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Q1 2005 Align Technology Earnings Conference Call

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## PRESENTATION

### Operator

Greetings, ladies and gentlemen. Thank you for standing by and welcome to Align Technology's Q1 2005 Financial Results Conference Call. [Operator Instructions]

It is now my pleasure to introduce Barbara Domingo, Director of Investor Relations. Ma'am, you may begin.

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### **Barbara Domingo** *Align Technology - Director Investor Relations*

Okay, thanks, Megan and welcome to everyone on the line. If you haven't received a copy of our press release, please go to the IR section on our website at [www.investor.aligntech.com](http://www.investor.aligntech.com).

Before we start the call today, I'd like to make some comments on forward-looking statements. During this conference call, we may make forward-looking statements relating to Align's expectations about future events, products and its future results. Including statements regarding expected financial results for FY05. Any forward-looking statements we make during this conference call are based upon information available to Align as of the date hereof. Listeners are cautioned that these forward-looking statements are only predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict. As a result, actual results may differ materially and adversely from those expressed in any forward-looking statements.

Factors that might cause such a difference includes, but are not limited to, risks that are detailed from time to time in Align's periodic reports filed with the SEC, including, but not limited to, its Annual Report on Form 10-K for the fiscal year ended December 31, 2004, which was filed with the SEC on March 3, 2005, and its Quarterly Reports on Form 10-Q. Align undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

Please also note that on this conference call we will provide listeners with several financial metrics determined on a non-GAAP basis for comparisons to previous quarters. Most of these items, together with the corresponding GAAP numbers and a reconciliation to the comparable GAAP financial measures where practicable, are contained in today's financial results press release, which we have posted on our website at [www.investor.aligntech.com](http://www.investor.aligntech.com) under Financial Releases and have furnished to the SEC on Form 8-K. We encourage listeners to review these items.

Additionally, we have posted a 9-quarter GAAP and non-GAAP revenue model on our website at [www.investor.aligntech.com](http://www.investor.aligntech.com), under "Historical Financial Data". Please refer to both these downloadable Excel spreadsheets for a more detailed line item information.

Today we're changing the format of the call slightly in order to give you an update on the OrthoClear litigation. Tom will start with our metrics and our Q1 accomplishments. He'll also speak to our long-term prospects. Roger George, our General Counsel, will then speak about the OrthoClear litigation. Lastly, Eldon will speak to financials and guidance. All will be available for Q&A.

With that said, I'd like to introduce Align Technology's President and CEO, Tom Prescott. Tom?



**Tom Prescott Align Technology - President and CEO**

Thank you, Barbara and welcome to everybody on the call today and on the web.

We're very pleased with the solid progress made in Q1. This visible improvement in operating results, coupled with our internal focus on key strategic programs, gives us confidence that we are on the right track to build a company that can sustain growth over the long-term. That said, while we are pleased with this progress, we are far from satisfied; there's still a lot of work to do.

We reported our best quarter ever, with \$51.2 million in revenue, a sequential increase of over 17% from last quarter. We reported EPS of \$0.03. In both cases, we exceeded our own guidance and the Street consensus. Underlying this performance improvement is the belief that many of the issues we encountered in the second half of 2004 have been, or are being, addressed.

Let me start with a few key growth metrics.

On the revenue line, both the orthodontist and GP dentist channel revenues and cases continued to increase. We saw a sequential increase among orthodontists of 18.2% to \$23.3 million. GP revenues sequentially increased 22.2% to \$20.7 million. Overall, 45% of total revenues came from U.S. orthodontists.

We shipped 29,300 cases worldwide to customers this quarter, an increase of 11% over the previous quarter. Q1 utilization for U.S. orthodontists was 4.45, for GP dentists was 2.38 and for international was 2.41. Utilization in all of our channels increased sequentially. We've posted these numbers, along with ASPs, on the Investor Relations site under "Historical Financial Data".

I'd also like to share some volume and channel statistics with you. An increasing number of doctors have submitted cases to us, and in the last quarter, 10,100 doctors worldwide started new cases. Over 1,100 doctors sent in cases for the very first time last quarter. The number of orthodontists submitting cases was 4,300 and 5,800 GP dentists submitted cases.

Additionally, we trained and certified almost 800 new GP's in the U.S. during the first quarter, bringing our base of certified GP's in North America to 14,600. Out of the nearly 31,000 doctors trained worldwide, 19,300 doctors have started at least one case and 16,000, or 83% of those, have generated multiple cases. Our base of doctors continues to grow and we believe that as the Invisalign System continues to improve more doctors will see the value of integrating this treatment into their practice.

Let's move on to some key accomplishments in this quarter.

One of our key strategic initiatives is to redesign and implement an entirely new consumer strategy. This entails an evolution in our demand creation model and encompasses a completely new campaign, including "New Creative", a fresh media approach targeted at lead generation and the beginning of a real branding effort, a completely new website integrated with the New Creative approach and a focused PR effort.

All of this is supported by extensive consumer and customer surveys and market research completed last fall. This is a very large effort and we have previously discussed a Q3 launch. In fact, our marketed team, our web development team, and our external partners have done a great job and we now expect to launch this integrated campaign by late May.

Phase one of the new website was launched on April 4th. The new consumer website at [www.invisalign.com](http://www.invisalign.com) has a new look and feel, including an enhanced doctor locator capability that designates premier providers, roughly those doctors that make up the top 5.0% of case starts.

Prospective patients have consistently requested that in addition to geographic proximity of Invisalign providers, we help them identify those practices with the most experienced clinicians. As we launch our new consumer campaign next month, we will integrate much of the New Creative content in this redesigned website.



Also included in the scope of that redesign was a new corporate website at [www.aligntech.com](http://www.aligntech.com). This site is now the center for Company information, including a section on current clinical studies, press releases, employment information, and a new Investor Relations area.

As far as media is concerned, the new consumer campaign will consist of 30- and 60-second TV spots targeted at cable and some network placements, as defined by consumer segmentation and demographics. The campaign will also include some radio and print media. It will be further supported by a PR strategy.

As you may recall, our current consumer strategy is primarily a direct response approach designed to create interest and drive potential consumers to a call center. Our new strategy will be designed to provide more motivation and less product-focused education and to compel prospective patients to visit our new website.

Virtually all patients in treatment have told us that website was where they received most of the information they needed to make a decision about treatment and about which clinicians they were interested in meeting. The new website has been redesigned to make that process more intuitive.

As described in an earlier call, though our media spending will roughly double year-over-year, our overall consumer spending will be up much less sharply - more like 40 to 50%. This is due to the new strategy and the decreased reliance on a call center.

We believe this new campaign will create interest and excitement in the market and among our consumers. While we are very pleased that we are launching a quarter earlier, we do want to point out that we expect much of this interest to convert to potential case starts late in 2005 and into 2006.

We are making real progress on other key strategic initiatives to ensure an improved customer experience, to enhance and expand our offerings, and to improve our clinical support and education.

Within the next two to three months, we will release the next version of ClinCheck software. This will include an integrated IPR, or Interproximal Reduction, along with comments area, a treatment planning wizard, an improved, more intuitive interface, automatic software maintenance and the ability to translate the treatment operator's comments to a clinician's local language. These are all-important features that we and our customers are looking forward to.

We are following a detailed product and systems roadmap, generally that we've described as "Invisalign 2.0", and are committed to delivering above our customers' expectations.

Also, in the new product area, we initiated a pilot for a new offering called "Invisalign Seven". Seven is the name for a new value-based product, a seven-stage aligner system to be used in treating simple cases. The pilot is running in three geographic areas - Georgia, Michigan, and Canada - and is designed to test different configurations, options, and flexibility.

The test price is \$775. It includes free case setups and is targeted to anterior treatment only, the front teeth. Although we are only a month into the pilot, feedback thus far has been great. There is substantial interest in this offering and we will update you on our progress in future calls. Ultimately, we expect a whole commercial launch for Seven in early 2006.

As part of the path towards Invisalign 2.0, there are a few programs like the bracket positioning template, compliance indicator, and next generation materials we have discussed previously. Each program is tracking well and will contribute to more predictable treatments, a full range of cases, and improved performance. We will provide more visibility when there are specifics to discuss.

Over the past few years we have consistently defined clinical education and support as a key element in our extended product offering, an essential factor in Invisalign adoption. During Q1, we made several significant steps to enhance the quality and mode of delivering education and support.

Early in Q1 we brought in Dr. Ray McLendon, a very experienced Invisalign orthodontist and prior member of our extended training staff,



to lead clinical education and support. He will incorporate best clinical practices as gleaned from our most experienced clinicians.

As part of these enhancements, we modified our certification criteria and the programs around that, beginning in March. A doctor is now considered certified when they have completed the certification class and submitted four cases through our new Invisalign Consulting Services, or ICS. ICS evolved from the acquisition of General Orthodontics in January. By gaining firsthand experience shortly after certification, a doctor develops a better understanding of the Invisalign technique and the cases they can treat more immediately.

Through ICS, we can now provide consulting services directly and easily connect a newly certified doctor with an orthodontist experienced with using the Invisalign technique. These consulting services can range from case evaluation to more comprehensive service. Consulting orthodontists are not expected to do the setup or treatment. Rather, they will help guide the newly certified doctor through the process of diagnosis, treatment planning and case management.

The fee for Invisalign certification now includes eight case evaluations and four comprehensive case services through ICS. The goal is to ensure a successful start and complete the international learning cycle within a short time after certification.

Beyond these improvements, during the first quarter we delivered over 50 clinical education events to our customer base. Dr. Lou Shuman originally helped create the existing clinical support approach, as well as build relationships with university dental and orthodontic programs. This latter activity has become even more important as we work to gain widespread adoption.

Since January, Lou has been focused solely on these strategic relationships, with the goal of getting Invisalign integrated into the curriculums of all major schools. We've made great progress and as more universities and related partners like the Panke Institute integrate Invisalign, we will keep you posted.

Let me mention a couple of important upcoming events before I turn to a brief status update on our North American sales group.

In early May, we will host the first Invisalign summit for GP dentists in Las Vegas. This first GP summit is modeled after the highly successful ortho summits and is filled with intensive workshops on Invisalign fundamentals, case reviews, the technology behind Invisalign, and tips and techniques for treating patients with Invisalign. We've signed up over 300 practices, combining nearly 1,000 doctors and staff and we expect an event that is certain to increase doctors' knowledge of Invisalign.

At the end of May, Invisalign will participate in the annual AAO conference in San Francisco. This is a yearly event attended by orthodontists from around the world. We will have a large booth with a focus on clinical education, product innovation, and a case gallery. Additionally, six very experienced Invisalign orthodontists will deliver presentations during sessions on different aspects of Invisalign treatment, from staff involvement to use of attachments to treating moderate-to-severe crowding, and treating Class II and III cases. This will be part of a new section titled "Removable Appliances".

This really represents industry progress, as several years ago no presentations on Invisalign were even allowed or permitted. While these major events cut into weekly case volumes by taking doctors out of their practices, we do consistently see practice expansion following each summit or major tradeshow.

Turning now to sales force.

As you know, a new competitor came to the market and tried to recruit our ortho sales force. We described this in some detail during a special conference call we held in February to discuss the litigation. In total, 14 Align sales reps left to join OrthoClear, most of them among the original group, which came to Align with our former VP of Sales. A few other sales reps departed for other reasons.

Additionally, the individual I brought into lead worldwide sales, Bob Mitchell, resigned to be CEO of a startup company in the interventional cardiology field, his first love.

I guess at some level, all this is a compliment. You want this kind of [tint] on your organization that everybody else wants. That said, this



was fairly disruptive and we are still working through filling those roles, along with the challenge of expanding the field team as we originally planned.

So just to give you some numbers around this, at the end of December, 2004 we had 34 ortho reps and 52 GP reps. In all those numbers, I refer only to sales reps that carried quotas. At the end of March 2005, our ortho sales rep headcount was down to 22. This includes the 14 that joined OrthoClear and a few others that departed for other reasons, as well as netting out the hiring of 6 ortho reps in the quarter and the promotion of a few of the reps.

We believe we are squarely on track to rebuild the ortho team. In a moment I'll let you know about how we're going about reestablishing that coverage.

On the GP side, we ended March with 58 GP reps, well on track to add 15 more GP reps in the first half of 2005. We currently have a full-scale program underway to recruit, train, and deploy more sales reps this year. We expect to have just over 100 total sales reps in the field by the end of the year. We have a very clear recruiting profile. We have a high impact process to onboard these new reps, getting them trained, connecting them with mentors in the sales team, and getting them deployed out in front of customers.

There are a number of new sales reps and a few sales managers in this development pipeline that will be deployed in the next month or so. We are seeing outstanding talent. I know this because I get to meet with each of the new training classes and I continue to be impressed at the caliber of people who join our team.

In the interim, we have had ortho reps covering multiple territories, GP reps and sales managers helping out, and customer support trying to fill gaps. These temporary measures have been put in place due to a tremendous effort by the Align team and some patience on the part of our customers. Many customers want and need better coverage and we expect to give it to them.

I am convinced that we will end this year with an even stronger sales force than when we began. So the leadership of this team is key. We are well along in our search process and are evaluating some very strong sales leaders for the VP role to take this organization to the next level. I'm looking forward to getting that important hire completed.

We continue to make real progress in every area of the Company. We brought in a world class R&D leader, Rok Sribar, to compliment the strong senior management team in place. During Q1, this team continued to lead the execution of a winning strategy. We are all committed to building Align into a great company.

This brings me back to OrthoClear. When we first became aware of their efforts to harm our Company, we were a bit reactive. We had to retain and then stabilize the sales force. We had to reassure customers, employees, and shareholders that Align's bright future was undiminished. I detest the stunning lack of integrity demonstrated by a number of individuals and hate how OrthoClear came to be.

All that said, Invisalign's a great product and getting better. Align is a terrific Company and getting stronger every day. I knew when I came here in 2002, that with the size of this market we would face competition at some point. Well, it would appear that now we have it and while we hate to spend money on the lawyers that we would rather invest in programs or drive to the bottom line, we were actually becoming energized as an organization.

We have a great product with real consumer pull and the potential to become an important brand. We have over 1,000 committed employees, totally focused on great customer satisfaction. We have an entire technology pipeline that will improve quality, reduce costs, enhance the user experience, and revolutionize orthodontic treatment.

We will be a very tough competitor in the marketplace, with first-mover advantages and far greater leverage than a new entrant. We will be a very tough competitor in court, where we will seek all remedies within the law. This market is very large. We believe competition will actually accelerate growth through delivery of better value to doctors and consumers.

We intent to grow this market and act as a leader. Someday - not today, but at some point - we'll look back at these times as challenges



that turned into opportunities. Align is ready for this competition and although we know the immediate path ahead may not be smooth, we are very committed to building the kind of Company that our shareholders, our customers, and our employees will be proud of.

Since I've been discussing OrthoClear, I'd like Roger George, our VP of Legal and Corporate Affairs and General Counsel, to provide an update on the litigation. Roger?

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**Roger George *Align Technology - VP of Legal & Corporate Affairs & General Counsel***

Thanks, Tom.

Let me start by saying that as we're in the midst of litigation with OrthoClear, there are many things that we cannot say about the litigation itself. I will attempt to give you as much clarity as possible about where we are in the lawsuit now, but please understand that there are many things we simply cannot discuss. As you know, the latest ruling from the court was a stipulated preliminary injunction. The ruling itself is posted on the IR website and I urge you all to read it.

In layman's terms, the three most important elements are i) that Align cannot disparage Muhammad Ziaullah Chishti and Mr. Chishti cannot disparage Align; ii) OrthoClear cannot solicit Align employees; and iii) OrthoClear cannot use Align trade secrets or proprietary information to develop, launch, or market their product.

The first element is pretty self-explanatory and results from a mutual contractual provision in Mr. Chishti's separation agreement.

With regard to second element - solicitation - the injunction entered by the court preventing OrthoClear from soliciting Align employees has been very effective and we have not had any additional employees leave Align to work for OrthoClear. Although recently we had some interested in going in the other direction.

The third element, preventing OrthoClear from using Align's trade secrets and proprietary information, is very important, but must be viewed in the context of the timing of any OrthoClear product launch. We believe and allege that OrthoClear's management team has used information gained as a result of their employment with Align.

Since the OrthoClear product has not yet been released, we do not know, at this point, precisely what Align trade secrets and proprietary information were used in its development. When and if the product becomes available, we will then be able to seek further relief from the court, including preventing OrthoClear from continuing to develop or market any product that was developed using Align's trade secrets or proprietary information.

We are pleased with the judicial process and results thus far. It is important to understand that the court has granted all of the relief Align has requested in the TRO and preliminary injunction proceedings. We are ready and poised to act as soon as we have the ability to analyze the OrthoClear product, if and when it is released.

Where are we today? We have begun the formal discovery process with OrthoClear. The parties will first negotiate a mutual protective order, then exchange documents and other writing information, and then proceed with depositions of the parties and witnesses. This process will take many months and the depositions will probably not start until late summer.

Many people ask why we have not commenced a patent infringement lawsuit. Given that the OrthoClear product is not yet released, patent litigation would be premature. While we anticipate that the OrthoClear product will implicate Align's patents, we will have to wait to evaluate those issues until the product is released.

Many of you on the call are wondering what we know about OrthoClear. Because we are a public Company, we are fortunate to have independent analysts who have taken additional steps and conducted some due diligence regarding OrthoClear.

Through these and other networks, we have heard or know the following --



OrthoClear has delayed launching their product. We have heard that this delay is due to some software glitches that they're experiencing. They have a website, listing doctors to contact regarding OrthoClear. A number of doctors originally listed on the website are no longer listed and we have heard from some doctors listed on OrthoClear's website that they did not provide permission for their names to be there.

According to filings, OrthoClear has made with the FDA it seems that the product is manufactured in Pakistan. W

e believe that OrthoClear may be working with a few doctors now in a beta type mode and that these doctors may have seen a product. No one at Align has seen a product.

We understand that their initial launch will be offered to a small group of doctors, with a commercial launch planned for later this summer.

We have heard that they have raised less money than initially thought. They have asked doctors to invest in their company and while some did, many others didn't and many of these doctors have provided us with information concerning that financing. It also seems as if money is being raised offshore.

We have heard that OrthoClear will have a presence at the AAO conference in May.

And finally, we have heard from some doctors that the OrthoClear sales reps have repeatedly canceled meetings with them intended to demo their product, have not rescheduled and have not given an explanation as to why they are canceling.

The discovery process and actual release of the product will provide valuable information regarding the extent of OrthoClear's and its employees' unlawful conduct. Until then, we will continue to investigate and pursue any violations of the injunction entered by the court restricting OrthoClear's activities, as well as any additional unlawful business practices engaged in by OrthoClear.

I'll turn the call over to Eldon now. Eldon?

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**Eldon Bullington *Align Technology - VP Finance and CFO***

Thanks, Roger.

As a quick reminder, our first quarter press release and 8-K filing of the same document are available on our website.

Q1 revenues, as Tom mentioned, were \$51.2 million, up 17.2% from last quarter and 30.5% from the same period a year ago. First quarter revenues by channel were \$23.3 million for U.S. ortho, \$20.7 million for U.S. GP, and \$5.2 million for international. These channels represent 46%, 40%, and 10% of revenues respectively. Worldwide training and other revenues were \$2.0 million.

Gross profit for the first quarter of 2005 was \$35.7 million or 69.7%, compared to \$28.7 million or 65.7% last quarter. This also compares to a gross profit of \$25.8 million or 65.8% for the first quarter of 2004. There was no stock-based compensation included in Q1 costs of revenues. For comparison purposes, non-GAAP gross margin, which excludes stock-based compensation, was 65.8% last quarter and 66.9% last year.

We continue to see improvements in our manufacturing line and fixed cost absorption associated with higher volumes. Operating expenses were \$33.5 million for the first quarter of FY05. This compares to \$28 million last quarter and \$24.9 million for the same quarter one year ago. OpEx includes only \$12,000 of stock-based compensation expense. Going forward, we no longer have stock-based compensation to expense.

For comparison purposes, non-GAAP OpEx, which excludes stock-based compensation, last quarter was \$27.9 million and for the same quarter last year it was \$23.1 million. OpEx for the first quarter reflect the sales, marketing, and R&D initiatives we have previously discussed, as well as legal and forensic costs for the OrthoClear litigation.





Net profit for the first quarter was \$1.9 million or \$0.03 per share, compared to a net profit of \$1.1 million or \$0.02 per share last quarter, and \$557,000 or \$0.01 per share in the same period one year ago. For comparison purposes, non-GAAP net profit last quarter was \$1.3 million or \$0.02 per share and for last year it was \$2.8 million or \$0.04 per share.

Again, a full GAAP and non-GAAP income statement and a reconciliation of GAAP to non-GAAP financials is available in our press release and on our website.

Now, on the balance sheet --

Cash, cash equivalents, and marketable securities at the end of Q1 of 2005 was \$69.5 million, compared to \$70 million at the end of 2004.

Our DSO were approximately 56 days, still below our standard terms in the U.S. of net 60 days.

Now I'll spend just a few minutes on the second quarter and speak about our full year 2005 guidance. We expect Q2 revenues to be in the range of \$53 to \$55 million, reflecting an increase of approximately \$2.0 to \$4.0 million for Q1 revenues.

Ortho channel, GP channel and international are expected to comprise approximately 44%, 42%, and 10% of Q2 revenues respectively. The remaining 4.0% approximates training and ancillary product revenues.

Case shipment volumes are projected to be in the range of 30,500 to 31,500 cases. Our Q2 revenues reflect blended ASPs of approximately in the range of \$1,650 to \$1,660 per case.

Q2 gross margins are projected to be in the 70 to 71% range, reflecting greater fixed cost absorption.

Operating expenses are projected to be in the \$37 to \$38 million range for Q2.

As Tom mentioned, we expect to continue with our plans to develop the Invisalign System and make Invisalign the best product for our doctors. This guidance also reflects OrthoClear-related expenses, including legal fees, forensic work, and sales force guarantees.

GAAP net profit is projected to be in the range of break-even to a profit of \$1.0 million or EPS of \$0.00 to \$0.02.

Let me turn to guidance for full year 2005 --

As Roger mentioned, we have heard that there's a delay in OrthoClear launching their product and they may not launch commercially until later this summer. Because of this, we're able to provide full year guidance based on the knowledge we have in our business today. Should an OrthoClear product launch impact Align's business at any point, we will likely revisit guidance at that time.

With that said, we're reiterating previously stated revenue guidance of \$210 to \$230 million, an increase of 22 to 33% over 2004. Channel breakdown is estimated to be 44% for U.S. ortho, 44% for U.S. GP, and 8.0% for international, of total 2005 revenues, with the remaining 4.0% approximating training and ancillary revenues.

Case volume for the full year is projected to be in the range of 120,000 to 135,000 cases. Full year GAAP gross margin is projected to be between 70 to 72%.

Full year OpEx guidance is expected to be in the range of \$145 to \$152 million. The full year 2005 OpEx guidance does not fundamentally change from previous guidance given in January 2005, but now includes the incremental \$10 to \$12 million for OrthoClear-related expenses that we discussed in March of 2005.



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Net profit, therefore, is expected to be in the range of \$3.0 to \$12 million. Our effective tax rate for 2004 continues to be approximately 10%.

Additionally, EPS for full year 2005 is expected to be in the range of \$0.05 to \$0.18. Our previous guidance, without the OrthoClear litigation, was an EPS range of \$0.15 to \$0.33.

Note also that we have only provided GAAP guidance. With the just-announced ruling by the SEC that we will not have to expenses stock options in the latter half of this year, we will only provide GAAP guidance this year.

Let me move on to the balance sheet projections for 2005 --

We estimate our cash balances at year-end to a range of \$65 to \$70 million.

DSOs are expected to average in the mid-50's.

We project CapEx in the range of \$19 to \$21 million for the year.

D&A is expected to be in the \$10 to \$12 million range for full year 2005.

We'll now go to the operator for Q&A. Operator?

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### QUESTIONS AND ANSWERS

#### **Operator**

Thank you, sir. [Operator Instructions]

Our first question, Tao Levy, Deutsche Bank Securities.

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#### **Tao Levy Deutsche Bank Securities - Analyst**

Good morning, every, just a couple quick questions. If I understand your comments, Tom, regarding certain new doctors that are going to get certified, they'll have to go through the training and then do four cases before they're officially certified. Is that correct?

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#### **Tom Prescott Align Technology - President and CEO**

That's correct.

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#### **Tao Levy Deutsche Bank Securities - Analyst**

What about the dentists or orthodontists that have previously been certified but have not submitted a case? Are they going to be de-certified or is there going to be added pressure for them to start submitting cases?

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#### **Tom Prescott Align Technology - President and CEO**

No, Tao, the way I would think about this is continuous improvement. As we continue to ask doctors, as they go through the process of initiating working with Invisalign, one of the things that they say is that they want to get through that cycle of four to five to six cases as quickly as they can. With as complete a possible support infrastructure as they can, shortly after certification. This is based on their feedback.

And so, actually, with bringing general orthodontics in now what we call ICS, we actually have an ability to kind of wrap around them and help facilitate that more quickly. Imagine that they had a best friend who was an orthodontist who could coach them through some simple cases. That's what we're effectively doing. We are not reaching back and applying that same standard to other doctors, but we are reaching out to those doctors that may not have had such an easy start.

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**Tao Levy Deutsche Bank Securities - Analyst**

Okay, perfect. And you know it's good to hear that you haven't lost any more people voluntarily to OrthoClear, but I was intrigued by your comments about people, or salespeople that you've lost, interested in coming back. I was wondering if you could maybe go into that a little bit?

**Tom Prescott Align Technology - President and CEO**

I'll let Roger speak to any of the OrthoClear issues.

**Roger George Align Technology - VP of Legal & Corporate Affairs & General Counsel**

Well and I'll speak to it by saying no. I can't really comment much more, Tao - and I'm sorry - beyond what I said in my presentation earlier. We are aware that there are people who have demonstrated real interest in coming back.

**Tao Levy Deutsche Bank Securities - Analyst**

Okay. And then, since I have you on the line, on the Ormco litigation, what's the status there? My understanding is you're going for an injunction. If in fact you get that injunction, will that prevent Red, White & Blue from being on the marketplace?

**Roger George Align Technology - VP of Legal & Corporate Affairs & General Counsel**

In theory. However, the injunction that is currently before the judge is accompanied by a filing from Ormco asking for an immediate stay from the injunction, should the injunction be issued, because Ormco alleges that they have come up with a workaround of the patent claims that they currently infringe. So there has to be deliberation by the judge and we obviously have to look into it, too, to see if there are on additional infringement claims.

**Tao Levy Deutsche Bank Securities - Analyst**

Perfect, great. Thanks a lot.

**Roger George Align Technology - VP of Legal & Corporate Affairs & General Counsel**

You're welcome.

**Operator**

Raj Denhoy of Piper Jaffray & Co.

**Raj Denhoy Piper Jaffray & Co. - Analyst**

Great. Thank you very much. I'd like to just ask you a question about the guidance. You did it on \$52 million here in the quarter and you're guiding towards \$53 to \$55 million next quarter and you didn't--those are both, I think, two very good quarters and you didn't really raise your overall guidance. At this point, are you factoring in some revenue hits eventually from OrthoClear?

**Eldon Bullington Align Technology - VP Finance and CFO**

Tao, actually we did just over--

**Tom Prescott Align Technology - President and CEO**

Raj.

**Eldon Bullington Align Technology - VP Finance and CFO**

Oh, I'm sorry, Raj. We did just over \$51 million in the first quarter, going to a range of guidance of \$53 to \$55 million. We really haven't skewed our numbers for any unusual factors in the business, other than our view of where we're at and where we're going and as I mentioned on the call that if any other factor affect our view we will certainly refresh our guidance accordingly.

**Raj Denhoy Piper Jaffray & Co. - Analyst**

Okay. So, at this point, I mean, you really haven't--I guess to cut to the chase, you haven't really factored in any potential revenue loss from them?



**Eldon Bullington *Align Technology - VP Finance and CFO***

Fair enough.

**Raj Denhoy *Piper Jaffray & Co. - Analyst***

Okay. I just wanted to make--

**Tom Prescott *Align Technology - President and CEO***

I think--yes. Raj, I think what Eldon said earlier was if and when we do see the product and it has implications for what's going on in our revenue ramp. We're going to come back and comment on that. But at this point in time, we're trying to build the business consistent with our game plan.

**Raj Denhoy *Piper Jaffray & Co. - Analyst***

That's perfectly fair and then, I guess on the ortho utilization in the quarter, I think it was nice to see that trend up as well, and I was curious if you could comment maybe on what was driving that. Did you see your referrals to orthodontists increase or was there maybe just a general uptick there? Was there something that you can kind of point to?

**Tom Prescott *Align Technology - President and CEO***

Well, again, there's a couple things that went on last quarter that made it look worse than it probably was.

One of those was we did drop -- and I want to be careful with my numbers. Barbara can help. We did drop, I think, several hundred orthodontists into the pool of new orthos and it's kind of the number of doctors that are doing a pretty static number and even 100 doctors more can change it slightly on a small base. The second thing that was going on, it was a down quarter for them in terms of leads, in terms of their productivity and so those things all stack up.

I think what I'd say this quarter is not racy but headed the right direction and certainly positive, from our perspective, since were scratching and clawing to cover all these important customers and we literally had half the territories not formally covered. So, I think our opportunity is to provide them with great coverage, help them grow their business, launch the new marketing programs, create some excitement and continue to see that grow. But we have a lot of work to do.

**Raj Denhoy *Piper Jaffray & Co. - Analyst***

Okay, just one last question. I notices the orthodontist channels, well the average price per case or revenue per case ticked up to about \$1,725 and I was curious. Was that a price increase or was that for the utilization of the full arch case or maybe you could explain that a little bit?

**Eldon Bullington *Align Technology - VP Finance and CFO***

Raj, there was a little bit of price in there, as you evolve from the fourth quarter to the first quarter. Also be careful that, as we talked about on our last call that we did have an adjustment in the window of our case refinements, which was about \$1.9 million worth of revenue.

**Raj Denhoy *Piper Jaffray & Co. - Analyst***

Right.

**Eldon Bullington *Align Technology - VP Finance and CFO***

But setting all of that aside, we did have a small price action during the fourth quarter and basically those cases started flowing through the business early in the first quarter. So there's a little bit of price impact in there in the U.S.

Also, if you look at our price chart you'll probably see international drop just a tad and that was a result of in the fourth quarter of last year, that in Europe we did a promotion to spur volume in that business. And if doctors participated at a particular level they could enjoy a volume-driven discount in the first quarter of this year. So you'll see the international ASPs drop a bit sequential and that'll probably persist through a good part of the year.



**Raj Denhoy Piper Jaffray & Co. - Analyst**

Okay, very good, thanks, nice quarter.

**Eldon Bullington Align Technology - VP Finance and CFO**

You bet. Thank you.

**Operator**

Ryan Rauch with Jefferies & Co.

**Ryan Rauch Jefferies & Co. - Analyst**

Good morning, congratulations on a great quarter.

**Tom Prescott Align Technology - President and CEO**

Thanks, Ryan.

**Ryan Rauch Jefferies & Co. - Analyst**

Just a handful of quick questions. Maybe Tom, can you start out and give any insight where you stand on the potential for a GP strategic alliance and the potential for a Japanese strategic alliance? I know you typically at least indicate you're moving forward on these types of calls, but can you just give us a quick overview there?

**Tom Prescott Align Technology - President and CEO**

Let me start with GP, first of all. We've said for really the last year, year and a half, that at some point in time, as we continue to scale this team, as we continue to train lots of GP doctors, it would likely make sense to find the right partners.

Now who the right partners and how you decide to do the work in the channel, those are all things that those are very significant choices. So what I would say is we're interested in thinking about that. We are not close to doing anything formally and I think just it's an opportunity that we're going to continue to evaluate.

On the Japanese side, again I left that out of my prepared comments a little bit because we had so much other information to talk about and it's not a near-term revenue opportunity. We actually just had the first ever symposium, Invisalign symposium in Japan, on Saturday and Sunday. On Sunday, actually, last week - it was just a couple days ago, actually - I was there and we had probably 250 of the most influential Japanese orthodontists. Very, very interest, spending all day hearing presentations by Japanese and American experienced orthodontists.

So, I think the way I'd think about this is our approach to Japan all along has been to take a very thoughtful, deliberate approach. And if you look back to some of the missteps that Align took as it entered the U.S. market, we did not gain the support of U.S. orthodontists, the specialists that were kind of gatekeepers at the time of new technology. And as a result, we've had to work uphill over some number of years to get back in their good grace.

We're trying to do just the opposite in Japan and we do have a small core team on the ground there, four or five people that have been working very hard with advisors and I've had multiple meetings over there. We've had very experienced doctors from Europe and the U.S. teaching some Japanese doctors. They've got cases they've started, they're developing their own clinical results and at the same time, with building a small core team, Align Japan, we've been working very hard to put together, to assess, who would be an ideal joint venture partner and when would you want to commence that.

We continue to do that. Our focus here is moving the business forward in a very logical way. We probably wouldn't move to any large-scale commercialization push without a joint venture partner at least lined up. But we are going to move forward, likely late this year and start initial certifications.

So, again, the idea will be to start with a core group of important influential Japanese doctors, helping them gain experience and really,



this is really a 3- to 5-year opportunity. This is not something that's going to provide meaningful impact on the top line near-term. In fact, it's going to cost us a little money. But I think Japan could wind up being an incredibly important market for us and very valuable for this enterprise for the long-term.

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**Ryan Rauch Jefferies & Co. - Analyst**

Okay, great and then Eldon, just a handful of housekeeping issues. On the fourth call you indicated you expected to end the first quarter with \$60 to \$63 million in cash and you ended with \$69.5 million. Clearly that has to be driven some by the strength of the quarter. But is there anything else going on there from a cash flow perspective and then what did you generate in cash flow in the quarter?

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**Eldon Bullington Align Technology - VP Finance and CFO**

Well, first off, we did a little bit better on our cash collections, which we've always had a solid accounts receivable profile. We did a little bit better and as far as some of our capital expenditures and timing, there was just a little bit of a timing issue between the first and what we'll do in the second quarter of the year. Nothing that impacts the overall flow or cadence of our business activities. But it was just a fundamental matter of timing. That's the primary key drivers.

As far as cash flow, I really don't talk about the myths in life other than net cash changes on the call. You'll have a chance to see that here in just a few days in detail in our 10-Q.

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**Ryan Rauch Jefferies & Co. - Analyst**

Okay and then are you still on track to automate your manufacturing line by year-end? And then it appeared that internationally ASPs were a little bit light in the quarter. Can you walk through maybe what happened there?

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**Tom Prescott Align Technology - President and CEO**

Okay, so it sounds like two questions there, really. The first issues is yes, we are driving forward with the plans to connect the business. We're going to have more to talk about, in the coming months about that. We don't want to kind of get ahead of ourselves. But that's why we talked about the capital budget in the timeframe.

We are pushing ahead as aggressively as we can to improve quality, reduce costs, and decrease variability in the entire process and really, automation goes to the heart of that. So it is a very, very important strategic initiative and we're making great progress.

The second question I want to come back again. It was the question about international?

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**Ryan Rauch Jefferies & Co. - Analyst**

Yes, just the ASPs looked a little light. Just curious what's going on there.

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**Tom Prescott Align Technology - President and CEO**

I'll let Eldon reiterate what he said earlier.

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**Eldon Bullington Align Technology - VP Finance and CFO**

Yes, as I mentioned just a few minutes ago in answering another question, we did have a volume incentive program in place in the fourth quarter to try to incent doctors to participate at a deeper level in their practices.

We did have some success with program in spurring volume and one of the aspects of that program is if the particular doctors participated during the fourth quarter at a specified level, they would have the opportunity to enjoy some discounting during 2005. So fundamentally, that is what you're seeing and as I mentioned, in answering Raj's question a few minutes ago, that you'll see that persist for the better part of 2005.

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**Ryan Rauch Jefferies & Co. - Analyst**

Okay and then just two final 10,000-foot questions. Tom, the question of the day just seems to be how, when you lost 14 salespeople in the quarter, did you have such a good quarter and maybe in your own terms could you just-- you probably have already done it, but just walk us through there?



And then two, there's seems to be a misconception that since your competitor manufactures in Pakistan and you used to have some presence there, that they have a pretty seamless manufacturing facility, etc, up and going. Can you just remind us what exactly you historically did in Pakistan and maybe what the differences are? Because my understanding is you never fully manufactured your product there and thanks a lot.

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**Tom Prescott *Align Technology - President and CEO***

So that's a mouthful. Let me maybe start with the first one and perhaps Roger and I together can carefully respond to what our original presence was in Pakistan. When we came out in January or in early February to discuss what we thought the implications of the litigation were, we were not at a point where we were comfortable to talk about impact on the business.

We were suspecting there could be significant disruption. We didn't know and we told everybody that as soon as we got visibility we may have to pull it down, in terms of our expectations. In fact, what our whole organization did was kind of jump into hyperdrive and as I said earlier, we have sales managers that started calling on key accounts and GP reps that helped out in a geographic area. And senior management that got on the road to go see customers - and you wouldn't expect that normally to help, would you - and customer support that had relationships with the local office people on a day-to-day basis. And we really asked our customers for help in getting through the challenge.

Some of them were also disappointed that their reps left and so what I'd say is I'm pleased. I don't want to talk in more detail, at a territory by territory level, kind of what happened. But I'm pleased that on the aggregate the departed, the areas where we had open territories kind of performed at very close to the same level than before these people left. And I'd say that's both patience on behalf of our customers and God bless them, and a lot of extra work on behalf of our team.

I wouldn't want to live on that, so before the finance people say hey, we can have fewer salespeople, the reality is we want to be fully staffed. And in fact, I think that it's probably highly likely that this Company has never been completely deployed the way we can and I'm really looking forward to having our deployment model catch up with our opportunity and seeing what we can really do. But we still got a few holes to fill.

So, again, maybe I think there's some luck involved. I think our customers were really gracious with us, but we've got some making up to do.

The second issue that Roger and I can maybe team up on -- we had a great group of people in Pakistan. There were several different things they did. The principle thing that was set up in Pakistan was what we called "treat" and that is what we now do in Costa Rica. We used to do principally treat in Pakistan. We also had a satellite operation in Sharjah in the United Arab Emirates near Dubai that was there kind of as a safety valve if something bad happened in Pakistan, kind of in the post-9/11 world and we had interruption to our business, we could quickly move employees over to the UAE. Temporarily house them and then still, hopefully, with some but not lasting disruption, be able to get cases set up and treat operations done.

We also, at one point in time, under the former leadership, they were looking at moving consumer call center and the customer service over there. That didn't work as well and we already had changed that. So we never did aligner fabrication over there. We never did the front end of the process, order entry. We never did kind of the road test stuff. So we did one element of manufacturing and that was treat.

I certainly don't want to comment--I don't want to comment on what OrthoClear is or is not doing. But I think the simple fact is, we've got--the way we look at it, they've got a lot. They've got an uphill battle. They've got a new company, a new process. We'll let the court process work and that's not something that concerns me day-to-day. That's something for our lawyers.

Our organization is proud of what we've done and we're going to try and even improve customer service and make the product even better and extend our lead and grow the business and be a very, very tough competitor in the marketplace.

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**Ryan Rauch *Jefferies & Co. - Analyst***

Thanks a lot. Have a great afternoon.

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**Tom Prescott *Align Technology - President and CEO***

Thanks very much.

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**Operator**

Taylor Harris with JP Morgan Securities.

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**Taylor Harris *JP Morgan Securities - Analyst***

Thank you. It's actually Taylor Harris here for Mike.

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**Tom Prescott *Align Technology - President and CEO***

Hi Taylor.

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**Taylor Harris *JP Morgan Securities - Analyst***

Hi there; just one question looking forward to 2006. Can you talk to us about the strategy around Invisalign Seven? Perhaps maybe frame the market opportunity relative to where you are now? Will there be some degree of cannibalization, etc and a few years out what percentage of your overall revenue base do you think that product could be generating?

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**Tom Prescott *Align Technology - President and CEO***

Well, I'm going to start with the easy part of that question, which is the last part, which is we're not ready to talk about that. It's in pilot mode. I'd like to get more market experience with it before I go further.

But we have described for some period of time that what we think of an Invisalign is it's the extended product plus the aligner, actually the aligners that move teeth. We're going to, over time, create more breadth to that product set of offerings, both the way we wrap clinical support and the extended product services around aligners and the aligners themselves, the work we're doing for the orthodontist or dentist.

So it's been our intention for some time to come out with let's call it a simple case offering that's more cost-effective and I think over time we'd like to make that even more cost-effective than our current offering. We'd like to get after those very simple cases where they might need 5, 6, 7, 8 aligners, a few months of work, but would not be willing to pay kind of what the market bears today, which is around \$3000-4000, even for a simple case.

So, imagine -- and this is based on a lot of consumer work and interviews with doctors around where pricing issues are. And imagine that you had a straightforward, simple, easy to use offering that people could come in and for a reasonable price get whiter, straighter teeth and they get anterior treatment. This is how you start getting at the huge population out there with very mild crowding.

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**Tom Prescott *Align Technology - President and CEO***

At the other end, I think we're working just as hard to try and extend what Invisalign can do and frankly, we're looking at Japan to help us there. Because most of that population is going to be complex cases that's going to combine some form of brackets with Invisalign treatment and so there's a whole range of offerings we're looking to develop across the kind of value points, from call it performance to value. And we will wrap kind of differing levels of different kinds of services, support, practice development, all the kinds of things we can do to help a practice really grow with Invisalign.

So, I think there's the core product, the aligners packaged in a way that fits case complexity and the practice dynamics and then there's the extended product that we wrap all around that and those things are both variables that we can play with.





So, I think, over time, where today most of our volume is full arch/dual arch treatment. I mean, we say we have multiple offerings, but the reality is that's mostly it. Over time that's going to change and I think that'll help ignite market growth. But again, I don't want to get into numbers yet. It's way too early to talk about that.

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**Taylor Harris JP Morgan Securities - Analyst**

Okay. So, but just generally, from your market research, would you be able to tell us perhaps of the patients who are interested in the technology, broadly, how many decide purely for cost reasons not to pursue it?

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**Tom Prescott Align Technology - President and CEO**

We've done it. I'm ready to talk about this publicly. We've done very detailed consumer and channel work to look at those points of resistance. But again, given that we're in a competitive environment now, I'm not going to provide any visibility to that, which could describe our strategies. So we do have what we think is a very clear view of what the value proposition is for consumers at differing levels of case complexity and for doctors at differing levels of case complexity and we intend to exploit that.

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**Taylor Harris JP Morgan Securities - Analyst**

Great and then just one final question. I may have missed this, but of your total sales force expectation for the end of the year of 100, how does that split out?

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**Tom Prescott Align Technology - President and CEO**

We believe we're going to be getting back towards being on a full FTE basis, getting staff towards where we were, around 34, maybe a little north of that, on ortho. And we'll be 65, maybe approaching 70 on the GP side by the end of the year.

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**Taylor Harris JP Morgan Securities - Analyst**

Great. Thanks a lot.

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**Tom Prescott Align Technology - President and CEO**

No problem.

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**Operator**

Tao Levy with Deutsche Bank Securities.

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**Tao Levy Deutsche Bank Securities - Analyst**

Hey thanks, just two quick follow-ups. Is there any insight that you guys are getting from European? There seems to be some interest in sort of price flexibility that you might have where you have the ASPs going down, because you did offer the coupons and at the same time you're seeing some nice volume increases.

And one of the push backs that we hear from orthodontists when we do our channel checks and especially what's attracting them to be interested in OrthoClear is the lower price point, which could potentially lead them to do more cases.

Is there anything that you guys are seeing there?

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**Tom Prescott Align Technology - President and CEO**

Well, I think those are two pretty different things and let's maybe look at what problem Europe was trying to solve. Europe is, as we have described over the last couple of years, when we really put--when the Company originally pushed forward in Europe it was kind of a broad, wide push to certify everybody and the hope was that the business would kind of create uplift and grow. What really happened is kind of what we know, which is doctors integrate a product into their practice for a set of clinical and experience and a whole set of reasons and we as a Company hadn't satisfied those reasons to create that adoption dynamic. So, a lot of what the European team has been successful at over the last year to two years is going back to basics, refocusing on who they call on rather than try to go broad with a lot more certifications. Trying to get the doctors they have trained to start using the product.

And so, rather than just dealing with a price resistance point issue in Europe, their promotions have really been more about getting



doctors to get back to doing cases. If they haven't done a case in six months or a year, getting them to come to a study club, offering them some promotion to get back to doing Invisalign to develop real experience. That was the problem they were trying to solve.

Now, at the same point, we understand that in any given market there is a value proposition and we have to deliver on that, both in terms of--and we're at the high end of that value proposition with an \$1,800 price. So this is one of the reasons why we try to kind of put platinum service around everything to live up to that value proposition and our biggest challenges are when we've got the high price and we don't live up to it.

And I think I'm going to very specific here. As we look at last year and a couple quarters where we perturbed the market, where we didn't perform as well as we should have in delivering on that value proposition, what happened? Some doctors cut back on their case volumes. It was like it's a higher cost and we didn't live up to their expectations. So the real clear lesson for us is yes we know there's a value proposition, we know what that envelope is.

We have to perform at the high end of that envelope all the time and we think there's an opportunity, longer-term, as we automate, drive quality, improve the product, reduce costs, get rid of variability. We think there are opportunities to get substantially more volume with our range of lower priced offerings. So, long way of answering that, sorry Tao.

But there is price resistance even among orthos that are current users and I think, over time as we evolve the product offerings, we're going to do more volume with them at a lower price.

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**Tao Levy Deutsche Bank Securities - Analyst**

All right and I just have one other. And one of the problems that plagued Align in the past with the greater advertising is that some of the doctors would do a bait and switch. Have you guys looked into ways that you can protect that from happening now, not so much to regular braces but towards OrthoClear, where the doctor might be offering both products. And obviously, if he's paying less or she's paying less for OrthoClear are they going to put the patient on that? Maybe--obviously you don't have to explain your strategy here, but is that something that's going on in your thinking going forward?

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**Tom Prescott Align Technology - President and CEO**

It has crossed our mind, Tao.

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**Tao Levy Deutsche Bank Securities - Analyst**

Okay. I thought it would. That's it. Great quarter.

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**Tom Prescott Align Technology - President and CEO**

Yes, we're on it. Yes.

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**Tao Levy Deutsche Bank Securities - Analyst**

Oh good. Thanks.

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**Operator**

Bill Goldman with HMC of New York.

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**Bill Goldman HMC of New York - Analyst**

Hello. I just wanted to get a sense. I know your guidance did not include the OrthoClear launch, but can you give us some sense of what that would be like, what your numbers would be like?

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**Tom Prescott Align Technology - President and CEO**

I'll let Eldon comment, because he's the one that framed the guidance here.

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**Eldon Bullington *Align Technology - VP Finance and CFO***

Well, as I said, we haven't taken that into consideration and really, our approach is we're watching the environment very closely. I think, as Roger discussed in his segment, and you kind of got a flavor in his dialog of what we're doing in that area, what we're doing to monitor the competitive landscape and basically our point is to be prepared to act and act proactively if and when the time comes.

And as far as what form that may take, I don't have a specific framework to talk about on that or anything that I want to talk about here. It's a matter of our approach is to be ready, be proactive, be forceful in the marketplace and be ready to react if and when we need to.

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**Bill Goldman *HMC of New York - Analyst***

What exactly does that mean? I mean, are you guys maybe going to bring pricing down to better compete? I mean, can you give us some sense of what you're planning to do?

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**Eldon Bullington *Align Technology - VP Finance and CFO***

So, what I don't want to do, Bill, is to try and kind of box with a shadow right now. What I'd rather do is just to say we've thought about a whole range of competitive scenarios. We're prepared to be a hard competitor and we've got a lot of flexibility and a range of things we can do.

And I'm not willing to get into any specifics about that, other than we've thought hard and long about how to be a successful Company and we're not about to start describing the details of our strategy in this environment. I should just stop there. I almost said something I shouldn't. We're just not going to describe that in a public setting and I hope you can understand that.

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**Operator**

There are no further questions at this time. Would management like to make any closing comments?

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**Tom Prescott *Align Technology - President and CEO***

Thank you, Operator. We appreciate your interest and all the good questions on a busy day and just again, we're glad to make solid progress here. We've got a lot to do. We're very busy and we're prepared to go in the marketplace and look forward to keeping you updated about that. That's it.

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**Barbara Domingo *Align Technology - Director Investor Relations***

Thanks a lot, everyone.

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**Operator**

Thank you, ladies and gentlemen, for your participation in today's teleconference. You may disconnect your lines at this time and have a wonderful day.

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