

MYLAN LABORATORIES INC

Form DEFA14A

June 16, 2005

SCHEDULE 14A
Proxy Statement Pursuant to Section 14(a)
of the Securities Exchange Act of 1934 (Amendment No. __)

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Mylan Laboratories Inc.

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On June 14, 2005, Mylan Laboratories Inc., a Pennsylvania corporation (Mylan or the Company), conducted an investor conference call, in which the Company announced its planned \$1.00 billion modified Dutch Auction self tender offer for shares of its common stock, its subsequent \$250 million open market common stock repurchase program, the doubling of its annual dividend and other key initiatives. A copy of the transcript of the investor conference call is attached hereto as Exhibit A.

IN CONNECTION WITH MYLAN S 2005 ANNUAL MEETING OF SHAREHOLDERS (THE ANNUAL MEETING), MYLAN WILL FILE RELEVANT MATERIALS WITH THE SECURITIES AND EXCHANGE COMMISSION (THE SEC), INCLUDING A PRELIMINARY PROXY STATEMENT AND A DEFINITIVE PROXY STATEMENT. INVESTORS AND SHAREHOLDERS OF MYLAN ARE URGED TO CAREFULLY READ THESE MATERIALS (IF AND WHEN THEY BECOME AVAILABLE), AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THOSE DOCUMENTS, BECAUSE THESE DOCUMENTS WILL CONTAIN IMPORTANT INFORMATION.

INVESTORS AND SHAREHOLDERS MAY OBTAIN THESE DOCUMENTS (AND ANY OTHER DOCUMENTS FILED BY MYLAN WITH THE SEC IN CONNECTION WITH THE ANNUAL MEETING) FREE OF CHARGE AT THE SEC S WEBSITE AT THE SEC S WEBSITE AT WWW.SEC.GOV. IN ADDITION, THE DOCUMENTS FILED WITH THE SEC BY MYLAN MAY BE OBTAINED FREE OF CHARGE BY DIRECTING SUCH REQUESTS TO: MYLAN LABORATORIES INC., ATTENTION: INVESTOR RELATIONS, 1500 CORPORATE DRIVE, CANONSBURG, PA 15317, OR FROM MYLAN S WEBSITE AT WWW.MYLAN.COM.

Mylan, its executive officers and its directors may be deemed to be participants in Mylan s solicitation of proxies from shareholders in connection with the Annual Meeting scheduled to be held on October 28, 2005. Information about the executive officers and directors of Mylan and their ownership of Mylan common stock is set forth in the proxy statement for Mylan s 2004 Annual Meeting of Shareholders, which was filed with the SEC on June 28, 2004, and in press releases and Forms 3 and 4 for executive officers who have since joined Mylan, and in Forms 4 and 5 filed thereafter.

MYLAN LABORATORIES, INC.

Moderator: Patrick Fitzgerald

June 14, 2005

7:30 a.m. CT

Operator: Good day everyone, and welcome to this Mylan Laboratories Strategic Business Update conference call. This call is being recorded. At this time, I'd like to turn the call over to the Vice President of Public Relations, Mr. Patrick Fitzgerald, please go ahead, sir.

Patrick Fitzgerald: Good morning, and thank you for joining us today. I'll start by reading the customary forward-looking statement information. This presentation will include statements that constitute forward-looking statements, including with regard to the company's future business and financial performance, including its revenues and earnings per share, the anticipated effects of today's announcements and the company's growth in product opportunities. These statements are made pursuant to the Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995.

Because such statements inherently involve risks and uncertainties actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to exposure to lawsuits and contingencies associated with the company's business; the company's ability to successfully develop, license or otherwise acquire and introduce new products on a timely basis in relation to competing product introductions; uncertainties regarding continued market acceptance of and demand for the company's products; the effects of rigorous competition and commercial acceptance of the company's products and their pricing; changes in market conditions or other uncertainties and matters beyond the control of management which could effect the company's earnings guidance, as well as the subjectivity inherited in any probability

weighted analysis underlying the company's assumptions and estimates with respect to the future. And the other risks detailed in the periodic filings filed by the company with the Securities and Exchange Commission.

The company undertakes no obligation to update these statements with revisions or changes after the date of this release. In addition, this presentation includes non GAAP financial measures. In accordance with Regulation G, a presentation of the most directly comparable measures calculated and presented in accordance with GAAP as well as a reconciliation of the differences between such measures, are included as an appendix to the presentation materials, and also are available on the company's Web site at www.mylan.com.

I'd now like to turn the presentation over to Robert J. Coury, Vice Chairman and Chief Executive Officer of Mylan Laboratories.

Robert Coury:

Thank you, Patrick. And good morning, everyone. Thank you for joining us today. As most of you know, I am Robert J. Coury, Vice Chairman and Chief Executive Officer of Mylan Laboratories. We are extremely pleased to have this opportunity to provide you with an update on Mylan, our outlook for our business and an overview of our strategy moving forward. We are making several significant announcements today, all of which are consistent with Mylan's goal of maintaining our leading market position within the generic pharmaceutical industry, while optimizing value for our shareholders.

Over the last year, we have spent considerable time analyzing the dynamics facing our industry and our company with particular focus on how to maximize our Nebivolol opportunity. As you know, our first preference was to launch Nebivolol ourselves in order to retain for our shareholders, the most value from this important product. Based on the information available at that time, we've concluded that the King acquisition would have allowed us to effectively market Nebivolol and maximize the value of this opportunity for our shareholders. It also would have

provided a platform which to establish a true brand franchise, which would have enabled us to combine Mylan's existing strength and its science with our own commercialization capabilities.

However, based on the changes of the King business and the lack of appropriate other acquisition alternatives we have chosen a different course for Nebivolol. Today, we are announcing that the best available option is to out license Nebivolol to a major brand pharmaceutical company, which will co develop and commercialize this product.

We have all ready initiated a thorough process to find the right partner for this tremendous potential opportunity. And we'll provide additional information when appropriate. We believe that this approach will be cash efficient, non dilutive and still will allow us to realize the potential significant value for our shareholders. A value that we do not believe is yet reflected in our current share price.

Having determined that we will out license Nebivolol, we also spent considerable time looking inward at our existing operations for further operational efficiencies. We concluded that the existing Mylan Bertek brand subsidiary is not the type of brand platform that will enable us to fulfill our long stated vision and objective of becoming a more balanced specialty pharmaceutical company. Thus, we are announcing today that we will be closing the Mylan Bertek subsidiary. We will transfer the responsibility for selling most of Mylan Bertek's products, predominantly brand generics to the Mylan Pharmaceuticals and UDL. We believe that this restructuring will quickly and significantly enhance our earnings per share, going forward.

Before I get to our core generics division, I'd like to take a moment to call to your attention to the significant achievements of two of Mylan's subsidiaries, UDL and Mylan Technologies.

First, UDL. UDL Laboratories is our unit dose package product subsidiary that provides hospitals, nursing home and other institutions with a portfolio of generic products and sophisticated,

barcoded, packaging designed to reduce dispensing air. UDL holds a dominant position with the largest unit dose product line in the United States. It has approximately 400 line items individually blistered, labeled and barcoded. And at fiscal 2005 it shipped over 800 million doses. UDL is well positioned capitalize on growth opportunities throughout the entire generics industry in unit dose and specialty packaging.

Next, Mylan Technologies. Our transdermal drug delivery subsidiary is truly one of my Mylan's hidden jewels and one of the most promising platforms for Mylan's future growth. Mylan technologies has developed and marketed more generic transdermal products than any company in the United States, and is the largest producer of transdermal patches for the US market. Mylan Technologies ANDA's include nitroglycerin transdermal system, (estrodial) transdermal system, and of course, fentanyl transdermal system.

As we look forward, Mylan Technologies will not only continue to add to its generic pipelines, but will enhance its focus on more a branded development opportunities. We intend to accomplish this through strategic alliances with large brand pharmaceutical companies that have a need and a desire to participate in this important drug delivery technology. We believe that these strategic alliances, structured appropriately will not be dilutive to the Mylan shareholders. In fact, the brand company's participation and the research and development of transdermal products, could be highly accretive to Mylan because of Mylan's participation in the commercialization efforts of any of these opportunities. In our opinion, there is not another transdermal platform that can match Mylan Technologies development speed, and state of the art technology, and this will present brand pharmaceutical companies an attractive opportunity to be active in this advanced drug delivery technology.

Now I'd like to turn my attention Mylan Pharmaceuticals, our core generics division. We are very proud to be a dominant force in the generics industry and remain extremely committed to our mission of delivering high quality, affordable pharmaceutical products to consumers. But today's

change in environment clearly demonstrates that we must adapt to remain competitive and deliver continuing growth to our shareholders. Much has been said by Mylan about the generics industry over the last past 18 months. And we were far ahead of our peers in predicting the current state of affairs. Knowing what we know today, it would be a mistake for Mylan to think that our future success will result from sticking to what we've understood to be business as usual. There has been a significant increase in the number of generic competitors over the last few years alone. We have also seen increased competition within Mylan's base business, especially in areas where Mylan had historically enjoyed market leading positions.

Mylan did not, and will not sit still while negative forces impact our industry. Mylan, as it has always done in the past, took the lead to address these issues head on in an attempt to mitigate the negative factors that we are experiencing in the marketplace today, as well as any future impact that these changes may have. For example, Mylan has lead various initiatives to try to resolve some of the issues in the generic industry, by working with the Food and Drug Administration, the Centers for Medicare and Medicaid Services, and through the judicial system on issues such as authorized generics, and the abuse of citizen's petitions, as well as further clarification of the intent of the Hatch Waxman legislation. We would like to recognize CMS for considering authorized generics to be brand drugs for the purposes of best price reporting. We anticipate that the upcoming version of the governor's association Medicaid recommendations will be supportive of this chance to CMS. We continue to believe that in the near term the CMS fix will be positive for our industry. We would also like to thank Senators Rockefeller, Schumer, McCain, Grassley, Leahy, and Congressman Waxman, as well as many others for their support, and continued efforts to restore the original intent of Hatch Waxman and the value of the 180 day exclusivity period.

We further applaud the remarks recently made by Mr. Jon Leibowitz, Commissioner of the Federal Trade Commission, who commented that the long term implications of authorized generic were potentially troubling, and would likely diminish the incentive for generic firms to challenge

patents and encourage substantial development and litigation costs, because we believe that over a long term, the issue of authorized generics will ultimately be fixed through legislation. We view these to be strong comments that represent a significant step in the right direction.

While we have not won every battle, we have, at a minimum achieved our well publicized primarily objective of simply defining the rules of engagement for the generic pharmaceutical industry. Given the rules of engagement as presently defined, it is Mylan's intention, going forward, to participate in the authorized generics market as appropriate. Mylan is the number one generic pharmaceutical manufacturer for a reason, and the strength of our science, manufacturing and distribution capabilities is unmatched in the industry. We are able to distribute unprecedented volumes of quality generic pharmaceutical products into the marketplace, while maintaining a leading market share. We firmly believe that our success is due to our highly motivated people who are consistently seeking new and innovative product solutions and efficiencies. We continue to believe that they are truly the most critical asset of Mylan.

Another important element of our success to date, has been the careful selection of products that we bring to market. It must be clearly understood that this is not an overnight or simply a short term process. The process of identifying, evaluating, developing products, as well as managing the legal and regulatory hurdles to successfully bring a product to market, can take anywhere from three to five years or longer to materialize. We suffered during our last fiscal year, in part due to the lack of enough of new product introductions.

Early in my tenure, we recognized and addressed this issue head on by enhancing our investments predominantly in research and development, as well as in general and administrative, with a heavy emphasis on legal. That investment has yielded today the deepest product pipeline in the history of Mylan, even more significant than just a sheer number of products in our pipeline, are the specific opportunities that they represent. To mention a few

potential near term catalysts, amlodipine, topiramate, oxybutynin and levofloxacin represent over \$5 billion in 2004 brand sales, according to IMS.

We also see an increase in the number of products coming off patent industry wide. And it is projected that over \$75 billion of brand pharmaceuticals could lose exclusivity between 2005 and 2008. Mylan is extremely well positioned to participate in industry up turn when it occurs. And we expect to achieve our disproportionately high share of new product launches. We intend to launch approximately 45 new products over the next two years, representing over \$35 billion in 2004 brand sales according to IMS. And anticipate launching over 100 new products, representing over \$79 billion in 2004 brand sales over the next five years.

In addition to our continued focus on further enhancing an all ready robust pipeline, we have added to our management strength in the generic pharmaceutical division by appointing two long time Mylan executives to senior management positions. Hal Korman, to President of Mylan Pharmaceuticals, and John Deiriggi to Vice President of Generic Business Development. Again, Mylan is expanding it s committed to expanding its leading position in the generic pharmaceutical industry. And we will continue to find new and innovative ways to drive down cost, and to come even more competitive.

If there have never been any quick fixes when faced with challenging times in the generic industry it is extremely important to note that Mylan, as it has demonstrated over its long history as the slide shows, has been through a number of extremely challenging cycles. And like these many periods before our Board of Directors and management team, have one of the strongest track records in charting the right course of action that allows us to thrive in our industry. And at the same time, continue to generic shareholder value. Our Board of Directors and management see no difference in our ability to address the challenges today as we have in the past. We believe that we are seeing the trough of this current difficulty cycle. And that while our current

share price, appears to reflect the challenges our industry continues to face, we do not believe that it reflects the opportunities that lie ahead.

In light of our view of what we understand now to be the rules of engagement to operate in the current generics environment, as well as our commitment to return its shareholder equity, while maximizing shareholder value, we are making two very important announcements today. First, on Thursday, June 16, Mylan will commence a modified Dutch Auction self tender to purchase up to \$1 billion of our common stock. So sequence of the completion of the Dutch Auction self tender, we plan to buy back up to an additional \$250 million worth of our stock from time to time on the open market or otherwise. Upon completion an depending on the actual purchase price, we expect to have purchased nearly 25 percent of our out standing shares in our company. The price range for the Dutch Auction will be \$18 to \$20.50 per share. There are several reasons why we believe that the Dutch Auction and follow on buyback strike the right balance between doing what is right for our business, and what creates value for our shareholders. We also believe that our stock is significantly under valued, at the current levels and have determined that our current cost of capital is high. As it relates to our business, the sheer magnitude of this buyback will enhance the impact of our earnings per share going forward, of any and all new opportunities that we add to our existing base business, such as any successful future paragraph or challenges. We also believe that the positive impact of the Nebivolol opportunity combined with the strength of our pipeline as well as any upside from positive legislative changes will be magnified for our shareholders, due to the significant reduction in our shares out standing.

It is worth noting that Mylan has an impressive history of successful stock buybacks, not including the buyback announced today, since 1997, the company has repurchased over \$27 million shares of its stock for a total investment of nearly a half a billion dollars. In conjunction with this buyback, we are also pleased to announce today, once again, another dividend increase, by doubling our annual dividend from 12 cents per share, to 24 cents per share. The new quarterly dividend of six cents per share will be payable on July 15, 2005, to shareholders of record on

June 30, 2005. An enhanced dividend policy going forward further reflects our current view of the generics industry trends. While we believe there are still many growth opportunities, we also believe that those growth opportunities have been devalued as a result of some of the changes within the industry that I have outlined today and over the past several months. As you know, it has been a long standing commitment of Mylan to focus on total return to shareholders, by striking a strong balance between our share appreciation and through our dividend policy. We are very positive about our outlook for the remainder of fiscal year, and our next fiscal year and beyond.

As a result of all of that, we are announcing today, and because we view our current fiscal year, fiscal 2006 to be a restructuring year, today, we are going to give two years of financial guidance. We are announcing today that our adjusted EPS guidance for fiscal 2006 will be between 92 cents and \$1.15 per share, and fiscal 2007 to be between \$1.20 and \$1.74 per share. Ed Borkowski, our Chief Financial Officer, will discuss our guidance for fiscal 2006 and 07 in more detail shortly.

As you can see, our Board of Directors and management team have spent a great deal of time analyzing our business, the sector and the opportunities and challenges ahead. We believe that the change of our capital structure is appropriate at this time, and will benefit our future. In addition, as I mentioned earlier, we see a number of opportunities ahead that we believe have not yet been reflected in our current share price.

Just a quick review of the rest of today's agenda. I'll first turn the presentation over to Dr. John O'Donnell, Mylan's Chief Scientific Officer, to provide the long awaited review and update on Nebivolol. And then, we'll turn to Dr. Carolyn Myers, Mylan's Vice President of Strategic Marketing, who will provide information on the commercial opportunity for Nebivolol. And then, next Ed Borkowski, our Chief Financial Officer will review and discuss the financial impact of

today's announcements, as well as provide financial guidance for fiscal 2006, and fiscal 2007. Following our prepared remarks, we will then open the call for questions.

Just one final note, or I should say comment before I turn the call over to Dr. John O'Donnell. I think it is important that I make mention of the recent press regarding the letter of Carl Icahn's control entity sent to Mylan approximately two weeks ago. We view that letter as simply a reiteration of the letters he sent us more than six months ago, in November 2004. At that time, our Board of Directors considered Mr. Icahn's letter and concluded that he had not made a serious offer for the company. And that the discussions with Mr. Icahn were not in the best interest of our company.

In view of the passage of time, and since this last consideration of this matter, our Board of Directors has reviewed the latest Icahn letter, and made the same determination as it did last November, that it was not a serious offer, and that discussions with Mr. Icahn were not in Mylan's best interest. Mylan has stated many times in the past, and I cannot be any more clearer today, that Mr. Icahn will not unduly influence Mylan's Board or distract this management team from executing on the right strategies that are in the best interest of all shareholders. Let it also be clear, that based on our views of Mylan's current share price, as well as our future outlook in the actions that we are outlining here today, it should be obvious that we are prepared to be buyers at \$20 a share, not sellers. Thank you. And I will now turn the call over to Dr. John O'Donnell.

John O'Donnell: Thank you, Robert. My role today will be to provide an overview of the Nebivolol development program to date, and future studies, which will be followed by the commercialization overview by Dr. Myers. The Nebivolol NDA for hyper tension indication was submitted to the FDA in April of '04. And Mylan has now received an approvable letter from the FDA. Final approval of Nebivolol is contingent upon successfully satisfying additional FDA requirements, regarding certain aspects of pre clinical data, and finalization of the labeling. The pre clinical data submitted in the NDA was based upon studies previously conducted by Janssen Pharmaceutica

Belgium, the company from which Mylan licensed Nebivolol. Currently, Mylan is conducting a pre clinical study, designed to address questions posed by the FDA. We believe that the data from the ongoing pre clinical study will satisfactorily resolve the FDA's questions.

As is typical there have been a number of inquiries to both Mylan and the FDA asking for more details on the pre clinical study. So I'd like to clearly communicate that we have a high level of sensitivity concerning the study which prevents us from commenting further today, other than to express our confidence in where we are today and where we stand going forward with Nebivolol. I'd like to call your attention to two additional very significant announcements that we are making today concerning Nebivolol. First, Mylan has signed a collaboration agreement with Menarini that allows us to use the SENIORS trial in support of a US submission for the congestive heart failure indication. As a result, Mylan intends to file an NDA for congestive heart failure indication using the SENIORS trial and supportive data. I will go into more detail on the existing SENIORS clinical trial in a moment. Let me give you some additional highlights first.

Nebivolol's composition of matter patent does not expire until 2020. Scientific information regarding Nebivolol was recently presented at the American Society of Hypertension meeting in San Francisco. Dr. Mike Bristow, co-director University of Colorado's Cardiovascular Institute presented his work on Nebivolol's cardio selectivity using human left ventricular myocardial tissue. And Dr. Preston Mason, President and Founder of Elucida Research, affiliated with Brigham & Women's Hospital, Harvard Medical School, also presented his research finding, regarding Nebivolol's ability to potentiate nitric oxide using stroke prone hypertensive rats. And using human venous and arterial endothelial cells.

Now I'd like to give a thorough overview of the studies that comprise the hypertension NDA, the proposed near and long-term pre clinical studies, and the Menarini senior trial in the elderly with congestive heart failure. The pivotal studies that supported the Nebivolol NDA are summarized on this slide. There were three mono therapy trials of Nebivolol versus placebo.

Two of these trials, 302, and 305 were studies that enrolled hypertensive patients from the general population. As we previously announced the results from 302, authored by Dr. Robert Weiss, Chief of Cardiology, St. Mary's Medical Center, Lewiston Maine; and Dr. Michael Weber, Professor of Medicine, SUNY Downstate College of Medicine, Brooklyn, New York, along with others, were presented at the American Society of Hypertension in May of '05. Study 202 was a trial that enrolled exclusively African American hypertension hypertensive patients. Study 321 evaluated Nebivolol versus placebo as add on therapy for patients who's blood pressure was not controlled by background therapy, with an ace inhibitor an ARB and a diuretic or some combination of these. Trial 306 was an open label study evaluating the long-term safety and blood pressure effects of Nebivolol.

In summary, there are four statistically significant efficacy studies conducted in the United States in one long-term US safety study, which supported the filing of the Nebivolol NDA to the FDA for hypertension. Mylan's near term lifecycle management plan is to further explore and expand the clinical benefits of Nebivolol by confirming the clinical benefits of Nebivolol in African Americans. To continue to differentiate Nebivolol from other beta blockers we are conducting studies on Nebivolol's tolerability profile, for example, fatigue and sexual dysfunction. And by studying the effects of Nebivolol in patients with metabolic syndrome, which includes people disposed to certain risk factors, such as obesity, diabetes, hypertension and hyperlipidemia. The object of the life cycle management program is to expand the knowledge of Nebivolol to continue to clearly differentiate Nebivolol from other major beta blockers.

As you can see, we have a number of additional areas that are under consideration. These include animal and human studies of the effects of Nebivolol on nitric oxide availability, the effects on blood vessels, on the kidney's, on exercise tolerance, and potentially an outcomes trial. As I mentioned, Mylan is extremely excited about the senior study that evaluate the effects of Nebivolol versus placebo on mortality and morbidity in elderly patients, average age of 76 with congestive heart failure. The trial was designed differently than previous conducted beta blocker

heart failure studies. The SENIORS trial included previously unstudied elderly patients. Previous beta blocker heart failure studies enrolled younger patients, with an average age in their early 60s. Furthermore, these studies only included patients with impaired left ventricular ejection fraction which is a measurement of the heart's ability to pump blood. In the SENIORS trial, patients were eligible, whether they had preserved or diminished left ventricular ejection fraction, which is more representative of patients with congestive heart failure. The results have been presented at the European society of cardiology meeting in Munich in 2004, and published in a European journal of cardiology.

The senior study was conducted by Menarini. And in February of 2005, Menarini submitted the study through the mutual recognition procedure to obtain the congestive heart failure indication in the European Union. And approval would be anticipated by the end of the year. As I mentioned earlier, Mylan in collaboration with Menarini anticipates approaching the FDA about filing an NDA using the SENIORS trial, and supportive data to request the CHF indication.

The SENIORS trial was conducted in compliance with ICH guidelines. And had a European administrative structure that included well known experts in the field of cardiovascular research as shown on this slide. All are recognized international thought leaders in the cardiovascular area, particularly the chairs of the subcommittees. Mylan is currently working with one of the two principal investigators as a consultant regarding the submission of SENIORS to the FDA.

In summary, Mylan received an approvable letter from the FDA and will work with the FDA to gain final approval. Mylan has designed near term life cycle development program to continue to differentiate Nebivolol from other beta blockers. In addition, we will explore clinical effects associated with Nebivolol's unique properties. In collaboration with Menarini Mylan will be approaching the FDA about submission of the SENIORS trial with supportive data requesting a congestive heart failure indication to further expand the clinical indication.

With all of that said, you can now see why we are extremely excited about the potential of Nebivolol and the Nebivolol franchise. I would like to thank my clinical and regulatory teams who have worked so hard, and will continue to play critical roles as we maximize this exciting opportunity for Mylan. I d now like to introduce Dr. Carolyn Myers who will address the commercial opportunity for Nebivolol.

Carolyn Myers:

Thank you, Dr. O Donnell. Is it a pleasure to have the opportunity to share with you my excitement about Nebivolol. I joined Mylan two years ago. For the last 15 years, I have worked in the sales marketing, and clinical areas. My experience includes both domestic and international brand management, including having led, and participated in a number of launches in the primary care, and specialty markets. Having worked in the cardiovascular market previously, I was also familiar with Nebivolol s unique properties and the significant market opportunity Nebivolol may be hold in the United States. In fact, this was a major reason why I joined Mylan. I believe that successfully introducing Nebivolol into the United States cardiovascular market requires clear differentiation from competitors and excellent execution of the commercial plan, which will require a significant competitive sales and marketing efforts, and a clinical development program as outlined by Dr. O Donnell.

Mylan has always recognized that Nebivolol will require a competitive sales and marketing efforts. And as such over the past two to three years, Mylan has considered many options, and taking many actions to support optimal commercialization of Nebivolol, including hiring me as well as others with branded pharmaceutical experience in assessing the best way to bring Nebivolol to market.

As Robert mentioned earlier, the best option to day is to out license Nebivolol to a major pharmaceutical company to maximize the Nebivolol opportunity. We expect that the target would be responsible for the full commercialization efforts, including sales and marketing. We also expect that Nebivolol will be commercialized with the competitive share voice in the beta blocker

market. And we anticipate that Mylan will maintain an option to co promote and that future clinical development would be shared.

Nebivolol will be entering the \$16 billion cardiovascular market. Both prescriptions and sales are growing in excess of five percent on a compounded annual basis since 2000. Of this market, hypertension and heart failure, represent approximately 80 to 90 percent of total prescriptions and/or sales. Nebivolol will compete in the beta blocker market. Overall sales of beta blockers in 2004 approached three billion and grew 23 percent compared with prior year. On a prescription basis, beta blockers are the market leaders, and account for 24 percent of market prescriptions. Last year, beta blocker total prescriptions increased nearly eight percent, growing faster than the market. Beta blockers represent a dynamic segment of the cardiovascular market, and are a cornerstone of cardiovascular therapy, for a variety of cardiac conditions. Even in a mature beta blocker market, new entrants continue to gain market share. Once we have successfully launched Nebivolol, our goal is to capture a market share commensurate with these later entrants.

To date, Nebivolol has been approved in more than 65 countries around the world marketed by Menarini, Janssen's ex-US licensee. Additionally, registration is pending in the countries shown in this slide in yellow, including the United States. In Europe, Menarini has successfully commercialized Nebivolol. Nebivolol sales in units in Europe show significant year-on-year growth compounded annual growth, both in terms of prescriptions and dollars has increased by 17 percent and 24 percent respectively since 2001.

Nebivolol's success in Europe is driven by its performance in both Germany and Italy. In fact, in Italy Nebivolol is the second most prescribed beta blocker, and the fourth most prescribed beta blocker in Germany. Not shown here, but important to note, Menarini launched in France this past summer, and performance is also proving to be very strong.

Nebivolol is poised to enter the large and important hypertension and heart failure markets in the United States. High blood pressure affects over 50 million Americans, and heart failure is a condition that affects about million Americans. As also explained, we are undertaking a number of studies to support the near term commercial success of Nebivolol. These studies are being conducted to continue to differentiate Nebivolol in the beta blocker market. Additionally, given the long patent life until 2020 we plan to explore various clinical aspects of the unique properties of Nebivolol, namely its effect on nitric oxide. The scientific community believes that nitric oxide may play a key role in vascular health. And we are hoping to work with scientists and clinicians to help us explore and understand the potential clinical benefits associated with nitric oxide.

Nitric oxide is a topic of significant scientific interest. Since the 1950s, there have been more than 67,000 citations, and PubMed on this topic, the majority of which appear since 1990. And in the past five years, the literature has doubled, indicating that the recent level of activity has increased significantly. In addition, there are at least 35 companies including ourselves, assessing the passive physiology of nitric oxide, on the vascular and cardiovascular systems.

As I mentioned, we will launch Nebivolol into the beta blocker market. The leading products are shown here. Toprol XL and Coreg are both branded and promoted. Atenolol and metoprolol immediate release, are the other two beta blockers, which are both generic. These four products now account for more than 80 percent of the beta blocker prescriptions written in the United States.

Mylan has always recognized that successful commercialization of Nebivolol will require launching with a competitive sales and marketing effort, and the continued investment in differentiating and enhancing the clinical profile of Nebivolol. The foundation of this success will be market development to create enthusiasm for Nebivolol, strong and competitive sales and marketing activities to drive acceptance and use of Nebivolol. And of course, medical education

to provider further enhancements, to position management of hypertension and related cardiovascular diseases.

Mylan has always known the potential of Nebivolol. And is committed to taking the right steps to ensure the commercial success of Nebivolol. I am very excited about the potential that Nebivolol may hold and the upcoming launch which will be a significant new product introduction into the United States cardiovascular market. I ll now turn it over to Ed Borkowski, our Chief Financial Officer.

Ed Borkowski:

Thank you, Carolyn and good morning. Today, I will review with you our financial guidance for fiscal 2006 and 2007. I will walk you through some of the detailed modeling assumptions we used in formulating our guidance, including net revenues, expenses as a percentage of net revenues, as well as the impact of each of the announcements, the closure of Mylan Bertek, out licensing Nebivolol and the recapitalization.

Because we view fiscal 2006 as a restructuring and transition year, we will be providing two years of financial guidance so that you can see the anticipated full impact of today s announcements. As well as, the anticipated full impact of our extensive pipeline of new product opportunities. We are forecasting adjusted EPS for fiscal 2006 in the range of 92 cents of \$1.15. It is important to note that our adjusted EPS guidance includes a partial year benefit for the share repurchase, and does not include certain ongoing R&D and marketing costs related to Nebivolol that will be incurred until an out license agreement is signed. It also excludes all Mylan Bertek costs, including costs related to the restructuring, which is anticipated to be completed by September 30, 2005. Essentially, we assume that the Mylan Bertek restructuring and Nebivolol out licensing was completed by April 1, 2005, the beginning of our fiscal year. For fiscal 2007 we are projected adjusted EPS in the range of \$1.20 to \$1.74. We have provided in an appendix a reconciliation between our adjusted EPS guidance, and our GAAP EPS guidance for fiscal year 2006, and an explanation of the difference for fiscal year 2007. In fiscal year 2006, the differences are the

Mylan Bertek costs, costs for Nebivolol and the restructuring expenses. In fiscal year 2007, the difference is the potential impact for the stock based compensation expenses upon adoption of statement, the financial accounting standards number 123.

It is also important to note that the spread in both the 2006 and 2007 adjusted EPS guidance, reflects the potential upside from the opportunities Mylan has before it. I will provide more detail in how we are incorporating and forecasting for these opportunities in a moment. Over the long-term we are projecting a compound annual growth rate in our EPS of approximately 20 percent, over the next five years. Our projections for fiscal 2006 and 2007 are the result of a very detailed bottom up product by product review, which considers historical performance, current market conditions, and future trends. We have a very deep product pipeline with over 45 new products, and six potential first to file paragraph four opportunities projected to launch in fiscal 2006 and 2007. The low end of our guidance assumes no paragraph four wins. The high end of our guidance assumes that we win the litigation with the brand companies on our six paragraph four opportunities, in fiscal 2006 and 2007, but we have competition from an authorized generic a launch. However, if the legislative environment changes with regards to authorized generics, we settle litigation with brand companies where the pricing and market share assumptions we are modeling improve, there could be additional upside to the high end of our ranges.

Our guidance also includes EPS savings of approximately 15 cents annually, based on the current number of shares out standing, related to the closure of Mylan Bertek. This number will increase, once the share repurchases have been completed. It excludes approximately \$17 million in restructuring charts, and other non reoccurring expenses related to the closing of Mylan Bertek which will be expensed over the remainder of fiscal 06.

Our forecast also includes an out licensing assumption for Nebivolol. Based on our anticipated deal terms, we are not projecting any R&D and selling and marketing expense in fiscal 06 and fiscal 07. We are also assuming no royalty revenue in fiscal 06, and only minimal royalty

revenue in 2007, presuming a launch of Nebivolol in fiscal 07. For modeling purposes, only, we are projecting, that we will repurchase approximately 65 million shares at a price of \$19 million per share, as part of the modified Dutch Auction self tender, and the \$250 million open market repurchase. We anticipate completing the Dutch Auction by July 15, 2005, and the open market repurchases by October 2005. We expect to use \$500 million in cash and 775 million in debt financing for the buyback, including transaction related costs. We assumed a weighted average interest rate of between six-and-a-half and seven-and-a-half percent. This slide provides guidance on a number of key line items to help you better understand the drivers of our EPS growth. As you can see, we anticipate that revenues for fiscal 2006 will be in the range of 1.135, to \$1.34 billion. For fiscal 2007, we are projecting revenues in the range of 1.25 to 1.6 billion. I will go into more detail on revenue shortly.

We anticipate that gross margins will be in the range of 52 to 54 percent for fiscal 2006, and 53 to 56 percent for fiscal 2007. We believe margins will grow slightly, due to higher margins from fentanyl and a greater number of higher margin new product introductions.

We will continue to invest heavily in generic R&D with R&D making up six to eight percent of revenues in both fiscal 06 and 07. This represents both growth as a percent of revenues, and in absolute dollars. I will review this in more detail later in the presentation. We anticipate that we will see SG&A in the range of 13 to 16 percent of revenues in fiscal 2006 and 12 to 15 percent of revenues in fiscal 2007. This reflects the continuing investment in legal, something which has all ready resulted in substantially more product opportunities, especially paragraph fours. Some of the decline in SG&A as a percent of net revenues in fiscal 2007, reflects the full effect of the closure of Mylan Bertek. For operating margins, we are anticipating a range of 28 to 35 percent in 2006, and 30 to 38 percent in fiscal 2007. And finally, we are assuming a tax rate of 34 to 36 percent in both years. Once again, I want to state that as a result of the assumptions just discussed, we are forecasting adjusted EPS in the range of 92 cents to \$1.15 in fiscal 2006, and \$1.20 to \$1.74 in fiscal 2007.

I will now provide additional details on our revenue projections. There is natural erosion inherent in any generics business. And therefore, we are projecting erosion in our base business over the next two years. However, based on the significant erosion that we all ready experienced in key products, last year, we view the base business revenue forecast that we are providing as appropriate based on what we know today. Additionally, we believe there is potential upside to our 2006 forecasts related to fentanyl in the event that we maintain our position as the only true generic. It should be noted that we have modeled in additional competition for fentanyl entering the market in both the second and third quarters of our fiscal year 2006.

New products are important to the growth of any generics business. And as you can see, the strong pipeline that we've invested in over the past several years is projected to delivery significant new product revenues over the next two years. The high end of our revenue ranges include potential revenue from six paragraph four opportunities in fiscal 2006 and '07, the most significant of which are amlodipine, topiramate, oxybutynin and levofloxaen. The combination of our base business, and substantial new product revenue over the next two years, is projected to result in healthy top line growth.

Mylan is a market leader in developing generic pharmaceuticals. As a result of our investment in R&D, we currently manufacture and market over 140 pharmaceutical products, and approximately 360 strengths, in over 40 therapeutic categories. Over the past 20 years, we have received over 175 ANDA and SANDA approvals and seven NDA approvals. In order to continue to build on this success, as you can see, we have significantly ramped up our investment in generic R&D over the past three years, which as previously stated has resulted in our largest product pipeline in the company's history. Again, we have 44 applications pending FDA approval, representing approximately \$35 billion in 2004 brand sales, and most are still growing. We also have approximately 144 products in development or advanced evaluation.

We are planning over 100 new launches over the next five years, and we continue to add to our pipeline of opportunities. We currently have 12 paragraph first to file opportunities with brand sales value of \$8.9 billion, and we continue to add to these opportunities.

In addition to the significant investments we are making in R&D and legal, Mylan continues to build for the future by investing substantially in our capital expenditures, such as manufacturing facilities and IT. Mylan leads the generic industry in manufacturing excellence. With the growth and the number of new product opportunities fueled by our R&D investments, we've made and continue to make significant investments in our state of the art manufacturing facilities, which will continue to allow us to effectively and efficiently manufacture, the increase number of new products, and provide us enhanced flexibility and responsiveness to capitalize on product opportunities. Upon completion of current capital expenditure plans, we will have more than doubled our manufacturing capacity. We shipped approximately 12.5 billion doses in fiscal year 2005 and once fully built out over the next several years, this expansion would allow us to product approximately 30 billion doses annually.

We expect to continue to invest at a higher level through 2007, as current projects are completing. However, we forecast returning to a normalized capital expenditure range of 40 to \$50 million in fiscal 2008. As we have said many times before, Mylan's Board and management are committed to growing shareholder value. Today, we have announced a number of measures that we are taking to better position Mylan for short and long term success. We continue to strengthen our core generics business through investment in R&D and legal, and have built the best product pipeline in our history. The steady cash flow from this business will allow us to continue to invest for further growth, while also increasing total shareholder return. We are making the necessary changes to the structure of our existing business, while also immediately returning value to shareholders. Going forward, we will maintain an officially capitalized balance sheet, and believe that it provides us with the flexibility necessary to take advantage of future external opportunities.

As a result of all of these initiatives, 2006 will be a restructuring and transition year for Mylan. However, we are extremely excited about our outlook for the future, and believe that we will continue to create a strong platform, from which to drive EPS growth and shareholder value going forward. I now would like to turn the call over to Patrick.

- Patrick Fitzgerald: Thanks, Ed. We'll now open the line for a question-and-answer session. Due to the number of participants on today's call and our desire to take as many questions as possible, we're limiting each participant to two questions. Please ask both questions together. We also request that questions remain focused on the significant announcements that we're making today. Operator, we're ready for our first question.
- Operator: Thank you, sir. To ask a question on today's conference, please press the star key followed by the digit one on your touch-tone telephone. Again, it is star one for questions. If you are on speakerphone equipment, be sure that your mute function is disengaged so your signal can reach us. Again, that is star one for questions. And we'll take our first question from Rich Silver from Lehman Brothers.
- Rich Silver: Two questions on Nebivolol. First of all, when you refer to the supportive data that would be required to file an NDA for heart failure, can you elaborate on whether that means another full study? Or whether you all ready have some data that would be sufficient for that filing. And then, the second question is what can you tell us in terms of the timing on announcing that pharma partner, thanks.
- Robert Coury: Thanks, Rich. Let me answer the second question first, and then I'll have Dr. O'Donnell address the first. We fully expect that we hope I mean we are in discussions, active discussions now. And we to be realistic, we think by the fall, we should be in a very good position to announce who the partner ultimately is going to be. John.
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John O Donnell: At this time, we are not planning to disclose what the supportive data is but we have gathered and are examining supportive data, and acknowledge that we will need additional efforts beyond the SENIORS.

Patrick Fitzgerald: Next question, please.

Operator: And we'll take our next question from Marc Goodman from Morgan Stanley.

Marc Goodman: Yes, my question has to do with the pre clinical study when will that be done for Nebivolol.

John O Donnell: Near the end of the year, calendar year.

Marc Goodman: Thanks.

Patrick Fitzgerald: Next question, please.

Operator: And we'll take our next question, from Tim Chiang from Bleichroeder.

Tim Chiang: Hi, I had a question for, John. You know, you mentioned Coreg and Toprol XL as two of the major branded products. I mean what do you see as the potential differentiating factors of Nebivolol compared to those two products?

John O Donnell: I think the lifecycle management program that we outlined clearly talks about some of the activity that we think are unique to Nebivolol that will allow us to differentiate it going forward.

- Robert Coury: And again, Tim, just to be clear, we are extremely sensitive as we have been all along. We are actively in discussions with the FDA. And until we have that final label negotiated and all of the work is submitted and turned in. We are just want to be careful about what we can say at this point. But we try to give our shareholders some visibility on exactly the areas that we're going after, but ultimately, it will be between us and ultimately the FDA to make that final determination.
- Patrick Fitzgerald: Next question.
- Operator: And our next question comes from Ian Sanderson from SG Cowen Research.
- Ian Sanderson: Thanks for taking the question. First, under your Nebivolol licensing deal with (Jansen), what first negotiation rights, if any, does J&J have to this compound? And secondly, the supportive data for heart failure, do you have have you gotten any guidance from the FDA that an active comparator might be required in those trials?
- John O'Donnell: We have not yet approached the FDA as I indicated in my earlier discussions. We are planning to approach the FDA this fall, and we'll be discussing that with them at that time.
- Robert Coury: And as far as J&J's rights, it is solely up to Mylan that, you know, to make the determination of who ultimately the partner is going to be. But as I mentioned in our last conference call, you know, J&J does have a consent to be unreasonably withheld.
- Patrick Fitzgerald: Next question, please.
- Operator: Our next question comes from David Maris from Banc of America.
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- David Maris: Good morning, two questions. First, Robert, you were very early in highlighting many of the issues in generics, one of which, though, is overseas competitors with that have lower cost structures. It was recently reported that Mylan was looking at buying part or all of Aurobindo. Aside from that specific company, how extensive are your efforts in India or for lowering your cost structure aside from the Bertek announcement today, you know, looking overseas? And then I'll ask my second question after that.
- Robert Coury: I'm sorry, David, I didn't hear the last piece of your...
- David Maris: I'll ask my second question after that. So the first question is what are your efforts looking outside of the US for...
- Robert Coury: Let me very clear, David, and try to give you some color about our efforts as a whole as we move forward and focus additionally on the generic space. It is our intention, you know, first of all the fact that driving costs down is simply a factor, simply being as competitive as we need to be in this very competitive environment. It's not something new. It's something that we need to continue to do and will continue to do as a business as a going concern. Our efforts in the generic space, David is going to be really focused on looking at as I stated before, I also think that the generic industry is right for consolidation. I think we're going to see a lot of that activity in the very near term here.
- I also think that the, you know, Mylan's focus in that effort is going to be to look at opportunities outside of our existing core competencies, outside the oral solid dosage forms that Mylan has done so well organically. Our objective is to expand the width of our ability to offer generic products, lower cost pharmaceuticals to the consumer by going outside what Mylan does so well. So that's where we're going to focus our attention.
- As far as the I'm sorry, you had a second question?
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David Maris: Well how much are you looking outside of the US on that effort? And

Robert Coury: David, I've got to tell you, I don't think there should be any limitations to any public company about where it looks. And I can't steer you specifically to anywhere. And to the extent that I feel that I've crossed that threshold, where, you know, we need to disclose any further, certainly I'll be here on this telephone talking to you and the rest of everybody else at the same time.

But I will just tell you that we Mylan has, in the past, looked elsewhere. We have a tremendous amount of, as you know, David, our API relationships, we have approximately 140 plus existing API relationships. As long as that competitive landscape, and as long as the number of API producers that are out there, and the natural competitive forces, to drive the API costs down, we will continue to do business as usual, but also continue to look at innovative ways with the API producers, to again, further enhance our own efficiencies. And so we will be to the extent that we do anything there, it will be, you know, different type of maybe relationships with API. I don't think acquisition of API producers is necessarily how to achieve ultimate efficiency.

Patrick Fitzgerald: Next question, please.

Operator: And we'll take our next question from Michael Tong from Wachovia Securities.

Michael Tong: Hi, Robert. I just want to ask you a little bit about your change in your game plan with respect to authorized generics. And how you see the authorized generic opportunity unfold for Mylan, specifically, what types of product characteristics would you be looking at in order to deem whether an authorized generic opportunity is appropriate for you? And the second question is, isn't a little bit hypocritical when you're trying to stop the authorized generic environment, and at the same time entering it at this late stage in the game.

Robert Coury:

Thank you, Michael. First of all, I will tell you that we, you know, I have said all along when I came into office, as you know, Mylan has done authorized generics prior to me coming into office. And when I studied that whole authorized generic scenario, I've had many discussions internally. And when I think about what I saw at that time, and what I projected looking out into the future, authorized generics did not seem to align themselves with what I understood the rules of engagement to be in the generic pharmaceutical industry.

And so as I explored the various positions taken by the regulatory agencies, I saw nothing but inconsistency in their positions. So I said, wait a minute, you know, here we are as CEO of a public company, we've got to put projections. We've got to put forecasts out there. People are relying on our probability weighting. How can you probability weight, I mean this is all ready a very volatile unpredictable business. And if we need to do our jobs in predicting the future, I should say the next best thing in an unpredictable business is trying to predict the unpredictable for our shareholders, then I certainly want to understand what are the rules of engagement. Is authorized generics legal? Are they not? How should they be accounted for? What are the views of the various regulatory agencies. So from day one, I've come out very strong and, you know, about I need to understand the rules of engagement so that I can do a better job for our shareholders in terms of projecting what Mylan's forecasts are in the future. And that I can be comfortable that the underlying support of those forecasts are intact.

So we proceeded to address the FTC. We proceeded to go down the legislative route. We proceeded we even went through the judicial process. We worked with CMS. We continue to do so to say wait a minute, here are your variant positions. You know, you can't have two regulatory agencies to take two different positions, please tell us what are the rules of engagement in authorized generics, because certainly the way I'm looking at the Hatch Waxman intent and the legislative and the statutory language, I've got to tell you this 180 day exclusivity meant what it meant, a generic, a true generic out there all by itself. And so to allow an

authorized generic or a brand pharmaceutical company to compete during that sacred timeframe that was set aside for the generic companies. And the reward for the generic companies are going after such frivolous patents and otherwise, I will tell you that we felt that the intent of the Hatch Waxman has been violated.

And what the generic what the brand pharmaceutical companies were basically relying on is a technical wording in the statute, because in the statute it doesn't say the word generic, but says the word ANDA. They are using that choice of word ANDA like a generic pharmaceutical industry doesn't even exist. The Hatch Waxman statute says ANDA. They're saying wait a minute, we don't have an ANDA, we have an NDA, and you can't tell us what to do, but yet we all have to we're all operating under these, what I call rules of engagement in this regulatory environment.

So it is not inconsistent. It is not hypocritical. I have been very vocal, very consistent about wanting to understand the rules of engagement.

Now going forward, I can tell you today that at least, as of today, as we stand, we've heard from the FTC, in terms of their current view, although I will tell you the FTC has taken special note about the long-term potential impact that this could mean. And the only country that have a natural balance between generic and brand. We're the only country that doesn't have price controls. You start with the that very natural balance that's all ready in place, you may find yourself down the road, especially with the pressure of healthcare costs, and reducing healthcare costs, not just on the federal level, but on a state level and otherwise, this is not what the intent was for Hatch Waxman. And you upset that balance, it could potentially long term have a negative effect. And what everybody is trying to accomplish, that's reducing healthcare costs. So but at least at present, OK, we have not gotten positions from the courts, from the FDA, from CMS, even though they're still working and the FTC.

So going forward, until such a fix is in place, and we know understand that it is legal, at least, at defined by what we understand today, until there is a fix, if you wanted to come into the generic pharmaceutical space, and if you understand, like we understand, now, that it seems to be OK to do authorized generics, why would you not go to the biggest, baddest, generic distribution house there is in the industry in terms of distributing your product. We have resisted, since I've come into office, to play in that particular arena. It's a low hanging fruit. I mean you cannot build a company's long-term viability on these type of deals. I've called it a fad before, just like hula hoops came in and went out, roller skating comes in and goes out. I think authorized generic is here. I don't think it's here long-term that's just my personal views. I've been very clear. And so while we understand what the rules of engagement are today, we fully intend on doing our part for our shareholders and capturing as much revenue and earnings per share, that we think makes sense, but yes, Michael, we will be extremely selective on which ones we get involved with. Thank you.

Patrick Fitzgerald: Next question, please.

Operator: As a reminder, it is star one for questions. We go next to David Woodburn with Prudential Securities excuse me Prudential Equity Group.

David Woodburn: Hi, thanks for taking my question. First one, with your guidance excluding additional fentanyl transdermals for some time, can you give us some clues or any thought on what's holding up the other approvals?

And then the second one is on unauthorized generics, again, with if the changes in best price calculations do go through, I mean the work that I've done so far on this shows that it would still be profitable for pharma, large pharma to still pursue those? Is that your expectation that they would continue? Or in certain cases, that the best price calculations would be preventive?

Robert Coury:

That's a very good question. I view the CMS fix more as a deterrent. I would say more of a deterrent. And in some instances, until you look at the model, the size of the compound, what you think that market share is going to be, I do believe it would actually stop, probably future authorized generic deals if CMS decides to take that position.

I think on the very, very larger ones, however, even if you calculate for best price purposes, there still maybe a reason why they might continue. So I think it's going to be more product by product. I don't look at what CMS is doing as the ultimate solution for authorized generics. But I do see it as a very substantial deterrent. And I do believe if CMS does take that ultimately position, it does align the regulatory agencies to be more consistent about its views in handling these authorized generics.

And as far as fentanyl is concerned, you know, I don't want to speak for the FDA, but I have been very, very clear about when I was asked a year ago, you know, why do I think Mylan is going to be the only one out there come January? I've been very clear in saying look, I can only go back to, you know, our program that we put before the FDA, the two-and-a-half, three years, that we've spent with the FDA. I did say that I fully expect as Mylan has done in the past, you know, we've helped the FDA understand the first class two transdermal product approved by the FDA, another one of Mylan's first. I did expect that I would at least you know, we would help knock off maybe a year for the next competitor. So I can't really say why the FDA is holding up other generic competitors. But obviously, as I stated in my opening remarks Mylan Technology's capabilities is just second to none. And it's those capabilities that I think that we're going to be able to leverage off of as we go forward for anybody out there that wants to play in the transdermal arena. Again, why would you go to any transdermal platform, although there's not that many other, why not come to the best? And our ability to bring products to market and the speed at which we can, and then manufacture the very large quantities.

Remember, in the transdermal arena, what you succeed in the laboratory, versus what you do when it comes to scale up are two different things, and that's where most people fail? Thank you.

Patrick Fitzgerald: Next question, please.

Operator: And we'll take our next question from Jim Dawson with Buckingham Research Group.

Jim Dawson: Yes, hi. Would Mylan consider launching a generic Ditropan XL at risk if there was no court decision by November of this year of '05?

Robert Coury: Mylan, first of all, that's a -- if we -- we would consider at the appropriate time, whether we launch anything at risk. And I will tell you that we have nothing more to say on that. I've got nothing more to say.

Patrick Fitzgerald: Next question, please.

Operator: We go next to Ken Trbovich with RBC Capital Markets.

Ken Trbovich: I appreciate you taking the questions. Two questions, I guess, on the modeling side just to clarify and a follow up, I guess. In terms of at risk launch, when you discuss the high end of your guidance does it include any at risk launch? And then, the second question with regard to the fentanyl comment regarding margin improvements, is that consistent to both the fiscal '05 and '06 guidance? Or is it just for '06?

Robert Coury: I'm sorry -- well first of all, let me answer the at risk, and then I need to ask again on the fentanyl question.

On the at risk, I mean I think it's very difficult to predict, for any company to predict in advance, whether or not it's going to launch something at risk. I mean you have to study all aspects of the case. You've got to be careful. You've got to study the judge's opinion. You've got to study there's just a tremendous amount of variables before one just sits there and simply launches at risk. And the analysis of launching at risk I truly believe, cannot really be done that far in advanced until you have all of the factors in front of you at the time a decision needs to be made.

So and then on the fentanyl question, what was that question again?

Ken Trbovich: I apologize. During the model discussion, there was mention of the gross margin contribution improving. And part of the explanation for that was because of the fentanyl program. I just wanted to know whether that was consistent in both the fiscal '06, and the fiscal '07 guidance.

Ed Borkowski: Yes, in terms of if a competitor is delayed, there are no other entrants into the market, there would be potential upside for both years, but we did not model it that way.

Patrick Fitzgerald: Next question, please.

Operator: We go next to Rich Silver with Lehman Brothers.

Rich Silver: Yes, my question has been answered, thanks.

Patrick Fitzgerald: Any additional questions?

Operator: We have a few questions remaining, but as a reminder to our participants, it is star one for questions. And we go next to David Maris with Banc of America Securities.

- David Maris: Yes, two follow up questions. First, Robert, Teva claims that they are just through their scale, they're kind of pulling away from the rest of the pack because they're larger than everyone in the US. And that wholesalers are moving towards just dealing with, you know, a smaller group. Do you think that that's true? Do you think that Mylan needs greater scale than where you are? You had mentioned of going into other dosage forms. What might that include? And then, I have a follow up.
- Robert Coury: David, rather than focus and talk about from a proprietary point of view, where our next focus is going to be, and obviously we have a couple of targets. You know, I will tell you that, you know, in terms of your comment about Teva, I would just say this to you. There's growth and then there's controlled growth. And, you know, growth without controlled growth can be a very dangerous thing. I will tell you that we are, you know, we watch our peers. We study our peers. We understand our peers implicitly. But what our peers do is what our peers do. And how they drive their business and their model is solely dependent upon their views and what they see. Saying that, I will tell you that our focus on growth will be a in very controlled way, and striking a strong balance between what our shareholders demand from us in terms of the delivery of earnings per share, and the growth there of, versus our ability to maintain, versus the strategic importance of our ability to maintaining our leading market position in many of the markets out there.
- Your second question.
- David Maris: You also mentioned that looking at different business combinations I mean during this whole process has Mylan been approached by other companies, and you've just found the combinations not to be attractive, or have there just not been any suitors?
- Robert Coury: You know, David, those discussions, first of all, are at the board level. And again I'm well aware of the many thresholds that we need to cross before I would ever come public with
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any of those discussions. You just have to know that again there's the acquirers, and then there's acquired. And I don't think Mylan has really ever been on the you know, Mylan has always been focused on being an acquirer.

At the same time I have to tell you that, you know, we are as Vice Chairman of the Board and only one member of 11 Board members, you know, these discussions are really held at those levels and this is a management conference call, not a Board of Directors call.

Patrick Fitzgerald: Next question, please.

Operator: We'll go next to Ivan Krsticevic with Elliot Associates.

Ivan Krsticevic: Yes, hi I have a couple of questions. Could you give us a little bit more color on the timing of the NDA filing for Nebivolol congestive heart failure? And the timing of the likely approval that you expect?

Robert Coury: I'm sorry can you please repeat that? I'm sorry.

Ivan Krsticevic: Yes, sure, no problem. With respect to the congestive heart failure (location) of Nebivolol can you give us a little bit more color on when do you expect to file an NDA? And in turn, when do you expect a likely approval?

John O'Donnell: The typical review times for the agency are 10 months to 12 months. And we would anticipate being in a position early next year to file the NDA for heart failure.

Ivan Krsticevic: And what is left at this point before that you need to do before you can file an NDA?

John O'Donnell: We're not going to comment on that at this time.

- Ivan Krsticevic: And I guess the other question I have relates to Mr. Icahn's offer. Given that he owns 10 percent of stock, is your largest shareholder, given his net worth is likely greater than the value of Mylan, the entire capitalization of Mylan stock, that he's willing to sign a standstill agreement, I'm just wondering why is it that the Board has taken the view that his offer is not a serious one? And that it has been at a meaningful premium to where the stock has been trading over the last six months?
- Robert Coury: Again, I think this is a management call. I'm glad that you've recited those impressive financial metrics, but I don't know how many companies you've bought or how you've gone over how many companies you've gone after, but I can only say that we've never considered you know, we've looked at what we call Mr. Icahn's proposal. There is nothing in that proposal that is clear to us, that is definitive, and I will leave it at that. Thank you.
- Patrick Fitzgerald: Next question, please.
- Operator: And our final question will come from Gregg Gilbert with Merrill Lynch.
- Gregg Gilbert: Thanks. A question for Ed, following today's announcements, financially speaking, how flexible will Mylan be to participate in M&A in terms of making acquisitions? And a question for John on transdermals, have you noticed any change in FDA's attitude towards generic transdermal products over the past six to nine months?
- Ed Borkowski: Obviously, with adding to debt, we do we still have capacity to look at acquisitions both from using equity and other means to finance them when appropriate if we do identify an opportunity that is appropriate for us to go after. So we believe we still have flexibility going forward. And we think it's a well balanced, efficiently managed efficiently capitalized structure at this time.
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John O Donnell: And we've not seen any changes from FDA in the last several months.

Patrick Fitzgerald: Well thank you everyone for participating today. And we look forward to updating you on our next conference call. Thank you.

Operator: That does conclude today's teleconference. Again, thank you for your participation. You may disconnect at this time.

END