect non-GAAP SG&A expenses to be in a range of \$675 million to \$785 million for 2010 as we continue our international commercialization of REVLIMID, VIDAZA and our patient support programs in the US.

Turning to taxes, our non-GAAP tax rate for the Second Quarter was approximately 18%. This improvement in the tax rate is the result of a one time benefit from a settlement related to state taxes. We expect the 2010 non-GAAP effective tax rate to improve to approximately 19.5% for the year.

As you are aware, we hedge our balance sheet foreign currency exposures in our Company foreign currency transactions and exposure led to certain revenue expenses based on foreign currencies. The impact of foreign currency on total revenue on a sequential quarter basis was immaterial. We are well positioned with our hedging programs to minimize the volatility of various foreign currencies effects on our earnings for the year. In addition, during the Second Quarter, we realized approximately \$5 million hedging and revaluation losses which are included in other income and expense.

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This was an exceptional quarter with record revenue and earnings. We ended the quarter with cash and marketable securities of approximately \$3.1 billion. We repurchased approximately 1.9 million shares of common stock during the quarter. We are updating our 2010 financial outlook. REVLIMID net product sales are anticipated to increase to a range of \$2.3 billion to \$2.35 billion, up from a previous range of \$2.2 billion to \$2.3 billion. Total revenue is now expected to increase to a range of \$3.4 billion to \$3.45 billion. Up from a previous range of \$3.3 billion to \$3.4 billion. This updated revenue guidance does not include Abraxis Bioscience. Non-GAAP diluted earnings per share are expected to increase to a range of \$2.65 to \$2.70 as compared to a range of \$2.60 to \$2.65 that was previously reported. The updated non-GAAP EPS guidance includes approximately \$0.05 dilution from the proposed acquisition of Abraxis Bioscience.

In summary, we continue to execute on the global expansion plan for hematology, oncology and information franchises. Our business model is driven by strong operating leverage and efficiency as evidenced by industry leading operating margins. We are truly well positioned to achieve our goals in 2010 and beyond and continue to deliver record operating results. Now I'll turn the call over to our Chief Executive Officer Bob Hugin who will give you his further update.

Bob Hugin - Celgene Corp. CEO

Thank you, Dave. Quite a quarter. The operating results of the quarter were highlighted by strong REVLIMID revenue growth with sales growing 48% year-over-year and 11% over the last quarter. Sales were up 15% quarter over quarter in the US with 4% sequential growth internationally.

Many factors contributed to this excellent performance, most notably recent data highlighted at ASH, ASCO, and EHA all supporting continuous REVLIMID therapy. VIDAZA growth accelerated in the quarter. Year-over-year global sales increased 43% with 10% growth quarter over quarter. Europe was the primary driver of this growth and international sales now represent greater than 50% of total sales. In addition to new markets, label expansion has the potential to be a major growth driver for REVLIMID in multiple indications. At EHA in June

Operator, do you hear music?

Operator

(Technical difficulties.) You may continue.

Bob Hugin - Celgene Corp. CEO

Thank you very much. Let's see.

As I was mentioning, new markets are important to our expansion and growth. Label expansion also has the potential to be major growth driver for REVLIMID in multiple indications. At EHA in June, positive updated data from MMO-15 was presented. The Phase III trial in newly diagnosed myeloma patients will be the backbone of our submission to European regulatory authorities later this year.

As we deliver in our near term value drivers, we're also focused on long-term value creation. We remain committed to maximizing the full potential of REVLIMID worldwide with pivotal studies, ongoing in lymphoma, CLL, MDS and prostate cancer. Recently we enrolled our first patients in our Phase III trial PSA 002 for APRENALAX in patients with psoriatic arthritis. We're optimistic that we'll be able to close the Abraxis acquisition in the coming 2 to 3 months. We look forward to updating you on our strategy for capitalizing on the opportunities and synergies of the combined companies as we clear regulatory hurdles.

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The fundamentals in our core myeloma business remain very strong. Growth in the US was driven by increasing new patient starts and duration gains. Our core European markets also produced robust results despite an increasingly challenging economic environment. Second line market share increased to nearly 40% in the four major European markets where REVLIMID is reimbursed. In the United Kingdom where REVLIMID is reimbursed in third line, market share is over 50%. We're monitoring the environment closely and believe that our guidance appropriately reflects the current economic reality.

In other international markets, we also saw strong sequential growth and are making good progress. The approval in Japan represents the most significant commercial development in the quarter. As I mentioned earlier, we're in the process of initiating a well planned launch in Japan which includes the introduction of our proprietary risk management system, (inaudible) to nearly 250 sites across Japan. We believe that our long-term interests are best served by ensuring that hematologists in Japan are well educated on the effective and safe use of REVLIMID to ensure a positive first experience. A proper foundation will pay significant long-term dividends.

Physician practice in oncology is data driven. New data is the life blood of hematology oncology products. In early June, data was presented for more than 100 posters and more than 20 oral presentations at the ASCO and EHA meetings. By every measure, these meetings were a great success for Celgene products.

Data from three pivotal studies demonstrated that continuous treatment with REVLIMID for patients with multiple myeloma has the potential to become the standard of care. In addition, abstracts were presented that demonstrated REVLIMID's activity in lymphomas and leukemias and exciting new data about pomalidomide in relaxed refractory myeloma was also highlighted. Based on these clinical based on the clinical and commercial potential of these results, we continue to accelerate the development of these products and indications as rapidly as possible.

We believe that we're just seeing the beginning of the impact of the paradigm changing data that supports continuous use of REVLIMID. In the IFM and CALGB studies presented at ASCO, continuous REVLIMID therapy demonstrated unprecedented reductions in the risk of disease progression in the post stem cell transplant setting with 54% and 58% risk reduction respectively. A week later, updated data that included 70% of events from MMO-15 were presented at EHA and the results were consistent. A 58% reduced risk of overall progression into non-stem cell transplant population. The data presented from the podium from MMO-15 and the IFM and CALGB studies all illustrated the progression free survival advantage of continuous REVLIMID therapy.

The three Phase III studies represent a pillar of our myeloma strategy, the generation of supportive data for early and continuous treatment of the disease. In addition to MMO-15, IFM and CALGB studies, other presentations at ASCO presented data demonstrating that REVLIMID combined with dexamethasone is a highly active induction therapy and that REVLIMID may even represent an alternative to stem cell transplant in certain patient populations.

We're continuing to develop our clinical strategy for the treatment of high risk smoldering myeloma while at the same time accelerating the development of Pomalidomide for the treatment of relaxed refractory myeloma where studies have demonstrated a 50% response rate representing the highest response rate of any single agent in relaxed refractory disease. We're committed to improving the treatment options in all lines of therapies for patients with multiple myeloma. Paradigm changing data, increased market share and duration and global expansion, all of these factors contributed to the very strong results that were produced this past quarter. As we seek to broaden our label indication as physicians become more aware of this new data, we're optimistic that our strong performance in this market will continue.

VIDAZA also produced excellent results in the second quarter. International VIDAZA growth was particularly strong as we continue to establish a leadership position in major European countries and other key markets. In the United States, revenues were up 3% quarter over quarter, maintaining market share leadership. VIDAZA remains the only agent in its class worldwide that demonstrates survival advantage in MDS AML. We have a number of ongoing studies to strengthen VIDAZA's role in the treatment of MDS and AML. Positive trends continue in the MDS del 5-Q market with REVLIMID. We're optimistic that we'll receive regulatory approval in Japan later this year and we're on track for an MDS del 5-Q submission in Europe soon after the MMO-15 myeloma filing in Europe.

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The international launch of VIDAZA is ongoing with global expansion and share gains coupled with increasing duration driving growth. Additional data on both REVLIMID and VIDAZA and MDS is expected at this year's American site of hematology meeting in December. In addition to the outstanding REVLIMID data and multiple myeloma that was presented at ASCO there were numerous other abstracts that highlighted the potential of REVLIMID and our broader hematology/oncology pipeline. Groundbreaking data from a study that evaluated the novel R squared REVLIMID plus RETUXAN combination of patients with follicular lymphoma demonstrated 97% response rate which included a complete response rate of 86% with duration now greater than six months. This represents a significant opportunity for REVLIMID and lymphoma and we expect to begin a pivotal Celgene sponsored study in the coming months. We also recently initiated an adaptive design study in patients with diffuse large T-Cell lymphoma. The concept for this study was based upon the differential response rate data seen in the biomarker defined subset of the patient population. In addition to these studies, we will continue to maximize the potential of REVLIMID in lymphoma with additional pivotal studies of mantle cell lymphoma and diffuse large B cell lymphoma. In leukemia, positive data was presented at ASCO that illustrates the potential of our pivotal CLL-008 trial which is evaluating REVLIMID as a first line therapy in elderly CLL patients.

It in addition to REVLIMID, our hematology/oncology pipeline had seven compounds in all stages of development. We expect to have results from our pivotal study evaluating if the (inaudible) in relaxed refractory peripheral T-Cell lymphoma in the next coming few weeks. With approximately 15 pivotal and Phase III trials from the (inaudible) pipeline, there will be a steady flow of important new data for the next several years leading to what we believe will be another 5 to 10 new indications in this period. I do look forward to our next presentation when we should be able to add Abraxane and the Abraxis pipeline to this slide.

Speaking of Abraxis, we're on track with all of our regulatory filings related to the transaction. Both companies submitted the required HartScottRodino filings two weeks ago and the S-4 proxy statement was submitted earlier this morning. Once the filing is declared effective by the SEC there will be an Abraxis shareholder meeting to approve the transaction. The transaction is expected to close shortly after that meeting. We do expect that the transaction will close before our next conference call in late October and look forward to updating you on our progress and plans at that time.

In addition to the hematology/oncology discussions, we continue to build a substantial portfolio of assets in our inflammation and immunology franchise. We now have six candidates in clinical development. This pipeline was a major focus at our R&D day in April and has continued to make excellent progress since then. We're not initiating our first trial at ACE-11 in renal anemia moving rapidly to Phase II in Krohn's disease with our cellular therapy PDA-001 and advancing our JNK inhibitor in idiopathic pulmonary fibrosis. Our most advanced program is Apremilast. In just the past few weeks, we have dosed our first patients in PSA-002. The first of our pivotal trials. We have an extensive development program for Apremilast in psoriatic arthritis, moderate to severe psoriasis, rheumatoid arthritis and other severe immune inflammatory diseases. All of our pivotal trials in psoriatic arthritis and psoriasis are targeted to be initiated before the end of this year.

It was an exceptional quarter, both in terms of financial and operating results and also in terms of positioning Celgene for the future. While producing strong bottom line results, we're also investing the future to sustain the success and high growth that we've achieved. We're executing on our plan and managing the challenges of healthcare reform in the US and budgetary pressures in the EU while making the sound strategic decisions to extend our capabilities around the world and to expand therapeutic franchises that capitalize on our existing strength.

As we close, I want to recognize and thank the Celgene team worldwide who all contributed to these extraordinary results of this past quarter. Superb results achieved in the challenging global economy. It's their dedication, their passion for the patient, their creativity and expertise that makes us so optimistic about the future.

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Thank you for joining us this morning. And we look forward to answering your questions. So, operator, please you can now open the call to questions.

QUESTIONS AND ANSWERS

Operator

Thank you. (Operator Instructions) Our first question is from Chris Raymond of Robert Baird and Company. Your line is open.

Chris Raymond - Robert W. Baird and Company Analyst

Thanks for taking the question. Just curious on the new REVLIMID revenue guidance. Just kind of doing the math quarter on quarter, even at the top end of the guidance, I know it's still early days here in terms of looking at the second half, but if you do the math, there is an implied decrease in quarter on quarter growth. And I'm wondering if there is something specific that we should be thinking about or if it's just a level of conservatism in that number. Thanks.

Bob Hugin - Celgene Corp. CEO

No. It's a good question, Chris. Clearly we wanted to raise the guidance. We think the results of the quarter were very, very strong. I think we do need to be careful that there could be summer seasonality in some markets. There clearly are some budgetary pressures in Europe. We're managing them quite well so far and I think our own outlook is that we'll continue to do that in an effective manner. So I think it's just appropriate that we're here with uncertainty in the marketplace. We certainly wanted to increase the guidance.

It's the Second Quarter in a row. So the guidance for the year at the beginning of the year has turned out so far to be fairly conservative. And so I think there isn't anything out there that we're seeing that other people aren't seeing. The trends are very positive. We're optimistic about the future. But I think we didn't want to raise the guidance. We didn't think it was appropriate to do so. I think you do reflect that there is hopefully better opportunities than guidance indicates, but we do want to be cautious with the environment that we're facing. But there isn't anything we know that's not out there.

Chris Raymond - Robert W. Baird and Company Analyst

Thank you.

Operator

Thank you. Our next question is from Jason Zhang of BMO Capital Markets. You may ask your question.

Jason Zhang - BMO Capital Markets Analyst

Hi. Thanks. Good quarter. Bob, have you provided us the average duration of REVLIMID in the US versus the European countries and also if you could share with us your current rate of the market share with regard to REVLIMID or REVLIMID together with Pomalidomide in a multiple myeloma market.

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Bob Hugin - *Celgene Corp. CEO*

Yes, the market share combined is about 65% overall in the US when you put our products across the lines in myeloma, which has continued to be very strong and clearly REVLIMID being the most widely prescribed drug in the US and Pomalidomide moving more towards second, third and fourth line therapy over time. In terms of duration, we've made the decision for competitive reasons to ensure that we retain the full negotiating leverage in all of the markets that we seek reimbursement, et cetera. So we just we don't think it makes sense for us to give specific duration information out. I think on the core of the trends in the US were positive on duration and we saw positive duration trends in the major developed markets outside of the United States. So continuation of a very positive trend, but the specifics are things that we just don't think is in our interest to publicly give out any longer.

Jason Zhang - *BMO Capital Markets Analyst*

In the past, if I could just follow up on that, we have seen in a half a month duration increase per quarter. At some point we're going to see that slowing down. But you said still positive, still increasing. Are we still in the same ballpark as half a month increase per quarter or is it a little different than what we have seen in the past?

Bob Hugin - *Celgene Corp. CEO*

I think the trends continue to be quite consistent with what we have seen in the past. The IFM CALGB data were only presented in June. So if we were to see an acceleration of that trend, it would be early to see that. But so far what we saw in the Second Quarter was consistent with the very positive trends we've seen before that.

Jason Zhang - *BMO Capital Markets Analyst*

Okay. Thanks.

Operator

Thank you. Our next question is from Geoffrey Porges of Bernstein. Your line is open.

Geoffrey Porges - *Sanford Bernstein Analyst*

Thank you very much. Congratulations. Great quarter. Just a couple of questions. First, you've got a lot of studies where you have a primary input of PFF. Could you comment on your interpretations or the significance of the FDA, advisory committee's discussion of the PFF signal for AVASTIN in breast cancer and whether that changes your expectations? And then just following up on that, you seem to imply that your filing in Europe is just going to be MMO-15. Is that correct or will you still be including JLGB-IFM data and then some of the other corporate group studies as well? Thanks.

Bob Hugin - *Celgene Corp. CEO*

First, on the latter question about the European filing, no, certainly MMO-15 will be the backbone of the filing. But we intend to include in that filing as much data and we have so many successful Phase III trials supporting newly diagnosed and maintenance therapy for REVLIMID. So we will we will be including multiple trials in that package to ensure the most robust data package and the most robust label as possible in that review process. So there is no change to that. If anything, we're more convinced to ensure that we have all of that data included in there. And the time line is unchanged to get that done before the end of this year.

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On the first question about PFF data, et cetera, I do think it is always important to ensure that you've got a close dialogue with regulatory agencies regarding end points of clinical trials, and we certainly would not pursue regulatory strategies without a good intensive of robust discussion with regulatory authorities in advance of initiating those trials. And I think the specifics I think you have to be careful of extrapolating one market segment to another. It very much depends on what therapies are available out there and what is available to be explored and examined in clinical trials in a particular patient setting. So I think that it's, again, always instructive to learn and listen. But we feel good about the direction that we're headed and we're engaged in a very robust discussion to ensure that our clinical trials meet the kind of criteria that are going to be important for both regulatory and reimbursement for positive outcomes upon successful completion of the trial. So I think we feel that our segments and our market indications are very well understood and I think we're targeting the right end points.

Operator

Thank you. Our next question is from Howard Liang of Leerink Swann. Your line is open.

Howard Liang - *Leerink Swann Analyst*

Thanks very much. Regarding the development plan for R squared, the pivotal trial for lymphoma that you highlighted, is this going to be a Phase III trial or is that similar to what you were outlining at the R&D data which is Pomalidomide Phase II?

Bob Hugin - *Celgene Corp. CEO*

We will in the relatively near term be able to give you a little bit more clarity. We are in the process of finalizing regulatory discussions as exactly what will be required in both the design and the the design of the trial in multiple markets. So the data is very, very positive. It really encourages especially when you look at the duration of those very, very strong responses. It's a subject of a pretty robust discussion right now with regulatory agencies. So as soon as we have clarity and we begin to initiate those trials, we'll give you full disclosure on what that design is.

Howard Liang - *Leerink Swann Analyst*

Thanks.

Operator

Thank you. Our next question is from Charles Duncan of JMP Securities. Your line is open.

Charles Duncan - *JMP Securities Analyst*

Hi, guys. Thanks for taking the question. Let me ask add my congratulations on a very good quarter. Bob, with regard to the Japanese commercial rollout, you mentioned RevMate. Could you tell us how that is different, if it is, from RevAssist in terms of the cost or the adoption curve impact that it may have? How is that really a different risk mitigation system?

Bob Hugin - *Celgene Corp. CEO*

Well, the RevMate system in Japan is clearly consistent with our very strong global philosophy of ensuring that REVLIMID is appropriately distributed in each individual market. And then markets clearly have differentiating characteristics. Japan is a market with a very, very significant sensitivity to past effects of drugs with birth defects. And overall a market very sensitive to side effect management. And so that we're very we're being, I think, very prudent here to ensure that we've got the right risk management system. It's something we've developed and our team has developed in very strong concert with important other constituencies in Japan, including the ministry and patient groups, et cetera. So it's been thoughtfully done. It's well planned out. We do not think you will have any long-term negative impediment. We'll get people confidence that it's a very safe system and it's going to be well-controlled and managed.

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That being said, putting the risk management system aside, Japan is a great market. And REVLIMID is a spectacularly well situated compound that fits extraordinarily well with conditions and market of Japan. An oral therapy with very manageable side effects. With strong effectiveness demonstrated in the label indication. So it's very important for us to establish Japan early on and make sure that physicians are very comfortable with how they administer the drug, how to safely do it, how to manage the side effects. And that's a marketplace if you establish a strong initial presence and physicians are comfortable with how they use a drug with initial 1, 2, 3, patients, you're going to see a very rapid uptake over the longer term. But in the near term we thought the reason we're talking about it, we want to make sure people don't get overly enthusiastic to see a dramatic ramp.

We're playing Japan and we're positioning ourselves for very strong long-term excellent performance, but we're going to do it the right way to ensure education is there, good solid risk management systems so that physicians, patients and the government and we are all comfortable that it's being done in a very prudent manner. And that's not to say that we're aren't just incredibly excited about having the approval on June 25, and to get pricing and reimbursement in such a short period of time really does reflect I think a few things. One, the importance of a new therapy for myeloma in Japan. The need for REVLIMID to get out to patients and also I think really the execution, the planning, the strategy of our Celgene team in Japan to produce that in such a short period of time, so we're very excited but we're going to do it in the best way to position for long-term success.

Operator

Our next question comes from Geoff Meacham of JPMorgan. Your line is open.

Geoff Meacham - JPMorgan Analyst

Hey, guys. Congrats on a good quarter. What can you tell us about the IMF guidelines for maintenance and what impact the data or guidelines could have on European first line or maintenance used prior to former approval and I have a follow-up?

Bob Hugin - Celgene Corp. CEO

Yes. I think it's still early to tell that how rapid and what markets specifically we're going to see the impact from the IFM and CALGB data. But there's no doubt when we look at our medical information resources there's a strong interest in understanding and learning about the data from many markets around the world. I do think in some markets we'll be successful like the US that people will understand the data and hopefully relatively rapidly use it appropriately to where the physician thinks it's appropriate to use. Certainly it's had an impact already in maybe dispelling some physicians reluctant to treat only to first response and not to treat through to progression. So I think there is a strong positive impact about continuous therapy from MMO-15, IFM and CALGB in all sectors in myeloma that we have begun to see over the first half of the year. I think specifically to the post transplant maintenance setting it will be market to market and I think it's a little bit early for us to have a strong view as to how and what that uptake will be. You have a follow-up, Jeff?

Operator

Our next question is from Yaron Werber of Citi. Your line is open.

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Yaron Werber - *Citi Analyst*

Hey, guys. I have two questions. One, can you give us a little bit of a sense of what the impact of healthcare reform was in the quarter? If I recall, it was about negative \$4 million last quarter. I'm just trying to get a sense there. And then also, I don't know if you can, but help us understand a little bit how all the price concessions in Europe will impact your business as we look to next year?

Dave Gryska - *Celgene Corp. CFO*

Yaron, it's Dave. I'll answer the first part and then Bob will take the second part. The impact on healthcare reform was between in Q2 between \$9 million to \$10 million and that's the same kind of estimate that we gave you last quarter. The revenue impact.

Bob Hugin - *Celgene Corp. CEO*

And then in Europe, the one impact we had in this past quarter was the 4% price rebate increased rebate in Spain for orphan drugs, 7.5% for other therapy. We were the 4% level starting June 1, of a rebate in Spain. That was the only meaningful event in the Second Quarter. Clearly people are focused on Germany for later this year with an increase of a 10% increase in the rebate in Germany and the specifics of that are still being finalized. But that looks pretty clear.

Yaron Werber - *Citi Analyst*

As we look out past 2010, our marketplaces are we look at it country by country. And clearly there is lots of pressure. I think the impact is more just on budgetary pressures, less on specific price declines. But we're going to see continued price declines and that's the reason why when we started REVLIMID internationally we established the benchmark price that we did. And so our original forecast we were expecting to see pressure just in normal course of events in 2011. So in some respects, we're not going to be as dramatically hit by if there are other price increases.

As we look out, it's a little early for us to get too granular and specific about 2011. But our outlook this far in advance using all of the information we have and the outlook for pressures in Europe is pretty consistent with what we have seen that our expectation is in line with our plan what we think the growth of REVLIMID will be over the next five years. So, again, these are tough times out there. But our team in each individual market I think are crafting a very unique and specific strategy to the markets. It is part of our strategy. We have got to manage price and duration over time. And it is nothing unusual in terms of what we're expecting and we're ready to manage the circumstances, though it certainly is a challenging environment. But we think 2011 initially looks pretty encouraging to us.

Operator

Thank you. And our next question is from Eric Schmidt of Cowen & Co.

Eric Schmidt - *Cowen & Co. Analyst*

I'm wondering if you could talk a little bit about accelerating US trends on REVLIMID quarter on quarter and maybe also comment on some of the deceleration and ex US growth? So a little bit more on the geographic split there. And then, Dave, I was a little bit confused as to what is in the 2010 guidance vis-a-vis Abraxis. Do I understand that your SG&A and R&D guidance include expenses assuming the merger closes in the second half but that any Abraxane revenues are excluded?

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Dave Gryski - *Celgene Corp. CFO*

So we'll answer the latter part of your question first, Eric. In our guidance, our revenue guidance and our SG&A and our R&D does not include Abraxis Bioscience. Okay. That is just Celgene standalone. And although we did estimate that assuming a transaction close as Bob said the next 2 to 3 months that there would be a \$0.05 dilution. So, again, to be clear, the R&D and SG&A is Celgene standalone. Total revenues are Celgene standalone. It's pretty difficult for us to get to the granularity before we close on those expenses for Abraxis but we've given you at least what the dilution would be in terms of the whole year in terms of updating our guidance on EPS. Any more questions on that?

Bob Hugin - *Celgene Corp. CEO*

And on the REVLIMID growth trajectory, certainly the US benefited from both an increasing number of new patients which is very encouraging for the long-term because the quarter was also positively impacted by increased duration. So as you have a very strong ramp of new patients and you have increasing duration, that bodes well for the future. So we always have to work very hard to ensure we have the best strategy and results in the US, but the trends are very positive there.

In Europe the underlying trends were very strong also on a comparative basis and market-to-market. There were some countries where growth was a little bit slower than it has been where there have been pressure on budgets, not specifically price cuts, but just authorities, hospital leaders saying, listen, where can we cut costs just to produce some fiscal restraint. That's our bigger issue that as economies need to come to grips with the fiscal challenges they have we're going to have to make sure that the value proposition Celgene is very, very clearly delineated. That's one of the great successes of REVLIMID that we have such a great value proposition and why it is continues to grow in all markets. And we saw in some markets accelerating growth. The UK, Canada were both very strong in the quarter. So I think we're going to continue to see some markets where we're going to see budgetary pressures, others where the duration and increasing market shares will offset that. So overall we feel very good about what is happening in Europe and the growth there will continue to be very strong over the next two years.

Operator

Thank you. Our next question is from Mark Schoenebaum of ISI Group. Your line is open.

Mark Schoenebaum - *ISI Group Analyst*

Hey, guys. Sorry. Thanks for taking my question. I appreciate it. Maybe a little bit of a bigger picture question for Bob, if I may. So you've done the ABII deal and the Gloucester deal and the Pharmion deal all M&A and all and oncology. I was just wondering what the Company is currently thinking regarding business development/M&A outside of oncology?

Bob Hugin - *Celgene Corp. CEO*

Well, we are clearly very excited about the potential of our immune inflammatory franchise the Apremilast and the Phase III program, the JNK program, the acceleration of PDA-001 in multiple indications and aggressively going forward in Krohn's. So we think it's a great franchise for us. But right now our focus has to be to closing the Abraxis transaction, ensuring that we execute a very, very positive integration that we maximize the opportunities that Abraxis brings to us. Both in terms of fully reaching the potential for Abraxane, both in its approved indications and ensuring that we get label expansion to the full potential of what's available to us. And we also think the mass technology portfolio has a number of other candidates in there that we think will stack up well and we'll look to develop those also, and we'll look for other compounds to use in that technology to develop.

So we're going to focus on the synergies of it, but also the growth opportunities of Abraxis. So I think for the near term we're going to continue to execute what we have on our plate. But I do think the potential of the immuno inflammatory franchise is such a great one and the trajectory is a very positive one and once we have the Abraxis transaction closed we don't need to do a deal or anything else, we'd look at things but certainly that's not going to happen in the near term here.

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Operator

Thank you. Our next question is from Rachel McMinn of BofA Merrill Lynch. Your line is open.

Rachel McMinn - *BofA Merrill Lynch Analyst*

Thanks very much. Two questions. Just one in Europe you talked about your filing strategy. Have you actually met with the EMEA recently to discuss the ON-5 data and your filing strategy? And then the second question is just on healthcare reform. Do you have any updated view for 2011? You had given guidance earlier in the year and just wanted to see if there were any changes to your thinking on that front? Thanks.

Bob Hugin - *Celgene Corp. CEO*

Yes. First, just on the healthcare front, we are just maintaining the guidance that we previously given of the \$80 million to \$90 million potential revenue impact in 2011. I do think as the fall approaches, we will have more clarity on that. And if that guidance should be lowered in terms of having a less of effect next year or more of an effect, we'll update you. But right now we do think the guidance is still firm from all of the information we have in terms of US revenue impact on US healthcare reform we wouldn't change that guidance. We have no information now that would lead us to do that.

And in Europe, I'm not going to go into the specifics of it, but we have a very active dialogue with multiple officials in different countries that we'll be involved in shepherding the REVLIMID newly diagnosed application through the European process. So that's an ongoing and very active dialogue and we're on track for submitting that filing by the end of the year.

Operator

Thank you. Our next question is from Brian Abrahams of Oppenheimer. Your line is open.

Brian Abrahams - *Oppenheimer & Co. Analyst*

Hi. Thanks for taking my question and congrats. My congrats as well on the strong quarter. When we saw the ON-5 update at EHA, it looked like REVLIMID was continuing to perform well. Looking at the PFF benefits were a bit more pronounced in the younger patients who were in the trial. So just wondering how you foresee this potentially impacting the positioning of the RNP plus R regimen and whether you expect there to be any age recommendations on a front line label? Thanks.

Bob Hugin - *Celgene Corp. CEO*

It's a little premature to speculate on what exactly will come out of the label in the discussions with the regulatory agencies. Certainly Prednisone is not a high growth regimen generally in the myeloma population. So I think our own strategy of doing MMO-20 which is our big largest Phase III trial in the myeloma marketplace which really examines REVLIMID and dexamethasone versus a Melphalan-based Pomalidomide regimen is really designed to say, listen, if we are able to get the broadest label possible and all of the data presented from all the clinical trials that we're hopeful that physicians will have the full course of options to say which specific patient would benefit best from REVLIMID dexamethasone, which patient would benefit most from Melphalan Prednisone and REVLIMID or other therapies. I think we're getting a good range of data from multiple clinical trials, Phase III trials. Certainly the REVLIMID ones have all had positive, positive results. And we're optimistic that in the next year or two as we get the MMO-20 data we'll have even more information to give physicians, more guidance as to what is best for newly diagnosed myeloma patients. We're very encouraged by what MMO-15 has had an impact already in the marketplace, we're optimistic the impact it will have in the regulatory our regulatory ability to expand the label. But MPR is not the will not be as any Melphalan-based regimen will not be for every single patient.

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Brian Abrahams - *Oppenheimer & Co. Analyst*

Thanks very much.

Operator

Thank you. And our final question comes from Thomas Wei of Jefferies & Co. Your line is open.

Thomas Wei - *Jefferies & Co. Analyst*

Thanks. Just a couple of questions. One, just to clarify the commentary on Japan, it sounds like we should expect that maybe longer term penetration could be as robust as some of your other territories but maybe the time frame to achieve that more extended relative to the experience with REVLIMID in the US and Europe. And then also just wanted to get an update on Pomalidomide. The next round of data on the post REVLIMID Valcade myeloma setting and the potential for you to file in a more accelerated fashion for that indication. Thanks.

Bob Hugin - *Celgene Corp. CEO*

Yes. First on Japan, I think you represented it very accurately. We're very, very optimistic about the potential of REVLIMID and myeloma in Japan and for all of the reasons that we discussed and hopefully you will keep your estimates as low as possible in the near term for us. But seriously, we think that success is as important to do it properly with a strong education emphasis and I'm sure that people have a good positive experience because the potential for Japan is such an important market to us over the next few years, we want to do it right and do it with the right trajectory. But we're very optimistic about what the potential is there. And I think since our last call the—or certainly since the last quarterly conference call the very important Phase II Pomalidomide trial is very rapidly finished accruing and we're going to hopefully look forward to that data as soon as it is available and there's a potential in the next three or four quarters we'll see that data, and that we'll initiate the Phase III trial in Pomalidomide by the end of the year. So I have to tell you when we think about priorities here, as we think about the rest of this year and 2011 the acceleration of Pomalidomide and making that available to the relaxed refractory myeloma population and the myelo fibrosis population, patient population is a critical corporate objective because it remains in that last refractory population a serious unmet medical need and an indication that we feel so strongly about the need to serve myeloma patients. So we're very encouraged by what we're seeing, the results, well, soon as we get the Phase II results we'll share them and see how they can be used and we'll accelerate the Phase III trial and we're accruing the pivotal trial in myelo fibrosis. So it really is hard to imagine a higher priority for us than the acceleration of Pomalidomide development. I want to thank everybody for joining us this morning and updating—getting updated on the Celgene story and participating with questions. We very much look forward to updating you through press releases as to the Abraxis transaction, the completion of that and look forward to updating you on our strategies and progress at our conference call for the end of the third quarter and late October. Thank you very much.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This concludes the program. You may now disconnect. Good day.

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